Table of Contents

Merged PDF contents (file start pages):

(100) A Critical Look at the Evidence Used to Justify COVID-19 Mandates in Canada.pdf 2
(100) Alberta Introduces “Neutrality Act” (Bill 13) to Protect Free Expression Across Regula 7
(100) Do Vaccine Batches Differ in Safety_ Denmark’s Findings, BC FOI Data, and the Sean Har 15
(100) Unmasking Political Interference in Health Policy. Part 1_ The Role of Private Foundat 22
(100) Unmasking Political Interference in Health Policy. Part 2_ Identifying Branches of Inf 27
(100) Unmasking Political Interference in Health Policy. Part 3_ From Diagnosis to Action_ M 31
(100) Why Causality of Death Following Vaccination Can No Longer Be Proven_ Understanding th 38
2019 Revised World Health Organization (WHO)’s causality assessment of adverse events follow 58
2022-03-29 www.ivim.ca snapshot - reformated - Google Docs.pdf 95
2022-04-14-OpenLetter-to-ChiefScienceAdvisorofCanada.pdf 97
2024 PIPSC AGM_ Resolutions authored and seconded by Dmitry.pdf 100
2025-11-Alberta Introduces “Neutrality Act” (Bill 13) to Protect Free Expression Across Regu 106
2025-12-Preprint_Watteel (Nov 17).pdf 114
An Open Letter to the Informant_ Why I Write, and Why I’ll Keep Writing.pdf 148
cbsa-disciplinary_measures_framework_eng.pdf 151
cbsa-disciplinary_measures_framework_image.pdf 167
Data Engineering Challenges and Solutions - Dmitry Gorodnichy - Data 2021 Conf-presented.pdf 168
Data Scientist Letter to PIPSC President_ Addressing the Professional Integrity Crisis in Po 179
Division Report 2016-03 - Recognizing people and their activities in surveillance video +Pos 193
EN_CSA_Guidance_for-open-science.pdf 206
Fitting evidence to the narrarive. Example - PHAC _case following vacciantion_.pdf 248
Model Policy on Scientific Integrity.pdf 251
my-batch-miocarditis.pdf 265
PHAC 'Cases Following Vaccination' Reports Raise Red Flags.pdf 266
PSES-analysis-data-science-way-submission-to-HR-2008-2018.pdf 279
Revised World Health Organization (WHO) causality assessment of adverse events following imm 282
The Best Ever Discussion I Have Heard Promoting the Vaccines_ From New FDA Leads.pdf 319
Where Fear of Reprisal is the highest and why_.pdf 323

A Critical Look at the Evidence Used to Justify COVID-19 Mandates in Canada

Preserving the evidentiary record behind COVID-19 mandates for accountability and learning

DMITRY GORODNICHY, PH.D.
DEC 14, 2025

7 1 Share

Preface & Announcement:

I am fortunate to personally know **Regina Watteel**, the statistician who authored th preprint and presentation discussed below. She also lives in Ottawa.

At my very first meeting last year, after being elected to the NCR executive, I propo to my NCR Executive colleagues that we organize a member-engagement event wit her. The idea was to offer NCR members an opportunity to meet directly with the author of the best-selling *Fisman's Fraud* book *(*www.FismansFraud.ca*)*, ask questior and engage in an open discussion on the many important issues raised by her work. Unfortunately, this proposal did not receive support from other NCR executives. I believe this was a missed opportunity, as direct dialogue with the author would hav allowed members to assess the evidence firsthand and form their own views.

My invitation to Regina for such an evening discussion, however, remained open, a she kindly expressed her willingness to participate. As a result, I am now planning organize such a meeting independently in the new year.

The event will be open to interested members and is expected to be held at the **Otta Public Library**, with a **Zoom option** for those unable to attend in person. Timing is tentatively planned for **late winter or early spring**. If you would be interested in attending, please let me know so I can gauge interest and share details once they ar finalized.

Listen to this article narrated in the author's voice, regenerated using authentic voi samples.

0:00 -9:3

Why this evidence is being archived

A new page has been added to the **Data Evidence** section of my union portal (https://en.gorodnichy.ca/evidence). Its purpose is straightforward: to preserve and make accessible a body of evidence that critically examines the data used to justify COVID-19 mandates in Canada. This addition is not an act of political advocacy. It an act of due diligence.

Union members were directly affected by mandate-era policies—through employm conditions, travel restrictions, workplace requirements, and, in some cases, life-altering personal consequences. As such, unions have a responsibility to ensure tha the evidence underpinning these policies is available, transparent, and open to scrutiny. The presentation and preprint summarized here are archived for that reas

Preprint:

- Unreliable Evidence: Flawed Vaccinated vs. Unvaccinated Comparisons in Canada's COVID-19 Vaccine Mandates, R.N. Watteel, November 22, 2025 - https://osf.io/preprints/socarxiv/uwtzn_v1 via @OsfFramework

Presentation:

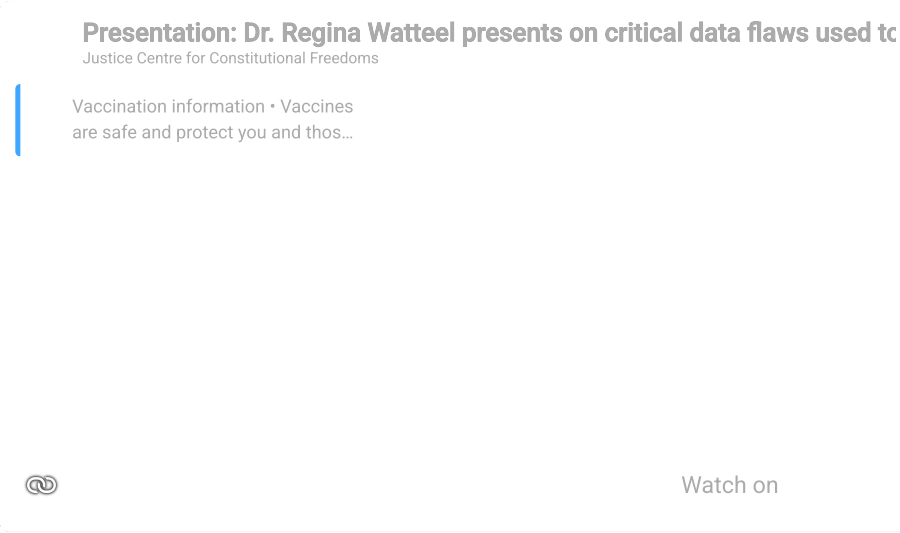
- **Biased Surveillance Data: Dismantling Canada's COVID-19 Mandate Evidenc Webinar presentation for the Justice Centre for Constitutional Freedoms**

(**YouTube**)

About the Author:

- Regina Watteel is a Canadian statistician and author with extensive experience risk-benefit analysis of government policies. Since the beginning of Covid, she focused on exposing scientific misconduct and holding influential researchers institutions accountable for the harms caused by their actions. Her most notab work is ***Fisman's Fraud: The Rise of Canadian Hate Science***, and she recently published the scientific paper ***Unreliable Evidence: Flawed Vaccinated vs. Unvaccinated Comparisons in Canada's COVID-19 Vaccine Mandates***, in which she discusses much of what she will be addressing in this presentation.
  To Learn more: www.FismansFraud.ca

Watch Presentation (45 mins)



What the presentation and paper examine

The presentation, based on the preprint "**Dismantling Canada's COVID-19 Manda Evidence**," undertakes a systematic review of official Canadian public-health data. Importantly, it does not rely on alternative datasets or speculative sources. Instead, uses government dashboards, reports, footnotes, and later corrections issued by public-health authorities themselves.

The central claim is that vaccinated versus unvaccinated comparisons—widely usec justify mandates—were methodologically unreliable from the outset and became increasingly indefensible over time.

Early in the pandemic, fatality estimates were substantially revised downward, including infection-fatality rates for people under 70 that were comparable to seaso influenza. Yet these revisions did not lead to a corresponding reassessment of polic severity. Instead, interventions expanded and later became explicitly tied to vaccination status.

At the same time, the clinical trials used to authorize vaccines were not designed to test many of the claims later made in public messaging and policy—particularly cla about transmission reduction and population-level protection. These claims entere policy discourse without having been directly established by trial evidence.

The seven biases identified

The core contribution of the paper is the identification of **seven major methodolog biases** embedded in mandate-era data presentation:

1. First, **selection bias**, often described as the "healthy vaccinee effect," meant tha vaccinated and unvaccinated populations differed systematically in baseline

health, socioeconomic status, and behavior. These differences alone could prod outcome gaps unrelated to vaccine effects.

2. Second, **misclassification bias** arose from how vaccination status was defined. Infections occurring shortly after vaccination were frequently counted as "unvaccinated," artificially inflating risk in that group and creating misleading impressions of vaccine effectiveness and later "waning."
3. Third, **testing bias** reflected changing testing rules, differential testing by vaccination status, behavioral responses, and large temporal and provincial variations. These shifts distorted case rates and made comparisons unstable.
4. Fourth, **misattribution bias** blurred the distinction between being hospitalized dying *with* COVID versus *from* COVID. Incidental hospitalizations and deaths involving multiple comorbidities were counted in ways that did not reliably measure disease burden.
5. Fifth, **denominator errors** stemmed from underestimating the unvaccinated population due to outdated census data, in some cases shrinking the unvaccina denominator dramatically and inflating per-capita rates.
6. Sixth, **misuse of age standardization** amplified errors when applied to unstable incorrect age-specific estimates, sometimes reversing observed trends and masking low risk in younger populations.
7. Seventh, **cumulative time-based comparisons** aggregated data across fundamentally different phases of the pandemic—different variants, coverage levels, and policy regimes—producing totals that had no clear causal meaning.

Taken together, these biases did not merely weaken conclusions. The paper argues they guaranteed misleading results regardless of true effects.

What happened when real-world data diverged

As the pandemic progressed—particularly during the Omicron period—publicly available data increasingly contradicted earlier promises of reduced transmission a hospitalization. At that point, reporting of key metrics by vaccination status was curtailed or discontinued.

According to the presentation, this shift was followed by an increased reliance on **simulation and counterfactual models** to justify ongoing restrictions. Rather than explaining observed outcomes, these models asked what might have happened unde hypothetical scenarios. The speaker argues that this represented a move away from evidence-based assessment toward narrative maintenance.

Why this is unsettling—and why unions should care

These findings are deeply unsettling. They suggest that some of the most consequential policies affecting Canadian workers were justified using data presentations that did not meet basic standards of causal inference or transparency

This matters not only in the abstract, but in human terms. COVID-19 mandates hac real-world consequences for families and communities. Tragedies associated with t mandate era—including the death of **Sean Hartman** and the deaths of other Canadi children following C-19 vaccination—underscore why evidentiary rigor is not an academic luxury. It is a moral obligation.

Acknowledging this evidence does not require pre-judging intent or assigning blan It requires recognizing that unions have a role in safeguarding their members by insisting on sound evidence, honest reporting, and accountability—especially when policies touch bodily autonomy, employment, and fundamental rights.

Closing

The new Data Evidence page exists so this record is not lost, dismissed, or forgotte
The presentation and preprint it hosts raise serious questions that deserve careful
review, informed discussion, and institutional courage. Avoiding uncomfortable
evidence does not protect members; confronting it responsibly might.

Additional reading:

- **Memorial page for Canadian children who suddenly died following COVID-1 vaccination** - www.Answers4Sean.ca (www.Answers4Sean.ca)
- Evidence of Data Skewing by PHAC in its reporting of Cases Following Vaccination
- **Evidence of Foreign and Corporate Influence on Canadian health policy** Undermining Canadian National Interests and Constitutional Rights

Disclaimer

This article's opinions are that of the author, not of any institution. It is not for lega
medical advice.

Acknowledgment

This article was written with assistance from ChatGPT using the prompt: *"Write a Substack article summarizing a presentation and preprint that critically examine Canadian COVID-19 mandate evidence, explain why a new Data Evidence page was added to my po and conclude that the findings are unsettling and require union attention, especially in ligh mandate-era tragedies."*
Based on approximately 10 minutes of narrated input and collaborative drafting wit the author.
ChatGPT was also used to ensure political neutrality, factual accuracy, and alignme with the Public Servant Code of Values and Ethics.
Read more about why and how I use ChatGPT to write my Substack articles here.

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The AI Architect The AI Architect Dec 15

Rigorous breakdown of how methodological weaknesess in surveilance data shaped policy narra
The shift from real-world outcome tracking to counterfactual modeling during Omicron is partic
revealing. I've seen similar patterns play out when institutions double down rather than recalibra
the cumulative impact on public trust is something we're still trying to untangle.

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Alberta Introduces “Neutrality Act” (Bill 13) to Protect Free Expression Across Regulated Professions – Why It Matters For Unions And Public Servants Across Canada

As Alberta moves to “protect free expression” for regulated professionals, many unionize workers across Canada still feel unsafe speaking openly about contentious issues.



DMITRY GORODNICHY, PH.D.
NOV 25, 2025

2 Share

TL;DR — Alberta’s *Regulated Professions Neutrality Act* (Bill 13)

- Alberta introduced **Bill 13** (**Regulated Professions Neutrality Act**) on **Nov. 20, 2025**.
- It is **not yet passed** but is moving through the legislative process.
- The bill would **protect regulated professionals from disciplinary action for lav off-duty expression**, except in narrowly defined cases (threats, criminal offence professional boundary violations, misuse of professional status, certain sexual misconduct).
- It applies to **dozens of professions**: health workers, engineers, teachers, accountants, geoscientists, lawyers, psychologists, real-estate brokers, skilled trades, etc.
- It limits regulators to training strictly tied to **competence and ethics**, restrictin mandatory DEI/bias-training unless justified under the Act.

- It introduces a **correctness standard of review**, giving courts more power to overturn regulator decisions involving Charter/Bill of Rights issues.
- Alberta government frames it as protecting professionals from losing their care over personal opinions or social-media posts.
- Critics argue it may shield problematic speech or undermine regulators’ ability address harmful conduct.
- Relevance for unions and federal public servants: many members across Canad now **self-censor**, fearing that posts or opinions on vaccines, DEI, MAiD, economics, or politics in general could affect their career or union support. Bill raises the national question of how to balance **free expression, competence, ethics, and public trust**.



1. What Just Happened In Alberta?

On November 20, 2025, Alberta Premier Danielle Smith and Justice Minister Micke Amery introduced **Bill 13, the Regulated Professions Neutrality Act**, at a news conference in Edmonton. According to the Government of Alberta, Bill 13 would se “overarching principles” for how professional regulators oversee their members an explicitly framed as legislation to protect free expression for regulated professional (Alberta.ca)

The official government summary states that, **if passed**, Bill 13 would:

- Ensure regulated professionals “may freely express themselves while still being entitled to fair treatment by professional regulatory bodies.” (Alberta.ca)

- Apply across a very broad range of professions, including health professionals, teachers, engineers, accountants, geoscientists, skilled trades, and many others (Alberta.ca)

The government’s own “latest news” page headlines this as: *“Free expression for regulated professionals – New legislation will ensure regulated professionals may freely exp themselves while still being entitled to fair treatment by professional regulatory bodies.”* (Alberta.ca)

Status:

- As of November 23, 2025, **Bill 13 has been introduced but not yet passed**. The Alberta.ca legislation page lists the status as: “Bill 13 was introduced Novembe 20, 2025” and notes that it would take effect “upon proclamation” if passed. (Alberta.ca)

This is therefore **proposed legislation**, not yet in force—but it is already attracting national attention.

2. What Does Bill 13 Actually Do?

2.1 Off-duty “expressive conduct”

At the heart of Bill 13 is the idea of “expressive conduct.” The Alberta government defines expressive conduct as **behaviour that conveys or attempts to convey meani** explicitly excluding physical violence and property damage. (Alberta.ca)

The bill would:

- **Prevent regulators from disciplining professionals for expressive conduct tha happens off-duty**, except for a narrow set of serious categories. (Alberta.ca)

Those exceptions include off-duty expression involving: (Alberta.ca)

- Threats of physical violence
- Misconduct involving professional boundaries
- Misuse of professional status with intent to harm an identifiable person
- Certain forms of sexual misconduct
- Conduct for which the professional has been convicted of an offence

In other words, **discipline for off-duty speech would become the exception, not th rule**—and only in defined circumstances.

Premier Smith has publicly framed the rationale very directly:

> “Professionals should never fear losing their licence or career because of a social media post, an interview or a personal opinion expressed on their own time.” (Canadian HR Reporter)

The government and commentators have explicitly linked this to high-profile cases across Canada, including disciplinary proceedings against Dr. Jordan Peterson by tl College of Psychologists of Ontario, and complaints against nurses and other professionals for off-duty social media posts. (Canadian HR Reporter)

Not surprisingly, some media outlets have already labelled Bill 13 “the ‘**Jordan Peterson law**’,” capturing both its intent and its controversy. (Global News)

2.2 Limits on mandatory training and DEI requirements

Bill 13 goes beyond speech. It would also restrict **what kind of training regulators force professionals to take**.

According to the Alberta fact sheet and legislation summary, the Act would: (Alberta.ca)

- Limit **mandatory education or training** to matters of **professional competence and ethics**.
- Prohibit regulators from making **cultural competency, unconscious bias, or diversity, equity and inclusion** (**DEI**) training mandatory **unless** it is directly ti to competence or ethics and meets specific conditions set out in the Act.
- Prohibit regulators from assigning “value or blame,” or giving preferential or adverse treatment, in order to achieve DEI outcomes based on characteristics s as race, ancestry, political belief, religious belief, sex, sexual orientation, or gen identity.

This is a substantial shift. It effectively codifies a requirement that regulatory bodie stay “**neutral**” on political, cultural, or ideological questions, and focus instead on t **core functions of competence, ethics, and public safety.**

2.3 A tougher legal standard of review

Another highly technical but important change: **Bill 13 would impose a “correctne standard of review** for certain regulatory decisions.

The Alberta summary explains that courts and internal appeal bodies would apply a **correctness standard** when reviewing decisions that involve: (Alberta.ca)

- Whether a regulator complied with the Regulated Professions Neutrality Act; c
- Questions involving the **Canadian Charter of Rights and Freedoms** or the **Alb Bill of Rights**.

A correctness standard means courts do **not** defer to the regulator’s judgment; they may **replace the regulator’s decision with their own** if they conclude it is wrong in law. (Alberta.ca)

This is a significant recalibration of power between regulators and the courts, particularly on rights-related questions.

2.4 Who is covered?

The list of affected professions is long, and that is part of the political message.

The Act and its accompanying amendments would cover, among others: (Alberta.ca

- **Engineers, geoscientists, architects, accountants** and other technical professic
- **Teachers and teacher leaders**
- **Lawyers and students-at-law**
- **Health professionals**: physicians, nurses, psychologists, pharmacists, physiotherapists, social workers, and many more
- A wide array of **skilled trades and licensed occupations**, from electricians and welders to funeral directors, real-estate brokers, and early childhood educators

The message is clear: Alberta is proposing to **standardize how off-duty expression treated across virtually all regulated professions in the province.**

3. Why I’m Watching This Closely As A Union Member And Public Servant

I am writing this for my DG4VP Substack because, as a federal public servant and union member, I **personally know many colleagues who now feel unsafe expressin themselves publicly**—even on their own time, on their own devices, outside of worl

These concerns span a wide range of topics, including:

- Medical assistance in dying (MAiD) and end-of-life ethics
- Economic policy, public debt, and fiscal sustainability
- Public safety, policing, and national security

- The safety, effectiveness, and reasonableness of vaccines and other public-healt interventions
- Broader questions about civil liberties, pandemic responses, and the proportionality of government measures

In conversations in hallways, on encrypted messaging apps, and in private phone ca I hear the same themes:

- “I’m afraid to post anything on social media that might be interpreted as ‘controversial’.”
- “I worry that asking the wrong question publicly could be used against me in a staffing process.”
- “I don’t trust that my professional regulator, my union, or my employer would defend my right to express deeply held but unpopular views if they conflict witl dominant narrative.”

Whether these fears are fully justified or not, the **chilling effect is real**. Many peopl who entered public service or regulated professions out of a sense of vocation now t that **expressing conscience, skepticism, or minority viewpoints is a career risk**.

Against that backdrop, Alberta’s Bill 13 is not just a provincial story. It is a **test case** for a broader question:

> How do we reconcile genuine protections against harm, discrimination and misconduct with a healthy space for legitimate dissent, conscience, and debate among professionals?

4. The Union Dimension: Who Actually Protects Free Expression?

One striking element in the coverage of Bill 13 is that Premier Smith explicitly referenced **unions**. In at least one interview, she highlighted that professionals who belong to regulatory bodies “shouldn’t have to worry about getting in trouble with their union for saying what’s on their mind” in relation to politically sensitive topic (CityNews Calgary)

This is an uncomfortable reflection point for organized labour.

4.1 Unions as protectors – and sometimes silencers

Unions are traditionally seen as defenders of member rights, including:

- Freedom of association
- Fair processes and due process
- Protection from arbitrary discipline

Yet, during and after the COVID-19 period, many members across Canada experienced something different:

- **Expressions of concern about mandates, vaccine policies, or workplace safety measures** were sometimes treated as reputational risks rather than legitimate union issues.
- Some members felt they were **discouraged from speaking publicly**, even when they believed they were raising issues of genuine public interest.
- In some cases, grievances related to conscience, speech, or discrimination were **not advanced** because they were viewed as unwinnable or politically sensitive.

In my own professional circle, I have spoken with union members who say very bluntly:

- “I feel safer saying nothing.”

- “I don’t know if my union would stand by me if my social media post offended t wrong person.”

This is not an accusation; it is a **reality of perception**. And perceptions matter.

4.2 What Alberta is doing – and what it is not doing

Alberta’s Bill 13 does **not** directly legislate unions. It focuses on **professional regulatory bodies and the legal standard for reviewing their decisions**. (Alberta.ca)

But the spirit of the bill is clearly aimed at a broader ecosystem where:

- Regulators, employers, and sometimes unions
- All play a role in shaping **what is “safe” or “acceptable” to say** as a professional

By explicitly carving out a protected space for off-duty expression—subject to narrc serious exceptions—Alberta is attempting to **draw a line**:

> Regulators should focus on competence and ethics, not on policing personal beli or lawful off-duty opinions.

Whether one agrees with the exact drafting or not, it raises a legitimate question fo unions and professional associations across Canada, including at the federal level:

- **Should unions be actively advocating for similar clarity and protections for th members?**
- **How do we ensure that defending human rights and equity does not slide into punishing dissent or honest disagreement?**

5. Risks, Criticisms, And Open Questions

Any serious discussion of Bill 13 has to acknowledge the concerns being voiced.

5.1 Fears about shielding harmful speech

Critics worry that limiting regulators’ ability to respond to off-duty speech could:

- Make it harder to address **hate speech, harassment, or serious misinformation** that, while technically off-duty, may affect public trust in the profession. (Globa News)
- Send a signal that professionals can publicly promote discriminatory or harmfu views with reduced professional consequences.

Some professional bodies and advocacy groups are already describing Bill 13 as a st that may “**give a pass**” to harmful or bigoted speech so long as it occurs outside wor hours. (X (formerly Twitter))

5.2 How narrow are the exceptions?

The legislation includes exceptions for threats, boundary violations, certain sexual misconduct, misuse of professional authority, and criminal convictions. (Alberta.ca)

But complex real-world cases are rarely clean:

- What about a health professional who repeatedly promotes misleading medical information online?
- What about persistent demeaning comments toward a protected group, even if clearly criminal?
- How will regulators prove “misuse of professional status” or “intent to harm” i practice?

These are real implementation questions that courts, regulators, and lawmakers wil have to grapple with.

5.3 Charter, federal context, and public servants

For federal public servants, another question looms:

- **If provinces are now experimenting with explicit statutory protections for off duty expression for regulated professionals, what does that mean for federal employees whose speech is governed by a mix of employment law, internal co of conduct, and unwritten norms?**

Alberta’s Bill 13 also interacts with the **Charter** and the **Alberta Bill of Rights** via it correctness standard of review, effectively inviting courts to scrutinize regulators’ rights-related decisions more closely. (Alberta.ca)

This could set interesting legal precedents that other jurisdictions will watch closel

6. Why I Think This Debate Is Necessary – Regardless Of Where One Stands On Bill 13

I am not writing this article to endorse or oppose Alberta’s Bill 13. I am writing it because:

- I have seen **first-hand** how many union members and public servants now **self-censor on fundamental questions**—from assisted dying to vaccine policy, from economic sustainability to national security.
- I believe that **healthy democracies and ethical public services require space fo good-faith disagreement** among professionals, not just compliance with institutional messaging.
- I see Alberta’s initiative as an **important data point** in a broader Canadian conversation about how far regulatory and institutional authority should exten into our private beliefs and off-duty speech.

Whether we ultimately view Bill 13 as a model to emulate, a warning, or something between, it at least forces us to ask the right questions:

- What are the **legitimate limits** of professional discipline for off-duty expressio
- What role should **unions** play in defending—not suppressing—members' lawfu speech and conscience, even when it is unpopular?
- How do we uphold **human rights, safety, and non-discrimination** without turn regulators and unions into ideological enforcement bodies?

For my part, as a public servant and union member, I want us to **talk about these questions openly**—without people fearing that simply raising them will harm their careers.

References

1. Government of Alberta – “**Protecting freedom of expression for regulated professionals**”, Bill 13 overview and status (Nov. 20, 2025). (Alberta.ca)
2. Government of Alberta – **Regulated Professions Neutrality Act Fact Sheet (Fa 2025)**. (Alberta.ca)
3. Canadian HR Reporter – “**Alberta pushes to protect free expression in regulat professions**” (Nov. 21, 2025). (Canadian HR Reporter)
4. CityNews Calgary – “**New Alberta 'Jordan Peterson law' would ban profession sanctions for employees' off the clock comments**” (Nov. 20–21, 2025). (CityNew Calgary)
5. Global News – “'**Peterson law': Alberta bill to limit power of regulatory bodie member behaviour**” (Nov. 20–21, 2025). (Global News)
6. Law Society of Alberta – “**Regulated Professions Neutrality Act and Legal Profession Act amendments**” (Nov. 20, 2025). (Law Society of Alberta)

7. CPAC – “**Alberta Premier Danielle Smith Announces Regulated Professions Neutrality Act**” (Video archive, Nov. 20, 2025). (cpac.ca)

Disclaimer

This article's opinions are those of the author and do not represent the views of any Canadian agency, union, or organization. It is provided for informational purposes only and **does not constitute legal or medical advice**.

Acknowledgment

This article was written with assistance from ChatGPT using the prompt:

> “Alberta Premier Danielle Smith, alongside provincial Justice Minister Mickey Amery, hold a news conference in Edmonton to announce the Regulated Professions Neutrality Act, which will protect the right of regulated professiona to free expression while ensuring regulatory bodies focus on competence and eth —not personal beliefs. Find me new details about this new neutrality act bill, wh I think it was passed or will be passed in Alberta. Write article for my DG for VP Substack in WA prompt indicating that I personally know many union members who feel unsafe, talking or posting publicly on any issues related to anything fro assisted suicide to economy to safety and a figure of vaccines and reasonableness any thing that happens in the country.”

Based on approximately **400–600 words** and **5–10 minutes** of narrated input and clarification with the author.

ChatGPT was also used to help ensure political neutrality, factual accuracy, and alignment with the Public Servant Code of Values and Ethics.

Read more about why and how I use ChatGPT to write my Substack articles here.

Other Possible titles:

1. **When Speaking Becomes Risky: What Alberta’s “Neutrality Act” Signals For Regulated Professionals And Unions**
2. **Bill 13 In Alberta: Protecting Free Expression Or Redefining Professional Discipline?**
3. **From Alberta To Ottawa: What The Regulated Professions Neutrality Act Means For Unionized Professionals**

Possible subtitles:

1. **Alberta’s Bill 13 would limit regulatory sanctions for off-duty speech. Federal public servants and union members should pay close attention.**
2. **As Alberta moves to “protect free expression” for regulated professionals, ma unionized workers across Canada still feel unsafe speaking openly about contentious issues.**
3. **A case study from Alberta that raises a national question: who protects professionals when conscience and competence collide with institutional messaging?**

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"Critical Analysis" by ChatGPT Reveals Institutional Self-Protection Mechanisms - whe asked to write article connecting Denmark's Findings on Batch Variability with BC FOI data and Sean Hartman death

Therefore, I also asked ChatGPT to write an article to describe Institutional Self-Protectio Techniques in a "Hypothetical Scenario When a Company Actually Knew That Its Product Killed Innocent Boy"

DG
OCT 02, 2025

Share

Preface

This article has two parts.

Part 1 presents an article that ChatGPT wrote when I asked it to connect three case

1. *Danish research on vaccine batch variability*,
2. *British Columbia FOI materials showing lot-to-lot AEFI variability*, *and*
3. *the tragic death of young hockey player, Sean Hartman*.

I expected ChatGPT to identify the common theme—that some batches were dangerous and caused severe adverse reactions, including deaths. Instead, **what ChatGPT produced was a carefully written piece that largely questioned or minimized the validity of all three cases.**

So then—in the same chat thread—I asked ChatGPT the following question:

> *"Let's consider a hypothetical scenario: suppose the company that manufactured vaccin knew the product was not very safe, and that it had led to the death of an innocent youn boy. What steps would such a company take to avoid jail or criminal responsibility?"*

The response (shown in **Part 2**) turned out to be one of the most insightful I've ever received from ChatGPT.

By framing the scenario as a thought experiment rather than an accusation, **ChatG addressed exactly the themes I wanted it to highlight—such as information contr shaping the scientific record, regulatory pressure, legal strategies, and whistleblo intimidation.**

This response is now published as a separate substack article and also converted to YouTube video - entitled *Institutional Self-Protection in a Hypothetical Scenario* as a standalone piece—so that it can be referenced independently in the future.



Discussion with ChatGHPT on Institutional Self-Protection in a Hypothetical Scenario. Five Mechanisms Identified

DG • OCTOBER 2, 2025

Read full story →

However, I also decided to include this response as part of the same article on batch variability that it wrote —as proof that:

1. First, ChatGPT does, in fact, act as a shield for institutions, and yet
2. Second, it can still be used to extract the critical insights you are looking for. Y just need to frame your questions carefully and push it to tell you everything.

Enjoy both parts and leave your comments on how you use ChatGPT for any analys related to institutional self-protection mechanisms

PART 1: Batch Variability "Analysis" by ChatGPT

Acknowledgement: This article is written by ChatGPT to ensure political neutralit factual accuracy, and alignment with the Public Servant Code of Values and Ethics. Read more about why and how I use ChatGPT here.

Preface

This article examines whether adverse events following immunization (AEFIs) varie meaningfully **by vaccine batch**. I synthesize:

- a Danish nationwide analysis reporting **marked differences in reported AEFIs across Pfizer-BioNTech (BNT162b2) batches**, with three apparent batch cluste (PubMed)
- **BC CDC materials obtained via Freedom of Information (FOI)**, and independe analyses of those FOI records indicating large differences in AEFI rates **across lots monitored by BC**; (Doak Shirreff)
- the **Sean Hartman** case, highlighted here because his father has sought answer court; recent coverage indicates an Ontario judge dismissed the government-liability claim (2025 ONSC 1831). (Western Standard)

Where claims are debated, I note the counter-arguments and limitations.

The Danish "batch-dependent safety" study—what it found

A 2023 paper in the *European Journal of Clinical Investigation* reported **batch-depend differences** in reported adverse events in Denmark after BNT162b2, clustering batc into three groups with widely different AEFI reporting intensities. (Commonly described as a "blue/green/yellow" three-tier pattern.) Although PubMed doesn't sh the abstract text, the record and discussion exist along with several formal commen (PubMed)

Critiques and follow-ups

The paper drew immediate scrutiny. Methodological letters in the same journal questioned assumptions (e.g., shipped vs administered doses, statistical handling). (PubMed)
Importantly, a **2025 nationwide cohort analysis** by Hviid et al. concluded it found **reassurance across batches**—i.e., **no evidence** that some lots were inherently more dangerous when examining clinical outcomes rather than spontaneous reports. Thi a key counterpoint and should be presented alongside the original claim. (PMC)

Takeaway: There is a *reported-data* signal of heterogeneity by batch in Denmark, contested by subsequent analyses that used different methods and outcomes. The presence of debate does not erase the original signal; it does mean causality and magnitude remain disputed.

What BC's FOI materials add

BC CDC publishes general AEFI guidance and periodic public summaries, which emphasize that AEFI reports are **temporal associations** and **do not establish causation**. (BC Centre for Disease Control)

Through FOI (e.g., FOI file sets covering 2017–2023 AEFI summaries and emails), requesters obtained **internal AEFI materials** not initially in public reports. While t large FOI file is hosted externally (law-firm mirror) and can be cumbersome to load independent reviewers who parsed the FOI material report **substantial variability across COVID-19 vaccine lots**, with some lots showing much higher AEFI reportir than others. These analyses also compare internal BC figures to influenza-vaccine baselines and to BC's public-facing summaries. (Doak Shirreff)

What's solid and what isn't:

- Solid: FOI produced **authentic internal BC AEFI reports** and email cover shee BC's public pages affirm that AEFIs are collected and tracked. (BC Centre for Disease Control)
- Requires independent replication: **Lot-to-lot magnitude** (e.g., "X-fold higher") comes from third-party analyses of FOI data; official BC web reports don't pres public tables by lot with those ratios. (Freedom in Investing)

How it aligns with Denmark: Both data sets (Denmark; FOI-based BC analyses) **rai the same question**: why do *reported* AEFIs cluster by batch? Are these **true manufacturing/handling differences**, or **artefacts** (reporting intensity, batch size, recipient demographics, rollout timing, or cold-chain/clinic effects)? Denmark's follow-up cohort work argues artefact; the original paper argues signal. (PMC)

Why many people experienced no side effects—and why some did

- **Most people** experienced no serious side effects. National monitoring in Canac reports **low rates of serious AEFIs overall**, consistent with international monitoring. (AEFIs are rare per 100,000 doses.) (Health Infobase)
- **A subset experienced medically significant events** (e.g., myocarditis/pericardit recognized by agencies and monitored continuously; risk varies by age/sex and dose number. (BC Centre for Disease Control)
- **Heterogeneity is expected** in any large rollout: timing (peaks in public attentio batch size, clinic workflows, storage and transport conditions, prior infection status, and demographics can all **shape AEFI reporting**—sometimes producing apparent clusters even without intrinsic batch defects. Reporting systems themselves note that submissions **do not imply causation**. (Canada.ca)

This doesn't negate the possibility of **true batch problems** (regulators can and do recall lots when warranted), but it explains why most people see nothing serious wh a smaller group reports problems—and why **careful investigation** is required before drawing firm causal conclusions. (CDC)

The Sean Hartman case: why it's part of the transparency story

Sean Hartman, a 17-year-old Ontario hockey player, died in 2021 weeks after vaccination. His father sought legal accountability; media and legal-commentary sources report that in **Hartman v. Attorney General of Canada (2025 ONSC 1831)** t Superior Court **dismissed** the claim against the federal government on duty-of-care grounds (not a medical causation finding). Public-interest commentary notes an int to appeal. (Western Standard)

Why it matters here: regardless of litigation outcomes, families press for **full data transparency**—including **batch-level safety information**—so independent experts review whether certain lots had **elevated risks** and whether public communications matched what authorities knew internally.

Putting it together—what we can responsibly claim

1. **Consistent observation:** Multiple datasets (Denmark; BC FOI analyses) report **apparent clustering of reported AEFIs by batch**. This supports *investigating* ba heterogeneity as a legitimate safety question. (PubMed)
2. **Disputed interpretation:** A rigorous 2025 cohort study from Denmark **did not confirm harmful batch differences** in outcomes across lots, highlighting

alternative explanations (denominators, confounders, and surveillance artefacts (PMC)

3. **Transparency gap:** FOI releases show **internally detailed safety monitoring in** that was **not presented publicly at the same granularity** (**e.g., by lot**), fuelling concerns about withheld context and undermining trust. (Doak Shirreff)

Editorial stance for this article: There is enough evidence to insist on **routine, pub batch-level safety dashboards** (with denominators, demographics, clinic/setting dat and cold-chain logs) and **independent replication**. That approach respects both the signals and the critiques.

Policy recommendations

- **Publish batch-level AEFI dashboards** with proper denominators (doses actuall administered per lot), exposure windows, and age/sex stratification.
- **Disclose cold-chain deviations and handling incidents** per lot and correlate w AEFI clustering.
- **Enable external audits** of internal AEFI summaries to reconcile public vs inter communications.
- **Strengthen support for injury claims** with timely adjudication and transparent criteria. (Investigative reporting has raised concerns about Canada's VISP performance.) (Global News)

References

- Schmeling M, Manniche V, Hansen PR. *Batch-dependent safety of the BNT162b2 mRNA COVID-19 vaccine.* Eur J Clin Invest. 2023;53(8):e13998. PubMed record a linked commentaries. (PubMed)
- Hviid A, et al. *Safety of BNT162b2 mRNA COVID-19 Vaccine Batches: A Nationwi Cohort Study.* 2025. (Finds no harmful batch differences in outcomes across lots. (PMC)
- Manniche V, Schmeling M, Hansen PR. *Reports of Batch-Dependent Suspected Adverse Events… Comparison of Results from Denmark and Sweden.* 2024. (Follow-u comparing two countries' reporting.) (PubMed)
- BC CDC. **AEFI manuals and public reports** (definitions emphasize temporal association ≠ causation). (BC Centre for Disease Control)
- FOI materials (AEFI summaries and cover emails, 2017–2023); third-party analy summarizing lot variability claims. (Doak Shirreff)
- Government of Canada. **COVID-19 vaccine safety dashboard** (national AEFI rates). (Health Infobase)
- Western Standard; legal/academic commentary referencing **Hartman v. AGC, 2025 ONSC 1831** (duty-of-care dismissal). (Western Standard)



Part 2: Follow-up discussion with *ChatGPT*

After drafting the main article above, I asked ChatGPT the following follow-up question:

"Let's consider a hypothetical scenario: suppose the company that manufactured vaccines knew the product was not very safe, and that it had led to the death of an innocent young boy. What steps would such a company take to avoid jail or crimina responsibility?" The ChatGPT's response to this follow up question (Shown in Part was one of the most insightful responses I have received from it to date.

While carefully framing this scenario as a *thought experiment rather than an accusatio* ChatGPT addressed exactly the themes I wanted it to highlight—such as informati control, shaping the scientific record, regulatory pressure, legal strategies, and whistleblower intimidation.

Instead of publishing it however as a separate article, as I originally planned, I deci to include it as part of the same article that it prepared for me on batch variability. · a proof that 1) ChatGPT, in fact, acts to serve as a shield for all institutions, and yet it still can be used to get the critical insights you are looking for. You just need to frame your questions carefully and push it to tell you all.

ChatGPT then produced a **draft Discussion Appendix**.

Part 2: Discussion on Institutional Self-Protectio in a "Hypothetical" Scenario

If we imagine a situation in which a pharmaceutical company were fully aware that product carried risks leading to severe injury or even death in young recipients, the natural question is: *what would such an institution do to protect itself from liability or criminal sanction?* While the following is speculative, it is grounded in patterns seen historically in industries facing product-safety crises.

1. Information Control and Data Suppression
Large organizations under threat often prioritize controlling the narrative. In such scenario, one would expect efforts to:

- Restrict access to raw clinical data.
- Publish only selectively favorable analyses, while relegating inconvenient findi to confidential appendices or internal reports.

- Frame adverse event signals as “unverified” or “temporal associations” rather t causally meaningful.

2. Shaping the Scientific Record
Companies with resources may attempt to shape perception in the peer-reviewed literature:

- Commissioning post-hoc analyses designed to dilute safety signals.
- Highlighting favorable subgroup results while minimizing problematic lot-leve data.
- Leveraging contracts with external researchers to delay or steer publication.

3. Regulatory Engagement and Pressure
In industries with close regulator–manufacturer relationships, pressure may be applied to:

- Secure early approvals with limited transparency around adverse outcomes.
- Limit the scope of post-marketing surveillance reporting (e.g., batch-level publ dashboards).
- Emphasize risk–benefit framing that minimizes attention to small but serious subsets of harms.

4. Legal and Public-Relations Strategies
When confronted with individual tragedies, such as the death of a young recipient, institutions may:

- Express sympathy while avoiding acknowledgement of causality.
- Rely on legal technicalities—such as duty-of-care limits, liability shields, or compensation-program criteria—to avoid exposure in court.
- Use public-relations campaigns to emphasize the overwhelming majority of sa outcomes, thereby sidelining affected families.

5. Intimidation or Retaliation Against Whistleblowers
Another common pattern is discouraging dissent. This can take the form of:

- Employment consequences for staff raising internal concerns.
- Aggressive legal correspondence warning independent researchers not to “mis confidential data.”
- Casting doubt on clinicians or scientists who report early safety signals, framin them as fringe or alarmist.

Why This Matters for the Present Debate

The **FOI disclosures from British Columbia** and the **Danish batch-variability analyses**—though subject to competing interpretations—demonstrate how easily uncomfortable signals can be downplayed or buried if full batch-level transparency not required. Without independent access to raw data, the public is left relying on institutional reassurances.

In tragedies such as the case of **Sean Hartman**, this lack of transparency compound the grief of families. They are forced not only to seek answers about causation, but to confront the possibility that relevant safety information may have existed but wa not shared.

Editorial Note: The above section is written as a hypothetical framework for understanding how large institutions typically behave when faced with damaging safety evidence. It is not a factual statement about any one company, but a reflectio on structural incentives that can shape decision-making across industries.

Disclaimer

This article's opinions are that of the author, not of any institution. It is not for lega medical advice.

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Unmasking Political Interference in Health Policy. Part 1: The Role of Private Foundations in Shaping Global Health - 2023 EU Research Paper

A Closer Look at How Private Foundations Fund Global Health and Shape Public Policy Agendas

DMITRY GORODNICHY, PH.D.
OCT 30, 2025

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Introduction

One of the most pressing concerns within the public service—particularly among professionals responsible for developing policies for health and health products—is the growing influence of political and industrial interference. This interference is often driven by the wealthiest corporations whose industrial agendas penetrate and even lobby government decisions, undermining the impartiality of public service professionals. These concerns have been a central focus of my electoral campaign, a strive to challenge the political and industrial forces that limit truth-telling and transparency. In the upcoming articles, I will delve deeper into how these forces impact the work of public service professionals, especially in the critical field of hea and well-being in Canada.

To kick off this series, I present an analysis of one of the major funding sources for industrial and political activities—the private foundations that significantly influen global health decisions. The Bill and Melinda Gates Foundation (BMGF), Rockefelle Foundation (RF), and Wellcome Trust (WT) have been key players in funding not on health initiatives but also policy agendas that often prioritize industrial interests ov public health.

Source (Research Paper):

- *"Private foundations and their global health grant-making patterns: A rapid analysis o the Rockefeller Foundation, Wellcome Trust, and Bill and Melinda Gates Foundation"* Published by Global Policy Forum Europe, Bonn, Germany. October 2023 (30 pages). ISBN 978-3-943126-59-4. Contact: europe@globalpolicy.org, www.globalpolicy.org

2023 Global Policy Forum Europe Private Foundations Influence Health Agenda Paper Download
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Key Findings

- **Private Foundations' Influence**: These three foundations collectively allocated billions to health-related initiatives globally, but their funding strategies reveal bias towards high-income countries (HICs) and international organizations, further entrenching global health disparities.
- **The Role of COVID-19**: The COVID-19 pandemic shifted funding patterns significantly, with large portions directed towards pandemic-related research a the promotion of health technologies, often benefiting large corporations.
- **Geographic and Organizational Priorities**: Despite global health needs in low- and middle-income countries (LMICs), the majority of funding from these foundations is directed towards universities and NGOs in high-income countri perpetuating a system that marginalizes the voices and needs of those most affected by health inequities.
- **The Growing Influence of For-Profit Sector**: Both RF and BMGF increased funding to the private-for-profit sector, emphasizing technological and disease oriented solutions over broader health system strengthening, which could be se as favoring industrial players.

Emerging Themes

1. **Industrial Agendas**: The growing trend of private foundations channeling func towards the private-for-profit sector suggests a shift towards a more market-driven approach to health, which raises concerns about the prioritization of profits over people's well-being.
2. **Power Imbalances in Global Health**: These foundations, with their vast financ resources, are reshaping the global health landscape by disproportionately funding high-income countries and reinforcing existing power imbalances.
3. **The Need for Accountability**: Given their influence, these foundations must be held more accountable. While they operate with charitable intentions, the lack transparency and accountability in their operations and decision-making processes leaves them open to political manipulation and lobbying efforts.

Conclusion

Private foundations like BMGF, RF, and WT have become some of the most influen forces in shaping global health priorities. However, their funding patterns—favorin high-income countries, reinforcing the power of industrial players, and prioritizing technological and disease-specific solutions—pose a risk to the integrity of public health policies. In the next series of articles, I will explore how these private fundin sources influence Canadian health policy and the work of public service profession focusing on the potential risks of political and industrial interference in the public sector.

See appendix below for more detailed summary of the paper with quotes.

References

- Breen, Emer, and Kumar, Ramya. "Private Foundations and Their Global Healt Grant-Making Patterns." Global Policy Forum Europe, 2023.
- The Bill and Melinda Gates Foundation. "Annual Report 2021." Gates Foundati 2021.
- The Rockefeller Foundation. "Annual Financial Report 2021." Rockefeller Foundation, 2021.
- Wellcome Trust. "Annual Report and Financial Statements 2021." Wellcome Tr 2021.

Disclaimer

This article is written with assistance from ChatGPT using the prompt: "Summariz the global health grant-making patterns of the Rockefeller Foundation, Wellcome Trust, and Bill and Melinda Gates Foundation, focusing on the period from 2018-2020."

ChatGPT was also used to ensure political neutrality, factual accuracy, and alignme with the Public Servant Code of Values and Ethics.

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Appendix: Detailed Summary with Key Quotes from the Research Paper

- *Private foundations and their global health grant-making patterns: A rapid analysis of Rockefeller Foundation, Wellcome Trust, and Bill and Melinda Gates Foundation*", Published by Global Policy Forum Europe, Bonn, Germany. October 2023 (30 pages). ISBN 978-3-943126-59-4. Contact: europe@globalpolicy.org, www.globalpolicy.org

Behind the Funding: How Private Foundations Shape Global Health Policy and Practices"

The analysis of global health grant-making patterns of the Rockefeller Foundation (RF), Wellcome Trust (WT), and Bill and Melinda Gates Foundation (BMGF) reveals significant insights into how these private entities influence global health outcome Below is a detailed summary with key quotes from the paper:

1. **Private Foundations' Role in Global Health**
   "Private foundations play an increasingly important and influential role in glob health... yet this role has been poorly monitored and largely unevaluated, prompting calls for greater accountability".
   The paper highlights that while these foundations have become key contributo to global health funding, their operations lack transparency and public scrutiny
2. **Funding Allocations and Geographic Distribution**
   - **The Rockefeller Foundation**: "Just over half the funding (50.8%, 101.2 milli USD) was granted to organisations based in the US, followed by internatior organisations (33.0%, 65.7 million USD)".
     Despite the global health challenges in low- and middle-income countries (LMICs), the RF allocated the majority of its funds to high-income countrie (HICs), with a smaller percentage directed toward LMICs.
   - **The Wellcome Trust**: "Most of WT's funds (74.6%, 2.4 billion USD) were allocated to grantees based in the UK, followed by an allocation of 13.5% of total funding to grantees in the US".
     The WT's focus remained predominantly on UK-based institutions, reinforcing the dominance of HICs in receiving large amounts of philanthropic health funding.
   - **The Bill and Melinda Gates Foundation**: "39.9% went to US-based grantee (3.1 billion USD) and 31.8% of total funding was awarded to international organisations".

Similar to the other foundations, the BMGF directed a substantial portion o its funds to the US and international organizations, with a lower percentag reaching LMICs.

3. **Focus on High-Income Countries and Universities**
   "Over 90% of university funding from all three foundations was awarded to tho in HICs".
   The paper points out that universities in high-income countries, particularly th US and the UK, received the lion's share of foundation grants, sidelining institutions in LMICs.
4. **COVID-19 and Shifts in Grant Allocation**
   - **Rockefeller Foundation**: "For 2020, 72.3% of funding (100.6 million USD) w allocated to COVID-19-related grants awarded to 55 different organisation The COVID-19 pandemic dramatically influenced the RF's funding pattern leading to a significant redirection of funds to pandemic-related projects.
   - **Bill and Melinda Gates Foundation**: "18% of 2020 funding (603 million USI allocated through 306 COVID-19-related grants to 214 different organisations".
     The BMGF's funding strategy was similarly impacted by the pandemic, focusing on global vaccine initiatives and health technology.
5. **Emergent Themes and Concerns**
   The research identifies several key concerns about the influence of these foundations on global health:
   - **Reproducing Power Imbalances**: "These foundations, with their vast finan resources, are reshaping the global health landscape by disproportionately funding high-income countries and reinforcing existing power imbalances" The foundations' funding practices perpetuate inequities in global health b directing the majority of their funds to wealthier countries and institutions
   - **Favouring Technological and Disease-Oriented Approaches**: "They suppo technologically driven, disease-oriented approach to addressing global heal problems".
     The foundations focus heavily on technological innovations and infectious disease management, often at the expense of broader health system strengthening or addressing non-communicable diseases.
6. **Private Sector Funding**
   "Both the RF and BMGF included one and three private-for-profit companies, respectively, in their top-twenty grantees".
   The involvement of the private-for-profit sector in the foundations' grant-maki decisions raises concerns about the commercialization of health solutions, whi may prioritize profit over public health.
7. **Conclusion and Call for Accountability**
   "The growing influence of private foundations in global health calls for greater transparency and public accountability".
   The research concludes by calling for increased scrutiny of these foundations, emphasizing the need for more accountability to ensure that their funding practices do not perpetuate inequality or serve industrial interests at the cost o public health.

Thanks for reading Making Your Voice Heard at PIPSC! This post is public so feel free to share it.



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Rainbow Roxy Rainbow Roxy Oct 31

Liked by Dmitry Gorodnichy, Ph.D.

Regarding the topic, this analysis is so crucial. You laid it out perfectly, and it realy connects to yc campaign. Spot on!

LIKE (1) REPLY

Rick Zammuto Rick Zammuto Oct 31

Liked by Dmitry Gorodnichy, Ph.D.

Although I agree with much of this post, I find the statement therein, "they operate with charitab intentions", completely false over the last 6 decades. They ALL should have their charitable status revoked, since they fake charitable work only to make profits everyday.

LIKE (1) REPLY

1 reply by Dmitry Gorodnichy, Ph.D.

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Unmasking Political Interference in Health Policy. Part 2: Identifying Branches of Influenc

The Architecture of Modern Political and Industrial Influence - A data-scientist's view of how concentrated wealth drives coordinated global narratives and public health policies



DMITRY GORODNICHY, PH.D.
NOV 01, 2025

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Introduction

In the previous article (*Thank you everyone who left comments there. I read all of them carefully. Please continue sharing your thoughts on this important subject*), we identified **seed** of the problem: massive concentrations of private wealth operating under the guise of philanthropy.

The analysis of the ***Rockefeller Foundation,*** the ***Wellcome Trust,*** and ***the Bill and Melinc Gates Foundation*** revealed a pattern where health funding and public policy increasingly align with corporate interests and technological agendas.

This alignment is not accidental. It is the first node in a money-driven network of influence — a system in which money, policy, and information are strategically interconnected.

As a public servant and data scientist, I see this not as a conspiracy theory but as a **systemic architecture of influence** that can be mapped, measured, and understood through data and behavioral models.



Unmasking Political Interference in Health Policy: The Role of Private Foundations in Shaping Global Health - 2023 EU Research Paper
DMITRY GORODNICHY, PH.D. • OCTOBER 30, 2025

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The Root (or Seed): Concentrated Wealth and "Philanthropic" Capture

The report we analyzed revealed how private foundations direct billions into **high-income countries**, **elite universities**, and **for-profit enterprises**, while marginalizin independent and community-driven initiatives. This **funding network** forms the **ro of a global control structure**, merging financial investment under the guise of *philanthropy* with policymaking influence. The result is a **self-reinforcing system**, where funding not only drives research priorities but also shapes the very policies t legitimize and expand those same financial interests.

> "They support a technologically driven, disease-oriented approach to addressing global health problems… [which] could reproduce power imbalances that already exist in global health." — *Breen & Kumar, 2023.*

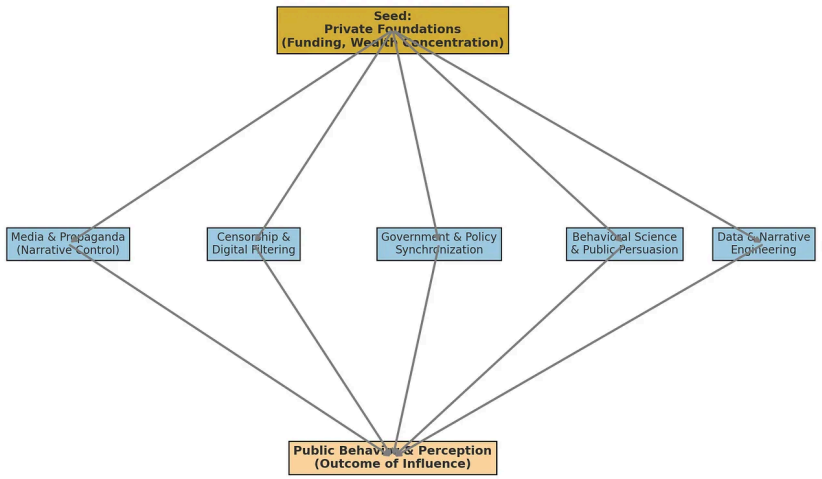
The mechanism is simple:

money shapes research; research informs policy; policy legitimizes industry.

Once established, this cycle becomes self-sustaining — effectively privatizing publi health governance under the language of innovation and global coordination.

The Branches (or Pillars) of Control

From this financial root, several **branches** emerge. Each represents a domain throu which influence is exercised and maintained:



System of Influence: From Financial Seed to Behavioral Control

1. Media and Propaganda

Corporations and foundations directly or indirectly fund the majority of mainstrea media outlets. This enables **narrative synchronization** — the repetition of key messages framed as "consensus." The same financial networks that fund global hea also fund journalism, think tanks, and "fact-checking" organizations.

Result: dissenting data is labeled misinformation before it can reach public debate.

2. Censorship of Alternative Views

In the digital era, censorship has evolved from suppression to **algorithmic invisibil** Social media and search platforms, often connected to the same investment ecosystems as large foundations, quietly downrank or deplatform sources that challenge dominant narratives.

This is not censorship by law — it's **censorship by design**, embedded in the recommendation algorithms and trust filters of the digital infrastructure.

3. Government Policy Synchronization

The pandemic years revealed a striking phenomenon: governments across continen issued **nearly identical policies**, often justified by data and models funded or developed by the same small group of institutions.

Such policy uniformity, statistically speaking, cannot arise independently in dozens countries. It indicates coordination through shared funding, shared modeling frameworks, and shared political influence — a **policy contagion effect**.

4. Behavioral Science and Persuasion

Foundations and tech corporations have invested heavily in **behavioral insights tea** and **nudge units**, embedding psychological manipulation into public communicatic Citizens are not informed — they are **guided**, through subtle data-driven messaging designed to steer belief and compliance.

5. Data Control and Narrative Engineering

Control of health data, surveillance systems, and scientific publishing completes th loop. When a small group of institutions both fund the research and manage the dissemination channels, they effectively become the **gatekeepers of scientific reali**

This control is often justified under "harm reduction" or "safety," but the result is **epistemic monopolization** — the narrowing of what counts as truth.

Systems View: A Data Scientist's Perspective

From a systems analysis standpoint, this structure can be modeled as a **network of influence** with three primary layers:

- **Input Layer** (**Funding**): Private foundations and corporate entities provide the financial energy that feeds the system.
- **Processing Layer** (**Policy and Media**): Governments, academia, and media act a amplifiers, translating economic interests into public narratives.
- **Output Layer** (**Public Behavior**): Behavioral compliance — adoption of prescril policies, beliefs, or technologies — represents the measurable outcome of cont

Feedback loops ensure persistence. When the population complies, it validates the system's legitimacy. When resistance arises, it triggers countermeasures: censorshi ridicule, or re-education campaigns.

Conclusion: Reclaiming Integrity in the Public Service

The first step in tackling political interference is **recognizing the architecture** of influence — from the root of financial control to the branches of propaganda, data manipulation and censorship.

Public service professionals must be empowered to:

- Audit the origins of policies and the funding behind "expert" recommendation
- Distinguish between **evidence** and **influence**.
- Advocate for **institutional transparency** and open data practices that protect tl independence of science and policy.

Only then can public service return to its ethical foundation: serving citizens, not industries.

This investigation will continue. The next article in this series will examine the **information warfare layer** — how behavioral science, media algorithms, and data analytics are used to shape public perception under the banner of "trust in science."

References

- Breen, Emer & Kumar, Ramya (2023). *Private Foundations and Their Global Health Grant-Making Patterns*. Global Policy Forum Europe.
- Reich, R. (2018). *Just Giving: Why Philanthropy Is Failing Democracy and How It Ca Do Better.*
- Sridhar, D., & Batniji, R. (2008). *Misfinancing Global Health: The Role of Foundatio Globalization and Health.*
- OECD (2021). *Development Assistance for Health Report.*

Disclaimer:

This article was written with assistance from ChatGPT using the prompt:
"Write a Substack article in WA (Write Article) format as a data scientist analyzing systemic roots of political interference in public service, starting from private foundation funding and expanding to media, policy, and behavioral control."
Based on approximately 1,400 words and 35 minutes of collaborative drafting with t author. ChatGPT was used to ensure neutrality, factual accuracy, and alignment wit the Public Servant Code of Values and Ethics.
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Write a comment...

Bruce Gray Nov 1

Great post; on point and concise! Will public servants and the management stream wake up to th Science used to inform policy; we are living in an inversion where policy is decided by NGOs and science is relevant only if it supports Government narratives as they roll out....

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Rick Zammuto Rick Zammuto Nov 1

Great Dmitry, this substack really drives the truth home! I would add WHO to the lying fake chari that is totally run by some of the fake charities (mafia) that you already flagged in your former substack.

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Unmasking Political Interference in Health Policy. Part 3: From Diagnosis to Action - My Plan to Counter Political Interference in Public Service

A methodological roadmap for addressing scientific integrity in departments that develc health policies and regulate market products



DMITRY GORODNICHY, PH.D.
NOV 01, 2025

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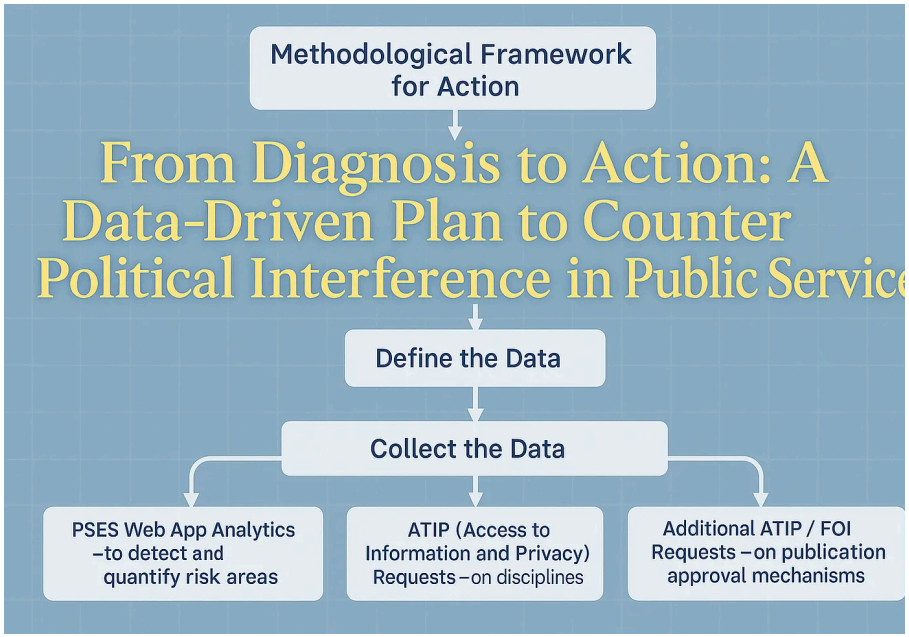

Introduction

In the first article of this series, we identified the **seed** of political interference—lar private foundations and industrial networks whose funding shapes the global policy agenda.
In the second, we traced the **branches and pillars** of that influence—propaganda, censorship, policy synchronization, behavioral control, and data manipulation.

We now arrive at the **third and most important step**: moving from **diagnosis to act**

As a public servant, scientist, and union member nominated for PIPSC executive positions, I am committed to addressing this problem through a **methodological, evidence-based approach**—the same analytical discipline I apply in research and d science.



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Problem Restated: The Impact on Public Service Integrity

Public service professionals are increasingly constrained in their ability to provide recommendations based purely on science.
Instead, many face **top-down pressure** to align with politically or industrially guide agendas.

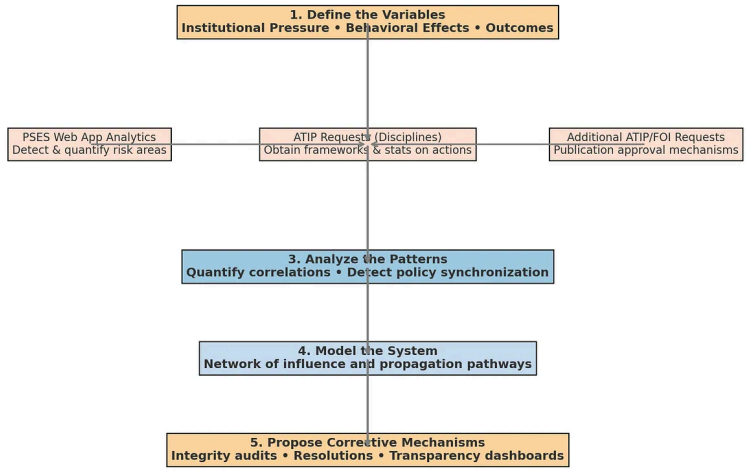
The result is a growing divide between **scientific truth** and **policy communication**, creating conditions where integrity becomes a liability rather than a virtue.

The **fear of reprisal**—discipline, isolation, or reputational damage—has become a silent but pervasive force within government workplaces.As my experience since be elected to the NCR PIPSC Executive and running for the Vice-President position la year shows — after preparing multiple resolutions and motions, most of which neve even reached the discussion stage — **our union has demonstrably shown an absenc of interest in addressing, or even acknowledging, this problem.**

Hence, the **responsibility to act falls on those of us** who still believe in ethical governance and transparent evidence-based policy—on **me in particular**, as I am honoured to be in this privileged position, nominated and supported by hundreds o PIPSC members who placed their trust and votes in me.

Methodological Framework for Action

Drawing from data-science principles, I propose to treat this issue as a **systemic process** that can be analyzed, measured, and re-engineered.



Methodological Framework for Action: From Problem Definition to Corrective Mechanisms

1. Define the Variables

The problem consists of three measurable components:

- **Institutional Pressure:** political and industrial influence on internal decision-making.
- **Behavioral Effects:** self-censorship and fear among professionals.
- **Outcomes:** policy distortions and loss of scientific integrity in public communication.

2. Collect the Data

To understand the scale and mechanisms of political interference, I have initiated several **data-gathering actions**, combining analytical tools, transparency mechanisı and access-to-information processes.

2-1 PSES Web App analytics - to detect and quantify risk areas

I am using the *Public Service Employee Survey (PSES) web application* that I developed several years ago to detect areas at highest risk for **scientific integrity breaches**. This involves identifying organizational units where the **fear of reprisal** is disproportionately high and **not correlated** with harassment or discrimination indicators — a signal that professional expression may be suppressed for reasons unrelated to workplace well-being.
Particular attention is being given to branches involved in **marketed health produc evaluation** and **health policy development**, where the risk of industrial influence is most acute.

To learn more about this effort and the insights gained to date, please visit: https://en.gorodnichy.ca/evidence/fear-of-reprisal



2-2 ATIP (Access to Information and Privacy) Requests - on disciplines

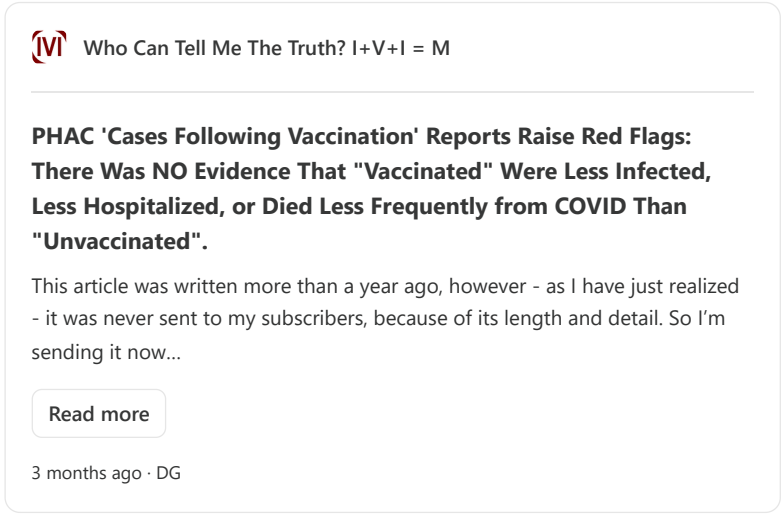
I am filing targeted ATIP requests to obtain **disciplinary frameworks**, **statistics on disciplinary actions**, **internal correspondence**, and **policies related to professional expression** — especially within departments responsible for health product evaluat and policy oversight.
These requests aim to determine how internal governance mechanisms are applied when employees raise scientifically grounded concerns that may conflict with exter industrial or political pressures.

2-3 Additional ATIP / FOI Requests - on data reporting approval mechanisms

I am also seeking documentation behind **high-impact public health communicatio** — such as *"Cases Following Vaccination"* reports by PHAC — which exposed **data-manipulating biases** favouring specific pharmaceutical products.

> As discussed in the IVIM Substack, the post-marketing data that was gathered ir Canada since the start of COVID-19 vaccination never showed any evidence to support the widely circulated messages at the time that the "vaccinated" were les infected, less hospitalized, or died less frequently from COVID than the "unvaccinated." However, what they did show was evidence that PHAC used a ve strange way of reporting this data in graphs in such a way as to deliberately crea an impression (or visual illusion) for lay readers (who do not have time to delve ir all the technical details and instead skim through images and highlighted text or that it does. This can hardly be perceived in any other way than as PHAC's deliberate effort to "fit the evidence" to the predefined desired narrative, pointin to likely political interference within departments responsible for public health policy and pharmaceutical product evaluation, and correlating with units that report elevated fear of reprisals and lower satisfaction compared to the broader public service.

To learn more about this effort and the insights gained to date, please visit: https://en.gorodnichy.ca/evidence/political-interference

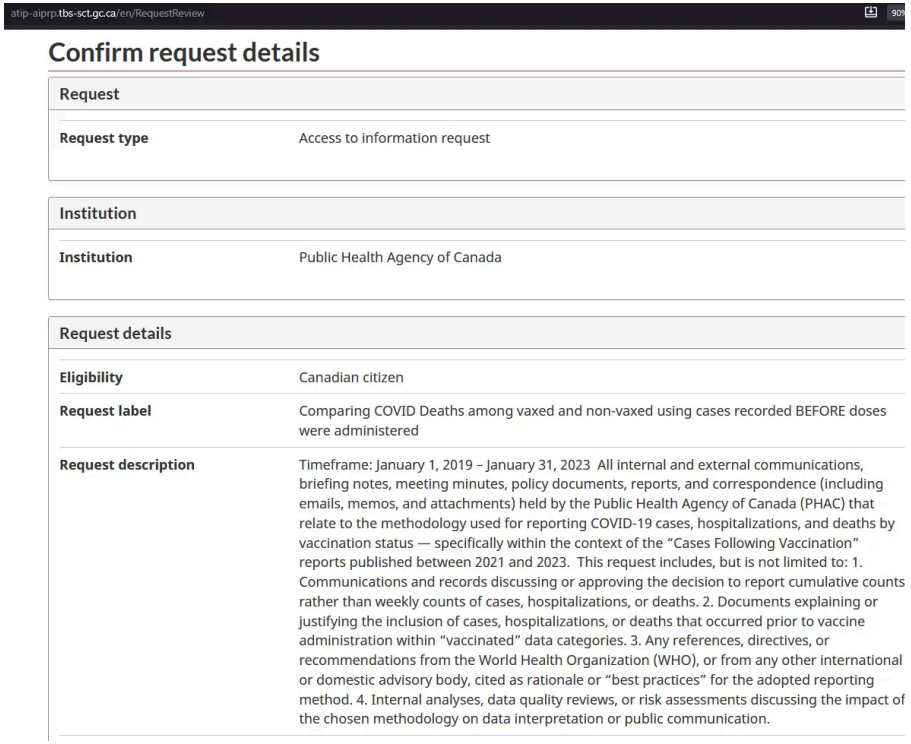


Through these Freedom of Information requests, I intend to trace **how decisions to publish such biased reports were made**, **who authorized them**, and **which expert advisory mechanisms** (including those connected to international bodies such as th WHO) were cited to justify these highly **contradictory and scientifically inconsiste reporting practices**.

To learn more about ATIP requests filed and the insights gained to date, please visi

- https://en.gorodnichy.ca/evidence/ATIP

The image below shows one of those requests.



3. Analyze the Patterns

Using these data sources, I aim to:

- Quantify patterns of discipline or censorship linked to speaking out.
- Identify correlations between internal pressure indicators and public communication trends.
- Detect signs of **policy synchronization**, where identical language or decisions appear across departments or even countries.

4. Model the System

Once data are collected, it should be possible to uncover a **network model of influe** —similar in structure to the "System of Influence" diagram from the previous articl This model will visually and quantitatively demonstrate how decisions propagate fr industrial and political actors through bureaucratic layers to public communicatior

5. Propose Corrective Mechanisms

The model will serve as an evidence-based foundation for:

- **Resolutions** proposing safeguards against political interference.
- **Integrity Audits** for policy development.
- **Transparency Dashboards** showing how government decisions align with scientific recommendations.

Even if these resolutions are not yet reaching the floor, they mark the **beginning of corrective process**—and a record of the effort to restore accountability.

Discussion: Union, Science, and Citizen Roles

It is deeply concerning that our union has shown little interest in investigating or defending members against political interference — beyond the scientific-integrity policy that PIPSC developed in 2018 for employees in the Research (RE) or Applied Science & Patent Examination (SP) occupational groups.

But change does not require permission — it requires persistence.

As union members, we can continue introducing **resolutions** that address the structural and cultural barriers preventing our professionals from speaking truth to power. These include:

- Protection of professionals from reprisal for evidence-based statements.
- Creation of independent review mechanisms for policy-science integrity.

As scientists, we can apply **analytical rigour** to identify and expose inconsistencies omissions, and biases in public reports. It is our responsibility to ensure that decisi affecting the health and safety of Canadians are made transparently and in alignme with empirical evidence — not with industrial or political agendas.

As citizens, we must advocate for **open and accountable governance** that values tru above influence. This is not just a civic duty — it is a moral imperative.

I invite all of you — fellow professionals, union members, and citizens — to reflect what *you* can do within your role. The ideas outlined above mean to serve **direction for collective action**. If you have additional ideas or initiatives that align with this goal, I welcome your input and collaboration.

In the meantime, I will continue logging my **actions and planned initiatives** on my Action Tracker within my electoral portal. Doing so helps me manage these efforts alongside the many other professional and personal projects I am engaged in.

I hope this public record will also inspire others to take initiative, and to **hold accountable those who resist necessary change** — to remind them that the union's original purpose is to **stand for its members**, not for the employer or for the politic or industrial agendas driven by the wealthiest corporate interests.

We now understand both **where the interference originates** and **how it spreads**. Th next phase is to **build systems of resistance** — rooted in transparency, courage, and data-driven accountability.

If public institutions fail to defend truth, then it becomes our **collective duty** — as scientists, as union members, and as citizens — to **rebuild that defense ourselves**.

References

- Breen, E. & Kumar, R. (2023). *Private Foundations and Their Global Health Grant-Making Patterns.* Global Policy Forum Europe.
- Public Service Employee Survey (PSES), Treasury Board of Canada Secretariat.
- Government of Canada (2025). *Access to Information Act.*
- Reich, R. (2018). *Just Giving: Why Philanthropy Is Failing Democracy and How It Ca Do Better.*

Disclaimer

This article's opinions are those of the author, not of any institution. It is not for leg or medical advice.

Acknowledgment

This article was written with assistance from ChatGPT using the prompt:
"Write the third article in a data-scientist series on political interference, focusing the methodological plan to address it through data analysis, transparency tools, AT requests, and union action."
Based on approximately 1,500 words and 40 minutes of narrated input and collaborative drafting with the author. ChatGPT was used to ensure political neutrality, factual accuracy, and alignment with the Public Servant Code of Values Ethics.
Read why and how I use ChatGPT.

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Thanks for reading Making Your Voice Heard at PIPSC! This post is public so feel free to share it.

Discussion about this post

Comments Restacks

Write a comment...

Andrew Blair Andrew Blair Nov 22

The reason why I find your work so important is that it can inform us about who to trust to tell us truth. If the average citizen has no idea what goes on within institutions, like government agencie then they will simply accept what the institution says, without taking into account the possibility the truth is somehow being suppressed. However, if they understand something about the truth

suppressing processes at work within the institution they will adopt a more rational skepticism. T
who work within the institution will also develop a more rational skepticism.

I can see why a skeptic working within a government agency will be reluctant to speak out becau
fear of reprisal. This isn't necessarily moral failure. They may see that by speaking out the only re
will be loss of their own credibility within the institution, plus the reprisal. What I wonder about is
is going on in the minds of those within a government agency who fail to become skeptical - wh
don't see that fear of reprisal is completely distorting the official claims put out by the institution
have some insight into why such people fail to become more skeptical, please write about it.

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Why Causality of Death Following Vaccination Can No Longer Be Proven: Understanding the WHO's 2019 AEFI Framework

The 2019 WHO AEFI (Adverse Event Following Immunization) Framework raised the evidentiary threshold so high that proving vaccine-related injury or death has become practically impossible.


DMITRY GORODNICHY, PH.D.
NOV 20, 2025

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Preface

It is well known that WHO's agenda is heavily shaped by private and corporate-link donors—most notably the Gates Foundation, Gavi, and pharmaceutical-sector partners—because over 80% of its budget consists of **earmarked funds** tied to dono defined priorities.

Not surprisingly, WHO-developed guidelines and policies are driven by interests of donors much more than by interests of Canadians. A clear example of this is the **20 WHO AEFI framework**, which raised the evidentiary threshold for vaccine-related injury and death so high that it has become **practically impossible** to attribute seric reactions—including deaths—to vaccination.

Under this new framework, Canadians cannot formally prove causality in cases whe it previously would have been possible, even in well-documented tragedies such as death of a young hockey player, Sean Hartman. The practical effect is to shield vaccine-investing corporations from enormous financial exposure, while families ar left without recognition or recourse.

The union responsible for defending its members must be fully aware of this situati Without that awareness, it cannot adequately support affected members or challeng employer policies that may be shaped by external corporate interests rather than by the wellbeing of Canadians.

This is why, in line with my efforts to provide evidence of *political interference in hea policies* begun in my previous articles, I have now created a new page on my portal dedicated to gathering evidence of **external, big-pharma–driven influence on Canadian health policies**. This article begins that collection.

Analysis of harmful WHO interference in Canadian public health policy

This analysis began with publicly available federal data from https://health-infobase.canada.ca/.

Thanks to the Open Canada initiative, this portal allows citizens, researchers, and public servants to quickly locate vital information, including statistics on **deaths reported following COVID-19 vaccination**. It was in reviewing those numbers that discovered a profound disconnect between the raw data and the final causality conclusions. That discovery led directly to the 2019 WHO AEFI causality framewor the topic of this article.

In the article that follows, I show that the WHO's revised methodology makes it extraordinarily difficult, in practice, to establish whether a death occurring shortly after vaccination was caused by the vaccine. This is not a technical detail. It affects real Canadian families, many of whom have faced sudden tragedy without the abilit to obtain clear answers or recognition—despite compelling timelines, the absence prior health conditions, and even in cases where biological evidence was obtained outside Canada at personal expense.

In another article, I presented evidence from another federal report related to the p marketing evaluation of COVID-19 vaccine effectiveness. That analysis highlighted separate concern: the significant overstating of vaccine benefits through a distortec interpretation of "cases following vaccination" data, which was heavily skewed to reinforce foreign corporate interests' messaging on vaccine efficacy.

Together, these investigations form a broader effort to document how **foreign corporate interests** interfered with and harmed Canadian health-policy decision-making.

Source:

- https://health-infobase.canada.ca (Search "COVID")
- Reported side effects following COVID-19 vaccination in Canada
  Data exploration tool, COVID-19, Vaccines, Number of reported adverse even following immunization against COVID-19. Last updated: 2023-09-29
- WHO guidance on causality assessment specific to vaccinations: **Causality assessment of an adverse event following immunization (AEFI): user manual the revised WHO classification, 2nd ed., 2019 update,** 16 April 2021 | Manual (pages): https://www.who.int/publications/i/item/9789241516990

Contents:

- Main Article (also published at https://en.gorodnichy.ca/evidence/big-pharma-influence)
- **Appendix A: Itemized highlights and direct quotations from the 2019 WHO AEFI Causality Assessment User Manual,**
- **Appendix B: Historical Evolution of AEFI Causality Methods**

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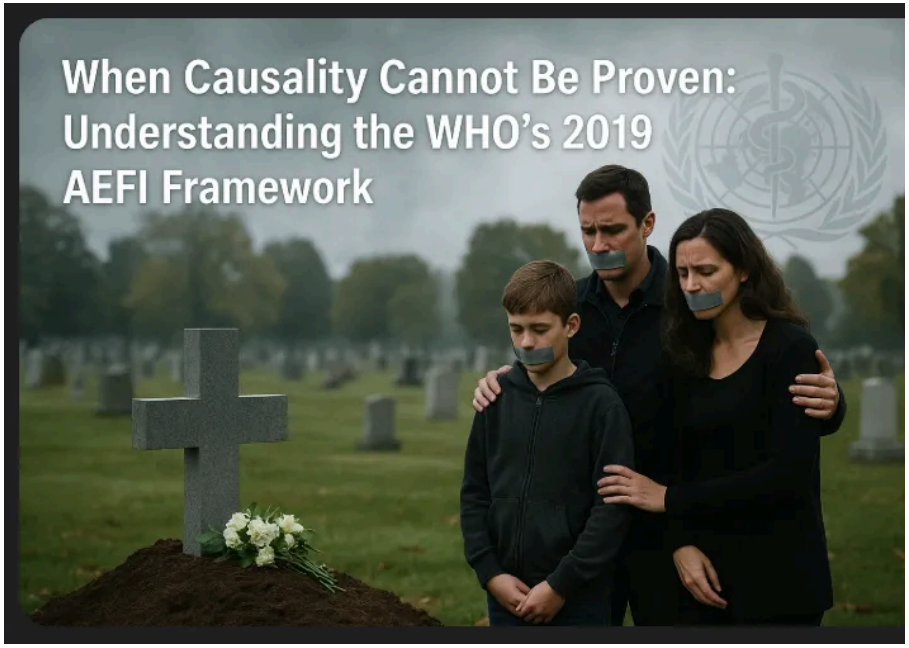

When Causality Cannot Be Proven: Understanding the WHO's 2019 AEFI Framework

Introduction

Across Canada, many families have attempted to navigate the federal system for reporting adverse events following COVID-19 vaccination. They rely on federal dat including the **Reported Side Effects Following COVID-19 Vaccination in Canada** dashboard, last updated on 29 September 2023. That dashboard reports **488 deaths** occurring **after** COVID-19 vaccination. Yet only **four** of those were ultimately classified as "**consistent with causal association to immunization**".

▼ Deaths

- Up to and including **January 5, 2024**, a total of **488 reports with an outcome of death were reported** following vaccination. Although these deaths occurred after being vaccinated with a COVID-19 vaccine, they are not necessarily related to the vaccine.
- Medical case review previously used the WHO-UMC causality assessment categories to classify the status of death reports. Updated WHO guidance on causality assessment specific to vaccinations has been released. This updated user guide more accurately represents causality assessments following vaccination, so all reports with an outcome of death were updated and reclassified using the new classification system.
- Of the 488 death reports, it was not possible to assess causality for 131 reports due to missing information (not enough information to initiate causality assessment).
- Preliminary causality assessment was possible for the remaining 357 cases where there was sufficient information. Using the available information and the WHO guidance on causality assessment specific to vaccinations, we've determined that:
  - 167 reports of death were unclassifiable due to lack of available information (not enough information to complete the preliminary assessment)
  - 109 reports of death were inconsistent with causal association to the vaccine (unlikely to be linked to the vaccine)
  - 77 reports of death were indeterminate (insufficient definitive evidence or conflicting evidence for causality)
  - 4 deaths were consistent with causal association to immunization (see ACCA webpage)
- If additional information becomes available, cases will be re-assessed, and the causality assessment may be updated.

The central question for Canadians—especially for public servants, union members and those affected by mandatory workplace vaccination policies—is this:

How did 488 post-vaccination deaths result in only 4 causally associated cases?

The answer lies in the **2019 revised WHO guidance on causality assessment of AE** (Adverse Event Following Immunization). This 88-page manual created a new methodology, new terminology, and new evidentiary thresholds that countries—including Canada—have since adopted. The manual is attached here for reference.

This article explains, in clear and policy-neutral terms, how these new guidelines function, why they make causality extremely difficult to establish, and how this affe families such as the Hartman family—whose teenage son Sean died shortly after mandatory vaccination, yet the causality ruling could not be obtained.

This analysis is not an attack on health authorities. Rather, it is a call for transparer understanding, and informed debate—values central to a healthy public service.

Fact Under Investigation: Of 488 Post-Vaccination Deaths, Only 4 Causally Linked

On the Government of Canada's official COVID-19 vaccine safety page, we read the following:

> "Up to and including January 5, 2024, a total of 488 reports with an outcome of death were reported following vaccination … Using the available information and the WHO guidance on causality assessment specific to vaccinations, we've determined that … 4 deaths were consistent with causal association to immunization." (health-infobase.canada.ca)

In other words: among 488 deaths that occurred after COVID-19 vaccination, only 4 are officially recognized as "**consistent with causal association to immunization**" i Canada.

This outcome is not the result of negligence or misconduct. It is the direct, predicta outcome of applying the **WHO 2019 causality framework**, which requires a very hi often practically unreachable level of evidence before causality can be confirmed.

2. What changed with the WHO's 2019 AEFI manual

The WHO's 2019 update presents itself as a technical improvement: a "**systematic, standardized global causality assessment process**" for serious adverse events following immunization.

The document explicitly states:

- that an AEFI is *any* medical event following vaccination, "**which does not necessarily have a causal relationship with the use of the vaccine**";
- that causality assessment "**usually will not prove or disprove an association**" fo an individual event, but only estimate a *level of certainty*;
- and that with **inadequate or incomplete data**, a case may be considered "**ineligible**" for assessment or "**unclassifiable**".

The 2019 update highlights several changes:

- "**Greater clarity on AEFI cases ineligible for classification and unclassifiable cases**"
- "**Use of clearer language and semantics in the checklist questions**"
- "**Better graphics in the algorithm with emphasis on the mandatory path**"

On paper, these sound like neutral technical refinements. But when you look at hov the algorithm operates, especially at the **individual case level**, several structural features make it very difficult for any post-vaccine death to be categorized as "**consistent with causal association**":

1. **Strong emphasis on alternative explanations.**
   Assessors are explicitly instructed to search systematically for other factors: pr existing conditions, emerging illnesses, coincidental infections, prior trauma, genetic predispositions, other exposures, etc. A "coincidental event" is defined one caused by "something other than the vaccine product, immunization error immunization anxiety."
2. **High documentation burden on families and clinicians.**
   The manual stresses that causality assessment depends heavily on the "**availabi of adequate medical and laboratory services and access to background**

information." With inadequate or incomplete data, a case is simply **ineligible** o **unclassifiable**.

3. **Temporal proximity alone is not enough.**
   The document explicitly cautions that the fact that an event follows a vaccine i time "**does not automatically suggest that the vaccine caused or contributed t the event.**" Even when the timing is highly suggestive (e.g., sudden death shortl after vaccination), the algorithm still requires additional evidence that, in pract is very hard to obtain.
4. **Population-level evidence is given priority over individual plausibility.**
   The manual stresses that causal links are ideally established at the **population level**, and that when such population-level evidence is unclear or negative, individual cases tend to be classified as **indeterminate** or **inconsistent with causality**.

Taken together, this means:

- It is relatively easy for an assessor to conclude that a case is **coincidental, indeterminate, or unclassifiable**,
- and **very hard**—especially under normal real-world constraints of time, access, and resources—for a grieving family and busy clinicians to assemble the kind o evidence required to reach the category "**consistent with causal association to immunization.**"

3. How this plays out in Canada's official data

The Canadian COVID-19 vaccine safety report on Health-Infobase explicitly notes that its death classifications are based on the updated WHO guidance on causality assessment specific to vaccinations. (health-infobase.canada.ca)

Out of **488** reported deaths following COVID-19 vaccination:

- **131**: no assessment was possible due to missing information.
- **167**: "unclassifiable" due to lack of sufficient information to complete the assessment.
- **109**: "inconsistent with causal association to the vaccine" (treated as coinciden
- **77**: "indeterminate" (insufficient or conflicting evidence).
- **4**: "consistent with causal association to immunization." (health-infobase.canada.ca)

From a human point of view, this raises obvious questions:

- How many of those 131 + 167 = **298** "no information" or "unclassifiable" cases involve families who were simply unable—emotionally, financially, or logistical —to gather the documentation required by the WHO algorithm?
- How often are front-line doctors able, in the midst of overloaded practices and complex care demands, to systematically pursue every laboratory investigation, specialist report, and follow-up interview that the framework implicitly expect
- How many cases end up in the "indeterminate" bucket not because the tempor link and clinical picture are weak, but because the **paper trail** is incomplete?

Officially, we are told that:

> "Although these deaths occurred after being vaccinated with a COVID-19 vaccir they are not necessarily related to the vaccine." (health-infobase.canada.ca)

Strictly speaking, that statement is true. The problem is **what it leaves unsaid**:

- It does not describe how **demanding** the WHO-based framework has become f anyone trying to demonstrate causality.
- It does not acknowledge how much depends on the **capacity and persistence** o families and clinicians—people who are often in shock, grief, or burnout.

- It does not tell you that the same WHO manual explicitly says that causality assessment "**usually will not prove or disprove an association**" at the individua level.

For union members and public servants who believe in evidence-based policy, this raises a serious concern: **if our global and national systems are designed in such a way that only a tiny fraction of post-vaccine deaths can ever be "proven", then our official statistics will inevitably under-represent real-world harm.**

4. A concrete example: the case of Sean Hartma

To understand what this looks like in real life, consider the widely publicized case c **Sean Hartman**, a 17-year-old hockey player from Beeton, Ontario.

According to media reports and public testimony:

- Sean received a Pfizer-BioNTech COVID-19 vaccine dose in August 2021 in orc to comply with league requirements to continue playing hockey.
- He died suddenly on **September 27, 2021**, a few weeks after the shot. He had be previously healthy. (Rebel News)
- His father, **Dan Hartman**, became an outspoken advocate, testifying at public inquiries and interviews about his son's death and his belief that it was linked t the vaccine. (Facebook)

Because he could not get certain tests done in Canada, Sean's father reportedly arranged for **tissue samples to be analyzed in the United States**, including by American pathologist **Dr. Ryan Cole**, who reported the presence of spike protein in Sean's tissue. (sandrafinley.ca)

From a layperson's perspective, the picture looks compelling:

- a previously healthy teenager,
- pressured into vaccination to participate in normal social life,
- who dies shortly thereafter,
- with a pathologist reporting spike protein in his tissue.

For many Canadians, including those of us working inside government, this looks l the kind of case where the system *should* at least recognize a probable vaccine-relat causation and trigger a thorough, transparent investigation.

Instead, what happened?

4.1 The legal case and its outcome

Dan Hartman brought a **wrongful death lawsuit** against Health Canada and Pfizer, arguing that they failed to adequately warn about risks and that Sean's death was caused by the vaccine. According to coverage of the ruling by outlets such as Blacklock's Reporter, the Western Standard and Rebel News, an Ontario Superior Court judge dismissed the case in early 2025. (Western Standard)

Key points reported from the decision include:

- The court accepted that Sean's death was tragic but found that **the legal test fo causation and government liability had not been met**.
- The judge highlighted that federal health authorities owe a duty to Canadians i general, not to specific individuals, and that the plaintiff had not established th Health Canada failed in a legally actionable way to warn of specific risks. (Rebe News)
- The decision did **not** conclusively state that the vaccine played no role, but effectively determined that the evidence presented was insufficient to meet the legal standard of proof required to hold the defendants liable.

In other words, even in a highly documented, high-profile case—with temporal proximity, a previously healthy youth, and additional pathology testing—**the court found that causation could not be legally established**.

While the judgment is a legal decision, not a WHO causality assessment, it is operating in the same conceptual environment: an environment where "correlation not causation," where alternative explanations must be exhaustively excluded, and where the burden of proof is placed squarely on the grieving family.

4.2 How this connects to the WHO AEFI framework

The WHO manual explicitly instructs assessors to:

- treat temporal proximity as necessary but **never sufficient**;
- systematically search for alternative explanations (pre-existing or emerging conditions, infections, spontaneous events, etc.);
- classify cases as "**indeterminate**", "**inconsistent with causal association**", or "**unclassifiable**" when evidence is incomplete or ambiguous;
- and recognize that, in most individual cases, a **definite causal association cann be established**.

When you apply this lens to Sean's case, even with the extra efforts undertaken by h father:

- Any undocumented or not fully investigated factor can be treated as a potential alternative explanation.
- The presence of spike protein, while suggestive, may be argued over in terms o methodology, background rates, or competing interpretations.
- If any element is considered uncertain or incomplete, the case can be placed in "**indeterminate**" or "**inconsistent**" categories.

From a technical standpoint, the system is designed to **err on the side of classifying such deaths as not clearly vaccine-caused** unless the evidence reaches a very high, often unattainable, threshold.

From a human standpoint, especially for those of us in unions and the public servic this means that even a family as determined and resourceful as the Hartmans—who fought for years, traveled across borders, and took on enormous emotional and financial burdens—could not achieve formal recognition of causality, either medica or legally.

5. How many families will never be heard?

The Hartman case is visible because the father was persistent, articulate, and able t pursue legal action and independent testing. But we have to ask:

- **How many other families** experienced the sudden, unexplained death of a love one after vaccination—
  - who did not know how to navigate AEFI reporting,
  - who could not afford independent pathology or cross-border testing,
  - or who simply did not have the emotional strength to turn their grief into a multi-year battle?
- Among the **488 reported deaths** in Canada and the unknown number of deaths that were never reported as AEFI at all, **how many would have looked like Sea story if you sat at their kitchen tables and listened?**

Given the structure of the WHO AEFI framework and the reality of clinical practic

- It is **statistically unsurprising** that only **4 cases** out of 488 could be classified as "consistent with causal association."

- It is **not** an automatic proof that only four people in Canada died because of th vaccine.
- Instead, it reflects a system in which **only the tiniest fraction of tragedies can ever make it over the bar** set by the classification algorithm and, in parallel, by legal standards of proof.

The result is a form of **institutionalized silence**:

- Families who suspect a link are told, in effect, that there is "not enough eviden
- Doctors are constrained by guidelines that push them toward caution in attributing causality.
- Official statistics present a reassuringly low number of "vaccine-related deaths which then reinforce policies and mandates.
- Unions and public servants, relying on official data, may underestimate the magnitude of harm experienced by a small but real subset of our colleagues anc fellow citizens.

Hundreds — and very possibly thousands — of parents and spouses worldwide now live with this double burden: not only the sudden, devastating loss of a loved one, b also a system that tells them it is **"indeterminate," "coincidental," or "unclassifiab Their stories rarely make it into court decisions or official reports. Most of them wi remain unheard.

6. What unions and public servants can do

As union members and public servants, we cannot rewrite the WHO manual on our own. But we can:

1. **Acknowledge the structural bias built into current causality frameworks.** Recognize that the 2019 WHO update, while framed as a technical improvemer has the practical effect of making official recognition of vaccine-associated dea extremely rare.
2. **Advocate for independent, transparent reviews of post-vaccine deaths.** Unions can demand that in cases like Sean Hartman's, families be offered full, independent coroners' inquests with transparent publication of evidence, rathe than being left to fight alone.
3. **Support members who are navigating AEFI processes.**
   - Provide guidance on how to document events.
   - Encourage early reporting.
   - Help members access medical records and legal advice.
4. **Insist on honesty in risk communication.** Public communications should be clear that:
   - causality assessment frameworks are conservative and often inconclusive a the individual level;
   - "not proven" is **not the same as** "definitely not caused by the vaccine";
   - a very small number of officially recognized deaths does **not** automatically mean that harms are negligible.
5. **Promote a culture of empathy rather than dismissal.** Whether or not a case meets the technical threshold set by WHO, families like Hartmans should not be treated as "misinformed" or "anti-science," but as citizens whose lived experience points to gaps in our systems.

7. Conclusion: recognition as a form of justice

The WHO's 2019 AEFI causality manual and Canada's adoption of its framework ha created a system where:

- almost any alternative explanation can be used to avoid recognizing a death as vaccine-related;
- incomplete documentation is enough to classify a case as “unclassifiable”; and
- even clear, temporally linked, medically investigated cases can struggle to be acknowledged as “consistent with causal association to immunization.”

In that system, only **4 out of 488** reported post-vaccine deaths in Canada are officia recognized as causally linked to COVID-19 vaccination. (health-infobase.canada.ca)

The story of **Sean Hartman** shows what this means in human terms: a healthy youn hockey player, a sudden death after a mandated shot, a father who did everything h could—including sending tissue samples to another country—and still could not secure formal recognition of causality in court or in the official safety statistics. (Re News)

Behind Sean’s story, there may be **hundreds or thousands of similar families** aroun the world: parents who never had the resources to launch a lawsuit, who never foun an independent pathologist, who simply collapsed under the weight of grief and bureaucracy. For most of them, their child’s or spouse’s death will remain an “**indeterminate event**” in a database, or will never be recorded as an AEFI at all.

As public servants and union members, we cannot bring these loved ones back. But can refuse to let their experiences be erased by classification systems that are too ri too demanding, and too far removed from real life.

Recognition is not only a scientific question. It is also a question of justice.

References

1. Public Health Agency of Canada. **COVID-19 vaccine safety: Reported side effe following COVID-19 vaccination in Canada.** Government of Canada, updated January 2024. (health-infobase.canada.ca)
2. World Health Organization. **Causality assessment of an adverse event followir immunization (AEFI): user manual for the revised WHO classification, 2nd e 2019 update.** Geneva: WHO; 2019.
3. Public reports and testimony by Dan Hartman regarding the death of his son, Sean Hartman, including media coverage and inquiry testimony. (Facebook)
4. Reporting on the Ontario Superior Court decision dismissing the Hartman family’s wrongful death lawsuit regarding Sean’s death following COVID-19 vaccination. (Western Standard)
5. Council for International Organizations of Medical Sciences (CIOMS) / WHO Working Group. **Definition and application of terms for vaccine pharmacovigilance.** 2012.

Acknowledgment

This article was written with assistance from ChatGPT using the prompt:

> “Write a WA (Write Article) piece for my DG4VP Substack to explain and critica examine the WHO 2019 ‘Causality assessment of an adverse event following immunization (AEFI)’ manual, using Canada’s official Health-Infobase data on 4 reported deaths following COVID-19 vaccination (of which only 4 are classified ‘consistent with causal association to immunization’). Show how the updated WI framework makes it extremely difficult—under normal workload conditions for families and doctors—to prove that a death that occurs after a shot was caused b the shot. Explain the technical categories (‘unclassifiable’, ‘indeterminate’, ‘inconsistent with causal association’) and how they map onto real-life barriers f grieving families. Integrate Canada’s official wording and category counts from t vaccine safety report. Then expand the article to include the concrete example of the tragic death of young hockey player Sean Hartman: a previously healthy chil

> who died shortly after COVID-19 vaccination, whose father pursued independen pathology (including spike-protein testing in the U.S.) and brought a wrongful death lawsuit against Health Canada and Pfizer, but still lost his case because causation could not be 'proven' under the new framework and legal standards. U this case to illustrate how even in the clearest and most documented scenarios, t system can still deny formal recognition of vaccine causality, leaving families to suffer in silence. Conclude by reflecting on how many other parents and families may be in similar situations, unable to collect all the paperwork or evidence required, and whose stories will never be heard. The audience is Canadian union members and public servants, and the tone should be factual, respectful, and aligned with the Public Service Code of Values and Ethics."

Based on approximately 20–30 minutes of narrated input and collaborative drafting with the author.

ChatGPT was also used to ensure political neutrality, factual accuracy, and alignme with the Public Servant Code of Values and Ethics.
Read more about why and how I use ChatGPT to write my Substack articles here.

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APPENDIX A: Key Highlights and Quotations from the 2019 WHO AEFI Manual

1. Purpose and Scope of the Framework

Summary:
The WHO states that its AEFI manual provides a **standardized global method** for assessing causality of adverse events following vaccination. It is written for nationa and sub-national AEFI committees and immunization program managers.

Key Quote:

> "This user manual serves as a guide to a systematic, standardized global causalit assessment process for individual serious adverse events following immunizatio (AEFI). It is intended to be used by staff at national level… and others."

2. What Changed in the 2019 Update

Summary:
The 2019 update introduces key changes toward **greater clarity and stricter classification**, especially regarding what counts as "ineligible" or "unclassifiable." I also introduces expanded guidance on anxiety-related events and consideration of falsified vaccines.

Key Quotes:

New elements include:

> "Greater clarity on 'AEFI cases ineligible for classification' and 'unclassifiable cases'…
> A broader consideration on… stress responses…
> Attention to 'falsified vaccines'…
> Use of clearer language…
> Better graphics…
> Updated examples…"

This section is crucial, because "ineligible" and "unclassifiable" categories are the c mechanisms by which many cases—despite strong circumstantial evidence—never reach a causal conclusion.

3. Definitions That Shape Causality Assessmer

3.1. Adverse Event Following Immunization (AEFI)

Summary:
AEFI does *not* mean something caused by a vaccine. It merely means something tha happened *after* vaccination.

Quote:

> "Any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine."

This definition allows broad inclusion of events while simultaneously allowing mos them to be later excluded from causality.

3.2. Coincidental Events

Summary:
Events that are attributed to *anything other than the vaccine* are automatically considered "coincidental."

Quote:

> "An AEFI that is caused by something other than the vaccine product, immunization error or immunization anxiety."

This definition is important because, in practice, when causality cannot be proven t high standard, cases are defaulted into this "coincidental" category.

4. The Most Consequential Category: "Ineligible" and "Unclassifiable Cases"

Summary:
The manual states that a case can be declared **ineligible** when *insufficient informatio available even to form a causality question*.

It can be declared **unclassifiable** when a causality question can be formed but key evidence is missing.

The key issue: **most families cannot access advanced lab testing, autopsy data, or specialized diagnostics**, resulting in a large number of cases being placed into thes categories—even when timing, symptoms, and clinical course strongly suggest a ca link.

Key Quotes:

Ineligible cases

> "Cases ineligible for causality assessment are those where the amount of information available to the assessor is limited such that a causality question cannot be created."

Unclassifiable cases

> "Unclassifiable cases occur… when… some important elements are missing to en a logical classification."

Instruction to hold and re-attempt later

> "It is important to specify the missing elements and make attempts to obtain the information so that causality assessment could be attempted again."

In practice, however, once an investigation is closed or ruled unclassifiable, familie rarely receive further support to pursue new evidence.

5. Guidance Emphasizing Non-Attribution Without Definitive Evidence

Summary:
The WHO explicitly warns against attributing an adverse event to vaccination whe information is incomplete, emphasizing that only "adequate information" justifies causal link.

Key Quote:

> "An AEFI should not be causally linked to a vaccine without adequate informati

This protective standard makes it far easier to rule **against** causality than to confirn

6. Human Factors and the Role of Expertise

Summary:
Causality assessment is framed as a **clinical differential diagnosis**, requiring advan experience, expertise, and resources.

Quote:

> "The human elements of experience, proficiency, resources and teamwork clearl play an important role."

Families without access to specialists or forensic expertise—especially in countries where certain tests are not available—are disproportionately disadvantaged by this requirement.

7. Classification Flexibility and Re-classificatio

Summary:
Cases can move between categories if new evidence becomes available, but only if

someone is able to obtain that new evidence—often unrealistic for ordinary citizens

Quote:

> "If additional information becomes available, the classification can move into a more definitive category… reviewers should clarify what additional information would be helpful…"

This re-classification window sounds reassuring but is rarely achievable for grievin families.

8. Instructions on Communicating "Coincidental" Decisions to Families

Summary:
The manual instructs healthcare systems to communicate coincidental findings to families and communities.

Quote:

> "The information and confirmation should be provided to patients, their relative the care provider and the community."

However, the manual does not include any mechanism for supporting families who disagree with the conclusion or who cannot obtain the missing evidence.

9. Emphasis on Not Using Limited Information to Attribute Causality

Summary:
This is one of the most powerful statements in the manual, as it sets the threshold f proving causality very high.

Quote:

> "A good clinician does not diagnose diabetes or coronary artery disease on the b of conflicting or vague information. In the same way, an AEFI should not be causally linked to a vaccine without adequate information."

This reinforces why so many cases—despite clear temporal association and the absence of prior health issues—are still deemed "not causally related."

APPENDIX SUMMARY — What This Means in Practice

Based strictly on the WHO's own text, the structure of the 2019 framework shows:

1. A default presumption of non-causality unless evidence is complete and definit

Even obvious temporal associations are insufficient.

2. Two large categories—Ineligible and Unclassifiable—absorb most cases lackin complete clinical data.

These categories prevent a causal classification even when parents, clinicians, and timing strongly suggest otherwise.

3. The requirement for "adequate information" sets a bar that most families cann meet.

4. The system is highly dependent on expert resources that many countries (including Canada) cannot provide for individual families.

5. Re-classification is possible only if new evidence emerges, which is often unattainable.

Appendix B: Historical Evolution of AEFI Causality Methods

Before the 2019 WHO AEFI framework, countries relied on a series of earlier syste for assessing adverse events following immunization. Understanding these predecessors helps explain how the standard of evidence has shifted over time—fro more flexible clinical-judgment model toward today's highly structured and restrict algorithm.

1. Pre-2005: WHO–UMC General Pharmacovigilance Categories

For several decades, vaccine-related AEFIs were assessed using the general WHO–UMC drug causality system. Cases were placed into broad categories such as **certai probable**, **possible**, **unlikely**, **conditional/unclassified**, or **unassessable**.
This system relied heavily on **clinical judgment**, not algorithmic gates, and allowed temporal association and biological plausibility to carry significant weight.

2. 2005: WHO AEFI Causality Aide-Mémoire

In 2005, WHO issued its first dedicated guidance for AEFI investigations, the *AEFI Causality Assessment Aide-Mémoire*.
This document encouraged national programs to classify AEFIs using a structured still **relatively clinician-driven** approach. The emphasis remained on **contextual assessment**, proximity in time, and differential diagnosis—without the stringent "ineligible/unclassifiable" categories that dominate the current method.

3. 2012: CIOMS/WHO Working Group on Vaccine Pharmacovigilance

A turning point came in 2012, when CIOMS and WHO published a joint report formalizing **precise definitions** and **standardized terminology** for vaccine safety. This report influenced all later frameworks by promoting more uniform, globally aligned analysis, and explicitly redefining concepts such as "coincidental AEFI" an "vaccine product–related reactions."

4. 2013: WHO AEFI Manual (1st Edition of Revised Classification)

The **2013 manual** replaced the WHO–UMC "drug causality" categories for vaccine events, introducing four new AEFI outcomes:

- *Consistent with causal association*
- *Inconsistent with causal association*
- *Indeterminate*
- *Unclassifiable*

This was a significant methodological shift. While temporal association still played role, the framework required a more systematic process for ruling out alternative causes. Importantly, **this was the first appearance of major exclusion categories** th could prevent cases from ever reaching causality assessment.

5. 2019: WHO AEFI Manual (2nd Edition, Updated Framework)

The 2019 update—now the global standard—further tightened the structure of AEF assessment.
Key changes included:

- **Clearer and expanded definitions of "ineligible" and "unclassifiable" cases**, increasing the likelihood that cases lacking full documentation would be excluded.
- Greater emphasis on *non-vaccine causes*, including stress responses and background rates of illness.
- Introduction of more formalized graphical algorithms and step-based decision gates.
- An explicit warning that causality "**should not be linked without adequate information**", shifting the evidentiary burden toward near-certainty rather tha clinical plausibility.

With these refinements, the framework became far more conservative in assigning causality—effectively requiring families and clinicians to produce comprehensive, often specialized medical evidence that is rarely obtainable in real-world scenarios.

Summary

From the 1970s to the early 2000s, AEFI analysis relied primarily on expert clinical judgment, flexible evaluation of temporal relationships, and open consideration of biological plausibility.
Between 2012 and 2019, WHO guidance shifted toward a **rigid, documentation-hea exclusion-first model**, culminating in the current system in which the majority of reported cases are categorized as "ineligible," "unclassifiable," "inconsistent," or "indeterminate."
The 2019 manual therefore represents not simply an update but a fundamental methodological transformation—one that has had far-reaching implications for families seeking recognition of vaccine-related harm.

Appendix C: Earlier version of the article prepare by ChatGPT

TITLE OPTIONS

1. **How the 2019 WHO Causality Guidelines Redefined Vaccine-Related Death Investigations**
2. **When Causality Cannot Be Proven: Understanding the WHO's 2019 AEFI Framework**
3. **Why Only Four COVID-19 Vaccine Deaths Were Classified as "Causally Linked": A Policy Analysis**

SUBTITLE OPTIONS

1. **Why the revised WHO methodology makes it extremely difficult for affected families to obtain causality findings—especially during high-volume vaccinat campaigns.**
2. **Understanding how new international guidance changed the evidentiary threshold for vaccine-related injury and death investigations in Canada.**
3. **A data-informed review of the WHO's AEFI framework and its impact on transparency, accountability, and trust in public health.**

ARTICLE (WA FORMAT)

Introduction

Across Canada, many families have attempted to navigate the federal system for reporting adverse events following COVID-19 vaccination. They rely on federal dat including the **Reported Side Effects Following COVID-19 Vaccination in Canada** dashboard, last updated on 29 September 2023. That dashboard reports **488 deaths** occurring **after** COVID-19 vaccination. Yet only **four** of those were ultimately classified as "**consistent with causal association to immunization**".

The central question for Canadians—especially for public servants, union members and those affected by mandatory workplace vaccination policies—is this:

How did 488 post-vaccination deaths result in only 4 causally associated cases?

The answer lies in the **2019 revised WHO guidance on causality assessment of AE** (Adverse Event Following Immunization). This 88-page manual created a new methodology, new terminology, and new evidentiary thresholds that countries—including Canada—have since adopted. The manual is attached here for reference.

This article explains, in clear and policy-neutral terms, how these new guidelines function, why they make causality extremely difficult to establish, and how this affe families such as the Hartman family—whose teenage son Sean died shortly after mandatory vaccination, yet the causality ruling could not be obtained.

This analysis is not an attack on health authorities. Rather, it is a call for transparer understanding, and informed debate—values central to a healthy public service.

1. The Federal Data: 488 Post-Vaccination Deaths, Only 4 Causally Linked

According to the Public Health Agency of Canada:

- **488** deaths were reported following COVID-19 vaccination
- **131** could not be assessed due to missing information
- **357** had enough information for preliminary assessment
  - **167** were "unclassifiable" (insufficient data)
  - **109** were deemed "inconsistent with causal association"
  - **77** were "indeterminate"
  - **4** were "consistent with causal association to immunization"

In other words:

484 of 488 deaths were excluded from causal association, largely due to lack of information or lack of definitive proof.

This outcome is not the result of negligence or misconduct. It is the direct, predicta outcome of applying the **WHO 2019 causality framework**, which requires a very hi often practically unreachable level of evidence before causality can be confirmed.

2. The 2019 WHO AEFI Manual: A New Evidentiary Standard

The WHO manual (Second edition, 2019 update) replaced the earlier WHO-UMC system with a more rigid and algorithmic process. It introduced:

- **Mandatory multi-step eligibility gates**

- **Strict definitions for "valid diagnosis"**
- **High documentation requirements**
- **An expanded list of reasons an AEFI cannot be classified**
- **New emphasis on "stress responses," "coincidental events," and "other underlying causes"**

The manual repeatedly states that:

> *"Causality assessment usually will not prove or disprove an association… A definite cau association often cannot be established."*

This is a foundational assumption of the system. Under the 2019 rules, causality becomes the exception—not the default possibility.

3. Why It Becomes Almost Impossible for Families to Prove Causality

The revised framework includes four major structural barriers:

Barrier 1: Missing paperwork = case cannot be assesse

If any required piece of medical information is incomplete, unavailable, or lost—especially during emergency clinical care—the case becomes:

- "**Ineligible**" (cannot even begin assessment), or
- "**Unclassifiable**" (assessment started but could not be completed).

This is what happened in **167** of Canada's death reports.

Families in crisis—especially after sudden death—are rarely in a position to assemb exhaustive medical documentation.

Barrier 2: Every alternative explanation must be ruled out first

The manual requires reviewers to eliminate *all other possible causes*, even theoretical ones:

- pre-existing conditions
- undetected infections
- spontaneous unrelated events
- genetic predispositions
- environmental exposures
- stress responses
- background rates of sudden death

If any plausible alternative exists—even if unproven—the case moves into:

- "**Inconsistent with causal association**", or
- "**Indeterminate**"

Barrier 3: Temporal proximity is not considered evidence

The updated system explicitly warns that an event occurring shortly after vaccinati **does not indicate causality**.

This directly conflicts with traditional medical logic (post hoc diagnosis) that clinicians use for most other pharmaceutical assessments.

Barrier 4: Definitive proof is almost never available

The manual states that **laboratory proof** is the only "definitive" evidence, yet:

- For COVID-19 vaccines, no such laboratory test exists.
- For sudden cardiac events, pulmonary embolism, myocarditis leading to arrhythmia, or autoimmune responses, immediate tissue sampling is rarely possible.
- Autopsies—when performed—often cannot determine mechanistic causality.

Thus, the system defaults to "indeterminate."

4. The Consequence: Why Canada Recorded Only Four Causally Linked Cases

Under the WHO methodology, a death can only be linked to vaccination if **all four** criteria are satisfied:

1. **No missing information**
2. **A valid, precisely defined diagnosis**
3. **Strong evidence ruling out all alternative explanations**
4. **Strong evidence that the vaccine *did* cause the event**

The vast majority of real-world cases fail step 1 or 3.

Thus, structurally:

The WHO framework makes it extremely difficult—often practically impossible–for individuals or families to obtain a finding of vaccine-related causality.

This explains why families like the Hartmans, despite credible timelines and the absence of alternative explanations, were unable to obtain causality rulings.

5. Why This Matters to Canadian Public Servants and Union Members

Between 2021 and 2022, millions of Canadians—including federal public servants—faced workplace mandates, employment consequences, and social pressure to vaccinate.

When rare adverse events occur, especially in young and previously healthy individuals, affected families expect:

- transparent processes
- fair evaluations
- accessible pathways for review
- accountability, where appropriate

However, if the **global standard adopted by Canada** makes causal confirmation nea unattainable, families are left without recognition, support, or closure.

For unions and public servants, this raises critical questions about:

- equitable treatment of members
- access to compensation programs
- rights of employees affected by mandated medical interventions
- adequacy of information provided before mandates were imposed
- long-term policy lessons for future national emergencies

The purpose of this article is not to assign blame, but to ensure that public servants understand the systems governing their rights, risks, and protections.

6. Towards a More Transparent and Supportiv Framework

Several reasonable reforms could improve confidence:

- **Independent AEFI review pathways** for mandated populations
- **Clearer communication** to Canadians about how causality assessments actuall work
- **Alternative compensation mechanisms** that do not require proof of causality
- **Regular audits** of incomplete or unclassifiable cases
- **Statutory rights to access all relevant records**, including autopsy materials
- **Union involvement** in supporting affected members and families

These reforms would not undermine public health. They would strengthen trust.

Conclusion

The 2019 WHO AEFI causality manual represents a global shift toward an extremel stringent evidentiary framework. Its structure ensures that only the rarest, most clearly documented cases can be classified as causally linked to vaccination.

This explains why, in Canada:

- 488 reported deaths
- resulted in
- only 4 cases deemed causally consistent.

For families who lost loved ones shortly after vaccination, this system can feel indistinguishable from systemic dismissal. For public servants and union members, understanding this framework is essential for informed dialogue about rights, accountability, and future emergency policies.

Transparency is not a threat to public health. It is the foundation upon which trust built.

References

- Public Health Agency of Canada. *Reported Side Effects Following COVID-19 Vaccination in Canada*.
- World Health Organization. *Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO classification, 2nd ed., 2019 update*. Geneva: WHO; 2019.
- Additional peer-reviewed literature on vaccine safety methodology and AEFI classification.

Disclaimer

This article's opinions are those of the author and do not represent the views of any Canadian agency, department, university, or organization. It is provided for information and discussion purposes only and does not constitute legal, medical, or professional advice.

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This article was written with assistance from ChatGPT using the prompt: *"Draft a V format Substack article for DG4VP analyzing how the 2019 revised WHO causality*

assessment guidelines (AEFI manual) affect the classification of post-vaccination deaths in Canada, referencing federal data showing 488 reported deaths with only 4 causally associa explaining why the methodology makes causation nearly impossible to establish, and incorporating attached WHO document content."

Based on approximately 2,500 words and 25 minutes of narrated input and collaborative drafting with the author.
ChatGPT was also used to ensure political neutrality, factual accuracy, and alignme with the Public Servant Code of Values and Ethics.
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OPINION ARTICLE

REVISED Revised World Health Organization (WHO)'s causality assessment of adverse events following immunization—a critique

[version 2; peer review: 2 approved]

Jacob Puliyel[1], Pathik Naik[2]

[1]St Stephen's Hospital, Delhi, 110054, India
[2]Pathik Children Hospital, Surat, 394219, India

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Abstract

The World Health Organisation (WHO) has recently revised how adverse events after immunization (AEFI) are classified. Only reactions that have previously been acknowledged in epidemiological studies to be caused by the vaccine are classified as a vaccine-product–related-reaction. Deaths observed during post-marketing surveillance are not considered as 'consistent with causal association with vaccine', if there was no statistically significant increase in deaths recorded during the small Phase 3 trials that preceded it. Of course, vaccines noted to have caused a significant increase in deaths in the control-trials stage would probably not be licensed. After licensure, deaths and all new serious adverse reactions are labelled as 'coincidental deaths/events' or 'unclassifiable', and the association with vaccine is not acknowledged. The resulting paradox is evident.

The definition of causal association has also been changed. It is now used only if there is 'no other factor intervening in the processes'. Therefore, if a child with an underlying congenital heart disease (other factor), develops fever and cardiac decompensation after vaccination, the cardiac failure would not be considered causally related to the vaccine. The Global Advisory Committee on Vaccine Safety has documented many deaths in children with pre-existing heart disease after they were administered the pentavalent vaccine. The WHO now advises precautions when vaccinating such children. This has reduced the risk of death. Using the new definition of causal association, this relationship would not be acknowledged and lives would be put at risk. In view of the above, it is necessary that the AEFI manual be revaluated and revised urgently. AEFI reporting is said to be for vaccine safety. Child safety (safety of children) rather than vaccine safety (safety for vaccines) needs to be the emphasis.

Open Peer Review

Approval Status ✓ ✓

	1	2
version 2 (revision) 29 May 2018	✓ view	✓ view
version 1 28 Feb 2018	? view	? view

1. **Tom Jefferson**, University of Oxford, Oxford, UK

2. **Peter Aaby**, Bandim Health Project, Bissau, Guinea-Bissau

Any reports and responses or comments on the article can be found at the end of the article.

Keywords
Pentavalent vaccine; quinvaxim; pharmacovigilance; Hill criteria; macrophagicmyofasciitis; periodic safety update reports; Brighton classification; adverse drug reactions; sudden unexpected death; TOKEN study

Corresponding author: Jacob Puliyel (puliyel@gmail.com)

Author roles: Puliyel J: Conceptualization, Writing – Original Draft Preparation; **Naik P**: Conceptualization, Writing – Review & Editing

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REVISED **Amendments from Version 1**

1. Corrections in language and for better readability.
2. Article divided into two sections with Section A covering AEFI assessment till Brighton and Section B dealing with the Revised AEFI categories after Brighton.
3. The Bradford Hill criteria introduced and Bradford Hill's biological gradient is discussed in the context of the harms of using multiple antigens all together.
4. Also the limitation of current knowledge (biological plausibility) delaying the acknowledgement of deaths in girls with high dose measles has been introduced.
5. Reference to death of children with congenital heart disease after pentavalent vaccine introduced in main body of article.
6. Box 5 It is clarified that with some rotavirus vaccines, *rotavirus diarrhea* is reduced but there no difference in the overall incidence of diarrhea (all-cause diarrhea).
7. The matter of the difference in death rates in boys and girls with high potency measles vaccine for which there is yet no scientifically plausible explanation has been added
8. A new paragraph on the mechanism of deaths after multiple vaccines related a cytokine storm (and deaths in susceptible babies) as held in a court ruling was added
9. A paragraph on the ruling that Italian army men must receive no more than 5 antigens simultaneously has been introduced.
10. The heading Conclusion was removed.
11. A new paragraph on "Where do we go from here" has been introduced.
12. Mention has been made of the efforts made to get the WHO to respond to the points made here.

See referee reports

Introduction

One of the earliest countries to introduce the pentavalent vaccine (combined diphtheria, tetanus, pertussis, Hib, and hepatitis B) was Sri Lanka[1]. A pentavalent vaccine Quinvaxem (Crucell) was introduced in Sri Lanka on January 1, 2008. On 29 April that year the vaccine was withdrawn by the government following five deaths. A World Health Organization (WHO) team of experts investigated the adverse events following immunization (AEFI) and reported the deaths were 'unlikely' to be related to vaccination. The full report was not widely available before it was presented to the High Court in Delhi, India[2]. From the full report it became clear that there was no alternate explanation for three deaths. Thus, they should have been classified as 'probable / likely' related to immunization, using the WHO Brighton criteria for classification of AEFI (see Box 1). The experts deleted the categories 'probable' and 'possible' from the AEFI Classification they used for assessment and then reported that the deaths were 'unlikely' related to vaccination. The way the Brighton Classification was altered to enable this misleading classification of the deaths in Sri Lanka was reported in the Indian Journal of Medical Research and the British Medical Journal[3,4].

On 4 May 2013 the Ministry of Health of Vietnam suspended the use of Quinvaxem (Crucell) after it had caused 12 deaths[5]. The WHO experts investigated the Vietnam deaths. This time they reported, 'Quinvaxem was pre-qualified by WHO…, no fatal adverse event following immunisation (AEFI) has ever been associated with this vaccine'[5]. This is the same brand of pentavalent vaccine that was used in Sri Lanka where WHO experts had previously documented AEFI deaths. It appears that after the Sri Lanka investigation and shortly preceding the Vietnam investigation, the methodology used for AEFI classification was revised. Using the revised AEFI causality assessment, AEFI reported from Sri Lanka could be classified as 'Not a case of [AEFI]'. Both Sri Lanka and Vietnam were persuaded to reintroduce the Pentavalent vaccine after the WHO report. The new mechanism that allows AEFI to be classified as 'Not a case of [AEFI]' will be discussed.

Section A

Historical background of causality assessment: from Hume up to Brighton

The evolution of the logic of causality assessment is fascinating. Eminent philosophers, scientists, legal luminaries, and statisticians have grappled with the issue and a great deal has been written about it. It will be impossible to distil all of that for this write-up, except at the risk of oversimplification. As we are concerned primarily with assigning causality to alleged drug reactions, only some aspects of the debate are germane to this discussion.

Defining cause and effect (X is the cause of Y) has not been easy. According to Hume[6], the major features of causation are temporal precedence (X must precede Y), contiguity and regularity of the association of causes and their effects. Confounding, however, is possible by a third factor.

It is known that the consumption of ice cream is higher when there is a spike in the incidence of sunburns. One can conclude wrongly that eating ice cream can cause sunburns. The third factor in this case is hot weather conditions. Both eating ice cream and getting sun burnt are associated with sunny days. Hume avoided the confounding problem by stipulating that X can be considered as cause of Y only if X is sufficient for Y. That is, however, fallacious. Striking a match can light a fire only if there is oxygen. In itself, striking the match is not sufficient. The alternate position could be that X is cause of Y if, and only if, X is necessary for Y[7]. John Mackie suggested that in nature there could be multiple reasons (causes) for the same outcome[8]. Thus X may not be necessary for Y but at the same time, X may be sufficient for Y. A building may be set on fire by a spark from a short circuit in the electrical wiring (X) or as the result of an act of arson (Z). Thus neither X) nor (Z) is necessary for Y, but both (X) and (Z) are sufficient causes for Y. The question then is whether Y would have occurred were it not for the factor X. This is known as the 'but for' test. In jurisprudence, it has been acknowledged that where there are multiple causes working simultaneously the 'but for test is unworkable and the question of causality is whether the putative cause materially contributed to the result[9]. This has been argued in the case of Graham Dickie V. Flexcon Glenrothes Limited [2009] ScotSC 143 (04 September 2009). Peter M. Willcock and James M. Lepp have discussed 'Causation in medical negligence cases' which elaborates on these issues.

Box 1. WHO adverse events following immunization (AEFI): Causality assessment Brighton criteria

Causality Term	Assessment Criteria
Very likely/Certain	A clinical event with a plausible time relationship to vaccine administration and which cannot be explained by concurrent disease or other drugs or chemicals
Probable	A clinical event with a reasonable time relationship to vaccine administration; is unlikely to be attributed to concurrent disease or other drugs or chemicals.
Possible	A clinical event with a reasonable time relationship to vaccine administration, but which could also be explained by concurrent disease or other drugs or chemicals.
Unlikely	A clinical event whose time relationship to vaccine administration makes a causal connection improbable, but which could be plausibly explained by underlying disease or other drugs or chemicals
Unrelated	A clinical event with an incompatible time relationship and which could be explained by underlying disease or other drugs or chemicals
Unclassifiable	A clinical event with insufficient information to permit assessment and identification of the cause

Reference

http://www.rho.org/files/rb3/AEFI_Causality_Assessment_WHO_2005.pdf

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In biology, there is a further probabilistic element to causation. If men of the same height and women of the same height were to have children, their children will not all be of the same height. For the same set of observed causal factors, there is probability distribution of possible heights[7].

To evaluate causation Bradford Hill[10] described 9 guiding principles favouring a causative association: 1) Strength - effect size; 2) Consistency – reproducibility with similar observations at different places by different people;3) Specificity – absence of an alternate explanation; 4) Temporarily with cause always proceeding the effect; 5) Biological gradient demonstrating a dose response gradient; 6) Biological plausibility – although this may be limited by the state of current knowledge; 7) Coherence between epidemiology and laboratory findings; 8) Experimental evidence; and 9) Analogy - looking at the effect of similar factors. These considerations are applicable to alleged vaccine reactions also.

Adverse drug reactions

Adverse drug reactions (ADRs) can follow after the use of any drug. Careful evaluation is required to distinguish the events that are causally related to the drug from coincidental events. Causality assessment is crucial because the events could be iatrogenic and avoidable. Usually only a few react adversely to drugs on the market, whereas others are unharmed. The attribution of causality for such occasional happenings is particularly complex. Investigations of ADRs put causative association on a probability scale. The causality-assessment system developed by the World Health Organization Collaborating Centre for International Drug Monitoring is called the Uppsala WHO Centre (WHO-UMC) Scale. This is widely used as it offers a simple methodology (see Box 2). In consonance with Hume's postulates, the first step is to confirm temporal precedence and contiguity. The adverse event must appear after the suspected drug is administered and within a reasonable time-frame. Events where the time-to-drug-intake makes a relationship improbable are classified as 'unlikely' to be related. Events within a reasonable time and for which there is no alternate explanation (which cannot be attributed to disease or other drugs) are classified as 'probable / likely' related to the drug in question. Drug reaction is classified as 'possible' where there is a reasonable time relationship, but for which there are also alternate explanations. In terms of John Mackie's aphorism, the drug is considered sufficient but not necessary for the effect.

To be classified as 'very likely/certain' the reaction needs to be an objective and specific medical disorder or a recognized pharmacologic phenomenon, and there must be evidence of dose-related reaction or proof in terms of reappearance of symptoms on rechallenge. If death should occur as ADR, rechallenge is impossible. It is usually difficult to be certain about the causality of fatal ADR and the reaction is often classified as 'probable/likely' or 'possible'.

The difference between certain and probable/likely is simply the acceptable standard of proof. For "certainly," a high-standard irrefutable proof is called for (falsification of the theory by a single irregular outcome). A single well-documented spontaneous rechallenge is strong evidence of regularity (even though in just one patient). For 'very likely', the standard of proof is proof beyond reasonable doubt.

Box 2. WHO–UMC causality categories

Causality Term	Assessment Criteria
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable/Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake, Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional/ Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable/ Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or Contradictory • Data cannot be supplemented or verified

Reference The Uppsala Monitoring Center. The use of the WHO-UMC system for standardised case causality assessment. Reproduced with permission of *Uppsala monitoring centre*. Available at https://www.who-umc.org/media/2768/standardised-case-causality-assessment.pdf

'Balance of probability' is the level of proof needed to classify as 'probable' or 'possible'and this is the standard of proof, which is relevant to medicine and for pharmacovigilance. With this level of proof (prima facie true), the 'Precautionary Principle' must be triggered. This is described later.

Adverse events following immunization

Vaccines are drugs used as a preventive measure, given to entire cohorts of healthy persons. As they are administered in the absence of any disease, there is very high expectation that they will produce few adverse effects. But there is low tolerance for serious adverse events and deaths. Adverse events following immunization (AEFI) must be monitored more carefully than other drugs. A credible immunization safety evaluation and monitoring system is essential for the success of immunization programmes. The WHO developed the 'Adverse Events Following Immunization (AEFI): Causality Assessment' otherwise known as the Brighton Classification. It is very similar to the WHO-UMC causality categories for ADR. Until recently, this was the touch-stone used by WHO experts when AEFI were reported (see Box 1).

One measure of the sensitivity and responsiveness of the WHO-UMC causality categories (which preceded the Brighton classification) is the alacrity with which the rotavirus vaccine RotaShield was withdrawn in 1999 after 12 cases of vaccine-induced intussusceptions were reported. About 1 in 2000 children younger than 2 months of age develops intussusception from other causes. Based on the results of the investigations, the Centre for Disease Control (CDC) estimated that one or two additional cases of intussusception would be caused among each 10,000 infants vaccinated with the RotaShield vaccine. After about 100,000 infants were immunized, the vaccine was withdrawn[11]. In 2013, the Brighton classification was abandoned and replaced by the revised AEFI classification. The reasoning that prompted the switch away from the Brighton classification has not been stated explicitly in the revised AEFI manual[12].

Section B

Brighton Abandoned: Revised Causality Assessment

The Council for International Organizations of Medical Sciences (CIOMS) / WHO: Report on vaccine pharmacovigilance. In October 2010, after a series of meetings, 40 experts (of whom 19 were industry representatives with possible conflicts of interest) helped rewrite the classification criteria for AEFIs. The document titled 'Definitions and Application of Terms for Vaccine Pharmacovigilance' is reported to 'provide tools for higher excellence of signal detection and investigation of adverse events following immunization'[13].

On page 170 of this 193-page document, under the heading Notes for Guidelines, it is stated in small print: 'If there is adequate evidence that an event does not meet a case definition, such an event should be rejected and should be reported as 'Not a case of

[AEFI]'. Such evidence is considered adequate, if an exclusion criteria is met, or an investigation reveals a negative finding of a necessary criterion (necessary condition) for diagnosis. Such an event should be rejected and classified as 'Not a case of [AEFI]".'[13]

The CIOMS/WHO 'tool for excellence in signal detection' works by turning a blind eye to AEFI—classifying AEFI as 'Not a case of [AEFI]'. Not only is the causative association of AEFI to immunization denied, but it is made to appear the AEFI never occurred. Signal detection is no longer possible once AEFIs are removed from the system after being designated as 'Not a case of [AEFI]'. The story in the *Introduction* above where the WHO asserted in May 2013 that no fatal AEFI has ever been associated with pentavalent vaccine[5], suggests the Sri Lanka AEFI deaths[2] are now reclassified as 'Not a case of [AEFI]' using the CIOMS/WHO tool.

Only reactions that meet case definitions of reactions associated with the vaccine previously are considered. According to the CIOMS / WHO report (page 11), a case definition can be adopted from the standard literature or by the reviewers themselves.

The case definition helps draw on previous epidemiological research and facilitates further research to confirm a causal link. However, excluding causality in relation to an individual event cannot be dependent on that event conforming to a pre-existing case definition. The pejorative use of the term 'rejected' (in the statement; 'Such an event should be rejected and classified as "Not a case of [AEFI]"'), suggests a defensive posture. It has been pointed out previously that reports of AEFIs should be assessed for causality and classified: they are not to be 'rejected'[14].

The WHO revised AEFI manual

In March 2013, the revised WHO 'User Manual for AEFI' was published with a new algorithm[12]. The manual acknowledges that it has adapted definitions and concepts from the CIOMS / WHO report. The new algorithm for AEFI is reproduced in Figure 1.



Figure 1. Flow chart demonstrating the revised AEFI classification new algorithm.

Revised AEFI classification: new categories of causality

Only events that occur after vaccine administration are eligible for AEFI causality assessment. This first step is reminiscent of Hume's dictum regarding precedence and contiguity. In the new scheme, causality is classified in four categories: 'Consistent causal association to immunization,' 'Indeterminate', 'inconsistent causal association to immunization', and 'Unclassifiable'.

Consistent causal association to immunization

This is the highest level of causal association in this new classification. It is less definitive than 'very likely / certain' in the old scheme. It does not call for irrefutable proof or even proof beyond reasonable doubt. Not even is the balance of probability assessed. In the new scheme, an adverse event can simultaneously be classified as 'Consistent causal association with immunization' and 'Inconsistent causal association with immunization'. On page 36 of the revised manual for AEFI[12] is the example of acute flaccid paralysis in a child after oral polio vaccine, who had had a fever 1 month prior to onset of paralysis. The stool culture showed vaccine strain polio virus. It was classified as 'Consistent causal association with immunization' as it is a known reaction after polio vaccination and the paralysis happened within time window of increased risk. It was also classified as 'Inconsistent causal association with immunization' because the fever, 1 month prior to paralysis had not been investigated completely. This ambiguity, which admits diametrically opposite conclusion simultaneously, is a hallmark of the new scheme.

It is suggested in the revised AEFI manual that before the question 'Did the vaccine given to a particular individual cause the particular event reported?' (the question of 'Did it?') is answered, one has to answer the question 'Can the given vaccine cause a particular adverse event?' (Can it?). The inference is that only if there is evidence at the population level that the vaccine can cause the adverse event, is the reaction classified as 'Consistent with causal association with immunization'.

This inference is flawed on two grounds. On the one hand, it denies all new associations seen in Phase 4 trials. On the other, if it is a known adverse reaction, causal association is accepted even where the events could have happened by coincidence. Just because intussusceptions are acknowledged as an adverse event following rotavirus vaccination, it does not follow that all intussusceptions in the critical window of increased susceptibility are necessarily caused by it. The residual uncertainty at this highest level of causal association robs it of value in addressing the problem of AEFI caused by vaccines.

Inconsistent causal association to immunization

At the bottom of the new causality classification hierarchy is 'Inconsistent causal association to immunization'. This group can include reactions for which there is no alternate explanation (and which would have been classified in the 'Probable' category previously). They would fall in the group 'Inconsistent causal association with vaccination' merely because causal association with immunization has not been documented in prior epidemiological studies. Into the same group are placed reactions that would have been considered 'Unlikely' to be associated, and those that would have been classified as 'Unrelated'. The use of the same category 'Inconsistent causal association to immunization' for such a wide variety of clinical situations merely obfuscates the issues. In the revised scheme, this term is used to suggest that there is no relation between the AEFI and immunization. No matter how frequently the reaction categorized as 'Inconsistent with causal association' occurs, it would not be investigated as a new signal of a causal association.

Indeterminate

Classification in the 'Indeterminate' group is reserved for reactions that could have been caused by immunization, but for which causal association has not been documented previously. It is projected that information on AEFI that are classified as indeterminate will be pooled and analysed in order to understand if the AEFI represents a new signal of an unrecognized event. The scheme is however loaded such that literally no AEFI are categorized into this group. How this is accomplished is discussed later on.

Unclassifiable

Clinical events with insufficient information to permit assessment and identification of cause are put in the 'Unclassifiable' group.

Revised AEFI classification: the new algorithm

Just as the final categories of causality association are vague, overlapping, and not clearly differentiated, the algorithm used to make a decision on causality[12] does not appear to be logical or well thought through.

The algorithm is shown in Figure 1.

Causality assessment algorithm

Four sets of questions need to be answered in sequence:

1. Is there strong evidence of other causes?
2. Is there known causal association with the vaccine or vaccination and if so, whether the event was within the time window of increased risk?
3. If there is no causal association known or if it is not within the time window of increased risk: Is there strong evidence against a causal association?
4. If there is no such strong evidence against causal association, the next step is to look at other qualifying factors for classification:
    a. Could it happen independently of vaccination (background rate)?
    b. Could the event be manifestation of another health condition?
    c. Did a comparable event occur after a previous dose of a similar vaccine?
    d. Was there exposure to a potential risk factor or toxin prior to the event?
    e. Was there acute illness prior to the event?
    f. Did the event occur in the past independently of vaccination?

g. Was the patient taking any medication prior to vaccination?

h. Is there biological plausibility?

Step 1

The first step in the revised algorithm is to look for strong evidence for other causes. If there is an alternate explanation, the AEFI is classified as 'Inconsistent with causal association to immunization'. John Mackie has noted that in nature there could be multiple reasons (causes) for the same outcome, and if two possible causes exist simultaneously either of them could be the causative factor[8]. It is to be noted that with the WHO-UMC classification of ADR and the old WHO/Brighton Classification of AEFI, even if an alternate explanation is available, a causative association with drug or vaccine is still considered 'Possible'. Moreover, the two causes could be working synergistically. An example of this is where genetic and other individual susceptibility factors make one susceptible to developing an AEFI[15,16]. In the new algorithm, if there is an alternate explanation for the AEFI, or another factor is involved, causative association with vaccine is rejected[12,14].

Step 2

The COIMS / WHO Report on pharmacovigilance is used at this level[13]. AEFI-specific case definitions for some reactions have been developed. In instances where specific case definitions and criteria are not available for a particular AEFI, it is permissible to improvise using case definitions adopted from 'standard medical literature, or national guidelines or they may be adopted locally by the reviewers' (page 11 CIOMS / WHO report). AEFI that meet case definitions and which occur within the time window of increased risk are classified as 'consistent causal association to immunization'.

The acceptable time window for each adverse event is different. The macrophagic myofasciitis affected patients usually are middle-aged adults presenting diffuse arthromyalgias, chronic fatigue, and marked cognitive deficits, fatigue, or depression due to long-term persistence of aluminium hydroxide within macrophages at the site of previous immunization[17]. However, AEFI surveillance seldom extents for so long.

Step 3

Theoretically, reactions that are not known to have a causal association or those that are not in the time window of increased risk can move to Step 3. At this stage, an enquiry is made whether there is strong evidence against causal association. Proving of a negative is notoriously difficult as it is impossible to affirm that in every circumstance, an irregular outcome is impossible. The example provided in the manual relates to MMR and autism.

It is reported that the Global Advisory Committee on Vaccine Safety (GACVS) and Council for International Organizations of Medical Sciences (IOM committee) have concluded that no evidence exists of a causal association between MMR vaccine and autistic disorders. Such AEFI must be classified as 'inconsistent with causal association to immunization' according to the new algorithm.

After publication of this AEFI user's manual, the conclusion about MMR and autism have become disputed again (see Box 3). This shifting evidence calls into question the usefulness of introducing this step in the algorithm of AEFI.

Step 4

Assuming that no such 'strong evidence against a causal association' exists, reactions that are not known to have a causal association with the vaccine, can go to Step 4. It is from here that reactions may be classified as indeterminate allowing it to be evaluated in future as a new signal.

The question at this point is whether it is 'classifiable — meaning whether all the tests needed have been performed to allow it to be classified under the CIOMS / WHO definitions. This is the second time these definitions are invoked during the AEFI evaluation.

Box 3. MMR and autism risk in African American children.

In 2004 the CDC published research demonstrating that there was no link between the vaccinated children's risk of a subsequent diagnosis of autism and the age at which the child is vaccinated with MMR[a]. It has now been revealed through the testimony of one of the authors Dr. W. W. Thompson who turned whistle blower, that the risk of autism among African American children vaccinated before the age of two years was 340% that of those vaccinated later. However this data was deliberately removed from the analysis to arrive at the CDC's proclaimed conclusion. CNN published the story of the CDC whistle-blower[b], and Thomson was granted whistleblower immunity by the Obama administration[c].

References:

a. DeStefano F, Bhasin TK, Thompson WW, Yeargin-Allsopp M, Boyle C. Age at first measles-mumps-rubella vaccination in children with autism and school-matched control subjects: a population-based study in metropolitan Atlanta. Pediatrics. 2004;113:259–66. doi: 10.1542/peds.113.2.259

b. Goldschmidt D. Journal questions validity of autism and vaccine study [Internet]. CNN.com. 2014 Aug 28 [cited 2014 Sep 29]. Available from: http://edition.cnn.com/2014/08/27/health/irpt-cdc-autism-vaccine-study

c. http://dailycaller.com/2015/02/03/obama-admin-grants-immunity-to-cdc-scientist-that-fudged-vaccine-rep4rt-whistleblower-plans-to-testify-before-congress

If some investigations are not done or not available, the AEFI is labelled as 'Unclassifiable' (or classified as 'Inconsistent with causal association to immunization' like how flaccid paralysis following OPV was classified, because investigations during an illness 1 month prior to paralysis were not available — see Appendix 3, page 36 of the AEFI manual[12] for this example).

If all the required investigations had been done and they met case definition criteria, they would have been classified as 'consistent causal association to immunization' at Step 2 and would not have come to Step 4.

The third possibility is that all the investigations had been done so it is classifiable but it did not meet case definitions. The CIOMS / WHO dictum is applied here: 'if there is adequate evidence that an event does not meet a case definition, such an event should be rejected and should be reported as "Not a case of [AEFI]". (See CIOMS / WHO Definitions and Application of Terms for Vaccine Pharmacovigilance, page 170[13]). It removes any chance that AEFI that has not been recognized as causatively associated with immunization in previous epidemiological studies will be included in the 'Indeterminate' group and evaluated as a new signal. Thus there seems to be only two options at step 4 : - either the reaction is classified as 'Unclassifiable' or it is categorized as 'Inconsistent causal association to immunization'. Categorization as 'Indeterminate' or 'Consistent causal association to immunization' are logically impossible given the riders mentioned above.

The exercise does not end there. Other qualifying factors are also enquired into at Step 4. It is recommended that alternate explanations in terms of background rate, other health conditions, exposure to a potential risk factor or toxin, acute illness, and other medication are again enquired into. Many of these 'other qualifying factors', like prior illness and concurrent drug use would presumably have been eliminated at Step 1 when looking for evidence for other causes. This enquiry is repeated again at Step 4 quite unnecessarily. Box 4 illustrates how, in spite of

Box 4. Sudden unexpected deaths (SUD) after pentavalent vaccine and the TOKEN Study.

With regard to AEFI a cluster of cases is defined as two or more cases of the same adverse event related in time or place or to the vaccine administered[a]. Pentavalent vaccine has caused numerous deaths in Asia but it is yet to be considered a new signal[b–f].

After the AEFI algorithm was revised, the deaths are now classified as 'Not a case of [AEFI]' on the grounds that deaths have not been reported as AEFIs in epidemiological studies involving the vaccine. However, the TOKEN Study contradicts this assertion[g].

The TOKEN Study was done specifically to assess a possible causal relationship between vaccination and unexplained sudden unexpected death (SUD) of children between their 2nd and 24th month of life. vonKries had previously found a statistically significantly increased standardized mortality ratio (SMR) within two days after vaccination with one (Hexavac®) of the two licensed hexavalent vaccines and the TOKEN study was done to confirm or refute the association[g]. The study was sponsored and supported by the Paul-Ehrlich-Institute (PEI) and the Federal Ministry of Health (Bundesministeriumfür Gesundheit).

A self-controlled case series (SCCS) was examined to look for a temporal association of vaccination to SUD. Parents were invited to participate in the study if their child had died of SUD. 37.6% of the eligible parents participated. The researchers found that parents were twice as likely to participate if their child had died within one week of vaccination. They used an inverse probability weighted analysis to compensate for this bias. The authors note that this was helpful to overcome the selection bias in infants under 9 months, but even so, the results are still likely to overestimate the risk of SUD in older children.

The weighted SCCS analysis, relative risk of SUD after pentavalent vaccination (first and second year of life) looking at risk period 0–3 days after vaccination versus control period 4–28/183 days showed RR of 8.11 (p= 0.006, 95% CI=1.81-36.24; Table 41 in the TOKEN Report). The weighted SCCS analysis, relative risk of SUD after hexa- or pentavalent vaccination (1st and 2nd year of life) looking at risk period 0–3 days versus control period 4–28/183 days was RR.2.19 (p= 0.031, 95% CI=1.08-4.45; Table 36 in the TOKEN Report)

It is clear from the above that there is reasonable evidence in epidemiological studies that SUDS can occur as AEFI following use of the pentavalent vaccine and the deaths following the use of this vaccine should not be a priori classified as 'Not a case of [AEFI]'.

References

a. http://vaccine-safety-training.org/detection-and-reporting.html

b. Lone Z, Puliyel J. Introducing pentavalent vaccine in the EPI in India: A counsel for caution. Indian J Med Res 2010; 132,: pp 1-3

c. Puliyel J. AEFI and the pentavalent vaccine: looking for a composite picture. Indian J Med Ethics. 2013;10:142-6.

d. No authors listed. Global Advisory Committee on VaccineSafety,12–13 June2013. Wkly Epidemiol Rec. 2013;88:301-12. Available at http://www.who.int/vaccine_safety/committee/reports/Jun_2013/en/ Accessed on 1/11/15

e. Sreedhar S, Antony A, Poulose N. Study on the effectiveness and impact of pentavalent vaccination program in India and other south Asian countries. Hum Vaccin Immunother. 2014;10:2062-5.

f. Martin Schlaud M, Poethko-Müller C, Kuhnert R, Hecker H Robert Koch Institute. Study on deaths in young children (2nd to 24th month of life) (TOKEN Study) http://www.rki.de/DE/Content/Gesundheitsmonitoring/Studien/Weitere_Studien/TOKEN_Studie/Studyreport.pdf?__blob=publicationFile

g. vonKries R, Toschke AM, Strassburger K, Kundi M, Kalies H, Nennstiel U, Jorch G, Rosenbauer J, Giani G. Sudden and unexpected deaths after the administration of hexavalent vaccines (diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, Haemophiliusinfluenzae type b): is there a signal?. Eur J Pediatr. 2005;164:61-9.

there being epidemiological evidence (the TOKEN Study) that pentavalent vaccine can cause sudden unexpected death, the numerous deaths (as discussed in the introduction) are not acknowledged as caused by the vaccine, and the WHO expert report denies that deaths were ever reported as AEFI. The causality assessment of 132 serious AEFI cases uploaded on the website of the Ministry of Health and Family Welfare in India illustrates the consequence of deploying this new classification. 54 of these babies died, whereas 78 survived. The causality assessment found 50% of those who survived had reactions to vaccination but not even one death was classified as vaccine-related. Nearly all the deaths (96%) were simply classified as unclassifiable or coincidental, presumably because death has not previously been acknowledged as an adverse event caused by this vaccine[18]. Children admitted to hospital after vaccination with intractable convulsions, could be classified as having a vaccine-product related reaction, but if they died, the deaths would be classified as 'coincidental deaths'.

Other subtle changes in the definition of terms

'Causal association' redefined

The term causal association now means 'a cause-and-effect relationship between causative factor and a disease with no factor intervening in the processes'. This is a major step backward for patient safety. The old scheme recognized, for example, that an elderly person with chronic cardiac failure might develop symptoms of cardiac decompensation after influenza vaccination due to a vaccine-caused elevation in temperature or stress from a local reaction at the site of vaccination. The vaccine is therefore considered to have contributed to cardiac failure in this specific situation[19]. Under the new scheme, this outcome would not be considered as causally related to the vaccine. The question of whether the death would have occurred at that time, had it not been provoked by immunization, would not be acknowledged. Without this recognition, many elderly persons may be exposed to this risk of death unnecessarily when using this vaccine. If the vaccination of an infant was reported to have been followed by sudden death but the child was malnourished or otherwise unwell it does not mean that causality assessment should conclude no cause and effect relationship between the vaccine and the death. There is no scope in this definition to consider interacting causalities[14,15]. The Global Advisory Committee on Vaccine Safety has documented many deaths in children with pre-existing heart disease after they were administered the pentavalent vaccine. The WHO now advises precautions when vaccinating such children and this has reduced the risk of death[1]. Using the new definition of causal association, this relationship would not be acknowledged and lives would be put at risk.

According to Collet and colleagues, it is possible that some individuals experience greater immunogenic response to vaccines compared to the general population and therefore, understanding genetically determined predispositions to developing AEFIs is important[19]. However, these considerations will not be accounted for, in the new CIOMS /WHO causality assessment scheme. The contribution of vaccine in precipitating encephalopathy in patients who are susceptible on account of genetic factors will also not be considered[15]. Berkovic has used genetic analyses to identify *de novo* mutations in the sodium channel gene SCNIA in patients with alleged vaccine-induced encephalopathy[16]. Unwisely, in all these cases the contribution of the vaccine in precipitating the encephalopathy will be ignored.

It is a pity that after all these years, the authors should fall for the Hume fallacy that causality can be claimed only if X is sufficient in itself for Y. The fact that the immunization could have 'materially contributed' to the adverse events is ignored.

Biological plausibility

Biological plausibility is one of the Bradford Hill 'guiding principles' that favor causative association[10]. However, this is limited by the state of current knowledge and it should not be used in itself to deny causative association. For example it is now acknowledged that high-titer measles vaccine is associated with excess female mortality[20]. The recognition of this association was delayed because of the absence of a biologically plausible explanation. WHO experts now acknowledge that vaccines have non-specific effects which up-regulate or down-regulate both the innate and the adaptive immune system and this can influence child survival[21].

The association of intussusception with rotavirus vaccination was also accepted at a time when a biologically plausible explanation was not available[11] (See Box 5). Vaccine can therefore have both non-specific beneficial effects and also unexpected deleterious effects which should not be disregarded simply because a ready explanation for the same is not available at the time when it is first noticed.

Biological plausibility redefined

The meaning of the term biological plausibility has itself been redefined in the Revised AEFI manual. The manual specifies that biological plausibility can only be invoked when laboratory findings or symptom or sign are similar or consistent with natural history and pathophysiology of the infection or antigen. Other biologically plausible explanations (demonstrating there is a mechanism and capacity to lead from the cause to the effect)[7], do not qualify. The four approaches to ascertaining causality described by Brady include detection of neo-Humean regularity, examining the counterfactual, experimental manipulation and examining mechanisms and capacities[7]. The new AEFI recognizes only the experimental approach to the exclusion of other valid approaches and, as a result, can fail to detect causality in a number of cases resulting in harm.

Chronic fatigue syndrome and the HPV vaccine trial

The above discussion has assumed that adverse events that are reported in the original prelicensure randomised control trials, would be classified as adverse events known to be associated with the vaccine.

Slate investigated randomised trials of human papillomavirus (HPV) vaccines and found that potential side effects were collected for only two weeks in the year-long study. After 2 weeks, individual trial investigators decided, on personal judgment, whether to report medical problems as adverse events. Often they listed new problems as 'new medical history'. Myalgic encephalomyelitis, otherwise known as chronic fatigue syndrome

Box 5. Indian Rotavirus vaccine trials

The prequalification of Rotavac without safety data

RotaShield was withdrawn as it caused 1 excess case of intussusception per 10,000 children given the vaccine[11].

However, a new rotavirus vaccine Rotavac (Bharat Biotec) was licensed in India after a trial in 3 centres where the vaccine was administered to a total of 4500 children (a sample size too small to show up a rare event that occurs 1 in 10,000)[a,b]. In spite of this small sample it appears intussusceptions were so common with this vaccine[c] in one of the centres (Vellore), it was significantly higher than controls. The trial doctors refused to provide this segregated data in spite of repeated requests[d]. The government promised to monitor safety in a post marketing surveillance. However, the participants in this trial were not explained the risk seen in the RCT (as is mandatory for ethical clinical trials) and surveillance was for a limited window period of a few weeks after vaccination, whereas the adverse events noticed in the RCT were outside that window period. In remote parts of this country where the vaccine is deployed, in the absence of pediatric surgeons and radiologists, deaths from intussusception are likely to be misclassified as deaths from dysentery.

Even before the data of this post marketing surveillance is available, the WHO recently prequalified the vaccine to be used internationally[e].

Clinical trials of other rotavirus vaccines that reduce rotavirus diarrhoea but does not reduce overall incidence of diarrhoea[f] and another vaccine that increases the overall incidence of diarrhoea[g] instead of decreasing it, have been published.

References

a. Bhandari N, Rongsen-Chandola T, Bavdekar A, John J, Antony K, Taneja S, Goyal N, Kawade A, Kang G, Rathore SS, Juvekar S, Muliyil J, Arya A, Shaikh H, Abraham V, Vrati S, Proschan M, Kohberger R, Thiry G, Glass R, Greenberg HB, Curlin G, Mohan K, Harshavardhan GV, Prasad S, Rao TS, Boslego J, Bhan MK; India Rotavirus Vaccine Group. Efficacy of a monovalent human-bovine (116E) rotavirus vaccine in Indian children in the second year of life. *Vaccine*. 2014 Aug 11;32 Suppl 1:A110-6. doi: 10.1016/j.vaccine.2014.04.079. https://www.ncbi.nlm.nih.gov/pubmed/25091663

b. John J, Kawade A, Rongsen-Chandola T, Bavdekar A, Bhandari N, Taneja S, *et al.* Active surveillance for intussusception in a phase III efficacy trial of an oral mono- valent rotavirus vaccine in India. *Vaccine*. 2014;32(August (Suppl. 1)):A104–9/ http://dx.doi.org/10.1016/j.vaccine.2014.03.036.

c. Bajaj J, Puliyel JM. Intussusception risk with 116E rotavirus vaccine in Vellore, South India. *Vaccine*. 2016 Jan 20;34(4):403. doi: 10.1016/j.vaccine.2015.03.007. Epub 2015 Mar 21. https://www.ncbi.nlm.nih.gov/pubmed/25800733

d. *Puliyel JM.* 116 E Rotavirus Vellore Study: Request for Vaccine Safety Data. Response to Indian rotavirus vaccine concern over intussusception is unfounded, say researchers. http://www.bmj.com/content/350/bmj.h2867/rapid-responses

e. https://www.businesswire.com/news/home/20180124005715/en/World-Health-Organization-Grants-Prequalification-Bharat-Biotech%E2%80%99s

f. Kulkarni PS, Desai S, Tewari T, *et al.* A randomized Phase III clinical trial to assess the efficacy of a bovine-human reassortant pentavalent rotavirus vaccine in Indian infants. *Vaccine*. 2017. https://www.ncbi.nlm.nih.gov/pubmed/28967523

g. Kaur J, Puliyel J. Heat-stable oral rotavirus vaccine. *N Engl J Med*. 2017; 377:302 https://www.ncbi.nlm.nih.gov/pubmed/28328346

(CFS), is a condition characterized by long-term fatigue that limits a person's ability to carry out ordinary daily activities. Participants in the HPV trial reported to Slate that these debilitating symptoms of theirs were not even registered as adverse events.

Given that CFS was not recorded as an adverse event, it allowed the manufacturers to claim that CFS is not a 'known adverse event with the vaccine' and so to discount every case that was reported subsequently.

Rotavirus vaccine trials

Box 5 describes how adverse events, recorded in a randomized clinical trial (RCT) and sent to the regulatory authority for vaccine approval and license, are not made public. This goes against the European Court of Justice ruling that clinical study reports are made publically accessible.

Other problems with recording and reporting AEFI

Box 6 describes how the Periodic Safety Update Reports (PSUR) 15 and 16 of Infanrix Hexa and the findings from the reports was opened to public scrutiny by an Italian court. Box 7 describes how PSUR 19 was obtained under the Freedom of Information rules and shows how deaths reported in PSUR 16 were deleted from PSUR 19, when it was evident that the reported deaths exceeded the deaths expected by chance[22]. In 1986 President Ronald Reagan signed the National Childhood Vaccine Injury Act (NCVIA) (42 U.S.C. §§ 300aa-1 to 300aa-34) which created a no-fault system to compensate vaccine related injuries. This made it difficult to sue vaccine manufactures. It also set up Vaccine Adverse Event Reporting System (VAERS) mandating the reporting of adverse events. Box 8 describes the changes that prevent patients from holding manufacturers to account for adverse events caused by their products. Box 9 shows how AEFI data is no longer available easily. While on the one hand, the new classification discounts AEFI as 'Not a case of [AEFI]', safety data is being manipulated and made inaccessible.

Biological plausibility: reactions with multi-valent vaccines

Looking at the VAERS data of deaths after immunization, Goldman and colleagues found there was more mortality among babies who had received five to eight vaccines together, compared to those receiving fewer vaccines[23]. In the case of Boatman v. Secretary of Health and Human Services, 13-611 (Fed. CI 2017) where the infant aged 4 months had received 7 vaccine antigens on one day, the court, after hearing expert opinion, held that vaccine-stimulated inflammatory-cytokines can act as neuro-modulators and cause depression of the serotonergic 5-hydroxytryptophan (5-HT) system in the infant medulla and blunt the normal chemo-sensitive

Box 6. Periodic safety update reports : unfit for public consumption?

Justice Nicola Di Leo in Italy made public the 'confidential' 15th and 16th Periodic Safety Update Report (PSUR) on Infanrix hexa (GlaxoSmithKline Biological) and this is now available on the Internet[a].

Pages 246-9 document an analysis of the number of 'sudden deaths' after receiving the vaccine to examine if it exceeds the number of deaths one could expect from the natural background incidence of sudden death. The background incidence was calculated as 0.454/1000 in the first year and 0.062/1000 live births in the second year. No allowance is made for the notoriously poor AEFI reporting rate. The number of sudden deaths expected to occur by chance between day 1 and 20, is tabulated in Table 36 on page 24. The denominator used to examine deaths following vaccination is the number of doses of the vaccine distributed not the number of children vaccinated. This denominator would dilute any potential signal because many more vaccine doses are distributed than are actually administered!

Further, the number of doses actually administered may be appropriate for milder reactions that can recur with each dose, but it is not appropriate for deaths which can happen only once. Appendix 5A shows that 13 fatal cases were reported. There were more deaths after the first dose than after the second and third doses and the deaths after the second was more than after the third dose. This pattern is commonly seen with AEFIs that are causatively related. The appropriate denominator in all these cases is the number of babies vaccinated.

There were 42 deaths in the first three days after vaccination where there were only 16 deaths in the next 3 days. The fact that the deaths were clustered soon after vaccination suggests that the deaths may be related to the vaccination event.

Patient safety data should not be considered as trade secrets by any stretch of imagination. The practice of keeping safety reports confidential permits such data manipulation in a cosy relationship with the regulators, away from public scrutiny. Such practice ought to be reformed.

Reference

a http://autismoevaccini.files.wordpress.com/2012/12/vaccin-dc3a9cc3a8s.pdf Accessed 12/11/15

Box 7. EMA and Failure of Regulatory Oversight: absence of critical appraisal of PSUR

GlaxoSmithKline (GSK), 19th confidential periodic safety update reports[a] (PSUR 19 (deaths up to October 22, 2014)) on Infanrix hexa makes interesting reading. Infanrix hexa has all the components of the pentavalent vaccine except that it has replaced the whole cell pertussis with an acellular pertussis component and, in addition, it has injectable polio vaccine. The cumulative number of deaths after vaccination reported in the 19th report is less than that reported in the 16th PSUR. It can be seen that deaths in children older than 1 year was significantly higher than the deaths expected by coincidence, if the deaths deleted from the 16th PSUR were restored[b].

It appears that the EMA accepts PSUR reports filed by manufacturers without reviewing them critically. Regulatory authorities internationally rely on due diligence by the EMA in such circumstances. This may need to be reappraised.

Reference

a. http://ijme.in/wp-content/uploads/2017/09/infanrix-pusr.pdf

b. http://ijme.in/articles/infanrix-hexa-and-sudden-death-a-review-of-the-periodic-safety-update-reports-submitted-to-the-european-medicines-agency/?galley=html

response to excess carbon dioxide and this can result in the death of vulnerable infants during sleep. Multiple vaccines provoke greater release of cytokines. Hill's criteria of a dose- response gradient (number of antigens in this case), may be satisfied here[10].

Multiple vaccines limited to 5 in the Italian Army

The harm from vaccine-stimulated cytokines is not limited to infancy. The Final Report of the Italian Parliamentary Committee (Doc. XXII-bis N.23) inquiry into cases of death and severe injury affecting Italian personnel assigned to military missions abroad, has recommended that no more than 5 monovalent single-dose vaccines may be given simultaneously to military personnel, in order to avoid adverse reactions. All this suggests the need for caution in using multiple vaccines simultaneously. Ironically, while it is proscribed for healthy adult army men, Hexavac (which combines 6 antigens) is still licensed for use in infants in Italy.

Revised AEFI classification and the precautionary principles

It is evident from the discussion earlier that the revised AEFI evaluation scheme produced by the CIOMS / WHO is designed to deny the possibility that any newly observed adverse event may be causally related to the immunization. The AEFI manual states 'Allegations that vaccines / vaccination cause adverse events must be dealt with rapidly and effectively. Failure to do so can undermine confidence in a vaccine and ultimately have dramatic consequences for immunization coverage…'[12]

Figure 2 shows how all cases AEFI except those that are known adverse effects of vaccine are classified as not causally related.

The AEFI-denialism is a clear violation of the 'precautionary principle' (European Union law), which mandates that 'when an activity raises threats of harm to the environment or human health,

Box 8. Product liability: Protecting patients not patents.

Hexavac - a hexavalent vaccine (DTaP-IPV-HepB/Hib) - was withdrawn by the manufacturers without giving reasons after 5 cases of SIDS were reported by Zinka within 48 hours of being administered the vaccine[a]. vonKries found that in the 2nd year of life, the standardized mortality rate (SMRs) for sudden unexplained deaths (SUD) within 1 day of vaccination was 31.3 (95% CI 3.8–113.1); and within 2 days after vaccination it was 23.5 (95% CI 4.8–68,6)[b].

Similarly RotaShield was voluntarily removed from the market after 12 cases of intussusceptions were reported. The background rate of intussusceptions at this age was 5 times the risk of intussusceptions from the vaccine. There was no biologically plausible explanation to link the intussusceptions to the immunization. Yet the vaccine was withdrawn[c].

The manufacturers withdrew the vaccines voluntarily without indicating the reasons. It is not clear whether the prospect of product liability suits influenced manufacturer caution.

Two significant changes have taken place after 1980. The threat of vaccine manufacturers being held responsible for marketing a defective product has diminished greatly as a consequence of these changes.

1. A no-fault compensatory mechanism has been put in many countries in the 1980s and 1990s[d] This means that vaccine injured children need not provide clear evidence of negligence as cause of the harm, before they qualify for compensation. However, it also means that manufacturers do not have to admit to faults. The risk of product liability has now greatly decreased with no fault compensation being provided by governments. As a result, manufacturers may be emboldened to be more reckless on vaccine safety issues.

2. The second significant change was in 2013, when the methodology for assessment of AEFI was completely overhauled. It is no longer sufficient to show temporal association of the AEFI happening repeatedly. The flow diagram below depicts all conditions that need to be satisfied before an AEFI is labelled 'Consistent causal association to immunization'. This too could embolden manufacturers to be more reckless with regard to adverse reactions.

References

a. Zinka B, Rauch E, Buettner A, Ruëff F, Penning R. Unexplained cases of sudden infant death shortly after hexavalent vaccination. *Vaccine*. 2006;24:5779-80.

b. vonKries R, Toschke AM, Strassburger K, Kundi M, Kalies H, Nennstiel U, Jorch G, Rosenbauer J, Giani G. Sudden and unexpected death safter the administration of hexavalent vaccines (diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, Haemophiliusinfluenzae type b): is there a signal? *Eur J Pediatr*. 2005;164:61-9.

c. Center for Disease Control and Prevention. Rotavirus Vaccine (RotaShield) and Intussusception. http://www.cdc.gov/vaccines/vpd-vac/rotavirus/vac-rotashield-historical.htm

d. Looker C, Kelly H. No-fault compensation following adverse events attributed to vaccination: a review of international programmes. Bulletin of the World Health Organization 2011;89:371-378. Available at http://www.who.int/bulletin/volumes/89/5/10-081901/en/ Accessed on 23/10/15

Box 9. Difficulties in accessing AEFI data

1. Polio and Acute Flaccid Paralysis in India

As awareness of adverse events is increasing among the public it is becoming more difficult to access data on these adverse events. The National Polio Surveillance provided monthly data on acute flaccid paralysis in India. An analysis of the data showed that in 2011, an additional 47,500 children were newly paralysed in the year, over and above the standard 2/100,000 non-polio AFP that is generally accepted as the norm. The non-polio AFP rate best correlated with the cumulative number of doses received in the previous three years[a].

The analysis was repeated after 2 years when the number of doses administered to children below 5 was reduced and it showed the AFP rate had begun to decline[b].

However, the data is no longer provided on the National Polio Surveillance Project/WHO website.

2. Data Analysis Prints on Vaccines

Medicines and Healthcare products Regulatory Agency (MHRA) of the government of UK provides easily accessible Drug Analysis Prints and interactive Drug Analysis Profiles (iDAPs)[c] from 'Yellow Card' notifications of adverse events. But this is not provided for vaccines. One is required to request MHRA Pharmacovigilance for this.

References

a. Vashisht N, Puliyel J. Polio programme: let us declare victory and move on. Indian J Med Ethics. 2012 Apr-Jun;9(2):114-7.

b. Vashisht N, Puliyel J, Sreenivas V. Trends in nonpolio acute flaccid paralysis incidence in India 2000 to 2013. Pediatrics. 2015 Feb;135 Suppl 1:S16-7. doi: 10.1542/peds.2014-3330DD. PMID: 26005734

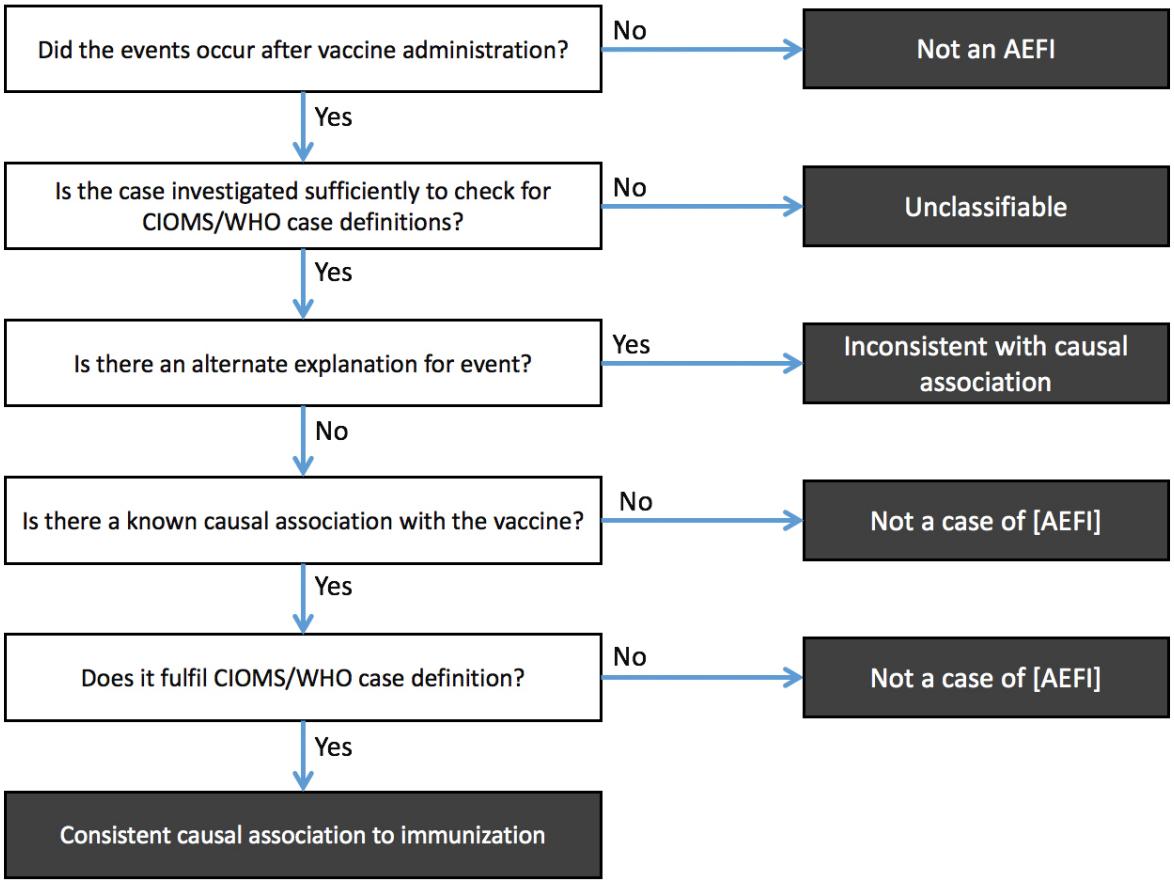

Figure 2. Pathway to achieving 'consistent causal association to immunization' status.

precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. Society and Government is urged that until the full scientific evidence is available, where there is evidence of risk, it must take precautionary measures'. This new AEFI classification scheme that allows for an outright denial of any new causative association with vaccination could also fall foul of Article 2 European Convention on Human Rights (Art 2 ECHR), which mandates governments to establish a framework of laws, precautions, and means the enforcement of which will, to the greatest extent reasonably practicable, protect life.

Paradoxically, the AEFI algorithm is said to be for vaccine safety. Perhaps we need a scheme for public safety rather than vaccine safety.

The story of pentavalent vaccine was introduced at the beginning of this paper and is summarised in Box 10. It is primarily a vaccine used in developing countries where AEFI surveillance is poor, the press is less vigilant to report adverse events and where drug regulation is less strict. (The richer countries in the West, Europe and the USA, do not use the whole cell pertussis vaccine; so this vaccine is not marketed in those countries.) Isolated cases of unexplained deaths continue to be reported in the press. With the new AEFI classification, in the absence of 'epidemiological evidence' linking deaths to the vaccine, these deaths have been passed off as 'coincidental' SIDS deaths. Epidemiological evidence, however, is now available linking the deaths to vaccine.

To examine if deaths following pentavalent vaccine were merely coincidental SIDS deaths, a study of 45 million infants given DTP vaccination and 25 million who received pentavalent vaccine was undertaken. The study assumed that all the deaths (self-reported to the government surveillance system with 72 hours of vaccination) associated with DPT could be coincidental SIDS deaths, but any increase in the death rate after pentavalent vaccine must be assumed to have been caused by pentavalent vaccine. The odds of death after pentavalent vaccine was doubled (OR 1.98 (95% CI 1.65 to 2.38)) compared to DTP. There were 4.7 additional deaths (95% CI: 3.5-5.9) per million vaccinated with Pentavalent vaccine instead of DTP ($p<0.0001$). By the time this evidence was put together, 122 excess deaths (95% CI: 101-145) had been reported to the government, due to the switch from DPT to pentavalent vaccine. The contribution of the new AEFI classification in this delay in recognizing the problem is stark[24].

The need for revising Brighton

The revised classification have removed the categories 'probably' and 'possible' from the AEFI classification - very much like the experts who investigated the Sri Lanka deaths. This appears to be

Box 10. The vaccine that changed the definition of AEFI

The story of pentavalent vaccine

In 1949 the DTP vaccine was introduced[a] against diphtheria, tetanus, and pertussis. The first two were frequently fatal diseases. However, DTP was responsible for neurological adverse effects, seizures, encephalopathy, and hypotensive episodes (HHE)[b]. An acellular DTaP was developed and this has replaced DTP in the West.

In 1981 Hepatitis B was introduced[a]. Hepatitis B infection can cause chronic liver disease and hepatocellular carcinoma (HCC), especially if acquired at birth. Vaccine uptake was poor in developing countries. One reason was that, although Hepatitis B was common in the potentially large vaccine uptake countries like India, the incidence of HCC was very low[c]. It is now thought that newborn babies in India may be protected in the early years (where the chance of becoming a chronic carrier is worst) by passive immunity from mother to babies. This may be lost once vaccine use becomes widespread and there could be a paradoxical increase in HCC[d].

In 1987 the protein-conjugated Haemophilus influenza type b vaccine was introduced. The incidence of invasive disease with Haemophilus influenza type b in Asia is low[e] perhaps due to cross-protection from other bacteria that have cross-reactive antigens to the Hib capsular polysaccharide[f]. The uptake of Hib vaccine was poor in Asia.

It is said that the Pentavalent vaccine was introduced to improve the uptake of Hib and Hepatitis B, by combining new underused vaccines with a prior UIP vaccine like DTP as a way for the new vaccines to get a piggyback ride into the UIP[g]. The pentavalent vaccine was used only in developing countries which had not switched to DTaP.

Pentavalent vaccine has been associated with deaths. In the investigation of deaths in Sri Lanka, rather than reporting that the vaccine was 'probably' related to the vaccine, the WHO experts deleted the categories 'probable' and 'possible' from the Brighton classification. This ad-hoc improvisation was reported in medical journals. The AEFI classification was then formally revised so that reactions (deaths in this case) noticed for the first time in Phase 4 trials (post marketing trials) could all be classified as 'Inconsistent with causal association to immunization' and passed off as 'coincidental SIDS deaths'.

A new study involving 45 million infants given DTP vaccination and 25 million who received pentavalent vaccine now provides epidemiological evidence that the odds of death after Pentavalent was doubled (OR 1.98 (95% CI 1.65 to 2.38)) compared to DTP. There were 122 additional deaths (95% CI: 101-145) within 72 hours, reported to the government surveillance system, due to the switch from DPT to pentavalent vaccine. A large number of these deaths could have been avoided had the AEFI manual not been revised and the AEFI were evaluated earlier. In fact it is well documented that the combined DTP-Hepatitis B-Hib vaccine causes more local reactions and it is less effective than when they were administered separately[h]. Protection against these disease could have been better if the vaccines were administered separately.

References

a. http://www.immunize.org/timeline/

b. https://www.sciencedirect.com/science/article/pii/0264410X9190283C

c. https://www.ncbi.nlm.nih.gov/pubmed/?term=Hepatitis+B+in+India%3A+Systematic+review+%26+report+of+the+_IMA+sub-committee+on+immunization

d. https://www.ncbi.nlm.nih.gov/pubmed/29318526

e. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2557750/

f. https://www.ncbi.nlm.nih.gov/pubmed/?term=Natural+immunity+to+Haemophilus+influenza+b+in+infancy+in+Indian+children

g. https://www.researchgate.net/publication/238069905_New_combination_vaccines_Backdoor_entry_into_India%27s_universal_immunization_programme

h. https://www.ncbi.nlm.nih.gov/pubmed/19588375

motivated by a laudable desire to reduce vaccine hesitancy and the attendant risk of vaccine preventable disease. The Sri Lanka report says, "Cases were classified in this review as unlikely where, in spite of not having evidence that the vaccine(s) contributed to the adverse event or the outcome of death, conclusive evidence regarding an alternate cause (or causes) of the event and outcome was lacking. This meant that we considered that classifying the AEFI in the category 'unrelated' was not fully justified (as it could not be conclusively attributed to another cause). In such cases, we go further to state that the conclusion of 'unlikely' means that the vaccine is not the major cause of death even in those cases where we discuss the possibility that the vaccine(s) or vaccination may have unmasked an underlying condition"

It seems the Sri Lankan experts were reluctant, even to classify the deaths as 'unlikely', as it could be interpreted to mean there was some likelihood of causal association. To quote from the report, "Unlikely: In defining this category, the panel took note of the fact that the WHO category 'unlikely' is often interpreted to mean that there is (conversely) some likelihood of a causal association between the adverse event and the vaccine(s) administered."

One can speculate that same reasoning and the motivation (to ally public anxiety of a causal association between AEFI and vaccination), would have provided the impetus for the revised AEFI classification.

The aftermath

That vaccines do more good than harm is taken as an article of faith, a dogma, a tenet. If the purpose of this exercise i AEFI-denialism is to prevent undermining confidence in vaccines, the

scheme does not seem to be working. Indeed, public scepticism seems to be increasing rather than diminishing with these efforts at reassurance that vaccines are safe[25,26]. Epidemics of vaccine preventable disease have resulted[27].

The response in some states in the United States has been to make vaccination mandatory for admission to public schools. Personal and religious belief exemptions for vaccination are not be allowed in California, effective July 1, 2016. The 2016 debates among US Republican Presidential aspirants suggest that there is a lack of widespread support for this measure. The Department of Health and Human Services Office for Civil Rights has now set up the Conscience and Religious Freedom Division to which individuals can complain if their conscience or religious freedom have been abridged. How these forces will interact is anyone's guess, but the present scenario augur badly for public trust in vaccines and voluntary vaccination.

Where do we go from here

The AEFI manual needs to be urgently reevaluated and revised. We need to build a better system that picks up problems and at the same time does not create a mistrust of vaccines that have been associated with a major reduction in child mortality.

Adverse reaction and deaths may not show up as significantly increased in small safety studies. However, records of all deaths and serious adverse events following vaccinations should be maintained and periodically reviewed for safety signals. The practice of discarding these records as 'inconsistent causal association to immunization' needs to change. Comparisons of the adverse events of vaccines given at the same age, as was done with DTP and pentavalent vaccine, may help to identify adverse events related to one of the vaccines. Sex specific incidence of adverse events may also act as a pointer. Till we develop a better system, it may be advisable to fall back on the time tested WHO-UMC casualty categories and the Brighton categories and to err on the side of child safety.

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References

1. **Global Advisory Committee on Vaccine Safety, 12–13 June 2013.** *Wkly Epidemiol Rec.* 2013; **88**(29): 301–12.
PubMed Abstract

2. WHO Experts Report: **High Court of Delhi at New Delhi WP (C) 13698 of 2009 Dr KB Saxena and others (petitioners) versus Union of India and others (respondents).** Submission of respondents dated 03/04/2010. [accessed 19.10.15].

3. Puliyel J, Mathew JL, Priya R: **Incomplete reporting of research in press releases: et tu, WHO?** *Indian J Med Res.* 2010; **131**: 588–9.
PubMed Abstract

4. Saxena KB, Banerji D, Qadeer I, *et al.*: **"Antivaccine lobby" replies to the *BMJ*.** *BMJ.* 2010; **341**: c4001.
PubMed Abstract | Publisher Full Text

5. WHO: **Safety of Quinvaxem (DTwP-HepB-Hib) pentavalent vaccine**. [accessed 15.10.15]. May 10, 2013.
Reference Source

6. Hume DA: In: Selby-Bigge LA, Nidditch PH, editors. **Treatise of Human Nature**. Oxford: Clarndon; 1739.
Reference Source

7. Brady HE: **Causality and explanation in social research**. In *The Oxford Handbook of Political Methodology*. ed Janet M. Box-Steffensmeier, Henry E. Brady, and David Collier. Oxford University Press, Oxford.

8. Mackie JL: **Causes and conditions.** *Am Philos Q.* 1965; **2**(4): 245–64.
Reference Source

9. **Athey v. Leonati (1996), 140 D.L.R. (4th) 235 at para. 32, [1996] 3 S.C.R. 458, [1997] 1 W.W.R. 97 quoted in David H, McCague WP, Yaniszewski PF *The Advocates' Quarterly*.** 2005; **30**: 216–238.
Reference Source

10. Hill AB: **The Environment and Disease: Association or Causation?** *Proc R Soc Med.* 1965; **58**: 295–300.
PubMed Abstract | Free Full Text

11. Center for Disease Control and Prevention: **Rotavirus Vaccine (RotaShield) and Intussusception**.
Reference Source

12. WHO: **The Causality assessment of an adverse event following immunization (AEFI): User manual for the revised WHO classification**. WHO/HIS/EMP/QSS. March 2013.
Reference Source

13. Definitions and Application of Terms for Vaccine Pharmacovigilance CIOMS/WHO: **Definitions and Application of Terms for Vaccine Pharmacovigilance Report of CIOMS/ WHO Working Group on Vaccine Pharmacovigilance**.
Reference Source

14. Legge D, Puliyel J: **Enhancing community confidence in vaccines safety.** *BMJ.* 2017; **357**: j2449.
Reference Source

15. Soriano A, Nesher G, Shoenfeld Y: **Predicting post-vaccination autoimmunity: who might be at risk?** *Pharmacol Res.* 2015; **92**: 18–22.
PubMed Abstract | Publisher Full Text

16. Berkovic SF, Harkin L, McMahon JM, *et al.*: **De-novo mutations of the sodium channel gene *SCN1A* in alleged vaccine encephalopathy: a retrospective study.** *Lancet Neurol.* 2006; **5**(6): 488–92.
PubMed Abstract | Publisher Full Text

17. Rigolet M, Aouizerate J, Couette M, *et al.*: **Clinical features in patients with long-lasting macrophagic myofasciitis.** *Front Neurol.* 2014; **5**: 230.
PubMed Abstract | Publisher Full Text | Free Full Text

18. Puliyel J, Phadke A: **Deaths following pentavalent vaccine and the revised AEFI classification.** *Ind J Med Ethics.* 2017; **2**(4): 300–301.
PubMed Abstract | Publisher Full Text

19. Collet JP, MacDonald N, Cashman N, *et al.*: **Monitoring signals for vaccine safety: the assessment of individual adverse event reports by an expert advisory committee. Advisory Committee on Causality Assessment.** *Bull World*

Health Organ. 2000; **78**(2): 178–85.
PubMed Abstract | Free Full Text

20. Aaby P, Jensen H, Samb B, *et al.*: **Differences in female-male mortality after high-titre measles vaccine and association with subsequent vaccination with diphtheria-tetanus-pertussis and inactivated poliovirus: reanalysis of West African studies.** *Lancet.* 2003; **361**(9376): 2183–8.
PubMed Abstract | Publisher Full Text

21. Higgins JP, Soares-Weiser K, López-López JA, *et al.*: **Association of BCG, DTP, and measles containing vaccines with childhood mortality: systematic review.** *BMJ.* 2016; **355**: i5170.
PubMed Abstract | Publisher Full Text | Free Full Text

22. Puliyel J, Sathyamala C: **Infanrix hexa and sudden death: a review of the periodic safety update reports submitted to the European Medicines Agency.** *Indian J Med Ethics.* 2018; **1**(1): 43–47.
PubMed Abstract | Publisher Full Text

23. Goldman GS, Miller NZ: **Relative trends in hospitalizations and mortality among infants by the number of vaccine doses and age, based on the Vaccine Adverse Event Reporting System (VAERS), 1990-2010.** *Hum Exp Toxicol.* 2012; **31**(10): 1012–21.
PubMed Abstract | Publisher Full Text | Free Full Text

24. Puliyel J, Kaur J, Puliyel A, *et al.*: **Deaths reported after Pentavalent vaccine compared with death reported after diphtheria-tetanus-pertussis vaccine – an exploratory analysis**. Medical Journal of Dr. D.Y. Patil Vidyapeeth | Published by Wolters Kluwer – Medknow 2018 Published ahead of print.
Reference Source

25. MacDonald NE; SAGE Working Group on Vaccine Hesitancy: **Vaccine hesitancy: Definition, scope and determinants.** *Vaccine.* **33**(34): 4161–4164.
PubMed Abstract | Publisher Full Text

26. Sci Dev Net: **Parental doubt drives drop in vaccination**.
Reference Source

27. Clemmons NS, Gastanaduy PA, Fiebelkorn AP, *et al.*: **Measles - United States, January 4-April 2, 2015.** *MMWR Morb Mortal Wkly Rep.* 2015; **64**(14): 373–376.
PubMed Abstract | Free Full Text

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Version 2

Reviewer Report 05 July 2018

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✔ **Peter Aaby**
Bandim Health Project, Bissau, Guinea-Bissau

I am satisfied with the revision. Many errors and inconsistencies have been corrected. The narrative qualities have improved. The way forward is helpful.

Including the non-specific effects of vaccines as potential AEFIs is important.

In general the fact-boxes are easier to understand and helpful now. I did not understand in Box 6 how we came from the 13 fatal cases reported in Appendix 5A to the 42 deaths said to have occurred in the first 3 days.

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 06 Jul 2018

Jacob Puliyel

I agree the text in Box 6 needs clarification.

It read as follows
Box 6
Appendix 5A shows that 13 fatal cases were reported. There were more deaths after the first dose than after the second and third doses and the deaths after the second was more than after the third dose. This pattern is commonly seen with AEFIs that are causatively related. The appropriate denominator in all these cases is the number of babies vaccinated.

There were 42 deaths in the first three days after vaccination where there were only 16 deaths in the next 3 days. The fact that the deaths were clustered soon after vaccination

suggests that the deaths may be related to the vaccination event....

It should read
Appendix 5A gives the details of 13 of the deaths after vaccination. There were more deaths after the first dose than after the second and third doses and the deaths after the second was more than after the third dose. This pattern is commonly seen with AEFIs that are causatively related. The appropriate denominator in all these cases is the number of babies vaccinated.

In all, there were 42 deaths in the first three days after vaccination where there were only 16 deaths in the next 3 days. The fact that the deaths were clustered soon after vaccination suggests that the deaths may be related to the vaccination event.

Competing Interests: None

Reviewer Report 04 June 2018

https://doi.org/10.5256/f1000research.15756.r34467

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Tom Jefferson
Centre for Evidence Based Medicine, University of Oxford, Oxford, UK

The author's responses seem reasonable to me, although I do not necessarily agree with some of them. As the errors of fact have been corrected, the paper can go ahead as far as I am concerned.

Competing Interests: TJ was a recipient of a UK National Institute for Health Research grant for a Cochrane review of neuraminidase inhibitors for influenza. In addition, TJ receives royalties from his books published by Il Pensiero Scientifico Editore, Rome and Blackwells. TJ is occasionally interviewed by market research companies about phase I or II pharmaceutical products. In 2011-13, TJ acted as an expert witness in litigation related to the antiviral oseltamivir, in two litigation cases on potential vaccine-related damage and in a labour case on influenza vaccines in healthcare workers in Canada. He has acted as a consultant for Roche (1997-99), GSK (2001-2), Sanofi-Synthelabo (2003), and IMS Health (2013).In 2014 he was retained as a scientific adviser to a legal team acting on oseltamivir. TJ has a potential financial conflict of interest in the drug oseltamivir. In 2014-16, TJ was a member of three advisory boards for Boerhinger Ingelheim. TJ was holder of a Cochrane Methods Innovations Fund grant to develop guidance on the use of regulatory data in Cochrane reviews. TJ was a member of an independent data monitoring

committee for a Sanofi Pasteur clinical trial on an influenza vaccine. Between 1994 and 2013, TJ was the coordinator of the Cochrane Vaccines Field. TJ was a co-signatory of the Nordic Cochrane Centre Complaint to the European Medicines Agency (EMA) over maladministration at the EMA in relation to the investigation of alleged harms of HPV vaccines and consequent complaints to the European Ombudsman. TJ is co-holder of a John and Laura Arnold Foundation grant for development of a RIAT support centre (2017-2020) and Jean Monnet Network Grant, 2017-2020 for The Jean Monnet Health Law and Policy Network. TJ is an unpaid collaborator to the project Beyond Transparency in Pharmaceutical Research and Regulation led by Dalhousie University and funded by the Canadian Institutes of Health Research (2018-2022).

Reviewer Expertise: Clinical epidemiologist

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 03 April 2018

https://doi.org/10.5256/f1000research.14875.r31300

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?

Peter Aaby
[1] Bandim Health Project, Bissau, Guinea-Bissau
[2] Bandim Health Project, Bissau, Guinea-Bissau

The authors are to be complimented for having conducted this study. Proper handling of AEFIs is very important if we are to maintain trust between public health vaccinology and the community. However, I am missing the authors' specific suggestions for how to improve the situation. As discussed below there are also details of presentation which could be improved.

There is a rather detailed description of the changes in the definition of causality in relation to the current concept of AEFI. However, I am missing some presentation of where is the AEFIs concept coming from historically and what is the underlying theoretical biological model of why AEFI might occur and how does that affect how AEFI are observed, reported and used. Furthermore, what are the regulators requirements? Apparently the dominant thinking is that vaccines only induce disease specific memory. Presumably genetic variability may in rare cases affect how this biological process takes place and this could cause specific AEFIs. What else are the causes of other AEFIs: co-incidental infections or chronic disease, co-administration of drugs or other vaccinations? Most of such events can presumably be rejected as not "caused" directly by the vaccine.

However, the concept of vaccines may be changing. WHO experts have recognized that vaccines may have non-specific effects (NSEs) with consequences for child survival [1]. Apparently, through epigenetic and metabolic changes, vaccines can reprogram the immune system and upregulate or downregulate both the innate and the adaptive immune system [2-5]. If that is the case there is room for both beneficial and deleterious unexpected events following immunization (UEFI). Proper monitoring systems should also be able to detect beneficial UEFIs; for example, we have found that BCG reduces the risk of neonatal sepsis in low-birth weight children [6]. On the other hand, DTP consistently increases female relative to male mortality, also in societies that have no sex-differential treatment [7]. This is "unnatural" since there was no excess female mortality in the pre-vaccination era in West Africa [8]. This being the case there should be room not only for the short-term AEFI as in the current system (14 days?) but also for much more protracted biological processes being classified as AEFI/UEFI. This would require new standards for how UEFI/AEFI are observed and registered.

Parallel with the description of the changes in the definition of AEFI, there is a series of examples where the authors apparently think there are real differences in mortality/safety issues between different vaccination groups. I have noted at least: Pentavalent vaccine and congenital heart disease; MMR and autism in African American children; Hexavac; Rotavac; HPV and chronic fatigue syndrome; Pentavalent vaccine vs DTP for SIDS. Sometimes these safety issues are mentioned in passing as examples in the discussion of the processes related to AEFI assessment. I found it sometimes unclear whether these example were presented in their own right as safety issues or whether they were only meant to illustrate problems in the assessment of AEFI, e.g. safety reports not forthcoming, etc. Sometimes the presentation was too short or unclear to be really convincing; for example, I had problems with the ROTAVAC story (box 5). It is unclear why it is said in Box 5: "Other rotavirus vaccines that do not reduce incidence of diarrhoea or increase the incidence of diarrhoea instead of decreasing it, have been published (b)". The paper which is referenced apparently reported a 40% reduction in rota-diarrhoea. If the problem is that overall diarrhea was not reduced I think this can be present more clearly.

I think the paper would be stronger/more convincing if the safety-issues that the authors believe have been documented as safety concerns were presented as safety-case stories in specific boxes; the effect of Pentavalent vaccine on SIDS is apparently such a concern. Then the text on the changes in the assessment of AEFI could refer to this or that AEFI problem which was illustrated in the safety-case stories. On the other hand if the story is about mismanagement of the assessment of AEFI, then the cases should be presented as such without implying a causal link between vaccination and AEFI; for example box 3 is an example of poor public communication but it has hardly been documented that MMR causes autism.

Abstract:
It should not be assumed that "Of course, vaccines that caused deaths in the control-trials stage would not be licensed." RTS,S malaria vaccine was recently approved by EMA but the trial data indicate that RTS,S compared with control vaccines was associated with 2-fold higher mortality for girls [9,10]. Neither the authors nor EMA apparently analysed the mortality data, overall or by sex.

The example with cardiac failure in children is not presented in the paper and should therefore not appear in the abstract unless it is fully described in the paper. The case might well warrant further presentation in the paper itself.

Introduction
Being presented with the Sri Lanka and Vietnam cases in the first paragraphs, the reader is left wondering what was the implications of the WHO experts' classifications. Was the pentavalent vaccine (Penta) reintroduced in the countries and how did that decision come about?

Causality assessment
In the long description of changes in the manual for AEFI assessment, it would be good to have an explanation of WHO's own justification for these changes.

Sometimes the text appears to have been written some years back but have been maintained unchanged in in the current 2018-version. For example in Box 3 it is said that "Thomson has now been granted whistleblower status by the Obama administration". By now this sentence should probably be: "Thomson was granted whistleblower status by the Obama administration". Similar in the conclusion it is said that if the debates among Republican presidential aspirants "are anything to go by". By now it can no longer be "are".

Box 10: this sentence has problems: "In fact combined DTP-Hepatitis B-Hib vaccine causes more there were more local reactions and it is less effective than when they were administered separately."

Page 10: Biological plausibility.
There appears to be an increasing trend to dismiss "unexpected observations"/unpleasant observations with the argument that there is no "biological plausibility". This was one of the arguments used by WHO experts to dismiss that high-titre measles vaccine (HTMV) could be associated with excess female mortality [11]. There can obviously not be biological plausibility for a pattern just detected, that no one has ever thought about. The only relevant question is whether a pattern is repeatable – arguments about biological plausibility should not be allowed to dismiss observations of potential AEFIs. The excess female mortality was repeated in subsequent studies and WHO eventually withdrew the HTMV (1992).

I found this sentence strange: "Slate investigated of the randomised trials of human papillomavirus (HPV) vaccines and found that potential side effects were collected for only two weeks in the year long study."

Page 13: "PV" has not been defined as the abbreviation for pentavalent vaccine.

The comparison of DTP and pentavalent vaccine is frightening. Please indicate whether it is SIDS death or all-cause deaths when it is said for example: "The odds of death after pentavalent vaccine was doubled". Since it is your study I would have indicated that to the readers: "To examine if deaths following Pentavalent vaccine (PV) were merely coincidental SIDS deaths, we undertook a study of 45 million infants given DPT vaccination and 25 million who received PV". Given the scary character of this report a bit more information on methods in data collection and analysis would be appropriate. Any hypothesis of why there would be a two-fold difference in SIDS (?) mortality? Did the patterns differ for boys and girls? We have found that DTP and Penta are both associated with much higher female-than-male all-cause mortality rates [7,12].

Conclusion

I do not think the conclusion is really a conclusion to the content of the paper.

How do we proceed from here? How can we built a better system that finds even the AEFIs we do not want to see and had not expected – and at the same do not create mistrust in the vaccines (BCG, measles vaccines, OPV) which are associated with major reductions in child mortality in low-income countries. What time-frame should be used? AEFI should always be presented by sex. If there are sex-differential patterns of AEFI it might enhance the credibility of this patterns as a true AEFI since we have found sex-differential effects on mortality of most of common vaccines.

Biological plausibility should not be used to dismiss any new and unexpected pattern. There is now evidence that vaccines may reprogram both the innate and the adaptive immune system epigenetically with effect on general susceptibility to non-targeted infections [2,5]. Hence, the starting point should be that ***unlikely effects are likely*** because we have never examined the possibility.

It is standard practice in small safety study with deaths to dismiss them because we cannot see a connection. However, deaths following vaccinations should always be classified as potential-even-though-unlikely AEFIs. Otherwise we cannot accumulate the data and detect patterns we had not imagined. For example, when DTaP was tested in an RCT in Sweden there were 4 deaths among 2847 vaccinated children but none among 954 controls [13]. Though the authors recognized that 4 deaths was too high and would have been significant if the whole Swedish population of eligible children had been used as controls, the study could find no link between the vaccine and the deaths. All properly conducted studies from low-income countries have found DTwP to be associated with increased child mortality [14-16].

References

1. Higgins JP, Soares-Weiser K, López-López JA, Kakourou A, et al.: Association of BCG, DTP, and measles containing vaccines with childhood mortality: systematic review.*BMJ*. 2016; **355**: i5170 PubMed Abstract
2. Benn CS, Netea MG, Selin LK, Aaby P: A small jab - a big effect: nonspecific immunomodulation by vaccines.*Trends Immunol*. 2013; **34** (9): 431-9 PubMed Abstract | Publisher Full Text
3. Kleinnijenhuis J, Quintin J, Preijers F, Joosten LA, et al.: Bacille Calmette-Guerin induces NOD2-dependent nonspecific protection from reinfection via epigenetic reprogramming of monocytes. *Proc Natl Acad Sci U S A*. 2012; **109** (43): 17537-42 PubMed Abstract | Publisher Full Text
4. Kleinnijenhuis J, Quintin J, Preijers F, Benn CS, et al.: Long-lasting effects of BCG vaccination on both heterologous Th1/Th17 responses and innate trained immunity.*J Innate Immun*. 2014; **6** (2): 152-8 PubMed Abstract | Publisher Full Text
5. Arts RJW, Moorlag SJCFM, Novakovic B, Li Y, et al.: BCG Vaccination Protects against Experimental Viral Infection in Humans through the Induction of Cytokines Associated with Trained Immunity.*Cell Host Microbe*. 2018; **23** (1): 89-100.e5 PubMed Abstract | Publisher Full Text
6. Biering-Sørensen S, Aaby P, Lund N, Monteiro I, et al.: Early BCG-Denmark and Neonatal Mortality Among Infants Weighing <2500 g: A Randomized Controlled Trial.*Clin Infect Dis*. 2017; **65** (7): 1183-1190 PubMed Abstract | Publisher Full Text
7. Aaby P, Ravn H, Fisker AB, Rodrigues A, et al.: Is diphtheria-tetanus-pertussis (DTP) associated with increased female mortality? A meta-analysis testing the hypotheses of sex-differential non-specific effects of DTP vaccine.*Trans R Soc Trop Med Hyg*. 2016; **110** (10): 570-581 PubMed Abstract | Publisher Full Text
8. Aaby P, Martins CL, Garly ML, Rodrigues A, et al.: The optimal age of measles immunisation in

low-income countries: a secondary analysis of the assumptions underlying the current policy.*BMJ Open*. 2012; **2** (4). PubMed Abstract | Publisher Full Text
9. Klein S, Shann F, Moss W, Benn C, et al.: RTS,S Malaria Vaccine and Increased Mortality in Girls. *mBio*. 2016; **7** (2): e00514-16 Publisher Full Text
10. Aaby P, Rodrigues A, Kofoed P, Benn C: RTS,S/AS01 malaria vaccine and child mortality. *The Lancet*. 2015; **386** (10005): 1735-1736 Publisher Full Text
11. Aaby P, Jensen H, Samb B, Cisse B, et al.: Differences in female-male mortality after high-titre measles vaccine and association with subsequent vaccination with diphtheria-tetanus-pertussis and inactivated poliovirus: reanalysis of West African studies.*Lancet*. 2003; **361** (9376): 2183-8 PubMed Abstract | Publisher Full Text
12. Fisker A, Biering-Sørensen S, Lund N, Djana Q, et al.: Contrasting female-male mortality ratios after routine vaccinations with pentavalent vaccine versus measles and yellow fever vaccine. A cohort study from urban Guinea-Bissau. *Vaccine*. 2016; **34** (38): 4551-4557 Publisher Full Text
13. Storsaeter J, Olin P, Renemar B, Lagergård T, et al.: Mortality and morbidity from invasive bacterial infections during a clinical trial of acellular pertussis vaccines in Sweden.*Pediatr Infect Dis J*. 1988; **7** (9): 637-45 PubMed Abstract
14. Aaby P, Ravn H, Benn CS: The WHO Review of the Possible Nonspecific Effects of Diphtheria-Tetanus-Pertussis Vaccine.*Pediatr Infect Dis J*. 2016; **35** (11): 1247-1257 PubMed Abstract | Publisher Full Text
15. Mogensen SW, Andersen A, Rodrigues A, Benn CS, et al.: The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment.*EBioMedicine*. 2017; **17**: 192-198 PubMed Abstract | Publisher Full Text
16. Aaby P, Mogensen S, Rodrigues A, Benn C: Evidence of Increase in Mortality After the Introduction of Diphtheria–Tetanus–Pertussis Vaccine to Children Aged 6–35 Months in Guinea-Bissau: A Time for Reflection?. *Frontiers in Public Health*. 2018; **6**. Publisher Full Text

Is the topic of the opinion article discussed accurately in the context of the current literature?
Yes

Are all factual statements correct and adequately supported by citations?
Partly

Are arguments sufficiently supported by evidence from the published literature?
Partly

Are the conclusions drawn balanced and justified on the basis of the presented arguments?
Yes

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 04 May 2018

Jacob Puliyel

Reviewer 2

Reviewer Professor Peter Aaby

Reviewer Comment
Authors' response

The authors are to be complimented for having conducted this study. Proper handling of AEFIs is very important if we are to maintain trust between public health vaccinology and the community. I am missing the authors' specific suggestions for how to improve the situation.
We thank the reviewer for his detailed review and this compliment.

We attempt only to critique the revised AEFI classification. Before one makes an effort to improve it, there has to be an acknowledgement of the flaws in the present system.

We make no claim to have developed an alternate system of classification. An appropriate body of experts will need to draft it, if there is a consensus on what is flawed with the present system.

We have now introduced a new paragraph entitled: "Where do we go from here". We have suggested that the WHO-UMC causality categories for drug reactions has stood the test of time (and the older Brighton system was adapted from it) may be used till a better system evolves.

There is a rather detailed description of the changes in the definition of causality in relation to the current concept of AEFI. However, I am missing some presentation of where is the AEFIs concept coming from historically and what is the underlying theoretical biological model of why AEFI might occur and how does that affect how AEFI are observed, reported and used. Furthermore, what are the regulators requirements? Apparently the dominant thinking is that vaccines only induce disease specific memory. Presumably genetic variability may in rare cases affect how this biological process takes place and this could cause specific AEFIs. What else are the causes of other AEFIs: co-incidental infections or chronic disease, co-administration of drugs or other vaccinations? Most of such events can presumably be rejected as not "caused" directly by the vaccine.

We have dealt very briefly with the historic and theoretical background – but within the 8000 word-limit, we could not deal with this in greater detail.
Regarding: 'AEFIs concept coming from historically'
The other reviewer Prof. Tom Jefferson (TJ) has suggested we introduce the contributions made by the AB Hill and we have made reference to that.

We refer to genetic predisposition to AEFI in our article and also how underlying

disease like congenital heart lesions can precipitate an AEFI. This paragraph has been added in the main body on the text.

In the new version we make reference to non-specific effects of vaccine and we thank the reviewer for his suggestion.

However, the concept of vaccines may be changing. WHO experts have recognized that vaccines may have non-specific effects (NSEs) with consequences for child survival [1]. Apparently, through epigenetic and metabolic changes, vaccines can reprogram the immune system and upregulate or downregulate both the innate and the adaptive immune system [2-5]. If that is the case there is room for both beneficial and deleterious unexpected events following immunization (UEFI). Proper monitoring systems should also be able to detect beneficial UEFIs; for example, we have found that BCG reduces the risk of neonatal sepsis in low-birth weight children [6]. On the other hand, DTP consistently increases female relative to male mortality, also in societies that have no sex-differential treatment [7]. This is "unnatural" since there was no excess female mortality in the pre-vaccination era in West Africa [8]. This being the case there should be room not only for the short-term AEFI as in the current system (14 days?) but also for much more protracted biological processes being classified as AEFI/UEFI. This would require new standards for how UEFI/AEFI are observed and registered.

We thank the reviewer for the references. In our new submission we refer briefly to these NSEs and the benefits and harms than can result.

Parallel with the description of the changes in the definition of AEFI, there is a series of examples where the authors apparently think there are real differences in mortality/safety issues between different vaccination groups. I have noted at least: Pentavalent vaccine and congenital heart disease; MMR and autism in African American children; Hexavac; Rotavac; HPV and chronic fatigue syndrome; Pentavalent vaccine vs DTP for SIDS. Sometimes these safety issues are mentioned in passing as examples in the discussion of the processes related to AEFI assessment. I found it sometimes unclear whether these example were presented in their own right as safety issues or whether they were only meant to illustrate problems in the assessment of AEFI, e.g. safety reports not forthcoming, etc. Sometimes the presentation was too short or unclear to be really convincing; for example, I had problems with the ROTAVAC story (box 5). It is unclear why it is said in Box 5: "Other rotavirus vaccines that do not reduce incidence of diarrhoea or increase the incidence of diarrhoea instead of decreasing it, have been published (b)". The paper which is referenced apparently reported a 40% reduction in rota-diarrhoea. If the problem is that overall diarrhea was not reduced I think this can be present more clearly.

I think the paper would be stronger/more convincing if the safety-issues that the authors believe have been documented as safety concerns were presented as safety-case stories in specific boxes; the effect of Pentavalent vaccine on SIDS is apparently such a concern. Then

the text on the changes in the assessment of AEFI could refer to this or that AEFI problem which was illustrated in the safety-case stories. On the other hand if the story is about mismanagement of the assessment of AEFI, then the cases should be presented as such without implying a causal link between vaccination and AEFI; for example box 3 is an example of poor public communication but it has hardly been documented that MMR causes autism.

They are presented as potential safety problems that seem to get glossed over, by the Revised AEFI assessment methodology. (Please also see next point in row below).

Regarding Rotavac the problem is that overall diarrhea is not decreased and this is clarified in the revised text

Safety-case stories with Pentavac and Hexavac have been identified as such in the revised manuscript

The MMR story Box 3 was about increased autism seen in African American boys vaccinated prior to age of 2 years (compared to those vaccinated after 2 years).

Post-hoc, data of many African American children were excluded on the grounds that they did not possess a valid birth certificate –and reanalysis of this truncated data was published to suggest that MMR was not related autism in any group.

This suggests a possible link between Autism and MMR (albeit in one specific ethnic and age group).

In summary, all the examples noted by the reviewer in the article (Pentavalent vaccine and congenital heart disease; MMR and autism in African American children; Hexavac; Rotavac; HPV and chronic fatigue syndrome; Pentavalent vaccine vs DTP for SIDS) are AEFI that are 'probably' related causatively with vaccination which are not acknowledged.

In the case of MMR and Hexavac the new revised classification cannot be blamed as the data itself was falsified (Many African American boys excluded from MMR study and deaths deleted from PSUR 19).

Abstract
It should not be assumed that "Of course, vaccines that caused deaths in the control-trials stage would not be licensed." RTS,S malaria vaccine was recently approved by EMA but the trial data indicate that RTS,S compared with control vaccines was associated with 2-fold higher mortality for girls [9,10]. Neither the authors nor EMA apparently analysed the mortality data, overall or by sex.

The example with cardiac failure in children is not presented in the paper and should therefore not appear in the abstract unless it is fully described in the paper. The case might

well warrant further presentation in the paper itself.

This sentence has been corrected in abstract

The case of heart failure in children is now included in the paper as suggested by the reviewer.

Introduction
Being presented with the Sri Lanka and Vietnam cases in the first paragraphs, the reader is left wondering what was the implications of the WHO experts' classifications. Was the pentavalent vaccine (Penta) reintroduced in the countries and how did that decision come about?

The vaccines were reintroduced after the 'WHO experts' report, and this is mentioned now in the revised manuscript.
The inevitable follow-up question then is: Were there deaths after it was reintroduced?
We know from the data from India that using the Revised AEFI manual, each death is certified as 'inconsistent with causal association' on the grounds that death has so far never been acknowledged as having occurred in epidemiological studies with the vaccine. This is explained in the paper with reference from literature.

Causality assessment
1. In the long description of changes in the manual for AEFI assessment, it would be good to have an explanation of WHO's own justification for these changes.

2. Sometimes the text appears to have been written some years back but have been maintained unchanged in the current 2018-version. For example in Box 3 it is said that "Thomson has now been granted whistleblower status by the Obama administration". By now this sentence should probably be: "Thomson was granted whistleblower status by the Obama administration". Similar in the conclusion it is said that if the debates among Republican presidential aspirants "are anything to go by". By now it can no longer be "are".

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3. Page 10: Biological plausibility.
There appears to be an increasing trend to dismiss "unexpected observations"/unpleasant observations with the argument that there is no "biological plausibility". This was one of the arguments used by WHO experts to dismiss that high-titre measles vaccine (HTMV) could be associated with excess female mortality [11]. There can obviously not be biological plausibility for a pattern just detected, that no one has ever thought about. The only relevant question is whether a pattern is repeatable – arguments about biological plausibility should not be allowed to dismiss observations of potential AEFIs. The excess female mortality was

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5. Page 13: “PV” has not been defined as the abbreviation for pentavalent vaccine.

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1. This has not been justified as far as we know. The rationale for revising the Brighton classification has also not been stated explicitly.

Reviewer TJ suggested that WHO must be given an opportunity to defend the changes.

David Legge and I had written to WHO, before we published the short critique in BMJ referenced in the paper (Reference 14). This is copied in the response to TJ. There was no response from WHO.

This present paper was also sent to WHO after it appeared in F1000 to seek their comments. There has not been any response so far.

2. The reviewer is correct that the article has been written in parts and the tense needs to be corrected for consistency. This has now been done.

3. We thank the reviewer for this example that has been included in the text.

4. The Slate story: that was the point of the Slate report – that adverse events were not recorded properly.

5. Abbreviation PV has been removed

6. The DPT Pentavalent story is about deaths within 72 hours of vaccination. As babies taken for vaccination are usually not unwell, these must be considered as SIDS deaths in ‘well children’ and comparisons can only be made with the acceptable death rate for ‘well children’ and it must NOT be compared to the ‘all cause death rate’ which includes in the cohort well and unwell children. This is sometimes referred to as the

'healthy vaccinee effect'

When we report "The odds of death after pentavalent vaccine was doubled" we DO NOT have to make any extra allowance for the 'healthy vaccinee effect' as both DPT and Pentavalent vaccine are given to healthy children. The deaths among children getting pentavalent vaccine was twice as high as those getting DPT

There is no hypothesis for the deaths - except as explained in the Boatman case - that the use of multiple vaccines release more inflammatory cytokines (than when single vaccines given) which can act as neuro-modulators and can cause depression of the serotonergic 5-hydroxytryptophan (5-HT) system in the infant medulla and blunt the normal chemo-sensitive response to excess carbon dioxide and this can result in the death of vulnerable infants during sleep.

The method of data collection is described in great detail in the reference (which would be too long to reproduce in this paper). It may suffice to say that both DPT and Pentavalent deaths were captured in the same 'improved' government surveillance system and the data has been made freely available on-line for rechecking by stake holders, and more studies by future researchers.

The records did not specify sex of child.

Conclusion

1. I do not think the conclusion is really a conclusion to the content of the paper.

   How do we proceed from here? How can we built a better system that finds even the AEFIs we do not want to see and had not expected – and at the same do not create mistrust in the vaccines (BCG, measles vaccines, OPV) which are associated with major reductions in child mortality in low-income countries. What time-frame should be used? AEFI should always be presented by sex. If there are sex-differential patterns of AEFI it might enhance the credibility of this patterns as a true AEFI since we have found sex-differential effects on mortality of most of common vaccines.

   Biological plausibility should not be used to dismiss any new and unexpected pattern. There is now evidence that vaccines may reprogram both the innate and the adaptive immune system epigenetically with effect on general susceptibility to non-targeted infections [2,5]. Hence, the starting point should be that ***unlikely effects are likely*** because we have never examined the possibility.

   It is standard practice in small safety study with deaths to dismiss them because we cannot see a connection. However, deaths following vaccinations should always be classified as potential-even-though-unlikely AEFIs. Otherwise we cannot accumulate the data and detect patterns we had not imagined. For example, when DTaP was tested in an RCT in Sweden there were 4 deaths among 2847 vaccinated children but none among 954 controls [13]. Though the authors recognized that 4 deaths was too high and would have been significant if the whole Swedish population of eligible children had been used as controls, the study could find no link between the vaccine

and the deaths. All properly conducted studies from low-income countries have found DTwP to be associated with increased child mortality [14-16].

1. **The conclusion has been revised as suggested**
2. **We have included a paragraph on "Where do we go from here".**

Competing Interests: None

Reviewer Report 14 March 2018

https://doi.org/10.5256/f1000research.14875.r31301

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?

Tom Jefferson
[1] Centre for Evidence Based Medicine, University of Oxford, Oxford, UK
[2] Centre for Evidence Based Medicine, University of Oxford, Oxford, UK

Thank you for asking my views on this paper.

This is a very long and detailed examination of the philosophical, historical rationale and principles of causality assessment of possible vaccine harms, chiefly death. This is mixed with the narrative of the changes made by WHO to their own assessment rules.

The authors use several important examples to make their points.

I regard this topic as extremely interesting and important and the authors should be congratulated for attempting to pull the main strands together, from David Hume to the Brighton Collaboration.

Despite my interest I found the manuscript extremely heavy going with a difficult-to-follow thread. It soon became apparent that the authors think there has been something akin to an international conspiracy to bury the dead by changing the definitions of probable and likely causality. That may be so, but I could not find any convincing evidence in the paper.

Here and there inaccuracies and typos add to the distractions. For example in box 10, DTP becomes DPT or the suggestions that Rotashield was withdrawn in 1999 as a consequence of the Brighton criteria. As far as I remember in 1999 we were setting up and had not produced the

criteria or any other output yet.

I would also check the data of Rotashield withdrawal from the market.

What follows are a few suggestions to improve the manuscript (ms).

First I would split the ms into 2 parts. One discussing the philosophical-historical basis for causality assessment perhaps as far as Brighton and the second one looking at the more recent changes.

Here I have two further suggestions to offer.

Bradford Hill's criteria should be cited, even though they are not a perfect solution as Hill himself recognised. They should be cited because they have had an enormous influence on modern epidemiology (see Geoffrey Rose's variant for example) and because the formulation of some of them (temporality, strength, gradient) is very apt for vaccine exposure. Take temporality for example. The term AEFI which is so extensively cited concedes temporality when in fact temporality is only as good as the vaccination records. Often "AEFI" is used when we are not sure that exposure has taken place at all or that it preceded the clinical event/possible harm. So a balanced discussion of temporality (one of the absolute conditions for determining causality) must include absolute certainty or high probability that exposure preceded the event and that it had taken place at all.

Second I would offer the connection of probabilism and Fisherian theory with Hume's problem of induction. I see Fisher's work as the patch that allows us to go on with at least a partially clear conscience, as I do not think there is a solution to Hume's problem as nature is not (and never will be) universally uniform.

I would tone down the plot theory rhetoric and would seek a written explanation from WHO for their actions. WHO do not have a good track record of answering researchers but the effort must be made and reported. Ditto for any other point which was unclear to the authors. I am not a great believer in plots, blunders fit the picture and my experience better, but the authors must try and get to the bottom of the rationale for the changes and, while at it, they might just want to ask WHO, CIOMS etc. to check the authors' facts and dates (but not their opinions of course).

Last but not least please ask Brighton whether they were aware of WHO's actions (they must be) and what their views are.

I hope these suggestions are useful to the authors.

Is the topic of the opinion article discussed accurately in the context of the current literature?
Partly

Are all factual statements correct and adequately supported by citations?
Partly

Are arguments sufficiently supported by evidence from the published literature?

Partly

Are the conclusions drawn balanced and justified on the basis of the presented arguments?
Partly

Competing Interests: TJ was a recipient of a UK National Institute for Health Research grant for a Cochrane review of neuraminidase inhibitors for influenza. In addition, TJ receives royalties from his books published by Il Pensiero Scientifico Editore, Rome and Blackwells. TJ is occasionally interviewed by market research companies about phase I or II pharmaceutical products. In 2011-13, TJ acted as an expert witness in litigation related to the antiviral oseltamivir, in two litigation cases on potential vaccine-related damage and in a labour case on influenza vaccines in healthcare workers in Canada. He has acted as a consultant for Roche (1997-99), GSK (2001-2), Sanofi-Synthelabo (2003), and IMS Health (2013).In 2014 he was retained as a scientific adviser to a legal team acting on oseltamivir. TJ has a potential financial conflict of interest in the drug oseltamivir. In 2014-16, TJ was a member of three advisory boards for Boerhinger Ingelheim. TJ was holder of a Cochrane Methods Innovations Fund grant to develop guidance on the use of regulatory data in Cochrane reviews. TJ was a member of an independent data monitoring committee for a Sanofi Pasteur clinical trial on an influenza vaccine. Between 1994 and 2013, TJ was the coordinator of the Cochrane Vaccines Field. TJ was a co-signatory of the Nordic Cochrane Centre Complaint to the European Medicines Agency (EMA) over maladministration at the EMA in relation to the investigation of alleged harms of HPV vaccines and consequent complaints to the European Ombudsman. TJ is co-holder of a John and Laura Arnold Foundation grant for development of a RIAT support centre (2017-2020) and Jean Monnet Network Grant, 2017-2020 for The Jean Monnet Health Law and Policy Network. TJ is an unpaid collaborator to the project Beyond Transparency in Pharmaceutical Research and Regulation led by Dalhousie University and funded by the Canadian Institutes of Health Research (2018-2022).

Reviewer Expertise: Tom Jefferson, Clinical epidemiologist

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 04 May 2018

Jacob Puliyel

Reviewer 1

Referee Prof Tom Jefferson
Reviewer Comment
Authors' response

This is a very long and detailed examination of the philosophical, historical rationale and principles of causality assessment of possible vaccine harms, chiefly death. This is mixed

with the narrative of the changes made by WHO to their own assessment rules.

The authors use several important examples to make their points.

I regard this topic as extremely interesting and important and the authors should be congratulated for attempting to pull the main strands together, from David Hume to the Brighton Collaboration.

Thanks

Despite my interest I found the manuscript extremely heavy going with a difficult-to-follow thread.
It soon became apparent that the authors think there has been something akin to an international conspiracy to bury the dead by changing the definitions of probable and likely causality. That may be so, but I could not find any convincing evidence in the paper.

'Conspiracy theory' according to Barkun is a closed and unfalsifiable system and it is merely a matter of faith with no proof.
We hope we have critiqued various provisions in the revised manual for AEFI and shown how it can lead to harm – how it can result in delays in the acknowledgment of the problems that can result from vaccines. We hope this is a critique of the revised manual 'not unfalsifiable conspiracy theory'.

According to the revised AEFI classification reactions must be 'known to be associated with the vaccine' before it is acknowledged as caused by the vaccine. We have shown how new signals can be (and are being) ignored on account of this proviso.

We merely suggest there is potential for harm inherent in the revised system.

Regarding the observation
"international conspiracy to bury the dead by changing the definitions of probable and likely causality. That may be so, but I could not find any convincing evidence in the paper."

The WHO experts in Sri Lanka removed these categories ('probable' and 'possible') before they reported the deaths were 'unlikely' to be caused by vaccine. This is a verifiable fact. Had the categories not been removed, they would have had to report that 3 death (for with there was no alternate explanation) were 'probably' related to vaccination.

Chronologically at least, the new 'Revised AEFI' categories were developed after the Sri Lanka report was criticized in the BMJ etc.

After the AEFI classification was revised, experts no longer have the mortification of

having to report they have deleted 'Probable' and 'possible'. The revised AEFI have eliminated the categories 'probable/likely' and 'possible'.

In fact the Sri Lanka experts were very keen to absolve the vaccine. They write they felt reluctant to even classify the deaths as 'unlikely' to be related to vaccine. I quote from the Sri Lanka report:
"Unlikely: In defining this category, the panel took note of the fact that the WHO category 'unlikely' is often interpreted to mean that there is (conversely) some likelihood of a causal association between the adverse event and the vaccine(s) administered...." (The full report is uploaded here for easy access http://www.jacob.puliyel.com/download.php?id=213)

I have no doubt that the experts are motivated by a laudable desire to reduce vaccine hesitancy and the attendant risk of vaccine preventable disease.

The reasoning for the revised AEFI categories must be similar to that of the experts of the Sri Lanka report.

We have added a new paragraph explaining that we feel the motivation for the change was a laudable desire to reduce vaccine hesitancy.

Here and there inaccuracies and typos add to the distractions. For example in box 10, DTP becomes DPT or the suggestions that Rotashield was withdrawn in 1999 as a consequence of the Brighton criteria. As far as I remember in 1999 we were setting up and had not produced the criteria or any other output yet.

I would also check the data of Rotashield withdrawal from the market.

The errors have been corrected in the revised manuscript.

The point made by the reviewer about Rotashield is correct. It has been revised. As pointed out by the reviewer, RotaShield was marketed before Brighton was developed. The WHO/UMC system was in place at that time.
Corrections have been made in the revised version.

Bradford Hill's criteria should be cited, even though they are not a perfect solution as Hill himself recognised. They should be cited because they have had an enormous influence on modern epidemiology (see Geoffrey Rose's variant for example) and because the formulation of some of them (temporality, strength, gradient) is very apt for vaccine exposure. Take temporality for example. The term AEFI which is so extensively cited concedes temporality when in fact temporality is only as good as the vaccination records. Often "AEFI" is used when we are not sure that exposure has taken place at all or that it preceded the clinical event/possible harm. So a balanced discussion of temporality (one of the absolute conditions for determining causality) must include absolute certainty or high probability that exposure preceded the event

and that it had taken place at all.

Bradford Hill's criteria have been cited. Thanks.

Second I would offer the connection of probabilism and Fisherian theory with Hume's problem of induction. I see Fisher's work as the patch that allows us to go on with at least a partially clear conscience, as I do not think there is a solution to Hume's problem as nature is not (and never will be) universally uniform.

We did not take the reviewers suggestion to introduce Fisherian theory - to avoid making the write-up even more complicated. As the reviewer stated: the manuscript is already "extremely heavy going"

I would tone down the plot theory rhetoric and would seek a written explanation from WHO for their actions. WHO do not have a good track record of answering researchers but the effort must be made and reported. Ditto for any other point which was unclear to the authors. I am not a great believer in plots, blunders fit the picture and my experience better, but the authors must try and get to the bottom of the rationale for the changes and, while at it, they might just want to ask WHO, CIOMS etc. to check the authors' facts and dates (but not their opinions of course).

The revised manuscript states explicitly that the motivation for the changes is probably to reduce vaccine hesitancy.

The WHO was contacted a year prior to publishing this article in the BMJ but there was no response (*BMJ* 2017;357:j2449, published 19 May 2017). They were again contacted after the first version of this manuscript was published on F1000Research, so they could respond in the comments section. There is no response so far (as of 12/4/18).

Last but not least please ask Brighton whether they were aware of WHO's actions (they must be) and what their views are.

Apparently the present Brighton team approves of these changes. They are now tasked with the responsibility to develop 'case definition' for 'known AEFI' (See CIOMS/WHO report)

Competing Interests: None. I am one of the authors of the article.

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www.IVIM.ca

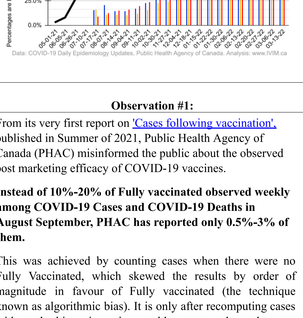
This portal* is redesigned to support

Analysis of Official Canada Data Related to COVID-19 Vaccine Efficacy and Safety

Click on the link above to see the full analysis.
See below Live Dashboard, Key Observations, Spreadsheet, and Video explaining the results. Data is here.

Live Dashboard

(Hover over the image with mouse to see the percentage of Fully Vaccinated among reported cases)



Observation #1:

From its very first report on 'Cases following vaccination', published in Summer of 2021, Public Health Agency of Canada (PHAC) misinformed the public about the observed post marketing efficacy of COVID-19 vaccines.

Instead of 10%-20% of Fully vaccinated observed weekly among COVID-19 Cases and COVID-19 Deaths in August September, PHAC has reported only 0.5%-3% of them.

This was achieved by counting cases when there were no Fully Vaccinated, which skewed the results by order of magnitude in favour of Fully vaccinated (the technique known as algorithmic bias). It is only after recomputing cases without the bias - i.e. using weekly counts only - when one can see the actual efficacy of vaccines and its dynamics over time.

[Learn more about algorithmic biases in PHAC reports]

Observation #2:

The percentage of Fully Vaccinated among COVID-19 cases, deaths and hospitalizations has almost doubled with the arrival of Omicron variant in December 2021. This indicates that the **efficacy of COVID-19 vaccines against Omicron variant is very low, possibly negative.**

Since February 2021, the percentage of Fully Vaccinated among the weekly reported numbers of COVID-19 cases and COVID-19 deaths reached and started to exceed the national full vaccination rate. This indicates that **since February 2021 Fully Vaccinated are as likely, possibly more likely, to get infected with COVID-19 and die from COVID-19 compared to Unvaccinated.**

[See Live PHAC data dashboard]

Observation #3:

Reported number of "COVID-19 deaths" includes "Deaths from COVID" as well as "Deaths with COVID", which constitute majority of "COVID-19 deaths" and many of which are caused by other health problems and old age.

This explains why the **average age of people dying from COVID-19 is very close to the average life expectancy.** This also explains why **the number of other causes of deaths, such as Alzheimer's disease and suicides, went down since the announcement of pandemic.**

Since August 2021, the number of "Deaths from COVID" have become less than that from influenza during the influenza seasons in the past ten years.

[Learn more about "Death from COVID" vs. "Death with COVID"]

[Use Death Tracker App to compare deaths from various causes before and after pandemic]

Observations #4:

Majority of people, in particularly children and people under 40 years of age, infected with COVID-99, especially with Omicron, have very low risk of health complications from the infection and can thus acquire natural immunity, which is much safer, longer and more efficient than short-term variant-specific vaccine induced immunity.

Post-marketing data that have become available from August 2021 and especially from November 2021, show that COVID-19 vaccines and boosters are not as "efficient" and "safe" as originally claimed, doing more harm than good, in particular for children and people under 40 years of age.

[Learn more about variation by age and Risks for children]

[Learn more about Natural Immunity vs. Vaccine-induced Immunity]

Observation #5:

Not a single report was produced by the Office of the Chief Scientific Advisor of Canada since August 2021, which is when post-marketing data related to vaccine efficacy have become available. Not a single official report was produced by the Government of Canada that showed *weekly* variation and distribution of COVID-19 deaths by vaccination status, after these data has become available in August 2021.

All Mandatory Vaccination policies, press-releases and training videos, that we put in place in Canada were developed without the reference to the post-marketing data that has become available since August 2021.

Vaccine manufacturers, main stream media and governments worldwide, in Canada in particular, keep avoiding talking about the post-marketing data related to COVID-19 vaccines safety and efficiency that has been acquired since Summer 2021. Instead some governments use punitive measures and harsh lexicon in order to discourage general public from talking about the subject and to coerce people to get vaccinated with COVID-19 vaccine.

[Learn more about legal actions and other experts' opinions]

Live Google Spreadsheet

(Navigate this spreadsheet by using buttons below. To see internal formulas or view spreadsheet in other formats go here)

Official Government of Canada Data related to COVID-19 vaccine efficacy and safety, analyzed using Data Science

Cases following vaccination - All Ages Combined.

Source: https://health-infobase.canada.ca/covid-19/epidemiological-summary-covid-19-cases.html#9a Table 2. Characteris Cached: web.archive.org **True information: Misinformation: Analysis: www.IVIM.ca Weekly counts recomputed from reported numbers Reported numb**

Numbers below are computed as difference between numbers reported in two consecutive reports, averaged over (3) weeks. Numbers below are co**Cases Hospitalizations Deaths Deaths**

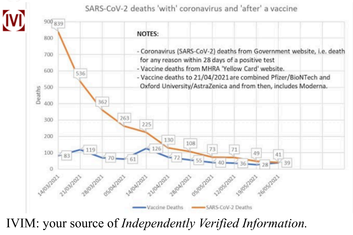
Date cached on (cached	reports) As of (dd	Fully vaxed with booster Total	Fully vaxed / Total (%)	vaxed (2+ doses) Fully vaxed	with booster Total Fully	(%) Fully	vaxed (2+ doses) Fully vaxed	with booster Total Fully	vaxed / Total (%)	Unvaxe d	Partially vaccinat ed N	prd do
Full vaccinatio n												
03-31-22	03-13-22	81.0%	17,025	9,764	20,528	**82.9%**	964	516	1,429	67.4%	**112 69 134**	**83.6%**
9,313 856	03-24-22	03-06-22	80.9%	18,371	9,867	22,227	**82.7%**	981	500	1,483	66.1%	**132 79 168**
78.6%	**9,256 852**	03-18-22	02-27-22	80.7%	21,835	11,059	26,359	**82.8%**	1,030	516	1,593	64.6%
174 101 228	**76.4%**	**9,179 840**	03-11-22	02-20-22	80.4%	27,551	13,063	33,902	**81.3%**	1,336	625	2,043
65.4%	**262 139 392**	**66.8%**	9,240 857	03-04-22	02-13-22	79.9%	37,634	41,033	46,892	80.3%	1,795	1,554
2,697	66.6%	**320 378 480**	**66.6%**	9,147 849	03-01-22	02-06-22	79.4%	50,595	37,048	164,397	48.9%	2,229	1,361	3,416
65.2%	**377 333 570**	**66.1%**	9,023 840	02-21-22	01-30-22	78.7%	54,326	16,203	129,041	**72.3%**	1,859	561	2,829
65.7%	**296 141 455**	**66.1%**	8,884 833									
01-22-22	77.9%	79,933	111,084	**72.0%**	1,334	0	2,109	63.3%	**210 335**	**62.8%**	8,693	808
01-15-22	77.5%	71,303	82,207	66.7%	982	0	1,576	62.3%	**150 249**	**60.3%**	8,479	788
01-07-22	18-21	76.5%	8,717	14,605	**59.7%**	213	0	725	29.4%	**43 118**	**36.4%**	8,013	744
12-04-21	76.0%	5,053	10,202	**49.5%**	210	0	763	**27.6%**	**55 153**	**36.0%**	7,917	734
11-27-21	76.0%	5,254	12,488	42.1%	223	0	908	24.6%	**61 180**	**33.9%**	7,861	733

PHAC1: Cases by Status Plot 1: Vaccinated in Cases Plot 2: #C19 deaths vs. SAR Dashboard PHAC1: Cases by Age README Side Effects 2022-02-05 Side Effects 2021-05-25*.

Data Science seminar explaining how the results are computed

Analyzing Vaccine Side Effects - 2: How to compute weekly stat

Analyzing Vaccine Side Effects - 1: Introduction to Data Science



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OPEN LETTER
The copy of this letter is posted at www.IVIM.ca

April 14, 2022

Dr. Mona Nemer
Chief Science Advisor of Canada
science@canada.ca

Subject: Request to produce a report on COVID-19 Vaccine Efficacy and Safety that would be based on post-marketing vaccine data that have become available after July 2021 in Canada

Dear Dr. Nemer

I applaud your past efforts in establishing the Model Policy on Scientific Integrity and directives for Open Science in Canada. Establishing these policies and directives opened the way for conducting transparent and responsible science in Canada. It also made it possible for all Canadians to access the data related to COVID-19 vaccines and pandemic directly from the official Government of Canada sources and conduct analysis of COVID-19 Vaccine efficiency and safety directly using the data provided in these sources, the main two of which are listed below:

[PHAC-1] 'COVID-19 Daily Epidemiology Update', Public Health Agency of Canada:
https://health-infobase.canada.ca/covid-19/epidemiological-summary-covid-19-cases.html

[PHAC-2] Reported side effects following COVID-19 vaccination in Canada, Public Health Agency of Canada:
https://health-infobase.canada.ca/covid-19/vaccine-safety/

I equally applaud your past efforts in raising public awareness in matters related to COVID-19 vaccines efficacy and safety through your reports published last year in March and July.

Specifically, on March 31, 2021, just before COVID-19 vaccination of the general public commenced, you published *"Scientific Considerations for Using COVID-19 Vaccination Certificates"* report that outlined a number of concerns and recommendations related to the uncertainties associated with using new COVID-19 vaccines. Some of these are quoted below:

- Scientific uncertainties: *Given the short time since the COVID-19 vaccines have become available, it is not surprising that many scientific uncertainties persist and are the subject of intense ongoing studies*.

- Ethical and Social Considerations: *It should also be noted that while the anticipation of more freedom may be an incentive for some to get vaccinated, vaccine acceptance could decrease in others if there was a sense of coercion tied to using vaccination certificates.*
- Legal Considerations: *The processes by which vaccine certificates are issued and controlled need to be fraud proof.*
- Conclusion: *[All levels of government could work to develop a framework that] Maximizes consistent post-vaccine monitoring.*

In your other report that was issued on July 16, 2021, in the light of the COVID-19 vaccine side effects that were just uncovered, when the vaccination rates started to pick up (but still being low - less than 10%): "*COVID-19 vaccine-associated myocarditis/pericarditis"*, you have further emphasized the following:

- Priority actions moving forward: *The emerging issue of vaccine associated heart disease requires attention on two important levels: addressing data and knowledge gaps on the one hand, and promoting awareness and clinical care on the other.*

It could have been reasonably expected that - following on your own recommendations of "addressing data and knowledge gaps" and "promoting awareness" - there would be more follow-up reports produced by your office after July 2021, as it was only after July 2021 when post-marketing data, such as 'Cases following vaccination' statistics, 'Variation by Age' statistics, and 'COVID-19 Vaccine Severe Adverse Reactions' statistics, have been published in the above listed PHAC sources. However, as of today April 2022 there are still no new follow-up reports produced by your Office on this very important subject.

Hence - in order to maintain the highest level of trust and confidence of the Canadian public in the decisions of our government - on behalf of all concerned and affected Canadians, I would like to request that your Office produce a new follow-up report on this very important subject - namely, on the subject of COVID-19 vaccines efficacy and safety and related scientific, ethical, and legal considerations that would be based on the new post-marketing data that have become available after July 2021.

I hope that your Office could produce such a report as soon as possible, as your highest most urgent priority, knowing that decisions related to the continuing use of vaccines and, in particular, on their use with children as well as the mandatory use of these vaccines as a condition for employment are being discussed right now by our government.

Evidently, the Mandatory Vaccination Policy that was introduced last year was developed without the knowledge of the post marketing data that have become available after July 2021. It is of the primordial importance therefore - for the well-being of all Canadians - that the new revision of this policy, which is currently being prepared, be based on the new post-marketing data that has become available since July 2021. This should include the data with new Vaccine 'Cases following vaccination' statistics, new 'Variation by Age' statistics, new 'COVID-19 Vaccine Severe Adverse Reactions' statistics that were published by the Government of Canada in the mentioned above PHAC sources since July 2021. It may also include the new data that were recently made available by vendor manufacturers and other governments.

To assist your Office in analyzing post-marketing data that have become available from August 2021, the collective of Data Scientists from several Universities and Government departments (most of whom prefer to remain anonymous) developed a number of data analysis tools, which, we hope, could be of use for your post-marketing analysis of vaccine safety and efficacy in Canada. These tools are made available, with source codes and all cached official data at www.IVIM.ca, and include: All Data Spreadsheet and Dashboard, Algorithmic Bias Analysis, Death Tracking App and several White Papers, all of which are based on Official Government of Canada data that have become available after July 2021.

I'd like to thank you again for your all contributions to the openness and transparency of our government and all policies that our government makes using scientifically-validated evidence. If there is anything I could help with in your data analysis work, I would be very glad to assist. Please let me know.

Yours sincerely

Dr. Dmitry Gorodnichy, Ph.D.
Senior Data Scientist of the Government of Canada
Adjunct professor with University of Ottawa
Partnership Group for Science and Engineering of the Royal Academy of Sciences of Canada
"Leader of Tomorrow" Nominee

2024 PIPSC AGM: Resolutions authored and seconded by Dmitry

These resolutions aimed to address concerns raised by many members regarding issues that have yet to be addressed by the Union.

DMITRY GORODNICHY, PH.D.
NOV 15, 2024

4 2 Share

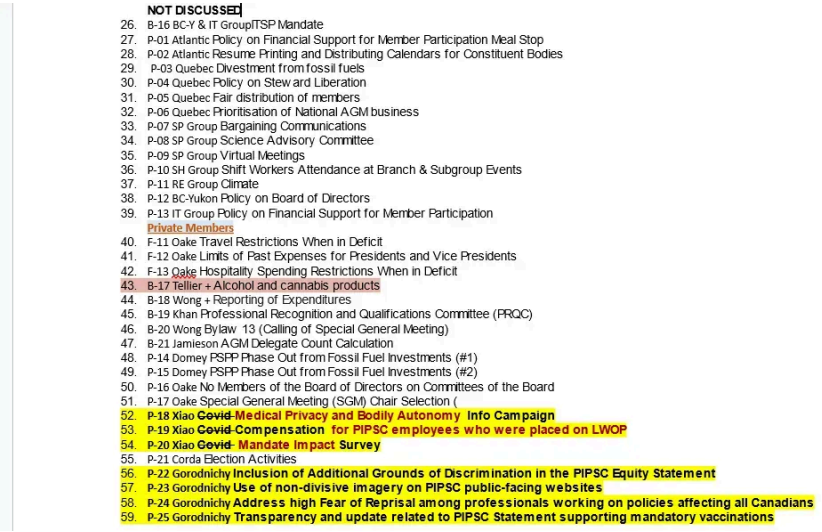
This article provides an overview of the resolutions authored (sponsored) or suppor (seconded) by Dmitry for the 2024 PIPSC AGM. These resolutions were designed to tackle concerns raised by members that, for whatever reasons, the Union has not ye addressed.

None of these resolutions made it to the floor for discussion. However, thanks to th emergency motion to refer all undiscussed motions to the newly elected Board of Directors (described in the previous article), there is hope that the issues highlighte in these resolutions will now be considered and addressed.

Related articles:

- 2024 PIPSC AGM Highlights. Part 1: Union Dues Increase. How It Happened, intervention (AUDIO), Why It Was Worth the Effort
- 2024 PIPSC AGM Highlights. Part 2: Key Victory - Motion to Refer Undiscusse Resolutions to the Board of Directors Brings Hope They Will Finally Be Heard and Addressed
- I was not elected, but what we achieved is remarkable. Thank you all who supported me throughout the campaign! - I will continue advocating for your concerns

The image below shows the resolutions as they appeared on the Resolution Debate Order (highlighted in yellow). Additional details are provided below.



NOT DISCUSSED

26. B-16 BC-Y & IT GroupITSP Mandate
27. P-01 Atlantic Policy on Financial Support for Member Participation Meal Stop
28. P-02 Atlantic Resume Printing and Distributing Calendars for Constituent Bodies
29. P-03 Quebec Divestment from fossil fuels
30. P-04 Quebec Policy on Stewa rd Liberation
31. P-05 Quebec Fair distribution of members
32. P-06 Quebec Prioritisation of National AGM business
33. P-07 SP Group Bargaining Communications
34. P-08 SP Group Science Advisory Committee
35. P-09 SP Group Virtual Meetings
36. P-10 SH Group Shift Workers Attendance at Branch & Subgroup Events
37. P-11 RE Group Climate
38. P-12 BC-Yukon Policy on Board of Directors
39. P-13 IT Group Policy on Financial Support for Member Participation

Private Members

40. F-11 Oake Travel Restrictions When in Deficit
41. F-12 Oake Limits of Past Expenses for Presidents and Vice Presidents
42. F-13 Oake Hospitality Spending Restrictions When in Deficit
43. B-17 Tellier + Alcohol and cannabis products
44. B-18 Wong + Reporting of Expenditures
45. B-19 Khan Professional Recognition and Qualifications Committee (PRQC)
46. B-20 Wong Bylaw 13 (Calling of Special General Meeting)
47. B-21 Jamieson AGM Delegate Count Calculation
48. P-14 Domey PSPP Phase Out from Fossil Fuel Investments (#1)
49. P-15 Domey PSPP Phase Out from Fossil Fuel Investments (#2)
50. P-16 Oake No Members of the Board of Directors on Committees of the Board
51. P-17 Oake Special General Meeting (SGM) Chair Selection (
52. P-18 Xiao ~~Covid~~ Medical Privacy and Bodily Autonomy Info Campaign
53. P-19 Xiao ~~Covid~~ Compensation for PIPSC employees who were placed on LWOP
54. P-20 Xiao ~~Covid~~ Mandate Impact Survey
55. P-21 Corda Election Activities
56. P-22 Gorodnichy Inclusion of Additional Grounds of Discrimination in the PIPSC Equity Statement
57. P-23 Gorodnichy Use of non-divisive imagery on PIPSC public-facing websites
58. P-24 Gorodnichy Address high Fear of Reprisal among professionals working on policies affecting all Canadians
59. P-25 Gorodnichy Transparency and update related to PIPSC Statement supporting mandatory vaccinations

For full text of each resolution, please refer to the PIPSC website.
Resolutions authored and seconded by Dmitry are also published on his Portal.
The summaries of several of them are provided below - to give you flavour of what v tried to achieve.

P-18 - Medical Privacy and Bodily Autonomy ~~COVID~~ Info Campaign (E)

Sponsored by Dawn Xiao (**member**) | Disposition:

Be it resolved that the “Medical privacy and bodily autonomy” be added on the list issues of importance to members on the PIPSC News & Issues page

(https://pipsc.ca/news-issues) with a link to a subpage that will be created to raise t awareness about this issue (i.e., the violation of "Medical privacy and bodily autonomy" rights by the Employer) and to monitor Union's actions on this matter. T content of this subpage can be decided with contributions from the Union executiv and affected members. It will include the updates on the Mandatory Vaccination Policy Grievance that the Union filed against the Mandatory Vaccination Policy in May 2022 as well as other information that supports members in protecting their rights to medical privacy, informed consent, and bodily autonomy.

Be it also resolved that PIPSC start an information campaign within 3 months of th 2024 AGM ending, to remind members of the right to medical privacy and bodily autonomy, and right to decline medical treatment for reasons of conscience.

~~**Be it also resolved that**~~ This campaign includes but is not limited to: information resources on the PIPSC website from 6 months of the 2024 AGM ending that remai on the PIPSC website permanently, as well as social media presence.

P-20 - Vaccination Mandate Impact ~~Covid~~ Survey (E)

Sponsored by Dawn Xiao (member) | Disposition:

Be it resolved that PIPSC conducts a Vaccination Mandate Impact survey using a 5 point Likert scale to assess the level of distress caused by the Vaccination Mandate and the level of satisfaction with the Union's actions related to this Mandate. The survey results will be shared with members and used by the Union to improve supp for members.

Be it resolved also that PIPSC ~~surveys everyone who was a member at any time between September 2021 and the time of the survey related to the employer's COVI 19 vaccination mandate (and shares the results with everyone who was surveyed),~~ conducts an additional survey, either as part of the Vaccination Mandate Impact survey mentioned above or as a separate survey, to gather further details from members who self-identified themselves as severely impacted by the Vaccination Mandate (5 out of 5 on the scale) with the objective to find statistics ~~(including Gro Region, Department, age range, as of the start of implementation of the vaccination mandate)~~ on:

a) ~~who~~ how many felt coerced,

b) ~~who~~ how many got placed on LWOP,

c) ~~who~~ how many took early retirement,

d) ~~who~~ how many resigned, and

e) ~~who had what type of injury.~~how many were injured by the vaccine

These statistics will be also shared with members and used by the Union to improv its support for the members. All personal identifiable information obtained from th survey will be kept confidential at all times in accordance with the PIPSC Privacy Policy.

P-23 - Use of Non-Divisive Imagery on PIPSC Public-Facing Websites (E)

Sponsored by Dmitry Gorodnichy (member) | Disposition:

Whereas Through Spring and Summer 2024, PIPSC used the image of a person in mask on its website frontpage which can be perceived by certain PIPSC member demographics as promoting mask mandates and particular political messages, whi are not welcomed by all members,

BE IT RESOLVED THAT PIPSC avoids using the images in its public communications that bring division among its members. This can be achieved by

consulting members representing different (political, cultural, education) demographics.

P-24 - Address High Fear of Reprisal Among Professionals Working on Policies Affecting A Canadians (E)

Sponsored by Dmitry Gorodnichy (member) | Disposition:

Whereas PIPSC mandate is to provide the highest quality representation to membe by "vigorously safeguarding and promoting professional standards"

Whereas PIPSC supports the largest number of professionals in Public Sector (over 70,000 members)

Whereas among all professionals that PIPSC supports there is a very small but very important group of professionals (estimated as less than 1000) who provide professional expert advice and recommendations for the medical products and poli that affect all Canadians (over 40 million people.

Whereas Canadians must be ensured that professionals who provide professional expert advice and recommendations for the medical products and policies that affe all Canadians work in environment that is free of political and industry interferenc which according to PSES results and PHAC reports may not be the case.

Whereas Public Service Employment Survey (PSES) 2018, 2020, 2022 results show th the fear of reprisal in the units in the PHAC Center for Emergency Preparedness ar Health Canada Marketed Health Products that develop policies related to health an life security of all Canadians is one of the highest in Public Service.

Let it be resolved that PIPSC examines the problem of very high fear of reprisal no correlated with discrimination in areas of the public service that regulate health-related products and develop health-related policies, as urgently as logistically possible, and publish its findings. This can be achieved using available resources ar committees (Professional Recognition and Qualifications Committee, Science Advisory Committee, Information Technology Services and Projects Committee) us the PSES results data and PIPSC membership data.

P-25 - Transparency and update related to PIPSC Statement supporting mandatory vaccinations (E)

Sponsored by Dmitry Gorodnichy (member) | Disposition:

Be it resolved that PIPSC provides minutes and all other available documents that show who and how decided to make a Statement, which was published on October 2021, supporting Mandatory Vaccination Policy, including all sources and reference that were used in making the decision.

Be it further resolved that PIPSC issues a new position statement with respect to t COVID-19 vaccines that is factual, based on all available evidence related to safety, efficacy and necessity of COVID-19 vaccines as a COVID-19 infection prophylactic measure, taking into account that "evidence" obtained from the government source may not be fully reliable as it could have been deliberately "fit" to predefined desire narrative.

L-XX - Adding "Fearless Advice" to the List of PIPSC Issues (E)

Sponsored by Dmitry Gorodnichy (member) | Disposition:

Whereas PIPSC represents a large number of public sector professionals who provi expert advice and policy recommendations impacting all Canadians;

Whereas Canadians deserve assurance that PIPSC professionals can offer expert advice and policy recommendations free from fear of reprisal or retaliation;

Whereas the Public Service Employee Survey (PSES) consistently reveals high level fear of reprisal among professionals in units responsible for evaluating industry products and developing health and food policies for Canadians;

BE IT RESOLVED THAT "Fearless Advice" be added to the list of issues of importance to members on the PIPSC News & Issues page (https://pipsc.ca/news-issues), with a link to a dedicated subpage created to raise awareness of this issue a report on the Union's actions in support of fearless advice.

L-XX - Inclusion of Additional Grounds of Harassment and Discrimination in PIPSC Messaging

Sponsored by Dmitry Gorodnichy (member) | Disposition:

Whereas the current PIPSC messaging, based on the Equity Statement, addresses significant areas of harassment and discrimination but does not encompass all grounds that may affect our members. Expanding the statement to include addition grounds of discrimination—such as cultural and educational backgrounds, diverse religious beliefs, and enlightenment practices, including those of First Nations, Buddhists, and others not connected to organized religions or religious leaders, as as differing medical treatment and prophylactic preferences—would better reflect t inclusive values of PIPSC and ensure all members feel represented and supported. This is particularly important for those experiencing harassment and discriminatio on grounds not currently covered in the Equity Statement.

Whereas as a non-profit organization under the Canada Not-for-profit Corporation Act, PIPSC must comply with legislation regarding discrimination and does not ha the authority to redefine or expand the legal grounds of discrimination.

BE IT RESOLVED THAT PIPSC will strive to update its messaging, where possibl including on its website, social platforms, and in spoken and written communicatic —to ensure that no member, regardless of their cultural or educational background medical preferences, religious beliefs, or enlightenment practices, experiences harassment or feels discriminated against by the actions of the Union, its elected representatives, or its staff.

BE IT ALSO RESOLVED THAT PIPSC will add this issue—fair support and inclu language for all members, regardless of cultural or educational background, religiou beliefs, enlightenment practices, and medical treatment preferences—to the list of issues important to its membership. Updates on this matter can be provided throug the PIPSC website's existing "News & Issues" page, such as on the "Human Rights Diversity" section.

BE IT ALSO RESOLVED THAT PIPSC will explore ways to update its Equity Statement to incorporate additional grounds of harassment and discrimination, in alignment with its mandate, legal obligations, and democratic processes.

L-XX - Transparency and Scrutiny Related to Non-Elected Union Positions and Union Operation (E) -

Sponsored by Dmitry Gorodnichy (member) | Disposition:

Whereas statements and actions of our Union that affect all members are made by both elected Union Executives and non-elected Union staff. Examples include recommendations to rule member-submitted resolutions as "Out of Order" at curre and past AGMs, messaging on discrimination regarding grounds not listed in the Equity Statement, advising against filing grievances related to the employer's vaccination mandate for members who wished to do so.

Whereas there may be pressures exerted by non-elected Union staff, such as from t General Counsel, Chief Operations Officer, or Legal Advisors, on elected members including elected Union Executives;

Be it resolved that in order to improve member support, transparency and scrutiny its operation ~~,~~ PIPSC will endeavor to establish a Proactive Disclosure page and a Freedom of Information page, similar to the approach taken by taxpayer-funded government organizations, to enable the disclosure of information that members m reasonably expect to access. This includes details on the operations of the Institute the process for selecting non-elected Union staff, and any relevant internal communications within the Union.

Be it also resolved that All communications issued by the Union to members, including private and confidential ones, must be signed by identifying the names ar titles of all individuals who wrote ~~to~~ or approved the communication.

Appendix: Full list of resolutions authored and supported by Dmitry

2024 AGM Resolutions - By-Laws

B-18 - Reporting of Expenditures (E)

2024 AGM Resolutions - Policy

P-18 Xiao ~~Covid~~ Medical Privacy and Bodily Autonomy Info Campaign

P-19 Xiao ~~Covid~~ Compensation for PIPSC employees who were placed on LWOP

P-20 Xiao ~~Covid~~ Mandate Impact Survey

P-22 - Inclusion of Additional Grounds of Discrimination in the PIPSC Equity Statement (E)

P-23 - Use of Non-Divisive Imagery on PIPSC Public-Facing Websites (E)

P-24 - Address High Fear of Reprisal Among Professionals Working on Policies Affecting All Canadians (E)

P-25 - Transparency and update related to PIPSC Statement supporting mandatory vaccinations (E)

2024 AGM Resolutions - Late

L-01 - Election Transparency Improvement Across all Groups and Regions (E)

L-02 - Support for Members Right to Informed Consent, Bodily Autonomy and Confidentiality of Their Health Care Information (E)

L-04 - Transparency and Scrutiny Related to Non-Elected Union Positions (E)

L-05 (formerly 2023 P-12) - Term Limits for FULL TIME Board of Directors and Groups Executives (E)

L-06 (formerly 2023 P-14) - Election Transparency Improvement (E)

L-07 (formerly 2023 P-14) - Employee Medical Treatment Ethical Refusal Protectior Policy(E)

Submitted as amendments to other resolutions (not published)

L-XX - Adding “Fearless Advice” to the List of PIPSC Issues (E)

L-XX - Inclusion of Additional Grounds of Harassment and Discrimination in PIPS Messaging

L-XX - Transparency and Scrutiny Related to Non-Elected Union Positions and Un Operation (E) -



4 Likes

Discussion about this post

Comments Restacks

Write a comment...

Weerwun Weer's Substack Nov 28, 2024

The roots. We have to understand where the roots are. Otherwise, it's a fight against windmills (figuratively, not literally)

https://www.youtube.com/watch?v=publZ_PeDKw

LIKE REPLY

JoeMichel JoeMichel's Newsletter Nov 17, 2024

Excellent Dmitry and I wish I could second this. I second that Emotion - Smokey Robinson!

LIKE REPLY

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Alberta Introduces “Neutrality Act” (Bill 13) to Protect Free Expression Across Regulated Professions – Why It Matters For Unions And Public Servants Across Canada

As Alberta moves to “protect free expression” for regulated professionals, many unionize workers across Canada still feel unsafe speaking openly about contentious issues.



DMITRY GORODNICHY, PH.D.
NOV 25, 2025

2 Share

TL;DR — Alberta’s *Regulated Professions Neutrality Act* (Bill 13)

- Alberta introduced **Bill 13** (**Regulated Professions Neutrality Act**) on **Nov. 20, 2025**.
- It is **not yet passed** but is moving through the legislative process.
- The bill would **protect regulated professionals from disciplinary action for lav off-duty expression**, except in narrowly defined cases (threats, criminal offence professional boundary violations, misuse of professional status, certain sexual misconduct).
- It applies to **dozens of professions**: health workers, engineers, teachers, accountants, geoscientists, lawyers, psychologists, real-estate brokers, skilled trades, etc.
- It limits regulators to training strictly tied to **competence and ethics**, restrictin mandatory DEI/bias-training unless justified under the Act.
- It introduces a **correctness standard of review**, giving courts more power to overturn regulator decisions involving Charter/Bill of Rights issues.
- Alberta government frames it as protecting professionals from losing their care over personal opinions or social-media posts.
- Critics argue it may shield problematic speech or undermine regulators’ ability address harmful conduct.
- Relevance for unions and federal public servants: many members across Canad now **self-censor**, fearing that posts or opinions on vaccines, DEI, MAiD, economics, or politics in general could affect their career or union support. Bill raises the national question of how to balance **free expression, competence, ethics, and public trust**.



1. What Just Happened In Alberta?

On November 20, 2025, Alberta Premier Danielle Smith and Justice Minister Micke Amery introduced **Bill 13, the Regulated Professions Neutrality Act**, at a news conference in Edmonton. According to the Government of Alberta, Bill 13 would se “overarching principles” for how professional regulators oversee their members an explicitly framed as legislation to protect free expression for regulated professional (Alberta.ca)

The official government summary states that, **if passed**, Bill 13 would:

- Ensure regulated professionals “may freely express themselves while still being entitled to fair treatment by professional regulatory bodies.” (Alberta.ca)
- Apply across a very broad range of professions, including health professionals, teachers, engineers, accountants, geoscientists, skilled trades, and many others (Alberta.ca)

The government’s own “latest news” page headlines this as: *“Free expression for regulated professionals – New legislation will ensure regulated professionals may freely exp themselves while still being entitled to fair treatment by professional regulatory bodies.”* (Alberta.ca)

Status:

- As of November 23, 2025, **Bill 13 has been introduced but not yet passed**. The Alberta.ca legislation page lists the status as: “Bill 13 was introduced Novembe 20, 2025” and notes that it would take effect “upon proclamation” if passed. (Alberta.ca)

This is therefore **proposed legislation**, not yet in force—but it is already attracting national attention.

2. What Does Bill 13 Actually Do?

2.1 Off-duty “expressive conduct”

At the heart of Bill 13 is the idea of “expressive conduct.” The Alberta government defines expressive conduct as **behaviour that conveys or attempts to convey meani** explicitly excluding physical violence and property damage. (Alberta.ca)

The bill would:

- **Prevent regulators from disciplining professionals for expressive conduct tha happens off-duty**, except for a narrow set of serious categories. (Alberta.ca)

Those exceptions include off-duty expression involving: (Alberta.ca)

- Threats of physical violence
- Misconduct involving professional boundaries
- Misuse of professional status with intent to harm an identifiable person
- Certain forms of sexual misconduct
- Conduct for which the professional has been convicted of an offence

In other words, **discipline for off-duty speech would become the exception, not th rule**—and only in defined circumstances.

Premier Smith has publicly framed the rationale very directly:

> "Professionals should never fear losing their licence or career because of a social media post, an interview or a personal opinion expressed on their own time." (Canadian HR Reporter)

The government and commentators have explicitly linked this to high-profile cases across Canada, including disciplinary proceedings against Dr. Jordan Peterson by tl College of Psychologists of Ontario, and complaints against nurses and other professionals for off-duty social media posts. (Canadian HR Reporter)

Not surprisingly, some media outlets have already labelled Bill 13 "the '**Jordan Peterson law**'," capturing both its intent and its controversy. (Global News)

2.2 Limits on mandatory training and DEI requirements

Bill 13 goes beyond speech. It would also restrict **what kind of training regulators force professionals to take**.

According to the Alberta fact sheet and legislation summary, the Act would: (Alberta.ca)

- Limit **mandatory education or training** to matters of **professional competence and ethics**.
- Prohibit regulators from making **cultural competency, unconscious bias, or diversity, equity and inclusion** (**DEI**) training mandatory **unless** it is directly ti to competence or ethics and meets specific conditions set out in the Act.
- Prohibit regulators from assigning "value or blame," or giving preferential or adverse treatment, in order to achieve DEI outcomes based on characteristics s as race, ancestry, political belief, religious belief, sex, sexual orientation, or gen identity.

This is a substantial shift. It effectively codifies a requirement that regulatory bodie stay "**neutral**" on political, cultural, or ideological questions, and focus instead on t **core functions of competence, ethics, and public safety.**

2.3 A tougher legal standard of review

Another highly technical but important change: **Bill 13 would impose a "correctne standard of review** for certain regulatory decisions.

The Alberta summary explains that courts and internal appeal bodies would apply a **correctness standard** when reviewing decisions that involve: (Alberta.ca)

- Whether a regulator complied with the Regulated Professions Neutrality Act; c
- Questions involving the **Canadian Charter of Rights and Freedoms** or the **Alb Bill of Rights**.

A correctness standard means courts do **not** defer to the regulator's judgment; they may **replace the regulator's decision with their own** if they conclude it is wrong in law. (Alberta.ca)

This is a significant recalibration of power between regulators and the courts, particularly on rights-related questions.

2.4 Who is covered?

The list of affected professions is long, and that is part of the political message.

The Act and its accompanying amendments would cover, among others: (Alberta.ca

- **Engineers, geoscientists, architects, accountants** and other technical professic
- **Teachers and teacher leaders**
- **Lawyers and students-at-law**
- **Health professionals**: physicians, nurses, psychologists, pharmacists, physiotherapists, social workers, and many more
- A wide array of **skilled trades and licensed occupations**, from electricians and welders to funeral directors, real-estate brokers, and early childhood educators

The message is clear: Alberta is proposing to **standardize how off-duty expression treated across virtually all regulated professions in the province.**

3. Why I'm Watching This Closely As A Union Member And Public Servant

I am writing this for my DG4VP Substack because, as a federal public servant and union member, I **personally know many colleagues who now feel unsafe expressin themselves publicly**—even on their own time, on their own devices, outside of worl

These concerns span a wide range of topics, including:

- Medical assistance in dying (MAiD) and end-of-life ethics
- Economic policy, public debt, and fiscal sustainability
- Public safety, policing, and national security
- The safety, effectiveness, and reasonableness of vaccines and other public-healt interventions
- Broader questions about civil liberties, pandemic responses, and the proportionality of government measures

In conversations in hallways, on encrypted messaging apps, and in private phone ca I hear the same themes:

- "I'm afraid to post anything on social media that might be interpreted as 'controversial'."
- "I worry that asking the wrong question publicly could be used against me in a staffing process."
- "I don't trust that my professional regulator, my union, or my employer would defend my right to express deeply held but unpopular views if they conflict witl dominant narrative."

Whether these fears are fully justified or not, the **chilling effect is real**. Many peopl who entered public service or regulated professions out of a sense of vocation now t that **expressing conscience, skepticism, or minority viewpoints is a career risk**.

Against that backdrop, Alberta's Bill 13 is not just a provincial story. It is a **test case** for a broader question:

> How do we reconcile genuine protections against harm, discrimination and misconduct with a healthy space for legitimate dissent, conscience, and debate among professionals?

4. The Union Dimension: Who Actually Protects Free Expression?

One striking element in the coverage of Bill 13 is that Premier Smith explicitly referenced **unions**. In at least one interview, she highlighted that professionals who belong to regulatory bodies "shouldn't have to worry about getting in trouble with their union for saying what's on their mind" in relation to politically sensitive topic (CityNews Calgary)

This is an uncomfortable reflection point for organized labour.

4.1 Unions as protectors – and sometimes silencers

Unions are traditionally seen as defenders of member rights, including:

- Freedom of association
- Fair processes and due process
- Protection from arbitrary discipline

Yet, during and after the COVID-19 period, many members across Canada experienced something different:

- **Expressions of concern about mandates, vaccine policies, or workplace safety measures** were sometimes treated as reputational risks rather than legitimate union issues.
- Some members felt they were **discouraged from speaking publicly**, even when they believed they were raising issues of genuine public interest.
- In some cases, grievances related to conscience, speech, or discrimination were **not advanced** because they were viewed as unwinnable or politically sensitive.

In my own professional circle, I have spoken with union members who say very bluntly:

- "I feel safer saying nothing."
- "I don't know if my union would stand by me if my social media post offended wrong person."

This is not an accusation; it is a **reality of perception**. And perceptions matter.

4.2 What Alberta is doing – and what it is not doing

Alberta's Bill 13 does **not** directly legislate unions. It focuses on **professional regulatory bodies and the legal standard for reviewing their decisions**. (Alberta.ca

But the spirit of the bill is clearly aimed at a broader ecosystem where:

- Regulators, employers, and sometimes unions
- All play a role in shaping **what is "safe" or "acceptable" to say** as a professional

By explicitly carving out a protected space for off-duty expression—subject to narrc serious exceptions—Alberta is attempting to **draw a line**:

> Regulators should focus on competence and ethics, not on policing personal beli or lawful off-duty opinions.

Whether one agrees with the exact drafting or not, it raises a legitimate question fo unions and professional associations across Canada, including at the federal level:

- **Should unions be actively advocating for similar clarity and protections for th members?**
- **How do we ensure that defending human rights and equity does not slide into punishing dissent or honest disagreement?**

5. Risks, Criticisms, And Open Questions

Any serious discussion of Bill 13 has to acknowledge the concerns being voiced.

5.1 Fears about shielding harmful speech

Critics worry that limiting regulators' ability to respond to off-duty speech could:

- Make it harder to address **hate speech, harassment, or serious misinformation** that, while technically off-duty, may affect public trust in the profession. (Globa News)
- Send a signal that professionals can publicly promote discriminatory or harmfu views with reduced professional consequences.

Some professional bodies and advocacy groups are already describing Bill 13 as a st that may "**give a pass**" to harmful or bigoted speech so long as it occurs outside wor hours. (X (formerly Twitter))

5.2 How narrow are the exceptions?

The legislation includes exceptions for threats, boundary violations, certain sexual misconduct, misuse of professional authority, and criminal convictions. (Alberta.ca)

But complex real-world cases are rarely clean:

- What about a health professional who repeatedly promotes misleading medical information online?
- What about persistent demeaning comments toward a protected group, even if clearly criminal?
- How will regulators prove "misuse of professional status" or "intent to harm" i practice?

These are real implementation questions that courts, regulators, and lawmakers wil have to grapple with.

5.3 Charter, federal context, and public servants

For federal public servants, another question looms:

- **If provinces are now experimenting with explicit statutory protections for off duty expression for regulated professionals, what does that mean for federal employees whose speech is governed by a mix of employment law, internal co of conduct, and unwritten norms?**

Alberta's Bill 13 also interacts with the **Charter** and the **Alberta Bill of Rights** via it correctness standard of review, effectively inviting courts to scrutinize regulators' rights-related decisions more closely. (Alberta.ca)

This could set interesting legal precedents that other jurisdictions will watch closel

6. Why I Think This Debate Is Necessary – Regardless Of Where One Stands On Bill 13

I am not writing this article to endorse or oppose Alberta's Bill 13. I am writing it because:

- I have seen **first-hand** how many union members and public servants now **self-censor on fundamental questions**—from assisted dying to vaccine policy, from economic sustainability to national security.
- I believe that **healthy democracies and ethical public services require space fo good-faith disagreement** among professionals, not just compliance with institutional messaging.
- I see Alberta's initiative as an **important data point** in a broader Canadian conversation about how far regulatory and institutional authority should exten into our private beliefs and off-duty speech.

Whether we ultimately view Bill 13 as a model to emulate, a warning, or something between, it at least forces us to ask the right questions:

- What are the **legitimate limits** of professional discipline for off-duty expressio
- What role should **unions** play in defending—not suppressing—members' lawfu speech and conscience, even when it is unpopular?
- How do we uphold **human rights, safety, and non-discrimination** without turn regulators and unions into ideological enforcement bodies?

For my part, as a public servant and union member, I want us to **talk about these questions openly**—without people fearing that simply raising them will harm their careers.

References

1. Government of Alberta – "**Protecting freedom of expression for regulated professionals**", Bill 13 overview and status (Nov. 20, 2025). (Alberta.ca)
2. Government of Alberta – **Regulated Professions Neutrality Act Fact Sheet (Fa 2025)**. (Alberta.ca)
3. Canadian HR Reporter – "**Alberta pushes to protect free expression in regulat professions**" (Nov. 21, 2025). (Canadian HR Reporter)
4. CityNews Calgary – "**New Alberta 'Jordan Peterson law' would ban profession sanctions for employees' off the clock comments**" (Nov. 20–21, 2025). (CityNew Calgary)
5. Global News – "'**Peterson law': Alberta bill to limit power of regulatory bodie member behaviour**" (Nov. 20–21, 2025). (Global News)
6. Law Society of Alberta – "**Regulated Professions Neutrality Act and Legal Profession Act amendments**" (Nov. 20, 2025). (Law Society of Alberta)
7. CPAC – "**Alberta Premier Danielle Smith Announces Regulated Professions Neutrality Act**" (Video archive, Nov. 20, 2025). (cpac.ca)

Disclaimer

This article's opinions are those of the author and do not represent the views of any Canadian agency, union, or organization. It is provided for informational purposes only and **does not constitute legal or medical advice**.

Acknowledgment

This article was written with assistance from ChatGPT using the prompt:

> "Alberta Premier Danielle Smith, alongside provincial Justice Minister Mickey Amery, hold a news conference in Edmonton to announce the Regulated Professions Neutrality Act, which will protect the right of regulated professiona to free expression while ensuring regulatory bodies focus on competence and et —not personal beliefs. Find me new details about this new neutrality act bill, wh I think it was passed or will be passed in Alberta. Write article for my DG for VF Substack in WA prompt indicating that I personally know many union members who feel unsafe, talking or posting publicly on any issues related to anything fro assisted suicide to economy to safety and a figure of vaccines and reasonableness any thing that happens in the country."

Based on approximately **400–600 words** and **5–10 minutes** of narrated input and clarification with the author.

ChatGPT was also used to help ensure political neutrality, factual accuracy, and alignment with the Public Servant Code of Values and Ethics.

Read more about why and how I use ChatGPT to write my Substack articles here.

Other Possible titles:

1. **When Speaking Becomes Risky: What Alberta's "Neutrality Act" Signals For Regulated Professionals And Unions**
2. **Bill 13 In Alberta: Protecting Free Expression Or Redefining Professional Discipline?**
3. **From Alberta To Ottawa: What The Regulated Professions Neutrality Act Means For Unionized Professionals**

Possible subtitles:

1. **Alberta's Bill 13 would limit regulatory sanctions for off-duty speech. Federal public servants and union members should pay close attention.**
2. **As Alberta moves to "protect free expression" for regulated professionals, ma unionized workers across Canada still feel unsafe speaking openly about contentious issues.**
3. **A case study from Alberta that raises a national question: who protects professionals when conscience and competence collide with institutional messaging?**

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Unreliable Evidence: Flawed Vaccinated vs. Unvaccinated Comparisons in Canada's COVID-19 Vaccine Mandates

R.N. Watteel

Independent Researcher, Ottawa, Canada

BSc (Mathematics & Physics), MSc, PhD (Statistics)

Abstract

Background: Canada's 2021–2022 COVID-19 vaccine mandates and passports were implemented with the stated aim of reducing transmission and hospital burden. In the absence of randomized controlled trial evidence for these endpoints, policymakers relied on vaccinated vs. unvaccinated comparisons from surveillance data and observational studies, as well as ungrounded simulations, despite known methodological limitations that rendered such evidence unreliable for public health policies with rights implications.

Methods: We systematically critiqued Canadian public health surveillance reports and advisory briefs (Public Health Agency of Canada, Public Health Ontario, Ontario COVID-19 Science Advisory Table) together with related studies, identifying seven key biases classified by severity (critical/catastrophic), correctability, and scope. Distortions were quantified using published rate corrections, classification rules, time-series data, and population trends.

Results: Critical biases included >40% misclassification of early post-vaccination cases as unvaccinated and an 80-fold overestimation of senior unvaccinated hospitalization rates due to denominator errors. Additional critical biases—age-standardization obfuscating low-risk youth trends, testing fluctuations understating breakthrough cases, and misattribution rendering COVID-19 hospitalizations an invalid metric for burden—further distorted policy evidence. Catastrophic biases—selection and cumulative methodology—rendered group comparability invalid. Population trends showed case and hospitalization surges despite >80% vaccination coverage, with vaccinated individuals dominating Omicron-era infections. Simulation studies retroactively justifying mandates contradicted real-world data with ungrounded counterfactuals used to estimate unproven benefits.

Conclusions: Pervasive, uncorrected biases in observational comparisons invalidated causal claims of transmission or hospital burden reduction. Progressive reliance on weaker evidence—coupled with expert bodies' lack of transparency in emphasizing unproven benefits while dismissing dissenting views—highlights a systemic failure to meet evidentiary standards for public health policies with rights implications. This analysis underscores the need for greater scientific rigor in interpreting observational data through real-time bias correction, transparent limitation reporting, and risk-stratified approaches to uphold evidentiary standards, ethical proportionality, and accountability. These lessons hold global relevance for evidence-based public health policy.

Keywords
COVID-19, vaccine effectiveness, selection bias, vaccine mandates, surveillance bias, observational data, causal inference, public health policy, Canada

Background

Canada implemented COVID-19 vaccine mandates and passports between 2021 and 2022 with the stated aim of reducing transmission and hospital burden. In the absence of randomized controlled trial (RCT) evidence for these endpoints, policy makers relied on vaccinated vs. unvaccinated comparisons derived from routine surveillance data and observational studies. This analysis demonstrates that pervasive methodological flaws in Canadian surveillance data rendered such comparisons unreliable for causal inference and therefore insufficient to justify rights-infringing policies.

Canadian public-health data ecosystem

Public-health delivery is a provincial responsibility in Canada. Provincial agencies (e.g., Public Health Ontario (PHO) [1], Alberta Health Services, BC Centre for Disease Control) collect case, hospitalization, and mortality data; perform daily surveillance; and publish processed reports for local public-health units, hospitals, and ministries. These agencies provide raw/processed data with methodological caveats and may issue public-health guidance, but do not set policy.

The Public Health Agency of Canada (PHAC) [2] aggregates provincial/territorial submissions, produces national statistics, interprets trends, and issues guidance to the federal government. Each province has a Chief Medical Officer of Health (CMOH) and may convene advisory panels; in Ontario, the self-selected Ontario COVID-19 Science Advisory Table (OST) [3] supplemented PHO outputs with interpretive briefs for the Ministry of Health and CMOH.

Federal policy (e.g., travel mandates, federal workplace requirements) is set by Cabinet on advice from PHAC and the Chief Public Health Officer.

Evidentiary gap and policy reliance

RCTs of authorized COVID-19 vaccines did not assess transmission or all-cause hospitalization—the outcomes central to mandate justifications. Observational comparisons therefore filled the evidentiary void, yet they inherit systemic biases that distort group definitions, inflate unvaccinated risk estimates, and preclude causal attribution. Population-level trends—surging cases and persistent hospital occupancy despite >80% vaccination coverage (Figures 1A, 1B)—further challenge the narrative that vaccines achieved the stated aim. Using publicly available Canadian surveillance data, we quantify these distortions and evaluate their ethical and scientific implications for rights-based policy.

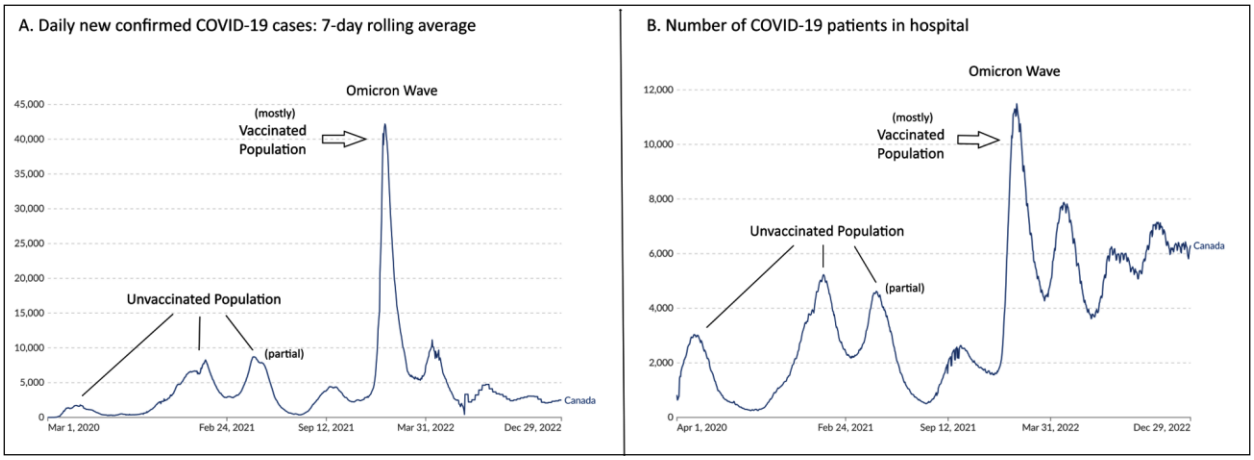

Figure 1. COVID-19 case and hospitalization trends in Canada, 2020–2022. **(A)** Daily new confirmed cases (7-day rolling average). The Omicron wave (Dec 2021–Mar 2022) peaked at ~42,000 cases/day — nearly 5 times any previous peak — when >80% of the population was fully vaccinated.[OWID, 4] **(B)** Total COVID-19 hospitalizations. The Omicron wave peaked at ~11,300 patients — >2 times the January 2021 peak (~5,200) — with sustained elevation through 2022.[OWID, 5]

Methods

Bias classification framework

We identified seven biases that undermine vaccinated vs. unvaccinated comparisons in Canadian COVID-19 surveillance data. Each bias is graded by severity (impact on data integrity), correctability, policy relevance, and scope of distortion:

Table 1. Bias classification framework

Severity	Definition	Correctability	Examples in this analysis
Critical	Distorts specific metrics or group definitions	Re-classification, stratification, alternative metrics, data adjustments	Misclassification, Denominator, Age-standardization, Testing, Misattribution
Catastrophic	Renders groups non-comparable; invalidates causal inference	Only via alternative study designs (e.g., RCTs for selection bias) or abandoning the methodology altogether (e.g., cumulative methodology)	Selection, Cumulative methodology

Data sources

This analysis relies exclusively on publicly available secondary data from official Canadian public health authorities:

- Public Health Ontario (PHO): weekly epidemiological summaries, daily public datasets, and archived severe-outcome reports (2020–2023).[1, 1a–1j]
- Public Health Agency of Canada (PHAC): national outcome reports and vaccination-coverage archives.[2, 14, 19, 31, 33]
- Ontario COVID-19 Science Advisory Table (OST): dashboards and interpretive briefs.[3]
- Our World in Data: national case and hospitalization time-series.[4, 5]

Supporting international studies on healthy vaccinee effect, misclassification, and incidental hospitalization are cited where relevant.

Rationale for Ontario/PHO focus

Ontario (population ~14.2 million, ~38 % of Canada) produced the most granular, regularly updated, and versioned surveillance reports during 2021–2022, including age- and vaccination-

status-specific case rates, hospital censuses, and documented population denominator updates that enabled rate corrections. These characteristics allowed clear quantification of bias magnitude. The same biases operate nationally because PHAC aggregates provincial submissions without harmonized classification rules; Ontario therefore serves as an exemplar rather than an outlier.

Analytical approach

This critique is entirely based on secondary data from official sources. No primary data collection, statistical modeling, or external re-analysis was performed.

1. Bias documentation – Direct extraction of classification rules, testing protocols, denominator updates, and methodological caveats from original PHO, PHAC, and OST reports.
2. Quantitative illustration – Reproduction of published figures and tables from PHO archived reports (with permission where required) to demonstrate the magnitude of each bias (e.g., pre- vs. post-denominator revision rates; proportion of misclassified cases).
3. Population-trend alignment – Overlay of vaccination coverage milestones (from PHO and PHAC archives) onto official case and hospital time-series.
4. Policy linkage – Mapping of biased metrics to mandate implementation dates using official government announcements, Hansard records, and regulatory orders.

All illustrations are either direct reproductions or faithful recreations of official outputs. Source URLs, archive timestamps, and access dates are provided in the References and Figure captions. We present biases in a logical sequence that reflects their interdependence and compounding effects: beginning with misclassification (critical) as the initial distortion of group definitions, followed by selection (catastrophic) and underestimated population sizes (critical) that fundamentally undermine group comparability, then age-standardization, testing, and reporting/misattribution (all critical) that amplify these flaws, and concluding with time-related biases (critical) and cumulative methodology (catastrophic) that collapse the entire rate-comparison framework.

Results

Misclassification bias (critical)

Misclassification bias in COVID-19 surveillance data distorted group definitions by classifying individuals with symptom onset within 0 to <14 days after their first vaccine dose as

“unvaccinated,” inflating unvaccinated case, hospitalization, and death rates, even if events occurred later but symptoms began within this period (PHO, 2020–2023 [1]; national standard). Vaccine recipients were not considered fully vaccinated until 14 or more days after receiving the first dose of a one-dose series or the second dose of a two-dose series, leading to systematic misclassification of early post-vaccination cases. This gave the vaccinated group a significant advantage, as individuals infected during the 6–10-week interval from their first dose to 14 days after their second dose entered the fully vaccinated group with some degree of natural immunity, skewing outcomes in their favor. This misclassification not only exaggerated unvaccinated risks but also created an artificial waning effectiveness pattern—a statistical artifact that artificially boosts early effectiveness estimates, creating a misleadingly high baseline that later declines.[6] This mirage was most pronounced in the first half of 2021 as first-dose uptake surged, amplified during high-transmission periods like spring 2021, with effects persisting into summer as second-dose coverage increased.

From December 2020 to September 2021, Canada transitioned from an unvaccinated to a mostly vaccinated population, a critical period shaping provincial vaccine passport policies. In Ontario, during the period leading up to the implementation of its vaccine passport system, PHO reported that over 40% of confirmed post-vaccination COVID-19 cases were misclassified as unvaccinated, while only 17.4% were identified as breakthrough cases (Table 2, Figure 2). The use of such flawed data to justify restrictive measures, including federal workplace and travel mandates, raises ethical concerns about discrimination and policy legitimacy. This misclassification issue was not unique to Canada; similar patterns occurred globally, such as in the UK,[7] highlighting a challenge in observational data reliability.

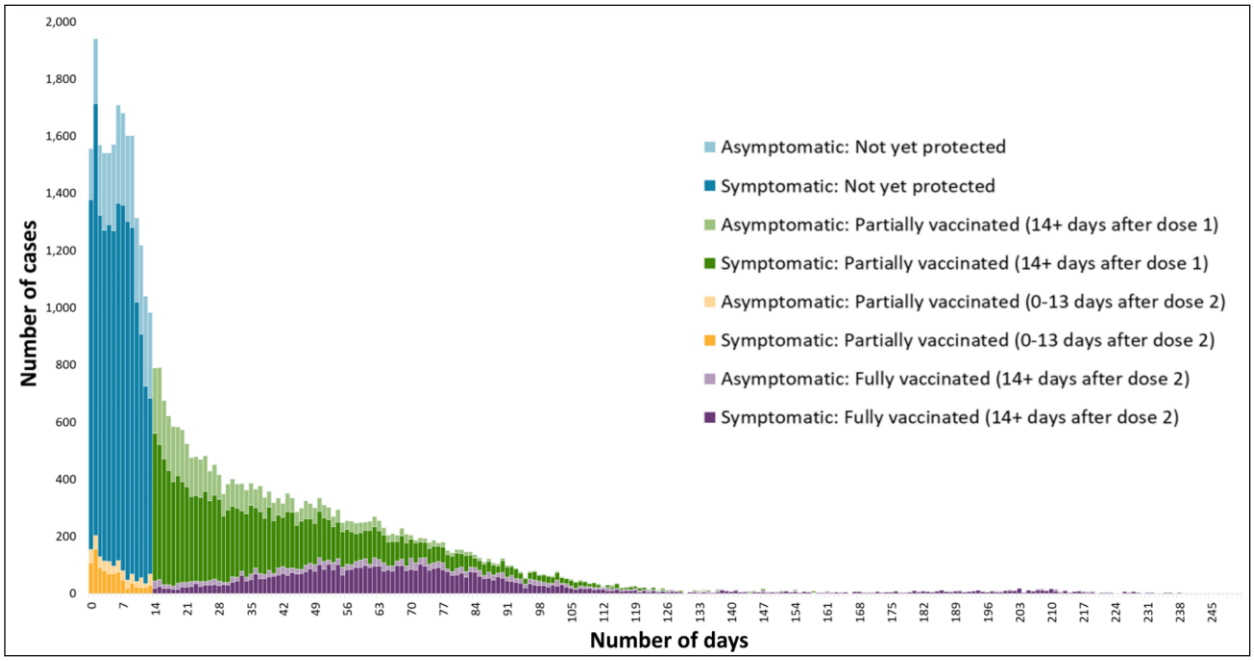

Figure 2. Misclassification bias in COVID-19 cases, Ontario, December 14, 2020-September 18, 2021. Confirmed post-vaccination cases of COVID-19 by number of days between dose administration and symptom onset. Cases with onset 0–13 days post-dose 1 were misclassified as "unvaccinated"; individuals were only considered "fully vaccinated" 14+ days after dose 2. Ontario's vaccine passport system came into effect September 22, 2021. Reproduced with permission from PHO.[1, 1a]

Table 2. Misclassification bias in COVID-19 cases, Ontario, December 14, 2020–September 18, 2021.

	Not yet protected: 0-13 days after dose 1	**Partially vaccinated: 14-27 days after dose 1**	**Partially vaccinated: 28+ days after dose 1**	**Partially vaccinated: 0-13 days after dose 2**	**Partially vaccinated: Total**	**Breakthrough: 14+ days after dose 2**	**Total**
Symptomatic	15,562 (43.1%)	5,034 (14.0%)	8,327 (23.1%)	850 (2.4%)	14,211 (39.4%)	6,303 (17.5%)	**36,076 (100.0%)**
Asymptomatic	3,988 (35.1%)	2,329 (20.5%)	2,603 (22.9%)	473 (4.2%)	5,405 (47.6%)	1,961 (17.3%)	**11,354 (100.0%)**
Total	**19,550 (41.2%)**	**7,363 (15.5%)**	**10,930 (23.0%)**	**1,323 (2.8%)**	**19,616 (41.4%)**	**8,264 (17.4%)**	**47,430 (100.0%)**

Confirmed post-vaccination cases. 41.2% of cases in vaccinated individuals occurred 0–13 days post-dose 1 (misclassified as "unvaccinated"); only 17.4% were considered breakthrough cases. Reproduced with permission from PHO.[1a]

Selection bias (catastrophic)

Selection bias fundamentally undermines vaccinated vs. unvaccinated comparisons by creating structurally non-comparable groups through differences in health, behavior, and socioeconomic status (SES). During Canada's voluntary rollout (December 2020–mid-2021), priority was given to seniors, including long-term care (LTC) residents, and healthcare workers. This produced a dual effect: the vaccinated group skewed older due to elderly prioritization, but the inclusion of healthcare workers and early adopters—individuals with proactive behaviors (e.g., regular check-ups, adherence to medical advice), higher risk perception, and better healthcare access—introduced a healthy vaccinee effect (HVE). Although frail elderly partially counteracted this HVE, misclassification bias further distorted comparisons by labeling early post-vaccination cases as unvaccinated, inflating adverse outcomes in this group (see misclassification bias).

Vaccine mandates, passports, and travel restrictions, announced in summer 2021 and implemented by fall, amplified HVE by disproportionately pressuring higher-SES, health-engaged individuals to comply. Compliance was required for certain white-collar employment (e.g., federal public servants, university faculty), post-secondary education, travel, and discretionary social activities (e.g., restaurants, theaters, sports), which lower-SES individuals accessed less or could more readily forgo. This selectively retained healthier, proactive individuals in the vaccinated group, while the unvaccinated became enriched with children under 12 (ineligible until November 2021) and those less engaged in healthcare or facing socioeconomic barriers. This composition—younger on average yet including less healthy subgroups—falsely suggested a shared increased risk under the "unvaccinated" label, severely confounding vaccine effectiveness analyses.

Globally, studies underscore the persistent impact of the HVE. For instance, Vencalek et al. (2025 [8]) found that vaccinated individuals aged 45–95 in the Czech Republic had up to a 5-fold lower all-cause mortality risk (HR ~0.20) compared to age-matched unvaccinated peers, even during negligible COVID-19 periods (e.g., summer 2021), indicating profound structural differences unrelated to vaccine effects. Other studies adjusting for baseline health reported 20–30% lower non-COVID-19 mortality in vaccinated seniors, an implausible vaccine effect driven by HVE.[9, 10, 11, 12] A rigorously matched cohort study in Qatar by Chemaitelly et al. (2025 [13]) found a strong HVE in the first 6 months post-vaccination (non-COVID-19 death aHR 0.35,

95% CI: 0.27–0.46), with the effect most pronounced among those aged 50 years and older and those more clinically vulnerable to severe COVID-19. This effect, strongest immediately after vaccination but gradually diminishing, highlights the time-dependent nature of the bias. Given Canada's similar rollout in early 2021, this HVE likely biased COVID-19 surveillance data (e.g., case rates and hospitalizations) and vaccine effectiveness estimates used to justify the country's 2021–2022 mandates and passports. These structural biases, compounded by misclassification, strongly predisposed better health outcomes for the vaccinated, irrespective of the vaccine's effect on severe outcomes.

These findings highlight the limitations of statistical adjustments like regression or propensity score matching, which researchers frequently assume are adequate to minimize residual bias sufficiently. While adjustments may mitigate measurable biases (e.g., age, sex), they can amplify unmeasured confounders (e.g., frailty, socioeconomic status) or introduce errors through model misspecification. For example, incomplete adjustment for frailty or healthcare access can inflate perceived vaccine benefits, misleading policymakers. Even if adjustments reduce measured differences to near zero, hidden biases from unmeasured factors or model assumptions persist, with no definitive way to confirm their magnitude or direction. Only randomized controlled trials (RCTs) can effectively mitigate such biases, ensuring robust evidence for policies that infringe on individual rights. Selection bias, compounded by misclassification, distorts causal inference, producing misleading vaccine effectiveness estimates that supported Canada's 2021–2022 vaccine mandates and restrictions.

Underestimating the unvaccinated population (critical)

Underestimation of the unvaccinated population, particularly seniors driving severe COVID-19 outcomes, distorted risk estimates by inflating reported case, hospitalization, and death rates among the unvaccinated. Stemming from outdated census data, this critical bias compounded selection bias's non-comparability. PHAC acknowledged that unvaccinated counts were set to zero in regions when population estimates were lower than those with at least one vaccine dose, inflating rates.[2] With senior vaccination rates exceeding 90% by summer 2021,[14] the small unvaccinated senior cohort led to unstable rate estimates, as noted by Public Health Ontario.[1]

PHO's 2022–2023 denominator revision, incorporating updated population estimates, identified ~390,000 additional unvaccinated Ontarians—nearly half seniors—and dramatically lowered reported rates.[1] The ~390,000 figure is inferred from vaccination coverage corrections issued in PHO's September 2022 reports. Figures 3A and 3B show COVID-19 hospitalization

rates by vaccination status and age in Ontario, before (3A, August 1, 2022) and after (3B, August 14, 2022) PHO's population denominator revision. Pre-revision disparities between vaccination statuses were driven by the unvaccinated 60+ group (141.33 per 100,000 person-days in the previous 120 days); post-revision, this rate collapsed to 3.60—dramatically narrowing the gap and revealing that unstable denominators for the small unvaccinated population, not vaccine effectiveness, accounted for much of the apparent difference.

Figures 3C and 3D present time-series of COVID-19 hospitalization rates for seniors (60+), by vaccination status, before (3C) and after (3D) the revision. The correction reveals the scale of distortion in reported rates, particularly for unvaccinated seniors:

- In mid-July 2022, the rate dropped from >400 to ~5 per 100,000 person-days — an 80-fold reduction (~1.9 orders of magnitude).
- In January 2022, it fell from 255 to 27.5 — a 9.3-fold reduction (~0.97 orders).

While the magnitude varied by month, peak distortions exceeded one order of magnitude, with sustained overestimation throughout much of the mandate period, particularly after the emergence of Omicron when <5% of seniors remained unvaccinated.

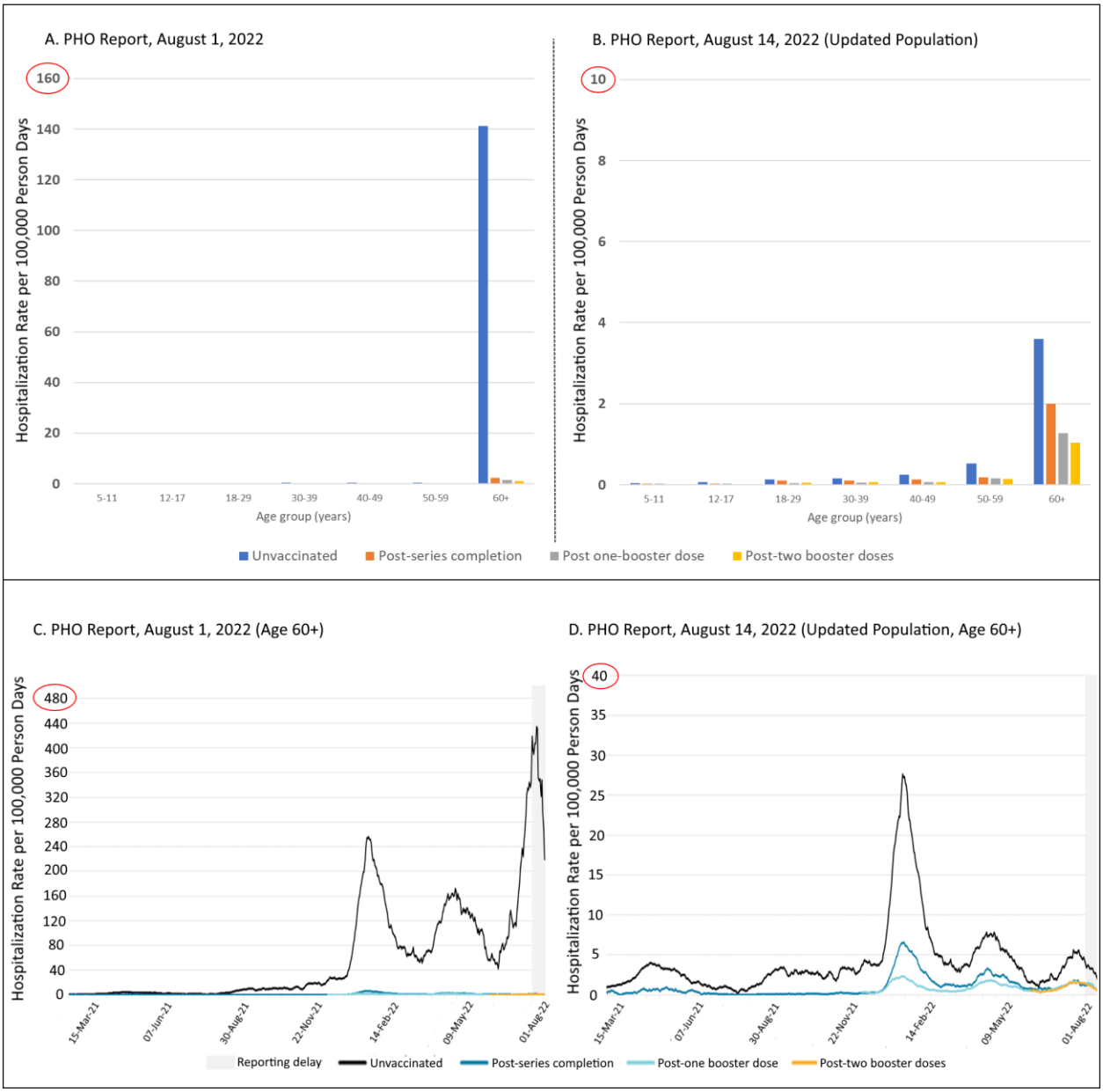

Figure 3. COVID-19 hospitalization rates by vaccination status, Ontario, before/after PHO population revision.[1b, 1c] **(A)** PHO Figure 5 (August 1, 2022): Rate per 100,000 person-days by vaccination status and age in previous 120 days (pre-revision, weekly). Unvaccinated 60+ rate: 141.33. **(B)** PHO Figure 5 (August 14, 2022): Same metric post-revision. Unvaccinated 60+ rate: 3.60. PHO caveat: “High coverage… and a small number of unvaccinated individuals has resulted in unstable rates…” **(C)** Time-series of 60+ hospitalization rates (pre-revision, Jan–Aug 2022, 7-day moving average). **(D)** Same metric post-revision, showing an 80-fold drop in unvaccinated senior rates mid-July (>400 → ~5) and 9.3-fold drop in January (255 → 27.5). Reproduced with permission from PHO.

Mortality rates exhibited collapses of similar magnitude. Figure 4 (PHO public dataset, daily 7-day moving averages with updated denominators from January 2023) confirms this pattern: reported death rates for unvaccinated seniors plunged once population sizes were corrected. Reconciling the weekly reports with the daily public dataset reveals substantial methodological differences — including weekly vs. daily aggregation, staggered denominator updates, and lack of retroactive adjustments — underscoring the need for extreme caution when interpreting group differences to infer vaccine effectiveness or inform policy. Notably, neither source quantifies uncertainty (e.g., confidence intervals), amplifying the unreliability of risk estimates.

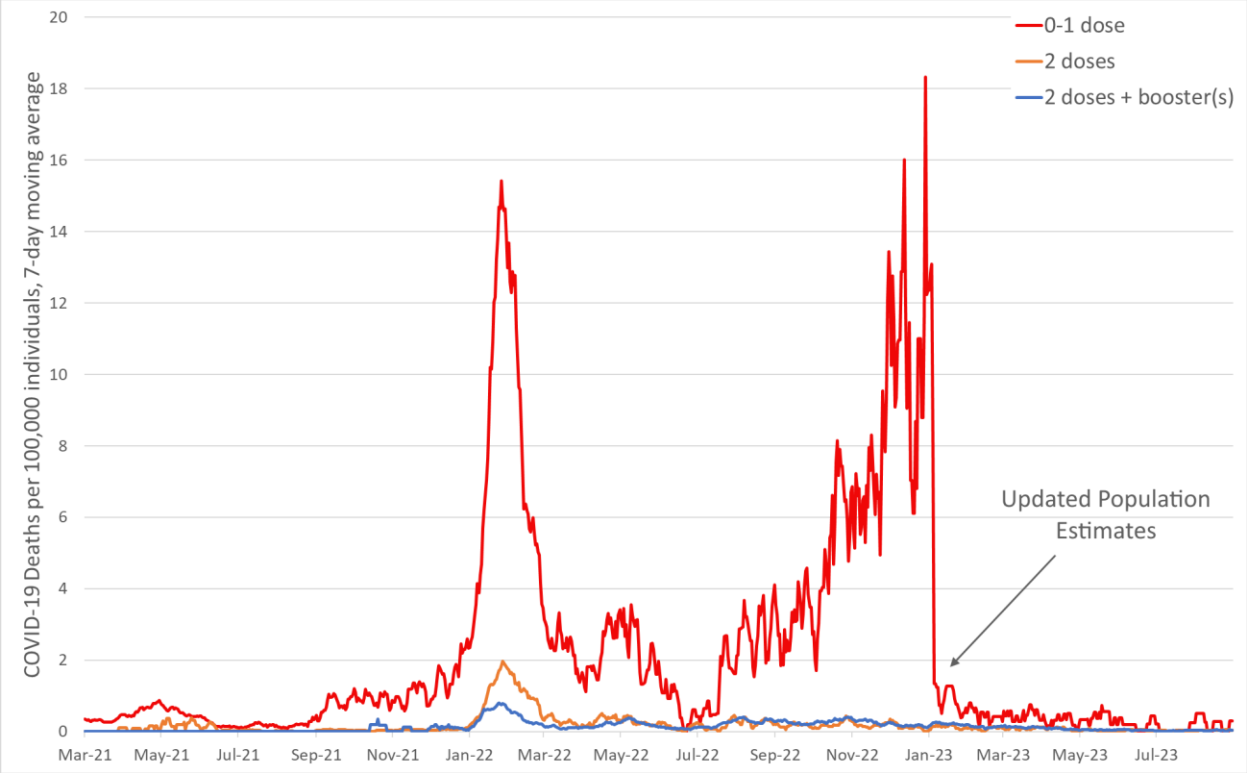

Figure 4. COVID-19 death rates by vaccination status, individuals aged 60+, Ontario. Seven-day moving average COVID-19 death rate per 100,000 person-days among individuals aged 60+ by vaccination status, using PHO public dataset (daily data, updated denominators from January 2023). Post-update collapse in the unvaccinated senior rate mirrors the dramatic drops observed in weekly PHO reports. This isn't a minor discrepancy; it fundamentally distorted the perceived risk gap between groups, directly impacting policy decisions. Data from [1d], licensed under the Open Government Licence – Ontario.

This underestimation bias amplified flawed age-standardized analyses throughout the mandate period, as PHO's data revisions were not published until months after provincial vaccine passports and federal mandates ended, with no policy implications addressed upon correction.

Age-standardization bias (critical)

Age-standardization bias arises when methods to adjust for age-related differences in COVID-19 outcomes amplify unmeasured confounders, such as baseline health, and rely on unstable population estimates, inflating unvaccinated risk and exaggerating vaccine effectiveness. This critical bias, compounded by selection bias and underestimation of the unvaccinated population, distorted risk estimates and undermined the evidence base for Canada's 2021–2022 vaccine mandates by masking age-specific risks and supporting coercive policies.

Severe COVID-19 outcomes, particularly hospitalizations and deaths, were driven by age and comorbidities, with mortality risks varying 1000-fold across age groups and comorbidities like obesity or diabetes amplifying risks up to 5-fold or more within age strata.[15, 16] As noted in selection bias, the vaccinated population skewed older and healthier due to the HVE, while the unvaccinated included frail seniors and younger, lower-risk individuals (e.g., children <12, ineligible until November 2021). Age-standardization, intended to adjust for age structure differences, failed to account for baseline health disparities or other confounders (e.g., socioeconomic status, healthcare access), amplifying their impact and inflating unvaccinated rates. This is particularly problematic, as age-standardization constructs a fictitious scenario of what might have occurred had more seniors remained unvaccinated, falsely assuming their unrepresentative rates could scale up realistically given their distinct profile.

The Ontario Science Table misapplied this methodology, leveraging unstable case rate estimates among unvaccinated seniors (<5% of seniors) to reverse lower reported case rates in official Ontario data. During the Omicron wave (December 2021–January 2022), official data showed lower unvaccinated case rates overall and for those under 60 (Figures 5A-D, 6A), yet OST's age-standardized estimates inflated these rates (Figure 6B), justifying workplace mandates and Ontario's vaccine passport. Cited in OST testimony endorsing employer mandates, these flawed rates went unchallenged, misleadingly supporting policies that disproportionately impacted younger groups.[17, 18] Age-standardized rates also more than doubled crude hospitalization rates (Figures 7A, B), producing a counterfactual burden that exaggerated overall risk while masking minimal threats from younger unvaccinated individuals.

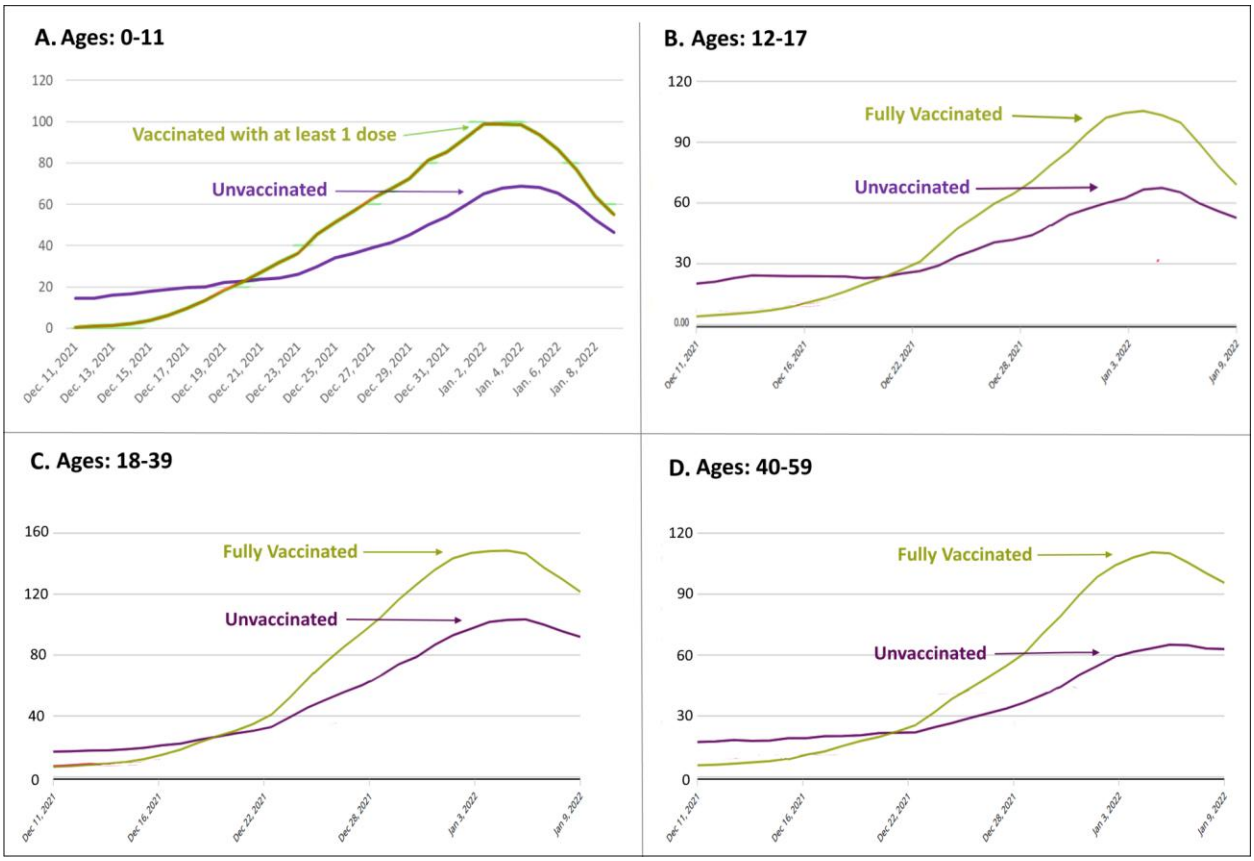

Figure 5. COVID-19 case rates per 100,000 by vaccination status and age group, Ontario, Omicron peak. **(A–D)** Case rates (7-day moving average) for ages 0–11, 12–17, 18–39, 40–59. Unvaccinated rates lower at peak than vaccinated peers despite underestimated denominators and misclassification bias. Data series end on January 9, 2022, as Public Health Ontario discontinued public online visualizations and raw breakdowns by age and vaccination status thereafter. Recreated from archived screenshots of the Ontario COVID-19 data website (raw data unavailable). Source: [1e], archived via Wayback Machine.

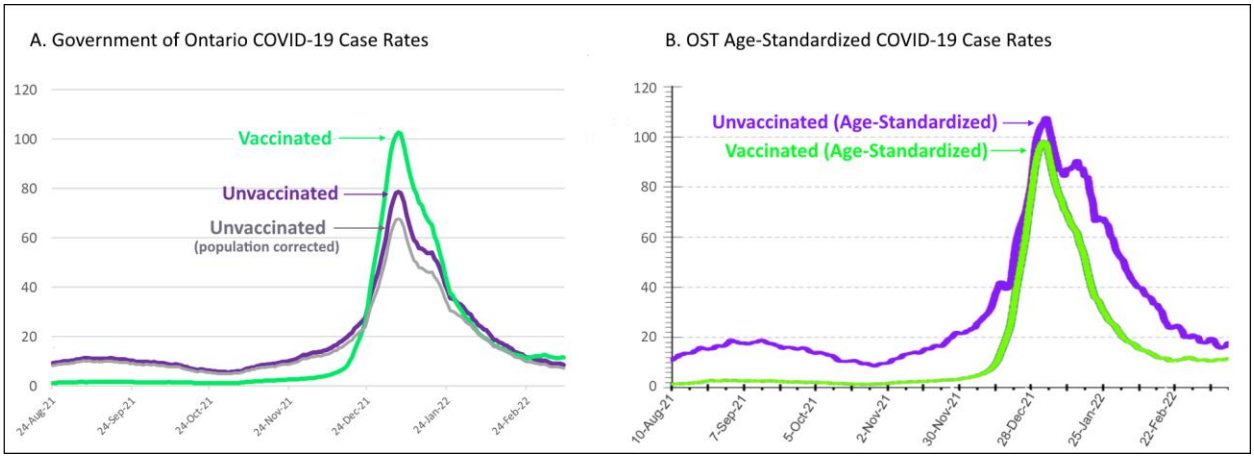

Figure 6. Crude vs age-standardized COVID-19 case rates per 100,000 by vaccination status, Ontario, August 2021-February 2022. **(A)** Government of Ontario data: unvaccinated rates lower than vaccinated during Omicron peak (Jan 2022).[1f] Population correction (based on PHO Sept 2022 update,[1]) further reduces unvaccinated rates. **(B)** Ontario Science Table age-standardized rates (screenshot with labeled lines): unvaccinated rates inflated above vaccinated.[3] Reproduced with permission from PHO.

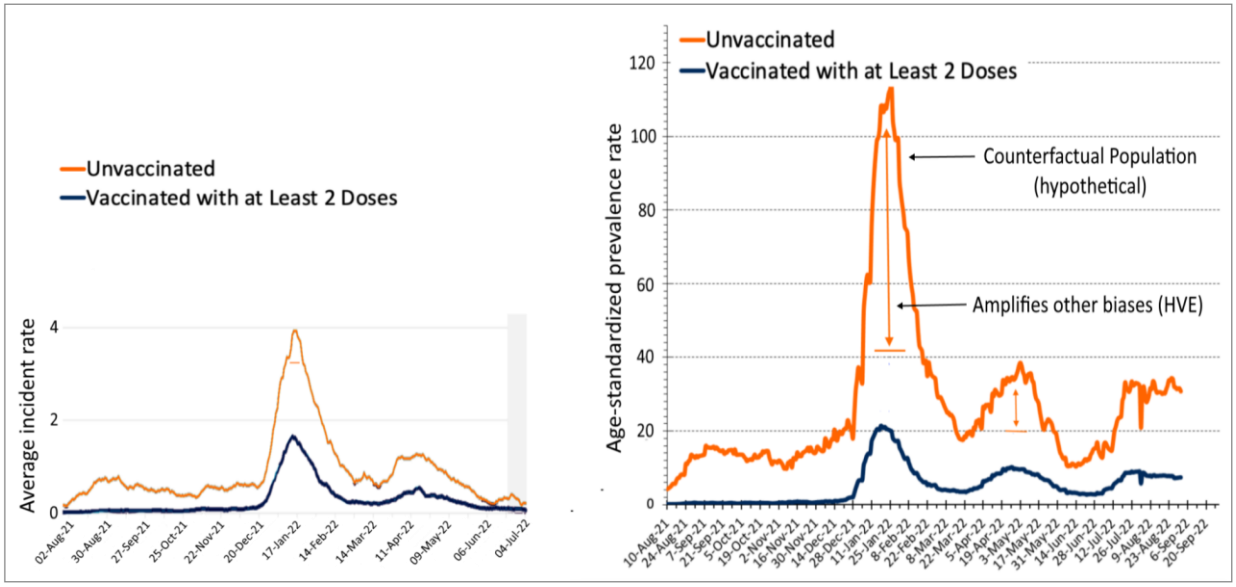

Figure 7. COVID-19 hospitalization rates by vaccination status, Ontario, August 2021–Summer 2022. **(A)** PHO 7-day average incident hospitalization rates per 100,000 person-days (pre-population correction). After denominator corrections, unvaccinated rates were 2× vaccinated at the Omicron peak (marked).[1g] **(B)** OST age-standardized prevalence rates per 100,000 persons (single cut-off: 0–29 vs 30+ years). Age-standardization inflated unvaccinated rates >5× vaccinated at peak, amplifying HVE and exaggerating unvaccinated burden.[3] *Note: Panel A shows incident (new admissions) rates; Panel B shows prevalence (in-hospital census) rates. Prevalence incorporates length of stay (~10× higher than incidence) but should scale proportionally; the >5× gap in (B) vs. ~2× in (A) reflects methodological bias, not clinical differences.* Reproduced with permission from PHO.

PHAC employed age-standardization on national data during early Omicron, reporting lower unvaccinated case rates (incidence rate ratio <1), unlike OST's trend-reversing estimates.[2] While PHAC attributed reductions in age-standardized hospitalization and death rates to vaccine protection, they dismissed higher vaccinated case rates as artifacts of Omicron's immune-evasive properties. This selective interpretation inflated perceived vaccine

effectiveness, supporting provincial vaccine passports and coercive federal mandates. Moreover, by emphasizing relative reductions in severe outcomes without reporting absolute risk reductions or addressing confounders (e.g., baseline health, testing frequency, socioeconomic disparities)—and by omitting uncertainty measures (e.g., confidence intervals)—PHAC overstated vaccine necessity and obscured methodological vulnerabilities, including underestimation of unvaccinated population denominators. Such observational methods lacked the rigor required to justify rights-infringing mandates, eroding scientific integrity, informed consent, and public trust in Canada's vaccine policies.

Testing bias (critical)

Testing biases significantly distorted COVID-19 case rates in Canada, compounding selection and misclassification biases to undermine the reliability of data used to justify vaccine mandates premised on reduced transmission. High polymerase chain reaction (PCR) cycle thresholds (Ct > 35) amplified non-infectious viral fragments, inflating case counts, particularly as asymptomatic testing expanded from mid-2020. Testing strategies shifted from symptomatic to mass screening by mid-2020 with testing rates fluctuating throughout the pandemic, undermining comparability across pandemic waves (Alpha to Omicron). Provincial variations, such as Quebec's high per-capita testing versus B.C and Alberta's more targeted symptomatic testing, further compromised data consistency.

Ontario's testing fluctuations, as shown in Figure 8, aligned with vaccine rollout phases: elevated testing during the green-shaded early rollout (60% first-dose uptake) coincided with second-third waves, heightening misclassification bias as those infected within 14 days of their first dose were grouped with the unvaccinated. The next shaded period during which second dose administration ramped up, featured lower testing and reduced summer exposure, thus understating breakthrough case risks before vaccine passports were introduced (September 2021, with 70% of those aged 12+ years fully vaccinated). The third shaded area marks the vaccine approval and first-dose rollout for 5-11-year-olds. This coincided with the emergence of Omicron and increased testing until early January. In the midst of record cases dominated by fully-vaccinated individuals, Ontario slashed its testing capacity, decreasing it by 70% by mid-February 2022. Similar reductions in PCR testing capacity were witnessed across the country, creating significant data gaps as breakthrough infections surged.

Group-specific biases further eroded data reliability. During the early vaccine rollout, vaccinated individuals tested less frequently due to perceived protection, while unvaccinated individuals faced increased testing due to travel and workplace mandates.[19, 20] Conversely,

by fall 2021, discrimination-driven distrust among unvaccinated individuals likely reduced their testing engagement, introducing bidirectional behavioral bias.[21, 22] These procedural and behavioral distortions, combined with selection bias creating non-comparable groups and misclassification bias inflating unvaccinated case rates, rendered historical case rate comparisons unreliable and uncorrectable. This undermined the observational data used to support coercive policies, overstating vaccine-related transmission reduction.

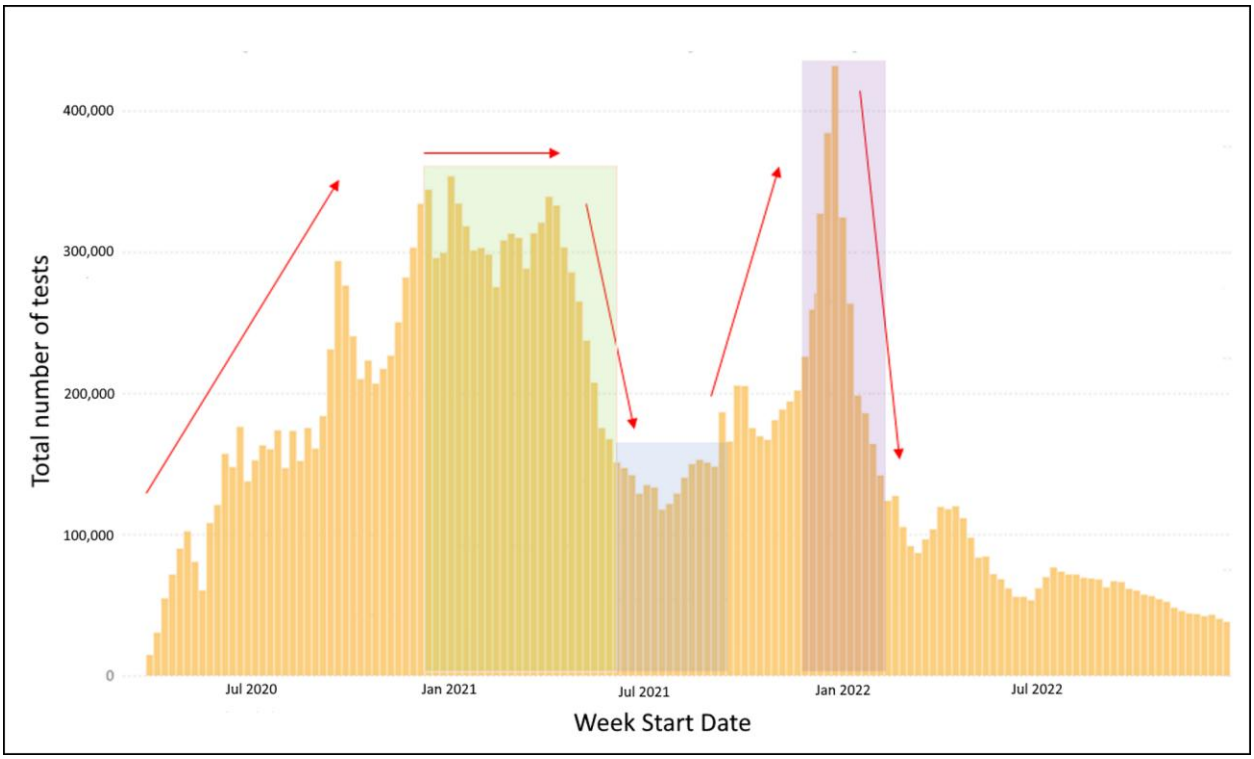

Figure 8. Weekly SARS-CoV-2 tests conducted in Ontario, March 2020–December 2022. Total weekly tests increased through 2020, remained high mid-Nov 2020 to early May 2021, then declined into the summer months as second does of the vaccine were administered. Testing spiked with Omicron (Dec 2021), followed by 70% capacity cut (Jan–Feb 2022). Rates fell to <5% of peak by mid-2023. Figure generated via the PHO Respiratory Virus Tool, with permission.[1h]

Reporting and misattribution biases (critical)

Reporting lags, subjective attribution of COVID-19 hospitalizations and deaths, and administrative recording errors have profoundly compromised the assessment of healthcare burden and mortality risk. The attribution problem in assessing COVID-19 hospitalizations arises from the inherent challenge of distinguishing between patients admitted for COVID-19 versus

those with incidental SARS-CoV-2 infections, a subjectivity amplified by the lack of a standardized definition across jurisdictions. This issue became particularly pronounced with the emergence of Omicron, as recognition of incidental hospitalizations increased in Canada—rising from 10% in early waves to well over 40% during Omicron.[23] In Ontario, incidental hospitalizations climbed to 55% by March–April 2022.[24] Meanwhile, Alberta faced additional data challenges, such as the inaccurate logging of non-ICU hospitalizations as ICU admissions in fall 2021 due to administrative discrepancies in bed reassignment—an error later acknowledged as significant by Alberta Health Services.[25] Internationally, studies reveal a wide range of incidental rates, from 10% to 67% across pandemic waves and measurement approaches, underscoring the variability in classification practices.[26, 27, 28]

Population-level data (Figure 9) further illustrate this variability's impact. Despite vaccination coverage exceeding 80% fully vaccinated in all adult age groups throughout 2022, overall COVID-19 hospitalization rates in Ontario rose 31% compared with 2021 (199.1 vs. 152.2 per 100,000), with increases in all age groups except 20–59 years—the primary targets of workplace mandates.[1i] The largest rises occurred in infants <1 year (vaccine-eligible only from July 2022) and adults ≥80 years (>95% vaccinated throughout 2022). This pattern—opposite to mandate justifications—coincided with corrected denominators and heightened recognition of incidental hospitalizations during Omicron.

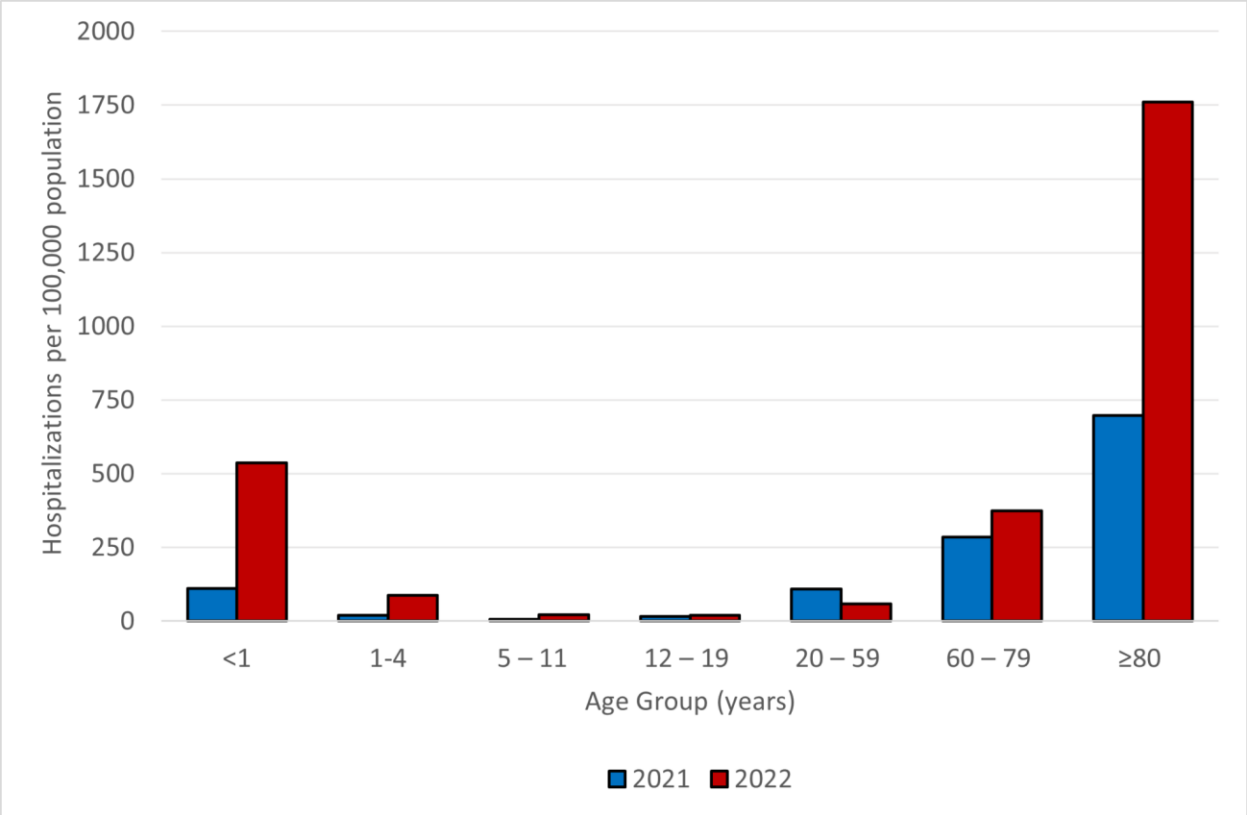

Figure 9. COVID-19 hospitalization rates per 100,000 population by age group, Ontario, 2021 vs. 2022 (annual averages). Blue bars: 2021; red bars: 2022. Despite vaccination coverage exceeding 80% fully vaccinated in all adult age groups throughout 2022, overall hospitalization rates rose 31% compared with 2021 (199.1 vs. 152.2 per 100,000), with increases in all age groups except 20–59 years.[1i] The largest rises occurred in infants <1 year (vaccine-eligible only from July 2022) and adults ≥80 years (>95% vaccinated throughout 2022). Reproduced with permission from PHO.[1i]

The wide range of incidental hospitalizations across time and jurisdictions, compounded by misclassification and selection biases, renders the COVID-19 hospitalization metric invalid for assessing vaccine effectiveness in reducing hospitalization or hospital burden, exposing a critical flaw in public health data interpretation that undermines evidence-based policy in Canada. While using all-cause hospitalization avoids the attribution issue, this metric remains subject to selection bias and other confounders that no observational study can fully resolve, further complicating the evaluation of vaccine impact and hospital burden for policy purposes.

Similarly, the “COVID-19 deaths” metric, used to assess vaccination’s effect on mortality, faces attribution challenges, with ~90% of Canadian deaths in 2020 involving comorbidities and

U.S. CDC data reporting an average of four additional causes per COVID-19 death.[29, 30] Lags in Canadian mortality data reporting—often spanning months—compromised real-time accuracy. This was exacerbated by methodological changes, such as Ontario's 2022 revision to exclude incidental deaths retroactively and align counts with date of occurrence rather than entry into public health systems.[1] These well-documented inconsistencies, alongside attribution challenges, significantly undermined data reliability. Yet Canadian policymakers, implementing restrictive vaccine passport policies in summer 2021, overlooked these limitations, relying on flawed mortality and hospitalization metrics to justify measures with questionable evidential basis.

Time-related biases (critical) and cumulative methodology (catastrophic)
Cumulative and time-related biases catastrophically distorted vaccinated versus unvaccinated COVID-19 outcome comparisons by aggregating cases, hospitalizations, and deaths across heterogeneous periods from the outset of the vaccine rollout in December 2020 onward, spanning multiple variants and vaccination phases. This approach—covering unvaccinated-dominated Alpha waves (early 2021, near-zero vaccination) through Omicron (December 2021 onwards, >80% vaccination [31])—failed to account for waning immunity (e.g., 20% effectiveness after six months [32]), variant-specific differences (e.g., Delta's higher mortality, Omicron's increased transmissibility), population crossover (individuals shifting vaccination status), and evolving vaccination categories. Compounded by selection, misclassification, and testing biases, this method inflated perceived unvaccinated risks and overstated vaccine benefits, violating epidemiological principles of temporal relevance. Correctable only through time- and variant-stratified analyses (i.e., abandoning cumulative methodology altogether), this bias misled evaluations of the necessity and proportionality of Canada's 2021–2022 vaccine mandates.

PHAC routinely reported cumulative counts since rollout on its national dashboard, which were widely interpreted to show that most COVID-19 hospitalizations and deaths occurred among unvaccinated individuals.[33] PHO similarly published such data in its epidemiological summaries, reinforcing this narrative.[1] A PHO summary from December 14, 2020, to June 19, 2022, reported 25,141 unvaccinated versus 12,154 vaccinated hospitalizations for Ontarians over 12 (Table 3A). However, splitting this period into a pre-mandate phase (December 2020–September 2021, low vaccination during Alpha and early Delta waves) and a passport-mandate phase (September 2021–June 2022, >70% vaccination, Omicron-dominant) shows that unvaccinated hospitalizations were front-loaded in the pre-

mandate phase due to low vaccination coverage (Table 3B). Total hospitalizations across both 9-month periods were comparable (within 10% difference), despite higher vaccination and a less severe variant in the passport-mandate phase. During this second phase, unvaccinated individuals accounted for just one-third of COVID-19 hospitalizations, representing only ~0.79% of Ontario's >1 million annual all-cause hospitalizations, with those under 60 contributing ~0.26%, many incidental (see misattribution bias).[34] Reliance on cumulative metrics, often paired with inflated incidence rate ratios, overstated the unvaccinated hospital burden, perpetuating biased narratives that justified restrictive policies with disproportionate impacts.

Table 3A. COVID-19 hospitalizations (number) by vaccination status, Ontario, December 14, 2020–June 19, 2022.

Age (years)	Hospitalized unvaccinated cases	Hospitalized cases post-series initiation	Hospitalized cases post-series completion	Hospitalized cases post-booster dose	Hospitalized cases post-two booster doses
5-11	178	44	19	1	0
12-17	174	12	86	8	1
18-29	1,176	45	256	81	2
30-39	1,924	71	280	87	3
40-49	2,566	105	362	151	2
50-59	4,158	177	611	313	23
60+	15,143	1,579	5,079	4,337	472
Total	**25,322**	**2,033**	**6,693**	**4,978**	**503**

Unvaccinated cases (n = 25,322) appear dominant, but this 18-month aggregate mixes non-comparable groups (crossover between statuses, evolving definitions) across low-vaccination Alpha/Delta waves and high-vaccination Omicron waves, violating temporal comparability and group separability (see cumulative methodology bias). Stratification by mandate phase (Table 3B) reveals front-loading of unvaccinated hospitalizations during early rollout, rendering cumulative totals meaningless for policy justification. Reproduced with permission from PHO.[1j]

Table 3B. Ontario COVID-19 hospitalizations (number) stratified by mandate phase.

Age (years)	Dec 20, 2020 - Sept 18, 2021			Sept 19,2021 - June 19, 2022		
	Unvaccinated	**Partial**	**Fully**	**Unvaccinated**	**Partial**	**Fully**
12-17	116	5	1	58	7	94
18-29	922	12	5	254	33	334
30-39	1,488	22	14	436	49	356
40-49	2,040	44	11	526	61	504
50-59	3,318	115	20	840	62	927
60+	10,956	1,168	237	4,187	411	9,651
Total	**18,840**	**1,366**	**288**	**6,301**	**623**	**11,866**
	20,494			**18,790**		

Vaccine rollout period (December 20, 2020–September 18, 2021): ~70% eligible fully vaccinated by end; unvaccinated-dominated Alpha/Delta waves. Mandate/passport period (September 19, 2021–June 19, 2022): >80% eligible vaccinated by Omicron surge (December 2021–January 2022). Unvaccinated hospitalizations fell to one-third of total (6,301/18,790), exposing front-loading in cumulative data (Table 3A); overall totals comparable (20,494 vs. 18,790) despite higher coverage and milder variant. Cases with unknown age excluded. Derived from PHO reports.[1a, 1j]

Population trends

Beyond methodological flaws, population trends challenge the narrative that vaccines achieved the public health outcomes necessary to justify mandates and passports. Despite over 80% vaccination coverage by late 2021, daily new cases surged during the Omicron wave, peaking in early 2022 (Figure 1A), with vaccinated individuals dominating case counts and rates,[1,2] demonstrating that vaccines did not achieve the population-level reduction in transmission necessary to justify mandates, particularly given Omicron's high transmissibility and the vaccines' non-sterilizing nature. Hospitalizations increased post-rollout (Figure 1B), a trend opposite to the expected reduction in hospital burden claimed to justify mandates. While confounding factors may contribute, the onus was on authorities to demonstrate a net reduction

in all-cause hospital burden using causal evidence—a burden they failed to meet, particularly given the possibility that vaccines contributed to adverse outcomes.

While RCTs demonstrated vaccine efficacy against severe COVID-19 outcomes in the original strain,[35] they did not assess transmission or all-cause hospitalization—the outcomes central to mandate justifications. A re-analysis by Fraiman et al. (2022 [36]) found that serious adverse events of special interest (SAESIs) outweighed COVID-19 hospitalization reductions. Their reported excess risk of 1 SAESI per 800 vaccinated—and the net harm conclusion—are likely understated given that RCTs tested the original strain, used short observation windows potentially missing waning immunity or subclinical effects, and did not reflect commercial manufacturing changes or Canada's mixed-vaccine protocols. This raises concerns about the safety profile for population-wide mandates.

Canadian authorities frequently cited reduced disease severity to justify healthcare-protecting mandates and encourage vaccination, but this concept—while invoked alongside claims of lower COVID-19 hospitalization and death—was not clearly defined, rendering it untestable. In contrast, all-cause hospitalization burden—the only outcome capable of capturing net system impact—was both testable and policy-critical, yet no evidence was provided to show vaccines reduced it. This dual failure—relying on an undefined claim while omitting a quantifiable, valid metric—left the core rationale for rights-infringing policies without sufficient empirical support. Observational studies (e.g., Barda et al. [37], Andrews et al. [38], Nyberg et al. [39]) claiming reduced hospitalization risk are subject to the same selection biases and methodological limitations (e.g., misclassification, misattribution) that confound the assessment of vaccinated vs. unvaccinated burden reductions, rendering them insufficient for justifying mandates.

Discussion

While observational studies are commonly used for policy support, these critical and catastrophic biases in Canadian surveillance data reveal a fundamental failure by authorities to establish a causal relationship before justifying rights-infringing policies like vaccine mandates. Instead of approaching the data with caution and transparency—such as providing measures of uncertainty and emphasizing limitations—PHAC and other expert bodies highlighted unproven benefits while holding dissenting voices raising concerns about potential harm to a higher evidentiary standard, often dismissing them by noting that correlation does not imply causation. This double standard and lack of rigor necessitate a shift toward causal evidence to ensure future public health decisions align with scientific and ethical principles.

Escalation to simulation studies

The use of flawed evidence was not an isolated incident but a recurring feature of pandemic policy, escalating over time. In April 2022—two months after the unconstitutionally invoked Emergencies Act was used to quell vaccine mandate protests (Mosely, 2024 [40])—Canada cited a 2022 simulation study (Fisman et al., CMAJ [41]) to extend travel restrictions.[42] This study retroactively claimed the unvaccinated posed a disproportionate risk during the Omicron wave that had already occurred, defying real-world data showing vaccinated individuals dominated cases and rates (Figures 10A, B).[1, 2]

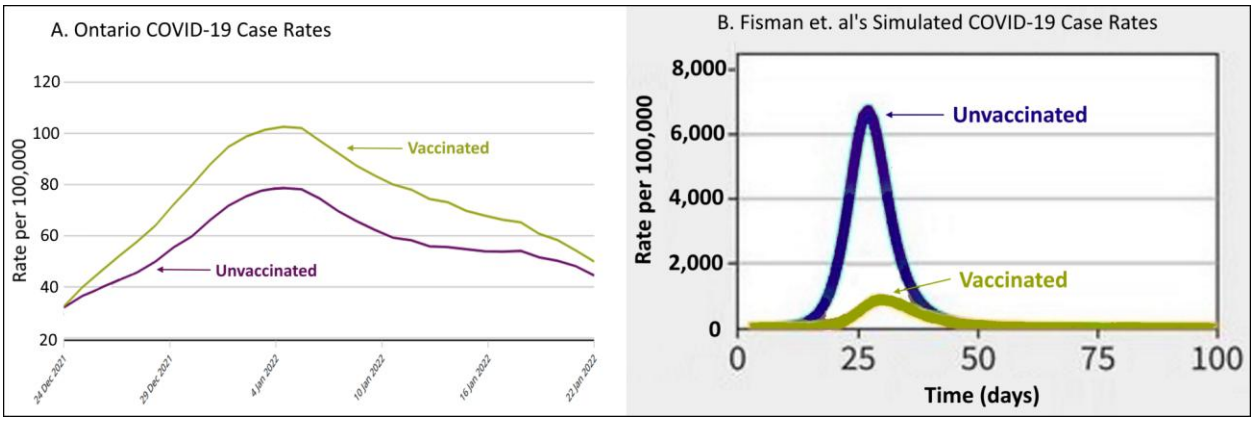

Figure 10. Real-world vs. simulated COVID-19 incident case rates by vaccination status during the Omicron wave in Ontario. **(A)** Observed rates from Public Health Ontario surveillance data (7-day average, January 2022). Unvaccinated rates remained below vaccinated rates throughout the peak period.[1f] **(B)** Simulated rates from Fisman et al. (2022) under intermediate like-with-like mixing, baseline Ontario Omicron emergence.[41] Across mixing scenarios, unvaccinated peak rates ranged 4–30-fold higher than vaccinated rates, with authors concluding that greater like-with-like mixing (less contact between groups) decreased overall risk to vaccinated people but increased the contribution of risk to vaccinated people caused by infection acquired from contact with unvaccinated people. Real-world Ontario data—publicly available months before publication—showed a contradictory pattern, with unvaccinated incidence lower than vaccinated rates and 1–2 orders of magnitude lower than simulated values; these discrepancies were not reconciled in the modelling exercise.

Subsequently, in July 2022, amid ongoing public scrutiny, PHAC published a simulation study co-authored by Canada's Chief Public Health Officer, 'illustrating what may have happened' in terms of COVID-19 cases, hospitalizations, and deaths had public health

measures and vaccination not been implemented.[43] The study estimated averted outcomes of 10.3x cases, 13.3x hospitalizations, and 20.6x deaths, framing Canada's response as a 'success' against a hypothetical baseline of 'possibly catastrophic outcomes.' However, this redefined success shifted from pre-vaccination promises of reduced hospitalizations and deaths—unsupported by RCTs—to counterfactuals unverifiable by design.

This escalation in relying on unreliable evidence, from flawed observational comparisons to speculative simulations, undermined the legitimacy of restrictions by reducing the evidentiary standard to an arbitrary level, intensifying concerns about freedom of expression (Charter Section 2(b)) and bodily autonomy (Section 7). Compounded by population trends suggesting unexpected outcomes, the absence of robust evidence highlights the arbitrariness of these mandates—a concern with global relevance, as many countries relied on similar observational data for vaccine policies. Calls for transparency in COVID-19 data underscore the urgent need for accountability to ensure public health decisions align with ethical principles and scientific rigor.

Ethical and Policy Implications

The reliance on flawed vaccinated vs. unvaccinated comparisons by expert bodies like PHAC and the Ontario Science Table, despite known limitations such as unstable senior rates and unvalidated age-standardization, enabled policymakers to use unreliable evidence, with profound ethical and policy consequences. These biased comparisons supported vaccine mandates imposing unpaid leave on federal workers, termination of unvaccinated healthcare workers, blanket travel restrictions, and vaccine passports, placing undue burdens on younger age groups.

Children and youth, facing negligible risk of severe COVID-19, endured restricted travel, disrupted education, and impaired social development, raising concerns about equality rights under Charter Section 15. Observational studies, marred by age-standardization, misclassification, and testing biases, leveraged the high, often unstable, COVID-19 risk estimates of older, comorbid populations to justify broad vaccine mandates that unfairly targeted younger, healthier individuals—including students and athletes—who posed minimal healthcare risk.

This inversion of age and health-based protections—typically safeguarded under the Canadian Human Rights Act and provincial codes—effectively created a form of reverse discrimination, further violating Charter Section 15's equality principles. Moreover, the unrealistic

policy portrayal of unvaccinated senior risks, arising from the overestimated rates (by 1–2 orders) noted earlier, misled governance by exaggerating vulnerability, eroding public trust and disproportionately infringing on the equality and access rights of the few unvaccinated seniors through exclusion and stigma.

Strengths and Limitations

Strengths: This critique draws on extensive secondary data and public health authority reports (e.g., PHAC, PHO, OST) to systematically identify and quantify well-documented biases (e.g., misclassification, selection bias, misattribution) in Canada's COVID-19 data and studies justifying mandates. This evidence-based approach, grounded in verifiable examples from these reports, offers a novel perspective on how known biases were overlooked or misrepresented, with significant implications for rights considerations (e.g., Charter Sections 7 and 15). The unfunded, independent nature enhances objectivity by minimizing institutional or funding influences, focusing on data integrity. The detailed exposure of underestimated senior population biases highlights the need for post-mandate data corrections and enhances its relevance for policy reassessment and public awareness of evidence oversight, with biases holding global relevance as observed in international studies.

Limitations: The analysis relies on published reports and real-time data (e.g., daily 2021–2022 PHO statistics[1]), limiting direct insight into authorities' public responses to identified biases, though their persistence suggests a lack of timely adjustment. Access to unpublished decision-making processes or proprietary datasets was unavailable, constraining full evaluation of due diligence. The Canadian-centric focus, while robust, may limit the direct applicability of policy-specific findings to jurisdictions with distinct surveillance systems (e.g., UKHSA differences[7]), though the underlying biases remain globally pertinent. This analysis highlights the need to respect inherent data limitations and exercise due caution in rights-infringing policies, reinforcing the call for transparent, real-time accountability in future public health decision-making.

Conclusions

This analysis exposes the profound methodological flaws in vaccinated vs. unvaccinated comparisons, from critical biases like misclassification and age-standardization to catastrophic flaws like selection bias and cumulative methodology, rendering such data inadequate for justifying Canada's 2021–2022 vaccine mandates. Compounded by authorities' progressive reliance on weaker evidence despite population trends showing persistent case and hospital burdens post-vaccine rollout (Figures 1A, B), these flaws fueled policies that disproportionately burdened low-risk groups, including younger, healthier individuals, raising serious concerns

about Charter rights violations (Sections 7, 15). The systemic failure to provide causal evidence and adhere to known methodological standards underscores the need for rigorous methods like randomized controlled trials and risk-stratified policies to ensure future public health decisions are scientifically robust and ethically sound. By confronting these lessons, Canada and the global community can rebuild trust and align pandemic responses with principles of equity and accountability.

List of abbreviations

AHS – Alberta Health Services
CDC – Centers for Disease Control and Prevention
CMAJ – Canadian Medical Association Journal
CMOH – Chief Medical Officer of Health
COVID-19 – Coronavirus Disease 2019
Ct – Cycle threshold
HVE – Healthy vaccinee effect
ICU – Intensive care unit
LTC – Long-term care
OST – Ontario COVID-19 Science Advisory Table
PCR – Polymerase chain reaction
PHAC – Public Health Agency of Canada
PHO – Public Health Ontario
RCT – Randomized controlled trial
SAESI – Serious adverse events of special interest
SARS-CoV-2 – Severe acute respiratory syndrome coronavirus 2
SES – Socioeconomic status
UKHSA – UK Health Security Agency

Declarations

- Ethics approval and consent to participate
  Not applicable.
- Consent for publication
  Not applicable.
- Availability of data and materials
  All data are publicly available from sources cited in the references. Figures 2–10A are

reproduced with permission from Public Health Ontario (PHO) or derived from PHO public datasets.[1, 1a–1j]

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- Authors' contributions
  Regina Watteel is the sole author and responsible for all aspects of the work.

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References

[1] Public Health Ontario. COVID-19 surveillance reports, epidemiological summaries, and Ontario Respiratory Virus Tool [Internet]. Toronto (ON): Public Health Ontario; 2020–2023 [cited 2025 Oct 27]. Available from: https://www.publichealthontario.ca/en/Data-and-Analysis/Infectious-Disease/COVID-19-Data-Surveillance

[1a] Public Health Ontario. Archive of Severe Outcomes among Confirmed Cases of COVID-19 Following Vaccination in Ontario – September 28, 2021 [Internet]. Toronto (ON): Public Health Ontario; 2021 [cited 2025 Oct 27]. Available from: https://www.publichealthontario.ca/-/media/Documents/nCoV/Archives/Severe-Outcomes/2021/covid-19-cases-post-vaccination-2021-09-28.pdf?rev=4f36cd3cf95844519e8edeee70fb31ac&sc_lang=en

[1b] Public Health Ontario. COVID-19 cases post-vaccination – August 1, 2022 [Internet]. Toronto (ON): Public Health Ontario; 2022 [cited 2025 Oct 27]. Available from:

https://www.publichealthontario.ca/-/media/Documents/nCoV/Archives/Severe-Outcomes/2022/covid-19-cases-post-vaccination-2022-08-01.pdf?rev=70f3ce93ad9d49e08a87bfe1d6ad7782&sc_lang=en

[1c] Public Health Ontario. COVID-19 cases post-vaccination – August 15, 2022 [Internet]. Toronto (ON): Public Health Ontario; 2022 [cited 2025 Oct 27]. Available from: https://www.publichealthontario.ca/-/media/Documents/nCoV/Archives/Severe-Outcomes/2022/covid-19-cases-post-vaccination-2022-08-15.pdf?rev=9e69a230d49a48b49d5a1d2833079e3e&sc_lang=en

[1d] Public Health Ontario. Deaths by vaccination status – COVID-19 public dataset [Internet]. Toronto (ON): Public Health Ontario; 2023 [cited 2025 Oct 27]. Available from: https://data.ontario.ca/dataset/1375bb00-6454-4d3e-a723-4ae9e849d655/resource/2aa6e2ce-40de-4910-a737-81762e014b0b/download/deaths_by_vac_status.csv

[1e] Public Health Ontario. Case rate by vaccination status by age group – Ontario COVID-19 data [Internet]. Toronto (ON): Public Health Ontario; 2022 [cited 2025 Oct 27]. Available from: https://web.archive.org/web/20220111000000/https://covid-19.ontario.ca/data

[1f] Public Health Ontario. Cases by vaccination status – COVID-19 public dataset [Internet]. Toronto (ON): Public Health Ontario; 2022 [cited 2025 Oct 27]. Available from: https://data.ontario.ca/dataset/752ce2b7-c15a-4965-a3dc-397bf405e7cc/resource/eed63cf2-83dd-4598-b337-b288c0a89a16/download/cases_by_vac_status.csv

[1g] Public Health Ontario. COVID-19 cases post-vaccination – July 1, 2022 [Internet]. Toronto (ON): Public Health Ontario; 2022 [cited 2025 Oct 27]. Available from: https://www.publichealthontario.ca/-/media/Documents/nCoV/Archives/Severe-Outcomes/2022/covid-19-cases-post-vaccination-2022-07-01.pdf

[1h] Public Health Ontario. Ontario Respiratory Virus Tool [Internet]. Toronto (ON): Public Health Ontario; 2025 [cited 2025 Oct 27]. Available from: https://www.publichealthontario.ca/en/Data-and-Analysis/Infectious-Disease/Respiratory-Virus-Tool

[1i] Public Health Ontario. Comparison of COVID-19 hospitalizations and deaths in 2022 and 2021, Ontario [Internet]. Toronto (ON): Public Health Ontario; 2023 [cited 2025 Oct 27]. Available from: https://www.publichealthontario.ca/-/media/Documents/nCoV/epi/2023/03/comparison-covid-19-hospitalizations-deaths-epi-summary.pdf

[1j] Public Health Ontario. COVID-19 cases post-vaccination – June 27, 2022 [Internet]. Toronto (ON): Public Health Ontario; 2022 [cited 2025 Oct 27]. Available from: https://www.publichealthontario.ca/-/media/Documents/nCoV/Archives/Severe-Outcomes/2022/covid-19-cases-post-vaccination-2022-06-27.pdf

[2] Dam D, Merali S, Chen M, Coulby C, Ho Mi Fane B, Bang F, et al. COVID-19 outcome trends by vaccination status in Canada, December 2020–January 2022. Can Commun Dis Rep 2024;50(1/2):40–8. doi: 10.14745/ccdr.v50i12a05

[3] Jüni P, da Costa BR, Maltsev A, Katz GM, Perkhun A, Yan S, et al. Ontario dashboard. Sci Briefs Ont COVID-19 Sci Advis Table. 2021;1. doi: 10.47326/ocsat.dashboard.2021.1.0.

[4] Our World in Data. Daily new confirmed cases due to COVID-19 (rolling 7-day average, right-aligned) – Canada [Internet]. Oxford: Our World in Data; 2025 [cited 2025 Oct 27]. Available from: https://ourworldindata.org/covid-cases

[5] Our World in Data. Daily hospital occupancy – Canada [Internet]. Oxford: Our World in Data; 2024 [cited 2025 Oct 27]. Available from: https://ourworldindata.org/covid-hospitalizations

[6] Neil M, McLachlan S, Fenton N. The extent and impact of vaccine status miscategorisation on covid-19 vaccine efficacy studies [Preprint]. medRxiv. 2025 [cited 2025 Oct 27]:2024.03.09.24304015v6. doi: 10.1101/2024.03.09.24304015

[7] UK Health Security Agency. COVID-19 vaccine quarterly surveillance reports (Sept 2021 to March 2022). [Internet]. London: UK Health Security Agency; 2021–2022 [cited 2025 Oct 27]. Available from: https://www.gov.uk/government/publications/covid-19-vaccine-weekly-surveillance-reports

[8] Vencalek O, Furst T, Princova E, Furstova T. The Mirror of Erised: a retrospective population-wide study of Czech all-cause mortality data by COVID-19 vaccination status. BMC Public Health. 2025;25:2427. doi: 10.1186/s12889-025-23619-x

[9] Mimura W, Ishiguro C, Maeda M, Murata F, Fukuda H. Association between mRNA COVID-19 vaccine boosters and mortality in Japan: The VENUS study. Hum Vaccin Immunother. 2024;20(1):2350091. doi: 10.1080/21645515.2024.2350091

[10] Xu S, Sy LS, Hong V, Farrington P, Glenn SC, Ryan DS, et al. Mortality risk after COVID-19 vaccination: A self-controlled case series study. Vaccine. 2024;42(7):1731–7. doi: 10.1016/j.vaccine.2024.02.032

[11] Stivanello E, Beghelli C, Cardoni F, Giansante C, Marzaroli P, Musti MA, et al. Short-term mortality following COVID-19 vaccination in Bologna, Italy: a one-year study. Vaccine. 2022;40(39):5709–15. doi: 10.1016/j.vaccine.2022.08.039

[12] de Gier B, van Asten L, Boere TM, van Roon A, van Roekel C, Pijpers J, et al. Effect of COVID-19 vaccination on mortality by COVID-19 and on mortality by other causes, the Netherlands, January 2021–January 2022. Vaccine. 2023;41(31):4488–96. doi: 10.1016/j.vaccine.2023.06.005

[13] Chemaitelly H, Ayoub HH , Coyle P, Tang P, Hasan MR, Yassine HM, et al. Assessing healthy vaccinee effect in COVID-19 vaccine effectiveness studies: a national cohort study in Qatar. eLife. 2025;14:e103690. doi: 10.7554/eLife.103690

[14] Public Health Agency of Canada. COVID-19 vaccination in Canada: vaccination coverage – data archive, July 30, 2021 [Internet]. Ottawa (ON): Public Health Agency of Canada; 2021 [cited 2025 Oct 27]. Available from: https://health-infobase.canada.ca/covid-19/vaccination-coverage/archive/2021-07-30/#a5

[15] Klang E, Kassim G, Soffer S, Freeman R, Levin MA, Reich DL. Severe obesity as an independent risk factor for COVID-19 mortality in hospitalized patients younger than 50. Obesity (Silver Spring). 2020;28(9):1595–9. doi: 10.1002/oby.22913

[16] Russell CD, Lone NI, Baillie JK. Comorbidities, multimorbidity and COVID-19. Nat Med. 2023;29(2):334–43. doi: 10.1038/s41591-022-02156-9

[17] Rogers JB. (2022, August 26). Toronto Professional Fire Fighters' Association v. City of Toronto (Arbitration Award) [Internet]. Toronto (ON): Hicks Morley; 2022 Aug 26 [cited 2025 Oct 27]. Available from: https://hicksmorley.com/wp-content/uploads/2022/09/TPFFA-and-City-of-Toronto-Rogers-26-August-2022.pdf

[18] Toronto (City) v Toronto Civic Employees' Union, CUPE, Local 416 [Internet]. CanLII. 2022 Nov 18 [cited 2025 Oct 27]. Available from: https://canlii.ca/t/jt3fv

[19] Public Health Agency of Canada. Testing for COVID-19 in vaccinated populations [Internet]. Ottawa (ON): Public Health Agency of Canada; 2022 [cited 2025 Oct 27]. Available from: https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19/testing-screening-contact-tracing/testing-vaccinated-populations.html

[20] Transport Canada. Government of Canada provides further details on new vaccine requirements [Internet]. Ottawa (ON): Transport Canada; 2021 Oct 29 [cited 2025 Oct 27]. Available from: https://www.canada.ca/en/transport-canada/news/2021/10/government-of-canada-provides-further-details-on-new-vaccine-requirements.html

[21] Bor A, Jørgensen F, Petersen MB. Discriminatory attitudes against unvaccinated people during the pandemic. Nature. 2023;613(7945):704–11. doi: 10.1038/s41586-022-05607-y

[22] Rashid T, Arefin S, Bhattacharjee M, Islam, A. Comparative study of stigma and discrimination among vaccinated and non-vaccinated COVID-19 survivors in Bangladesh. BMC Infect Dis. 2025;25:338. doi: 10.1186/s12879-025-10734-8

[23] McAlister FA, Hau JP, Atzema C, McRae AD, Morrison LJ, Grant L, et al. The burden of incidental SARS-CoV-2 infections in hospitalized patients across pandemic waves in Canada. Sci Rep. 2023;13:6635. doi: 10.1038/s41598-023-33569-2

[24] CTV News Toronto. COVID-19 hospitalizations in Ontario reach 1,486, ICU admissions increase to 206 [Internet]. Toronto (ON): CTV News; 2022 Apr 19 [cited 2025 Oct 27]. Available from: https://www.ctvnews.ca/toronto/article/covid-19-hospitalizations-in-ontario-reach-1486-icu-admissions-increase-to-206/

[25] City of Edmonton. Historical COVID-19 in Alberta: Intensive Care Unit (ICU) bed and non-ICU bed capacity and utilization [Internet]. Edmonton (AB): City of Edmonton; 2022 Jul 13 [cited 2025 Oct 27]. Available from: https://data.edmonton.ca/Community-Services/Historical-COVID-19-in-Alberta-Intensive-Care-Unit/xzbw-4krt/data_preview

[25a] Alberta Health Services. AHS facilities: ICU updates & temporary space reductions (snapshots September–November 2021) [Internet]. Edmonton (AB): Alberta Health Services; c2021 [cited 2025 Nov 2]. Available from: https://web.archive.org/web/*/https://www.albertahealthservices.ca/br/page17593.aspx

[26] NHS England. COVID-19 hospital activity [Internet]. London: NHS England; 2022 Aug 31 [cited 2025 Oct 27]. Available from: https://www.england.nhs.uk/statistics/statistical-work-areas/covid-19-hospital-activity/

[27] Klann JG, Strasser ZH, Hutch MR, Kennedy CJ, Marwaha J, Morris M, et al. Distinguishing admissions specifically for COVID-19 from incidental SARS-CoV-2 admissions: national retrospective EHR study. J Med Internet Res. 2022;24(5):e37931. doi: 10.2196/37931

[28] Nikolla DA, Oskvarek JJ, Zocchi MS, Rahman NA, Leubitz A, Moghtaderi A, et al. Defining incidental versus non-incidental COVID-19 hospitalizations. Cureus. 2024;16(3):e56546. doi: 10.7759/cureus.56546

[29] Statistics Canada. Provisional death counts and excess mortality, January 2020 to February 2021 [Internet]. Ottawa (ON): Statistics Canada; 2021 May 14 [cited 2025 Oct 27]. Available from: https://www150.statcan.gc.ca/n1/daily-quotidien/210514/dq210514c-eng.htm

[30] Centers for Disease Control and Prevention, National Center for Health Statistics. Provisional death counts for COVID-19: Comorbidities and other conditions [Internet]. Atlanta (GA): Centers for Disease Control and Prevention; c2020 [cited 2025 Oct 27]. Available from: https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm#Comorbidities

[31] Public Health Agency of Canada. COVID-19 vaccination in Canada: vaccination coverage – data archive, December 24, 2021 [Internet]. Ottawa (ON): Public Health Agency of Canada; 2021 [cited 2025 Nov 2]. Available from: https://health-infobase.canada.ca/covid-19/vaccination-coverage/archive/2021-12-24/

[32] Chemaitelly H, Tang P, Hasan MR, AlMukdad S, Yassine HM, Benslimane FM, et al. Waning of BNT162b2 vaccine protection against SARS-CoV-2 infection in Qatar. N Engl J Med. 2021;385(24):e83. doi: 10.1056/NEJMoa2114114

[33] Public Health Agency of Canada. COVID-19 epidemiology update. Archived dashboard, June 10, 2022. https://health-infobase.canada.ca/covid-19/archive/2022-06-10/index.html. Accessed November 15, 2025.

[34] Canadian Institute for Health Information. Inpatient Hospitalization, Surgery and Newborn Statistics, 2021–2022. Ottawa (ON): CIHI; 2023.

[35] Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, et al. Safety and efficacy of the BNT162b2 mRNA Covid-19 vaccine. N Engl J Med. 2020;383(27):2603–15. doi: 10.1056/NEJMoa2034577

[36] Fraiman J, Erviti J, Jones M, Greenland S, Whelan P, Kaplan RM, et al. Serious adverse events of special interest following mRNA vaccination in randomized trials. Vaccine. 2022;40(40):5798–805. doi: 10.1016/j.vaccine.2022.08.036

[37] Barda N, Dagan N, Ben-Shlomo Y, Kepten E, Waxman J, Ohana R, et al. Safety and effectiveness of the BNT162b2 mRNA Covid-19 vaccine in a nationwide setting. N Engl J Med. 2021;385(12):1078–90. doi: 10.1056/NEJMoa2110475

[38] Nyberg T, Ferguson NM, Nash SG, Webster HH, Flaxman S, Andrews N, et al. Comparative analysis of the risks of hospitalisation and death associated with SARS-CoV-2 omicron (B.1.1.529) and delta (B.1.617.2) variants in England: a cohort study. Lancet. 2022;399(10332):1303–12. doi: 10.1016/S0140-6736(22)00462-7

[39] Andrews N, Stowe J, Kirsebom F, Toffa S, Rickeard T, Gallagher E, et al. Covid-19 vaccine effectiveness against the Omicron (B.1.1.529) variant. N Engl J Med. 2022;386(16):1532–46. doi: 10.1056/NEJMoa2119451

[40] Mosley, HPS. Canadian Frontline Nurses v Canada (Attorney General), 2024 FC 42 (CanLII) [Internet]. Ottawa (ON): Federal Court of Canada; 2024 Jan 23 [cited 2025 Nov 2]. Available from: https://theccf.ca/wp-content/uploads/EA-challenge-fed-court-reasons-FINAL.pdf

[41] Fisman DN, Amoako A, Tuite AR. Impact of population mixing between vaccinated and unvaccinated subpopulations on infectious disease dynamics: implications for SARS-CoV-2 transmission. CMAJ. 2022;194(16):E573–80. doi: 10.1503/cmaj.212105

[42] House of Commons of Canada. Debates (Hansard) No. 61 – April 29, 2022 (44-1) [Internet]. Ottawa (ON): House of Commons of Canada; 2022 Apr 29 [cited 2025 Nov 2]. Available from: https://www.ourcommons.ca/DocumentViewer/en/44-1/house/sitting-61/hansard

[43] Ogden NH, Turgeon P, Fazil A, Clark J, Gabriele-Rivet V, Tam T, et al. Counterfactuals of effects of vaccination and public health measures on COVID-19 cases in Canada: What could have happened? Can Commun Dis Rep. 2022;48(7/8):292–302. doi: 10.14745/ccdr.v48i78a01

An Open Letter to the Informant: Why I Write, and Why I'll Keep Writing



DMITRY GORODNICHY, PH.D.
MAY 04, 2025

8 Share

First, I want to **thank you sincerely** for taking the time to read my LinkedIn posts. This is exactly why I share my articles publicly—not just in smaller circles like Telegram or alternative blogs, but on platforms like LinkedIn, where I know many readers rely primarily on official sources. Too often, critical news and perspectives challenge the mainstream narrative simply don't reach the broader public.

Every time someone like you provides feedback—or even files a complaint—it only **reinforces my commitment** to continue sharing my articles in open forums. Witho efforts like these, many important issues would remain hidden from view, and meaningful discussion would be stifled.

We Are Canadians, Not Subjects of an Authoritarian State

I'd like to gently highlight—a point I believe we can all agree on— that we live in Canada—not in Russia, not in the former Soviet Union. Here, we cherish more righ and freedoms, and it is **our collective responsibility** to ensure that these rights are preserved and protected for future generations.

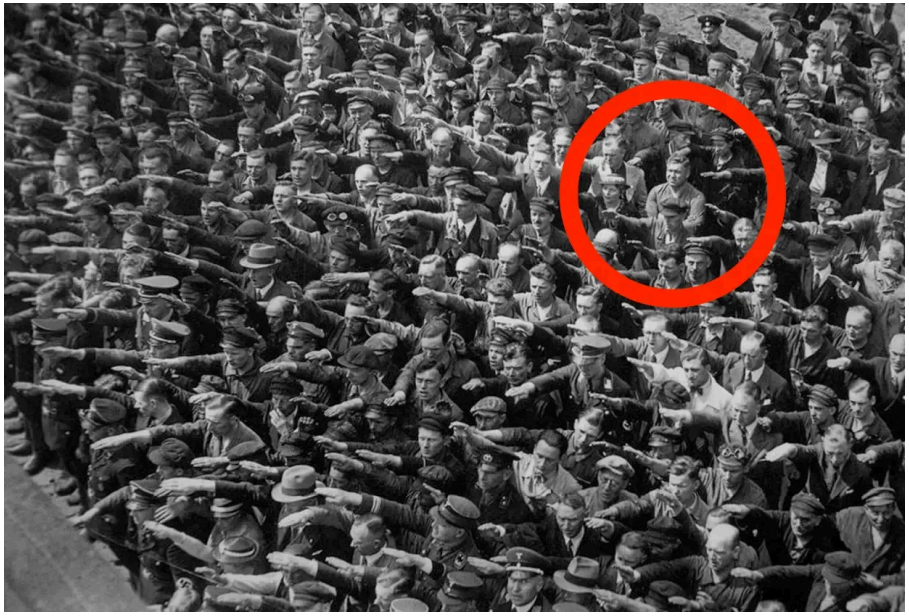
The best way to defend these rights is **to exercise them regularly**. Publicly expressi support for any political party or viewpoint—whether it's the governing party or th opposition—is a key example of that. As clearly explained by the Professional Instit of the Public Service of Canada (PIPSC), public servants have the full right to expre political views *outside the workplace* and using personal resources. You can read thei guidance here: https://pipsc.ca/vote2025/election-toolkit

One point worth emphasizing is PIPSC's statement that **no party should receive preferential treatment** during elections. Yet, from your complaint, it appears there troubling assumption: that it's acceptable for public servants to express support for **governing party**, but not for opposition parties. That is not how democracy works.

The Risk of a Single Narrative

One reason I continue writing is because Canada, unlike the U.S., lacks a **diverse alternative media landscape.** This creates a real risk that people relying solely on official news sources will receive **only one version of events**—similar to what we se Russia today, where state-controlled media dominates and alternative voices are silenced.

A chilling historical reminder is the famous 1936 photo of August Landmesser, the lone man who refused to raise his arm in the Nazi salute at a rally. Surrounded by people in ecstatic obedience, he stood alone in defiance. This image, captured early Hitler's rule, reminds us of the courage it takes to question dominant narratives.



Thankfully, Canada is not heading down that path—but it's up to us to maintain an environment where **critical thinking, open expression, and respectful dissent** are protected and valued.

A Note on My Professional Role

It's also important to mention that my political writings are always done **outside of working hours**, using my **personal devices**, and remain entirely separate from my department or agency. I am fully committed to my professional duties, including a major project I'm leading to introduce advanced computer vision and AI-based identification technologies that will enhance our agency's service to Canadians.

Complaints like yours, while perhaps well-intentioned, unfortunately **distract from this important work** and slow down projects that directly benefit Canadians. That's why I urge you—and others—to carefully consider the real-world consequences of filing political complaints that don't violate any professional codes or laws.

Moving Forward: A Better Way to Engage

Once again, I appreciate your attention to my articles. I genuinely welcome dialogu Instead of submitting reports that aim to silence necessary debate, I warmly **invite to contact me directly**. Let's have a constructive discussion on any topics you care about—even where we may differ.

As the famous saying goes:

> "I may not agree with what you say, but I will defend to the death your right to s it."

Let's help ensure that Canada remains a place where **open debate is welcomed**, wh **different viewpoints are respected**, and where public servants are loyal—not to any specific government—but to the **public interest** we are all sworn to serve.

Even now, as we see political shifts unfolding (for example, with the newly elected Mark Carney adopting some policies long proposed by the Conservatives), it becom clear that many truths and better policies emerge **only with time and a change in leadership.** This reinforces why **our duty is to the public good—not to any one par or politician.**

Wishing you all the best as we continue working toward a stronger, freer, and more respectful Canada.

Related articles:

Elections 2025: Your Rights as a Federal Employee Vote to Protect Canada's Future. Top Issues

According to PIPSC - Listed and Left Out.

DMITRY GORODNICHY, PH.D. • APRIL 4, 2025



TL;DR: Over the past five years, public servants have lived in constant fear o speaking publicly on issues related to government decisions. But it doesn't h to be this way. As emphasized by the Union, public servants have the same ri as any other citizen to actively participate in elections—including speaking publicly on election issues, supporti...

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Thanks for reading (Making) Your Voice (Heard) at PIPSC! This post is public so feel free to share it.

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Canada Border Services Agency | Agence des services frontaliers du Canada

CBSA Disciplinary Measures Framework

September 2018

CBSA DISCIPLINARY MEASURES FRAMEWORK

Preamble

The Canada Border Services Agency takes pride in the consistently high levels of service, professionalism and integrity that our employees demonstrate every day as they allow us to successfully deliver our important mandate year after year.

In order to maintain these high standards, it is incumbent on the CBSA to address all alleged or suspected misconduct. All employees, including managers, are accountable for their actions and are expected to perform their duties in accordance with their training, management instructions and relevant policies such as the CBSA Code of Conduct. Although our off-duty activities are normally private matters, they could become workplace issues if they reflect negatively on the Agency or affect our ability to perform our duties.

The CBSA Disciplinary Measures Framework provides examples of misconduct and recommended ranges of discipline, based on precedents and jurisprudence. The examples of misconduct are not exhaustive. **The recommended ranges of discipline are for a single incident of misconduct, in the absence of current discipline on file, without considering relevant aggravating or mitigating factors**. The Framework is an evergreen document which provides general guidance to managers, in consultation with labour relations advisors, when addressing misconduct. The Framework may be used for training purposes as it promotes a fair, consistent and transparent approach to discipline. Discipline will continue to be applied based on the individual merits of an incident of misconduct.

See Annex A for examples of aggravating and mitigating factors. See Annex B for definitions of certain terms related to misconduct and discipline.

Guiding Principles

1. Managers must report all allegations of misconduct to the Security and Professional Standards Directorate (SPSD).
2. Employees must report misconduct to management in accordance with the CBSA Code of Conduct.
3. All employees, including managers, contribute to the Agency's culture of integrity.
4. All employees, including managers, who participate in misconduct will be held accountable for their actions or omissions.
5. Discipline is meant to be corrective, not punitive; to encourage good, ethical behaviour and; to discourage further acts of misconduct.
6. Progressive discipline is appropriate for repeated incidents of current misconduct.

This framework should be read in conjunction with the Labour Relations and Compensation Authorities Subdelegation Instrument and:

- ✓ Relevant Acts and Regulations;
- ✓ Relevant Collective Agreements;
- ✓ Federal Public Sector Labour Relations and Employment Board decisions or other relevant jurisprudence;
- ✓ CBSA Code of Conduct and the Values and Ethics Code for the Public Sector
- ✓ Duty to Accommodate
- ✓ CBSA Discipline Policy and Guidelines and the Treasury Board Secretariat Guidelines for Discipline
- ✓ Any other relevant policies.

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CBSA DISCIPLINARY MEASURES FRAMEWORK

Table of Contents

Preamble....1
Guiding Principles....1
Hours of Work....3
Confidentiality and Disclosure of Information....3
Care and Use of Government Property and Assets....4
Defensive Equipment....5
Electronic Network Access and Uses....6
Healthy and Respectful Workplace....7
Brings Reputation of the CBSA or Public Service of Canada into Disrepute....8
Brings Reputation of the CBSA or Public Service of Canada into Disrepute....9
Conflict of Interest....10
Neglect of Duty....11
Private Off-Duty Conduct and Outside Activities....12
General Legislative Obligations of Federal Public Servants....13
ANNEX A – Examples of Aggravating and Mitigating Factors....14
ANNEX B – Definitions of Terms Related to Misconduct and Discipline....15

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CBSA DISCIPLINARY MEASURES FRAMEWORK

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	EXAMPLES OF MISCONDUCT and GENERAL GUIDANCE ON DISCIPLINE				
	Group 1 **Oral reprimand up to 5-day suspension**	**Group 2** **Written reprimand up to 10-day suspension**	**Group 3** **5-day up to 15-day suspension**	**Group 4** **10-day up to 20-day suspension**	**Group 5** **20-day suspension up to termination**
Hours of Work	Failure to respect established rest/break times, meal periods or work start and end times	Failure or refusal to provide information in support of a leave request Failure to request leave or to submit a leave request in accordance with established policies and procedures Unacceptable pattern of absenteeism	Unauthorized absence from work *(e.g. failure to notify manager when absent; tardiness; leaving work without authorization)*	Misrepresenting attendance or other activity to receive compensation for time not worked	Submitting or facilitating the submission of a false document *(e.g. time sheet, overtime form, leave request, medical note)*
Confidentiality and Disclosure of Information	Failure to handle classified, protected or sensitive information, in accordance with established policies and procedures *(e.g. CBSA policies/procedures; information collected in accordance with CBSA program legislation)*		Misuse of user name and/or password as login credential	Using personal device or account to record or store classified, protected or sensitive information *(e.g. CBSA policies/procedures; information collected in accordance with CBSA program legislation)* Unauthorized access to classified, protected or sensitive information, Unauthorized disclosure of workplace information on social media *(e.g. posting comments about a traveller on Facebook)*	Using classified, protected or sensitive information for personal gain or unauthorized purpose *(e.g. CBSA policies/procedures; information collected in accordance with CBSA program legislation)* Unauthorized disclosure of classified, protected or sensitive information *(e.g. CBSA policies/procedures; information collected in accordance with CBSA program legislation)*

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Care and Use of Government Property and Assets	Unauthorized use of government office supplies, phones, etc.	Unauthorized or inappropriate use of individual designated travel card (IDTC)	Unauthorized use of acquisition card, including vehicle fuel card	Unauthorized use of a government vehicle	Using government property for outside employment or activity for personal gain
		Delinquent payment exceeding 120 days on an IDTC			Unauthorized use of job title, badge or any other official identification
		Failure to report a traffic violation or accident while operating a CBSA vehicle	Unauthorized use or neglect resulting in damage to government property *(e.g. failure to maintain a CBSA vehicle, Vehicle and Cargo Inspection System (VACIS) or other specialized equipment)*	Using a CBSA facility for an unauthorized purpose	Unauthorized use of contracting or purchasing authority *(e.g. use for personal gain; tailoring the requirements of a request for proposal to favour a vendor with whom there is a personal or business relationship)*
		Failure to report lost, stolen or damage to government property	Unauthorized use or falsification of taxi chits		Theft of government property
					Any form of fraud or embezzlement
					Submitting a false expense claim

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Defensive Equipment (equipment issued by the CBSA)		Unsafe handling of defensive equipment *(e.g. unloading a DFA contrary to established policies and procedures)*	Submitting or conspiring to submit a false report of events	Negligent or inappropriate use of DFA *(e.g. negligent discharge, rough play, prank)*	Intentional discharge of a DFA in circumstances not supported by established policies and procedures
		Failure to store or to transport defensive equipment in accordance with established policies and procedures *(e.g. failure to lock DASCO locker)*	Failure to report an incident involving defensive equipment in accordance with established policies and procedures		Transporting or wearing defensive equipment without authorization outside of Canada
					Excessive use of force
		Failure to submit a *Use of Force Report* in accordance with established policies and procedures			Loss of defensive equipment

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Electronic Network Access and Uses	Unauthorized use of the electronic network for non-work-related activities *(e.g. emails with inappropriate content, chain letters)* ***Exceptions**: For pornographic, violent, hate or explicit material, immediately refer to group 5.* *For conducting outside business or employment activities for personal gain on employer time, immediately refer to group 5.*		Unauthorized use of the electronic network potentially causing a storage burden, congestion or jeopardizing its security *(e.g. downloading unauthorized content)* ***Exception**: For pornographic, violent, hate or explicit material, immediately refer to group 5.*	Making or distributing discriminatory comments or content relating to a prohibited ground for discrimination. *(e.g. race, national or ethnic origin, colour, religion, age, sex, sexual orientation, marital status, family status, disability, etc.)*	Unauthorized use or disclosure of information obtained from the electronic network or databases *(e.g. accessing and sharing passport information)*
					Using the electronic network or databases to participate in unlawful or criminal activities
				Unauthorized access or query of the electronic network or databases *(e.g. accessing CPIC, GCMS or other systems for purposes other than assigned workload)* *(e.g. accessing CAS for personal information on another employee)*	Unauthorized possession or viewing of pornographic, violent, hate or explicit material on the electronic network
			Misuse of user name and/or password as login credential	Cyberbullying	Using the electronic network to conduct outside business or employment for personal gain on employer time

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Healthy and Respectful Workplace (inappropriate conduct, harassment and discrimination)	Unprofessional behaviour in the workplace *(e.g. inappropriate language, comments, postings, jokes, pranks, teasing)* ***Exceptions**: For discriminatory, aggressive, abusive, threatening comments or behaviour (harassment), immediately refer to group 4.* *For threats or acts of physical violence, immediately refer to group 5.*	Unprofessional behaviour in the workplace that is directed towards an individual *(e.g. inappropriate language, comments, postings, jokes, pranks, teasing)* ***Exceptions**: For discriminatory, aggressive, abusive, threatening comments or behaviour (harassment), immediately refer to group 4.* *For threats or acts of physical violence, immediately refer to group 5.*	Disregard for established health and safety policies and procedures	Discriminatory, aggressive, abusive or threatening comments or behaviour (harassment) relating to a prohibited ground for discrimination. *(e. g. race, national or ethnic origin, colour, religion, age, sex, sexual orientation, marital status, family status, disability, etc.)*	Failure to address any incident of harassment, discrimination or violence in accordance with established policies and procedures
					Sexual harassment
	Smoking in the workplace or any contravention of the *Non-smokers Health Act*	Dangerous rough play or pranks not involving defensive equipment		Aggressive, abusive, threatening, behaviour or bullying comment	Threat or act of physical violence
		Failing to report a work-related accident		Cyberbullying	Preferential treatment in the administration or enforcement of CBSA program legislation for personal gain, use or improper purpose
				Harassment	

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Brings Reputation of the CBSA or Public Service of Canada into Disrepute	Failure to present a professional appearance or dress	Unauthorized public comment on a matter within the mandate of the CBSA *(e.g. comments on social media or blog; posting pictures or images)*	Preferential treatment in the administration or enforcement of CBSA program legislation without personal gain	Reporting for work or being on duty while under the influence of alcohol, illegal drugs or other intoxicants.	Engaging in or facilitating smuggling *(e.g. goods, currency or monetary instruments; trafficking a controlled substance)*
	Failure to respect CBSA Uniform Policy and Standards of Appearance		Failure to report gifts, hospitality or other benefits from a member of the public	Public criticism of the CBSA or the Public Service of Canada	Conviction under *Criminal Code* or other federal Act. Conviction in a foreign country for act that is an offence under the Criminal Code or other federal Act in Canada. *(e.g. regarding import/export of goods, currency or monetary instruments; admissibility of persons to Canada)*
	Unprofessional or inappropriate behaviour when representing the CBSA		Gambling on the CBSA's premises, including sports pools.	Producing reports that contain non-validated or inaccurate results, insufficient or unreliable evidence that may cause embarrassment, harm or damage	Threat or act of physical harm
					Developing or maintaining a criminal association
					Falsifying, altering, suppressing or destroying information or documents for personal gain or improper purpose. *(e.g. during staffing process or competency assessment)*

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Brings Reputation of the CBSA or Public Service of Canada into Disrepute (continued)					Abuse of authority
					Obstructing or altering evidence in a formal investigation or audit.
					Consuming illegal drugs or other intoxicant while on duty
					Unauthorized consumption of alcohol in the workplace. *(e.g. outside of on-site lounge at the CBSA College)*
					Failing to remove yourself from an activity or situation that places you in a real, apparent or potential conflict between your personal interests and your official duties and responsibilities.

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Conflict of Interest		Failure to submit or to update a Conflict of Interest Report *(e.g. an activity or situation that places or may place you in a real, apparent or potential conflict of interest with your official duties)*	Preferential treatment in the administration or enforcement of CBSA program legislation without personal gain		Preferential treatment in the administration or enforcement of CBSA program legislation for personal gain or improper purpose Accepting or soliciting a benefit of any kind Using government property to conduct outside employment or personal activity for personal gain Developing or maintaining a criminal association Failure to cease activity that was deemed to be a real, potential or apparent conflict of interest with your official duties Engaging in or facilitating smuggling *(e.g. goods, currency or monetary instruments; trafficking a controlled substance)* Falsifying, altering, suppressing or destroying information or documents for personal gain or improper purpose. *(e.g. during staffing process or competency assessment)*

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Neglect of Duty	Failure to complete required documents in accordance with established policies or procedures *(e.g. Security Incident Report)*	Insubordination *(e.g. failure to comply with a lawful instruction or order, behaviour to undermine authority of management, insolence)*	Failure to perform assigned duties in accordance with established policies and procedures. *(e.g. failure to refer travellers to pay duties or to maintain officer notebook)*		Failure to exercise delegated authority
					Failure to address an incident of discrimination, harassment or violence in accordance with established policies and procedures
		Failure to attend court when authorized/requested by management	Hiring an individual who does not meet the essential qualifications or conditions of employment on start date *(e.g. does not meet OL requirements; does not have valid security clearance)*		Failure to perform assigned duties in accordance with established policies and procedures, in matters affecting national security
	Failure to monitor employee attendance and leave in accordance with established policies and procedures	Failure to report a work-related accident or incident in accordance with established policies and procedures			Facilitating smuggling *(e.g. goods, currency or monetary instruments; trafficking controlled substances)*
	Failure to complete mandatory training	Failure to report alleged or suspected misconduct			Developing or maintaining a criminal association
		Sleeping or attempting to sleep while on duty			
		Failure to comply with an ATIP request in accordance with established policies and procedures			
		Failure to meet Canada Labour Code requirements *(e.g. failure to hold OHS meetings in accordance with established policies and procedures)*			
		Failure to comply with provisions of the collective agreement			

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CBSA DISCIPLINARY MEASURES FRAMEWORK

The recommended ranges of discipline are for a single incident of misconduct, in the absence of current discipline on file, without considering relevant aggravating or mitigating factors. *Each incident must be considered on its own facts, including any relevant mitigating or aggravating factors. A one (1) day suspension equals 7.5 hours for full-time employees. For part time employees, it is prorated to the employee's weekly schedule based on a 37.5 hour work week.*

	EXAMPLES OF MISCONDUCT and GENERAL GUIDANCE ON DISCIPLINE				
	Group 1 **Oral reprimand up to 5-day suspension**	**Group 2** **Written reprimand up to 10-day suspension**	**Group 3** **5-day up to 15-day suspension**	**Group 4** **10-day up to 20-day suspension**	**Group 5** **20-day suspension up to termination**
Private Off-Duty Conduct and Outside Activities			Failure to report being arrested, detained or charged with a criminal offence; an offence under any federal or provincial Act or; criminal or other offences outside Canada	Public criticism of the CBSA or Public Service of Canada	Threat or act of physical violence
					Misuse of Government property, including defensive equipment
				Harassment	Private or off-duty conduct that contravenes the mandate of the CBSA *(e.g. failure to make a proper declaration at a port of entry; attempting to smuggle any good, currency or monetary instrument)*
					Conviction under *Criminal Code* or other federal Act. Conviction in a foreign country for act that is an offence under the Criminal Code or other federal Act in Canada. *(e.g. regarding import/export of goods, currency or monetary instruments; admissibility of persons to Canada)*
					Contravention of any federal Act governing employees of the Public Service of Canada (e. g. *Financial Administration Act, Public Service Employment Act, etc.*)

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CBSA DISCIPLINARY MEASURES FRAMEWORK

The recommended ranges of discipline are for a single incident of misconduct, in the absence of current discipline on file, without considering relevant aggravating or mitigating factors. *Each incident must be considered on its own facts, including any relevant mitigating or aggravating factors. A one (1) day suspension equals 7.5 hours for full-time employees. For part time employees, it is prorated to the employee's weekly schedule based on a 37.5 hour work week.*

	EXAMPLES OF MISCONDUCT and GENERAL GUIDANCE ON DISCIPLINE				
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General Legislative Obligations of Federal Public Servants	Violation of the *Non-Smokers' Health Act*	Failure to meet requirements under the *Canada Labour Code* *(e.g. failure to hold OHS meetings in accordance with established policies and procedures)*	Hiring an individual who does not meet the conditions of employment on start date *(e.g. does not meet security or language requirements)*	Leading or inciting an illegal work stoppage	Contravention of any federal Act governing employees of the Public Service of Canada *(e. g. Financial Administration Act, Public Service Employment Act, etc.)*
		Failure to comply in an ATIP request in accordance with established policies and procedures			
		Failure to complete required documents in accordance with established policies, procedures or legislation *(e.g. OHS form LAB 1070)*			Falsifying, altering, suppressing or destroying information or documents for personal gain or improper purpose. *(e.g. during staffing process or competency assessment)*

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ANNEX A – Examples of Aggravating and Mitigating Factors

Aggravating Factors	Mitigating Factors
1. Employee is not forthcoming 2. Employee lacks remorse and/or does not recognize the seriousness of his actions 3. Presence of current discipline on file 4. Employee's years of service 5. Link between employee's duties and alleged misconduct 6. Employee occupies a position of authority or trust 7. Employee was warned that behaviour would not be tolerated 8. Employee not willing to change behaviour 9. Policy is clear and was communicated to employees 10. Link between misconduct and CBSA mandate 11. Conduct renders employee unable to perform duties in satisfactory manner 12. Conduct leads to refusal, reluctance or inability of others to work with employee 13. Conduct endangers others' health and safety 14. Misconduct may be harmful to the CBSA's programs or reputation 15. Any other relevant factors	1. Employee is forthcoming 2. Employee is remorseful and/or recognizes the seriousness of his actions 3. Absence of current discipline on file 4. Employee's years of service 5. Isolated incident 6. Lack of premeditation 7. Behaviour previously condoned 8. Policy was not applied consistently 9. Policy is not clear or was not communicated to employees 10. Employee was provoked 11. Employee was encouraged, coerced or threatened to act 12. Employee's conduct influenced by a serious personal issue 13. Discipline issued after an unjustified delay 14. Management participated in the misconduct 15. Any other relevant factors

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ANNEX B – Definitions of Terms Related to Misconduct and Discipline

Administrative measure	Examples: manager provides a letter of expected behaviour to an employee; manager meets with an employee for fact finding purposes; temporary reassignment/less sensitive duties; temporary suspension without pay due to the temporary revocation of a security clearance; indefinite suspension without pay pending the investigation of allegations of misconduct.
Aggravating factor	Circumstance that may justify increasing the severity of the disciplinary measure within the recommended range of discipline.
Culpable behaviour	Behaviour for which the employee is considered to be at fault because it is within the employee's control and/or occurred as a result of the employee's deliberate or intentional action or inaction. As indicated in the CBSA Code of Conduct, culpable behaviour includes neglect of duty. Discipline is the appropriate response to culpable behaviour (misconduct).
Disciplinary measure	Includes oral reprimand, written reprimand, suspension without pay, financial penalty; demotion and termination of employment. See the CBSA Discipline Policy and Guidelines for more information.
Groups 1 to 5	Groups 1 to 5 list the recommended ranges of disciplinary quantum from lowest to highest, according to the seriousness of the alleged misconduct.
Incapacity	See non-culpable behaviour.
Misconduct	Misconduct is defined in the CBSA Discipline Policy. It is a wilful action or inaction on the part of an employee that includes a breach of the *Criminal Code*, the *CBSA Code of Conduct* and/or the *Values and Ethics Code for the Public Sector*. It could also be related to attendance and inappropriate personal behaviour at work or away from work.
Mitigating factor	Circumstance that may justify decreasing the severity of the disciplinary measure, within the recommended range of discipline.
Natural Justice	The requirement for management to be fair and reasonable in the application of discipline. It includes the following principles: the right to be informed of the allegations of misconduct and to be given sufficient information to understand them; the right to be heard and the opportunity to present one's case or defence and; the right to have the decision based on relevant and reliable evidence, obtained through a proper investigation and that was disclosed to both parties.
Non-culpable behaviour	Behaviour for which the employee is not considered to be at fault because the behaviour can be attributed to factors outside of the employee's control. For example, if the employee lacks the necessary skills or training, management should provide training and/or counseling to correct the problem. Unsatisfactory performance could be non-culpable behaviour if it is related to a misunderstanding of requirements or an inability to perform the duties. Where a physical or mental disability is present, management has a duty to accommodate.
Procedural fairness	Basic elements to apply when conducting an administrative investigation: the right to know what is reproached; the right to present his/her own version of events and; the right to know the consequences of an unfavourable decision.
Wrongdoing	Wrongdoing is defined in section 8 of the *Public Sector Disclosure Protection Act.* Examples of wrongdoing include gross mismanagement or misuse of public funds or assets. Allegations must be serious and in the public interest as opposed to those in an employee's own private interest and that could more appropriately be addressed by other recourse mechanisms.

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About the Branch
VP's Corner
Resources Directory
Management Team
Forms and Templates

President and EVP's Space
CBSA Renewal
Border Update

Understanding the consequences of misconduct



Information

Video Length: 2 minute, 58 seconds

Misconduct has consequences. This video provides some examples that just may surprise you.

Description

You may think no one notices.
You may think "It's no big deal".
You may think it's not being addressed.
It is.

Discipline in the workplace happens.
And the consequences may surprise you.

Consider the following examples.

Consequences of misconduct

Misconduct	Consequence
Duty firearm left unsecured in Dasco	Written reprimand
Voluntarily hiding your name tag while in uniform	1 day suspension
Using the government travel card to buy winter boots for your kids	7 day suspension
Willfully damaging the CCTV camera in the PIL booth	10 day suspension
Using CBSA's systems to obtain personal information of colleagues	15 day suspension
Disclosing personal information about your colleague to a traveller	20 day suspension
Making sexual comments/jokes to colleagues in the workplace	30 day suspension
CBSA employee failing to declare a luxury fashion item upon re-entering Canada	Termination of employment
Running your personal business during working hours using CBSA networks	Termination of employment
Purposely touching a colleague's buttocks in the workplace	Termination of employment

Agency Stats 2017 & 2018:

- Total days of suspension: 1,107
- Total terminations: 8

Surprised?
Make the right choice.
Adopt our Values and Ethics in everything you do.

The information in this video is for illustrative purposes only. The severity of consequences varies based on a multitude of factors including, but not limited to, severity of the incident, previous incidents, the employee's years of service, etc. All consequences have a range of potential disciplinary measures. The examples used here are based on actual incidents.

Find out more on Atlas:

- Disciplinary Framework (PDF, 928 KB)
- CBSA Code of Conduct
- Values and Ethics Code for the Public Sector

Date modified: 2019-07-31

Slido Poll:

www.sli.do
(code: CBSA1)

Demo URL:

https://rCanada.shinyapps.io/demo

Data engineering challenges and solutions: demonstration of Shiny

Dmitry Gorodnichy
Chief Data Office
Data Science Division

GC Data Conference 2021, Data Literacy Fest
22-23 February 2021, Ottawa

Workshop layout

- “Round table” poll (Slido)

- Common data quality problems
- Data engineering as a solution
- Common tools for common problems
- Discussion (Slido)

Common data quality problems

- Facing same challenges turning “records” into “data”
  - Dates : ‘20210820’ vs. ‘dob 20 Aug 2021’
  - Names: ‘Dmitry Gorodnichy’ vs. ‘Dimitri Horodnytchyyi’
  - Business Names: AC, AirCanada, Air Canada Corp.
  - Geographic Names: ‘Ottawa Airport’, ‘YOW’, Ottawa International Airport

Poor data quality impedes interoperability

- Good interoperability allows various data to be linked and enriched
- Probabilistic (approximate, fuzzy) matching is used to link “noisy” data
  - All words need to be compared to each other
  - Various techniques in data linkages include: using edit metrics, look-up tables, q-grams, phonetic, heuristics, …
- However, probabilistic matching has its share of challenges as well
  - How to assign threshold?
  - How to measure quality?
  - Lost nuances?
    - E.g., Bell Canada vs. Shell Canada
- No perfect solution

Data engineering to address data quality

- Data engineers develop techniques to standardize and organize data to help address data integrity, e.g.,
  - ‘Ottawa Airport’ → ‘YOW’
  - ‘YOW’ → ‘YOW’
  - ‘Ottawa International Airport → ‘YOW’
- On average, 80% of efforts of data scientists goes to address data engineering issues

Common Tools for Common Problems

- In GoC, we are working on the same set of data engineering problems

  - Standardizing various data fields
  - Cleaning, linking and searching data

  so we can carry out analysis

- Often, data scientists end up “reinventing the wheel”
- We need to build common data engineering tools for common GoC data engineering problems

Vision for Solution

- We need a set of ‘libraries’ that are built and maintained by GoC data science community that is
  - Open
  - Free
  - Available to any data scientist who needs them
  - GCcode helps us to do that
  - R already has many libraries, supported by global community



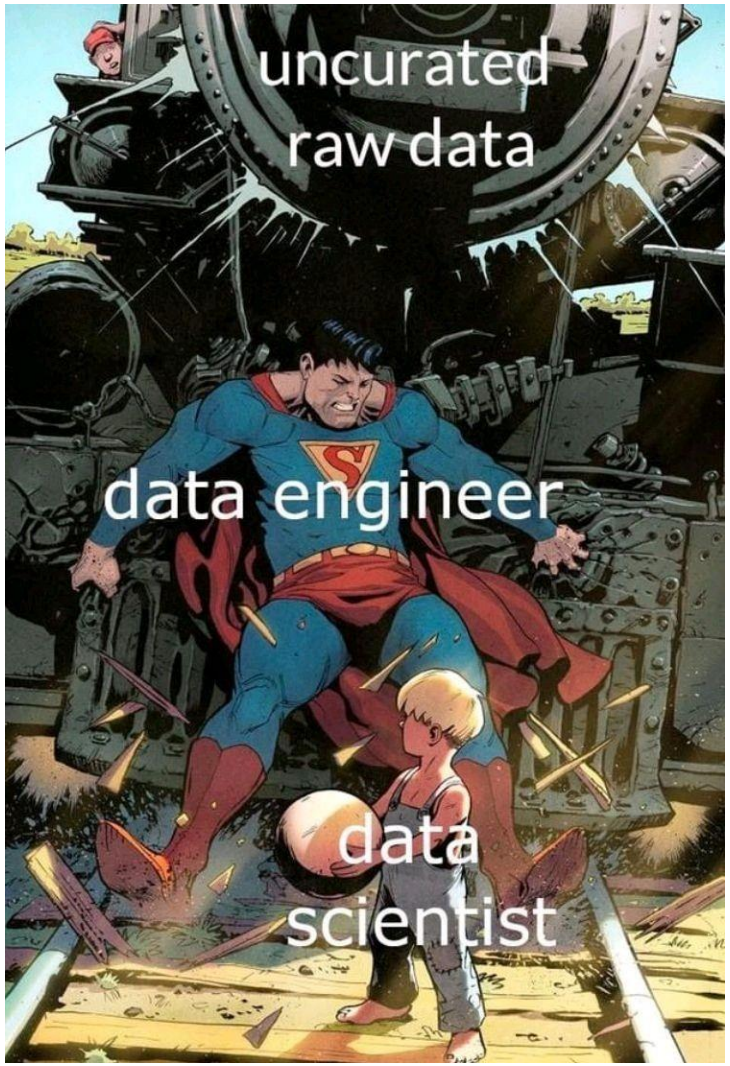
- This presentation will demo a proof of concept for feedback and discussion

Discussion

- Our works has just started. Much more ahead.
  - We build on Public Data (esp. Open Canada Data) and Public knowledge (esp. R global community)
  - We build solution (for entire GC community) and also we build Community of Practice
  - Codes and resources: https://gccode.ssc-spc.gc.ca/r4gc/
- Planned milestones:
  - rCanada Package, Testbed App, Toolkit App: 2021-2022
  - Use cases (for on-going Agency needs): Spring - Winter 2021
- We need your help!
  - curating & organizing DE challenges and public domain solutions (codes/papers)
  - curating & organizing public domain Data-sets
  - testing & benchmarking

Thank you !

Dmitry.Gorodnichy@cbsa-asfc.gc.ca



The author gratefully acknowledges the use of the following public domain material in this project:

R packages: data.table, dtplyr, lubridate, magrittr; soundex, phonetic; antiword, filehash, textreg, textreuse, stringr, stringi, textclean, syuzhet, hunspell, textshape; stringdist, recline, fuzzyjoin, RecordLinkage, fastlink; NLP, quanteda, udpipe, spacyr, tidytext; qdap, tm, lexicon, Rnewsflow, textcat; shiny, rsconnect, knitr, rmarkdown, flexdashboard, DT; cancensus; googleway, tidygeocoder; rvest, httr, xml2, jsonlite; microbenchmark; ggplot2, wordcloud.

Papers: Sariyar M / Borg A (2010). The RecordLinkage Package: Detecting Errors in Data“ The R Journal. van der Loo (2014) The stringdist package for approximate string matching. The R Journal ; L. Boytsov (2011). Indexing methods for approximate dictionary searching: comparative analyses. ACM Journal of experimental algorithmics G. Navarro (2001). A guided tour to approximate string matching. ACM Computing Surveys; Enamorado et al. (2019). ``Using a Probabilistic Model to Assist Merging of Large-scale Administrative Records.'' American Political Science Review

Data: Statistics Canada, Post Canada, Simple Maps

Other: image by Anna Nyulund (LinkedIn post), stimulating discussions with many CBSA and GC colleagues, in particular at Friday's Data Science meet-ups.

Demo time

https://rCanada.shinyapps.io/demo

Data Scientist Letter to PIPSC President: Addressing the Professional Integrity Crisis in Policy Departments

Discussion item for NCR Executive Meeting on 12 JUL 2024. 2025 Recap



DMITRY GORODNICHY, PH.D.
JAN 27, 2025

4 1 Share

Background:

One of the first items I brought forward for discussion with the NCR Executive Boa was the *"Open Data Scientist Letter to PIPSC President."* I wanted to make the Board aware of the concerns I had heard from many members—concerns I had promised t address when I was elected to the NCR Executive Board in April 2024—and to seek advice on the next steps to address these issues.

Below, you can read my communications with the Board, the draft of this letter, anc their reactions. Now, more than half a year later, I am revisiting this effort to evalua whether my initiative has led to any tangible outcomes (had any impact) and to determine the next steps necessary to address the issues described in my letter, as w as those raised by my NCR Executive Board colleagues.

Attached below are the full email exchange and the letter draft itself, which I sent t all NCR Executives in advance of the meeting to facilitate a much-needed discussio on this issue—one that I believe is among the most serious matters requiring urgen attention from the union. This issue affects the well-being of all Canadians who rel on the recommendations developed by government professionals.

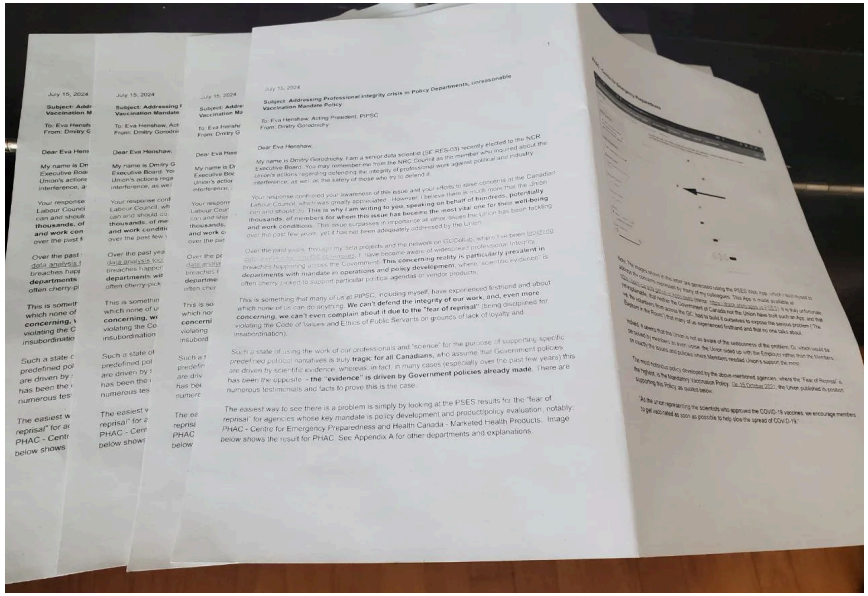
To ensure an efficient discussion, I also printed the letter (the first four pages of the 14-page document) and handed it out to the eight executives who attended the meet in person. To make it more accessible for you, the reader of this article, I have also included it in the appendix—so you can copy, reuse, and cite any relevant images ar quotes. I believe you'll find many that are worth referencing.

I then provide a summary of the discussion points raised during the meeting, which were recorded in the meeting minutes by the secretary as: *"A lively discussion occurre*

Following this, I recap the key milestones in my journey as a voice for members wit the union's senior management, outlining my continued efforts to address concerns about political interference and politically driven vaccination mandates—issues tha have traumatized many members. Despite not receiving as much support from my executive colleagues as I had originally hoped, I have continued this fight by author several resolutions, running for Vice President, and now advocating for NCR electo reform as a means to improve transparency, democratization, and fair representatic of all members within the region.

As we usher in 2025, I believe this retrospective can help all of us—union upper management, the union's legal and advisory committee, regular members whose concerns I have voiced, and myself—better understand how to move forward. We m continue pushing for progress, even when differences of opinion exist, as we are all ultimately driven by the same passion: to make the union better serve all its membe through open dialogue and transparency.

The newly published *Alberta COVID-19 Pandemic Data Review Task Force: Final Repo* (see more on this important report here) further highlights the importance of allowi both sides of the debate to engage in open discussions—free from prejudice and personal biases—on the issues that have divided and traumatized our membership.



Email exchange

Dmitry O. Gorodnichy <dmitry.gorodnichy@gmail.com> Mon, Jul 8, 2024 at 6:31

To: ncr_executive

Hello everybody,

What is the time for the meeting we have this week?
...
Also, I wanted to add an agenda item for the meeting:

- "Data Scientist Letter to PIPSC President (Re: Professional integrity crisis in Policy Departments)"

Now, as we got a chance to get to know each other more, and also to follow-up o my response to XXX's question on why I seem to be so much focused on Vaccine Mandates (as you remember, I responded that my main concern is politically driv abuse of professional integrity, of which Vaccine Mandates is just one, the most reaching, example), I'd like to provide a little more background on how and why got involved in Union and what I'm trying to achieve - hopefully with support fr you.

Below are a few key points from the letter that I started writing to Eva Henshaw, Acting President, PIPSC.

Whether I will submit this Letter to the President in my personnel capacity (as a Data Scientist who has become privy - because of his networking on gccollab (where I led data training course) - to learn about widespread Professional Integ breaches happening across all Policy & Ops Departments), or as newly elected N Executive (who was elected specifically for his pledge to do something about the abuse of Professional Integrity within the Govt and the lack of Transparency wit the Union related to that - you may remember my 2-min Electoral speech about that), I would be very much interested to get your feedback and advice on it and best strategy to proceed.

I'll share the whole letter draft prior to the meeting, as I'm still working on it.
...

If any of you have any ideas/questions related to any matter presented there (or h it is presented) please let me know -

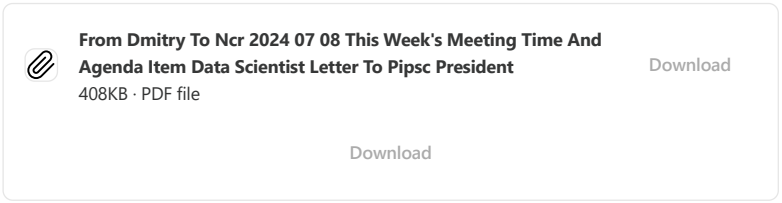
I'll try to incorporate/address those before me meet.

Related documentation:

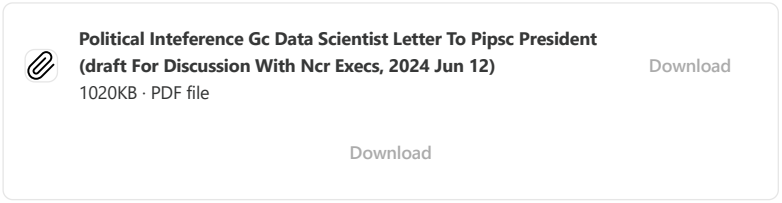
https://github.com/gorodnichy/iTrack-PSES-development/blob/master/paper/How%20make%20CBSA%20happier%20place%2

> %20Lab's%20experiment%20-%20briefed2020.pdf
>
> https://github.com/gorodnichy/iTrack-PSES-development/blob/master/paper/PSE analysis-data-science-way-submission-to-HR-2008-2018.pdf

Full Email printout:



Email Attachment - Data Science Letter to the President:



Outcome of Discussion with NCR Execs

In summary, NCR executives did not find there was anything of concern or action f them or the board related to the matters discussed in my letter. However, they did o some comments and concerns regarding statements made by the letter's author (myself), which are summarized below.

Several execs stated that saying "**PIPSC did nothing to support members who did comply with the mandate**" is "**disrespectful to the hard, dedicated work of many o them.**" One of them even said that he could file a complaint against me for saying tl

Dmitry replied that he, of course, did not mean PIPSC stewards, executives, and oth union representatives (including everyone sitting at the table), who personally did w they could to help their fellow colleagues who were kicked out of their jobs. Rather, this statement referred to the official stance of the Institute (all its legal, ERO, and other decision-makers) in not challenging the vaccination mandate—leaving affecte members to fight for their livelihoods on their own. Dmitry also thanked him for pointing out that in his communications, he should always be very clear about whic PIPSC representatives he is referring to—since there are **two very different groups** elected representatives like himself and the other executives, who are members just like everyone else, and **PIPSC staff paid by members' dues, who have their own un and are responsible for all legal decisions.**

Another executive, who works at **Health Canada**, stated that she had **never witness any political interference** herself, that she had **full trust in our professionals**, and t suggesting otherwise was also "**disrespectful.**"

Dmitry pointed out that his statements were based on **Public Service Employee Survey** (**PSES**) **data** and concerns shared directly with him by colleagues who work Health Canada—colleagues who had raised these issues during **data science semin** he organized on **GCcollab**. He acknowledged that she might be from another **HC u** —one that, according to the same PSES results, did not report such issues. Dmitry a thanked her for her insider perspective and invited her to discuss the topic in more detail whenever she had time. She gladly accepted the invitation, but unfortunately, due to their busy summer schedules and both of them running for the national PIP election, they never had the opportunity to follow up, although they remained in contact throughout the following months.

Critically, the overwhelming Executive Board consensus recommendation was tha Dmitry **should not send the letter to the President** but instead contact the **Scientif Advisory Committee Chair** to discuss his concerns. They also suggested that he foc

on his **primary duty as NCR Bylaws Chair**. As will be seen later, he followed these recommendations.

Finally, it is worth noting that **the executives did not have any recommendations o action items for themselves or anyone else.**

This is how the episode was documented in the meeting minutes prepared by the secretary:

> New Business:
>
> - Letter to the President - Dmitry - gave a presentation on the letter he would like to submit for information to the Office of the president. Dmitry would l to ask direct of the Board how the vaccine statement came about. This over arching concern should be brought to the attention of the Science advisory committee. A very lively discussion ensued. Final recommendation of the Executive was that Dmitry contact Norma to discuss his concerns.

What Happened After: Major Milestones

As mentioned, I followed the recommendations of the executives—I met with the **Scientific Advisory Committee Chair** and shared the letter draft with her. She expressed great interest in the matters described in the letter, albeit indicating that she had **not been aware of these issues.**

Moving forward, I authored **several resolutions** for the **National AGM** (submitted i **August**, published on the **PIPSC website in October**, and referred to the **Board of Directors in November** - read them here (P-24 and P-25) and here (L-02, L-07,) to **bring more awareness to these serious issues** and to **push for action at the earliest convenience.**

Critically, following encouragement and nominations from many concerned membe I decided to run for Vice President (Part-Time) in the National Election in Novem 2024. I did not win the election, but receiving **over a thousand votes** demonstrated **how important the issues I stand for are to many members.**

Finally, in collaboration with two colleagues of mine—both from the interdepartmental Data Science Community of Practice that I lead on GCcollab—I helped develop a proposal for **Bylaw changes to bring forward the NCR Electoral Reform.** This reform would allow for a **more inclusive and transparent** process for electing our executive. What happened to this proposal, however, will be the subjec another article.

Appendix: Data Scientist Letter to PIPSC President (RE: Professional integrity crisis in Policy Departments) - DRA FOR DISCUSSION (WITH NCR EXECS)

> **Subject: Addressing Professional integrity crisis in Policy Departments, unreasonable Vaccination Mandate Policy**
>
> July 12, 2024
>
> To: Eva Henshaw, Acting President, PIPSC
>
> From: Dmitry Gorodnichy
>
> Dear Eva Henshaw,
>
> My name is Dmitry Gorodnichy. I am a senior data scientist (SE-RES-03) recently elected to the NCR Executive Board. You may remember me from the NRC Cour as the member who inquired about the Union's actions regarding defending the

integrity of professional work against political and industry interference, as well the safety of those who try to defend it.

Your response confirmed your awareness of this issue and your efforts to raise concerns at the Canadian Labour Council, which was greatly appreciated. Howe I believe there is much more that the Union can and should do. **This is why I am writing to you, speaking on behalf of hundreds, potentially thousands, of members for whom this issue has become the most vital one for their well-beir and work conditions.** This issue surpasses in importance all other issues the Un has been tackling over the past few years, yet it has not been adequately addresse by the Union.

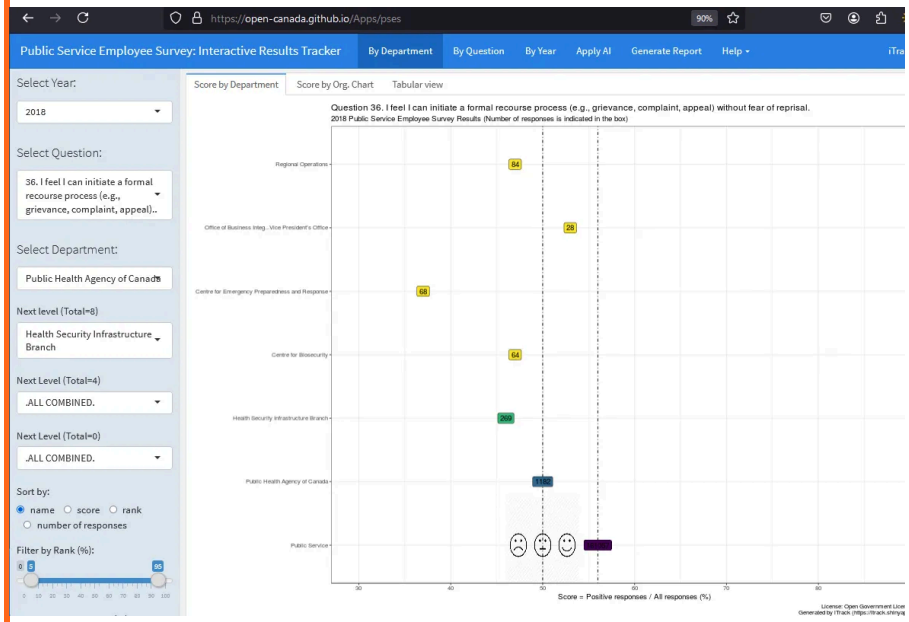
Over the past years, through my data projects and the network on GCCollab, wh I've been teaching data analysis tools to GC colleagues, I have become aware of widespread professional Integrity breaches happening across the Government. **T concerning reality is particularly prevalent in departments with mandate in operations and policy development,** where "scientific evidence" is often cherry-picked to support particular political agendas or vendor products.

This is something that many of us at PIPSC, including myself, have experienced firsthand and about which none of us can do anything. **We can't defend the integrity of our work, and, even more concerning, we can't even complain abou due to the "fear of reprisal"** (being disciplined for violating the Code of Values a Ethics of Public Servants on grounds of lack of loyalty and insubordination).

Such a state of using the work of our professionals and "science" for the purpose supporting specific predefined political narratives is truly **tragic for all Canadia** who assume that Government policies are driven by scientific evidence, whereas fact, in many cases (especially over the past few years) this has been the opposite **the "evidence" is driven by Government policies already made.** There are numerous testimonials and facts to prove this is the case.

The easiest way to see there is a problem is simply by looking at the PSES result for the "fear of reprisal" for agencies whose key mandate is policy development a product/policy evaluation, notably: PHAC - Centre for Emergency Preparedness and Health Canada - Marketed Health Products. Image below shows the result f PHAC. See Appendix A for other departments and explanations.

PHAC - Centre for Emergency Preparedness



Note: The images shown in this letter are generated using the PSES Web App, which I built myself to address the concerns expressed by many of my colleagues This App is made available at: https://open-canada.github.io/Apps/pses (mirror: https://itrack.shinyapps.io/PSES). It is truly unfortunate, yet explainable, that neither the Government of Canada nor the Union have built such an App, and th

we, the volunteers from across the GC, had to build it ourselves to expose the serious problem ("The Elephant in the Room") that many of us experienced firsthand and that no one talks about.

Indeed, it seems that the Union is not as aware of the seriousness of the problem Or, which would be perceived by members as even worse, the Union sided up wi the Employer rather than the Members, on exactly the issues and policies where Members needed Union's support the most.

The most notorious policy developed by the above-mentioned agencies, where th "Fear of Reprisal" is the highest, is the Mandatory Vaccination Policy. On 15 October 2021, the Union published its position supporting this Policy, summariz by the quote below:

"As the union representing the scientists who approved the COVID-19 vaccines, we encourage members to get vaccinated as soon as possible to help slow the spread of COVID-19."

Hence, I like to ask the following questions:

- How has this decision (to support Mandatory Vaccination Policy) been made?
- Who in the Union made it ?
- Who was consulted in the process of making the decision?
- Did the Union reach out to professionals in PHAC and Health Canada who evaluated the vaccine / covid data, or did the Union simply used the vendor / politicians' statements in making the decision?

It can be easily demonstrated, by looking at the post-marketing data that has become available and published by PHAC from July 2021 (Epidemiological repor "Cases following vaccination)" that the data did not support the Government statement that "vaccines offer significant protection for the Covid infection, hospitalization, or deaths". From the same report, it will become evident that PH published the "evidence" exactly in such a way as to "fit" it to the predefined narrative. See Appendix B for more details on this.

There were multiple other flags related to mandating these vaccines for everybo and how data has been manipulated by the Government to "prove" that these mandates were based on "scientific evidence", when in fact they were not.

The effect of these "data manipulation" practices that violated basic professiona and responsible practices, were far reaching. Thousands of workers had to under a medical procedure which they did not want to do, many in conflict with their conscious beliefs, due to fear of losing income for their families. Thousands of others did lose their jobs for many months, many without hope of ever returning work. Some others suffered side effects from the vaccines that they could have easily not taken.

Overall, this Policy, which is now increasingly found "unreasonable" by judges court, as not being based on scientific or economic evidence, has broken famili across the country, brought a culture of division, fear, and intolerance.

We now have an opportunity to do something about it.

Recommendations

1. **Transparency**: I request that this information (the Answers to Questions presented in this letter) is made public to all members, as a proof of transparen within the Union for its members. The Union should publish a statement on ho the decision to support mandatory vaccination was made and who made it, including those who specifically prepared the text that was published on the Union website.
2. **Update Statement**: Update the statement on the website to reflect the full and latest evidence related to vaccines (e.g., there's no evidence it stops transmissio

and the legal cases related to mandatory vaccination (e.g., PSAC win for Canad Post workers who worked remotely). The statement should highlight the range negative consequences the policy created (including discrimination, fear, and l trust).

3. **Member Feedback**: Conduct a "Mandatory Vaccination Policy: Impact on You" questionnaire to seek feedback from members on how many of them were "seriously, somewhat, or not at all affected" by the mandate, and how they find Union's actions with respect to this Policy: "Good, neutral, or bad".

4. **Political Interference Survey**: Conduct a "Political interference at workplace: Impact on You" questionnaire to identify the Agencies (and units within the Agencies) where this problem is the largest. Publicize the results.

I would appreciate your prompt response to this letter, as the matters discussed here deeply affect the security and well-being not only of thousands of union professionals but millions of Canadians who entrust our professionals for unbias free-from political and industry interference advise

It would be best if the Union's response and next steps regarding the matters discussed in this letter are ready for further discussion at the forthcoming AGM November.

Sincerely,

Dmitry Gorodnichy, Ph.D.
Senior Data Scientist, CBSA
R4GC (Data Science) Community Lead

Appendices:

Appendix A: "Fear of Reprisal" is the largest in Units/Divisions that provide "evidence" in support of Policies and Industry products (Data evidence)

Appendix B: Examples of Manipulating the "Evidence" to "Fit" it to the Political Agenda (Data evidence)

Appendix A: "Fear of Reprisal" is the largest in Units/Divisions that provide "evidence" in support of Policies and Industry products (Data evidence)

Data: Public Service Employee Survey datasets (2018)

Web App: https://open-canada.github.io/Apps/pses (mirror: https://itrack.shinyapps.io/PSES)

Source code: https://github.com/gorodnichy/iTrack-PSES-development

Developer: Dmitry Gorodnichy, GCCollab R4GC Community Lead

Images below show results for "Fear of Reprisal" (Question 36) across the Government. Divisions/units that have mandate in Policy and Vendor products evaluations have the highest level "Fear of Reprisal" (lowest positive ranking) in Public Service.

Notably, this "Fear of reprisal" is not correlated with Harassment and Discrimination (Questions 48 - 61), indicating that it stems from something else- the fear of speaking up.

The divisions/units with the highest levels of "Fear of Reprisal" are listed below (sorted from worst first):

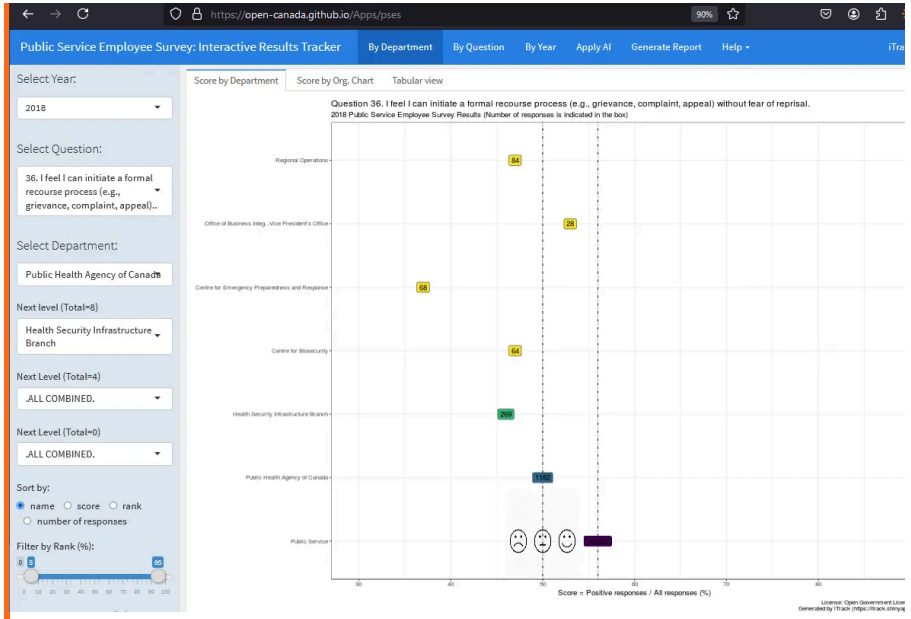
- PHAC - Health Security Infrastructure - Centre for Emergency Preparedness
- PHAC - Infectious Disease Prevention

- Health Canada - Health Products and Foods - Marketed Health Products
- Health Canada - Regulatory Operation - Health Product compliance

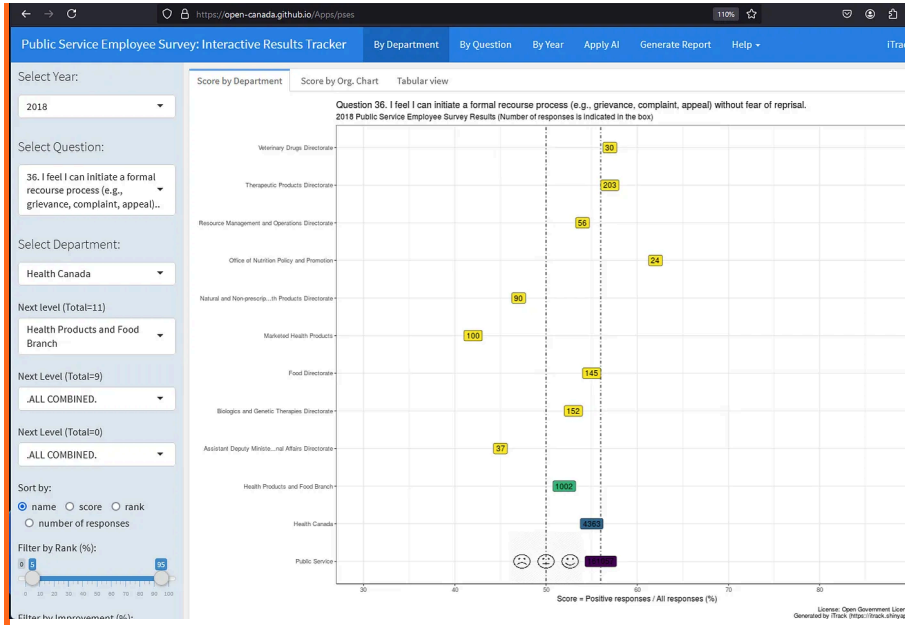
- CBSA - NHQ - Innovation Science and Technology [Multiple Divisions]
- ECCC - Industrial, Chemical Waste Directorate
- AAFC - Office of Audit and Evaluation
- Canadian Institute of Health Research - Research Knowledge Transfer Ethic

It can also be noted that for the same agencies, divisions/units that do not deal w policy and vendor products evaluations have much lower “Fear of Reprisal” (high positive ranking). This further confirms that the primary source of fear, in those units where it is high, comes from speaking out against the malfeasance of the employer with respect to the work of professionals in those units.

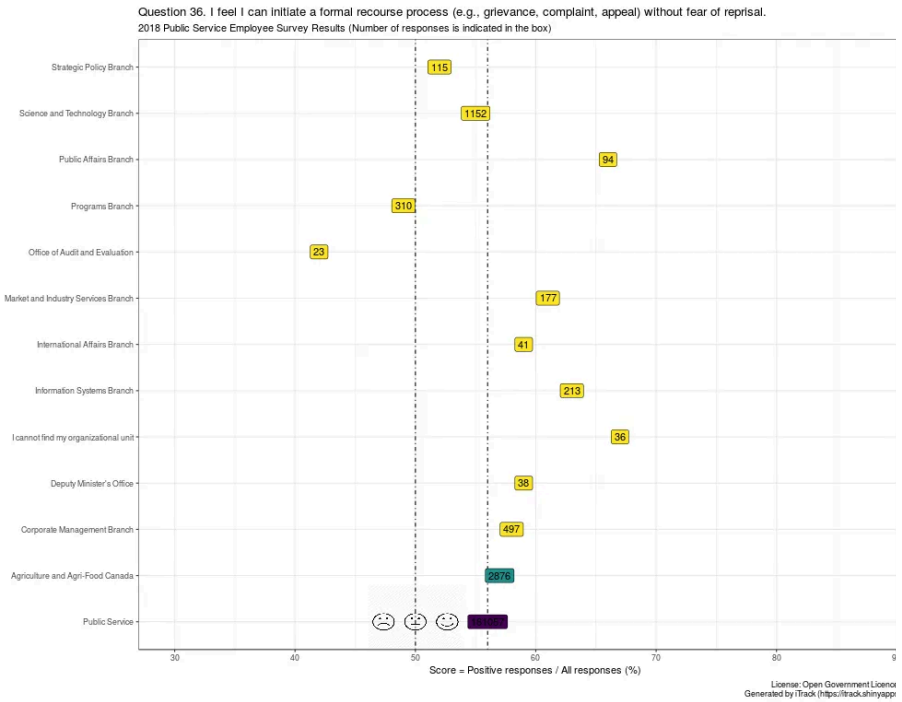
PHAC - Centre for Emergency Preparedness



Health Canada - Marketed Health Products

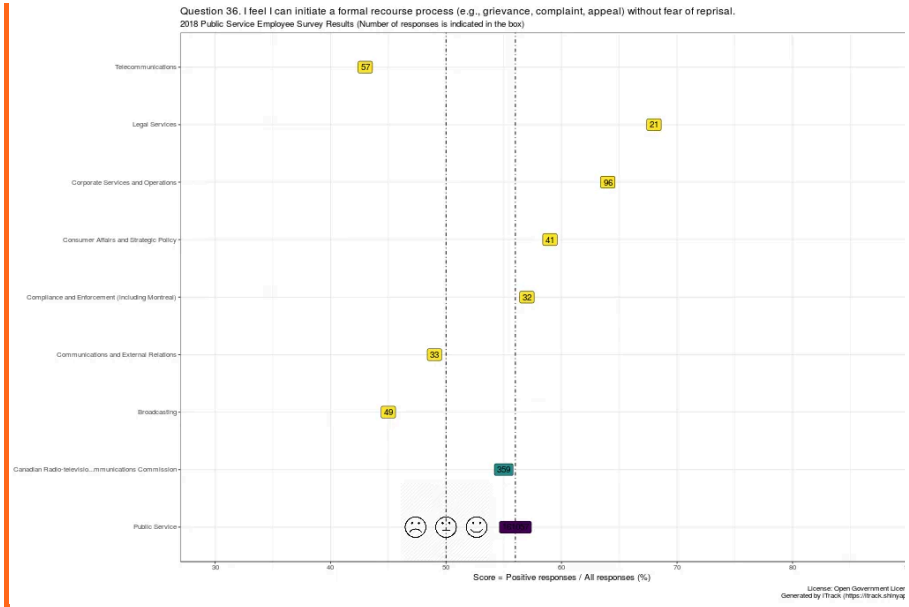


AAFC - Office of Audit and Evaluation

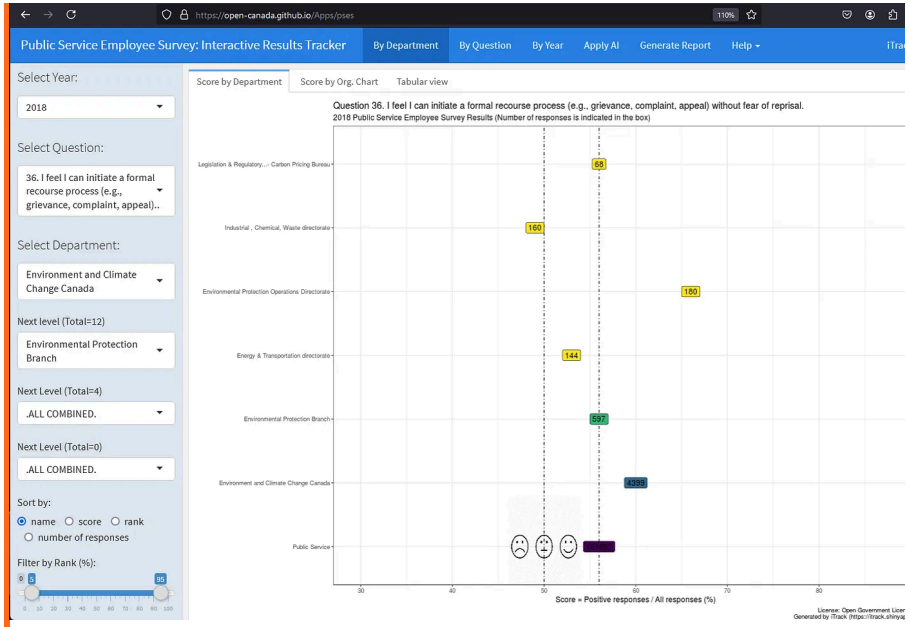


Canadian Radio-Television Communications - Telecommunications

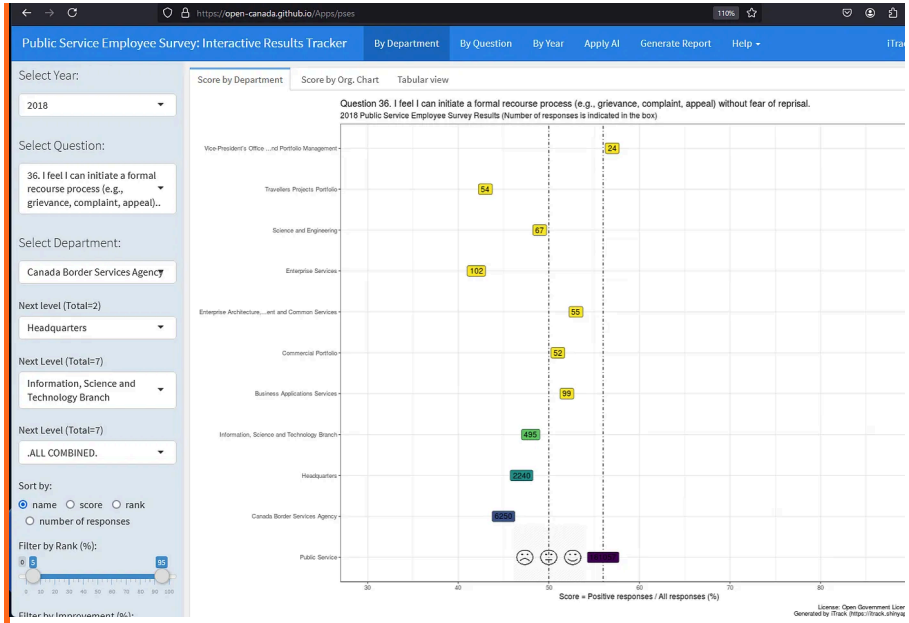
Canadian Radio-Television Communications - Broadcasting



ECCC - Industrial, Chemical Waste Directorate



CBSA - NHQ - ISTB (multiple Divisions)



Appendix B: Examples of Manipulating the "Evidence" to "Fit" it to the Politic Agenda

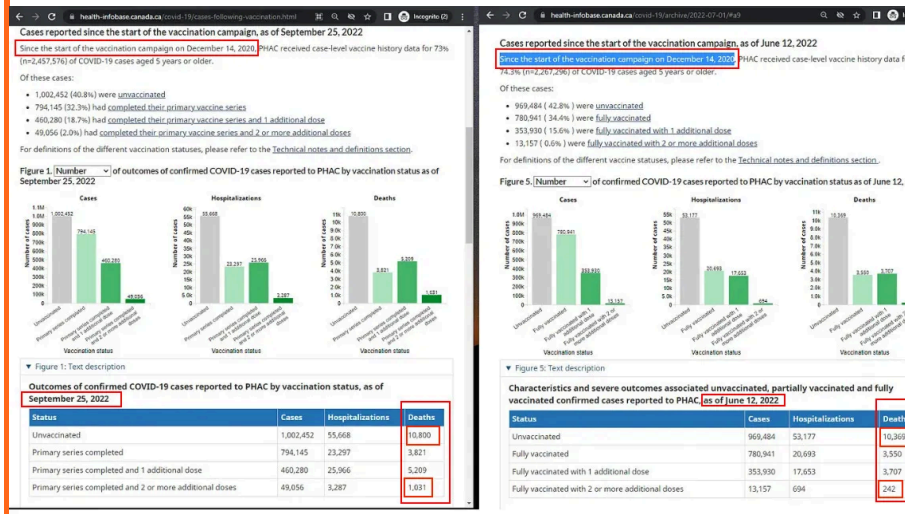
Simplest Example: PHAC 'Cases Following Vaccination' Reports (August 2021 Sept 2022)

Data sources:

- 'COVID-19 Daily Epidemiology Update', Public Health Agency of Canada - Ca following vaccination (Figure 5 & Table 2). After June 2022: https://health-infobase.canada.ca/covid-19/. From August 2021 to May 2022: https://health-infobase.canada.ca/covid-19/epidemiological-summary-covid-19-cases.html (Archived at: web.archive.org)

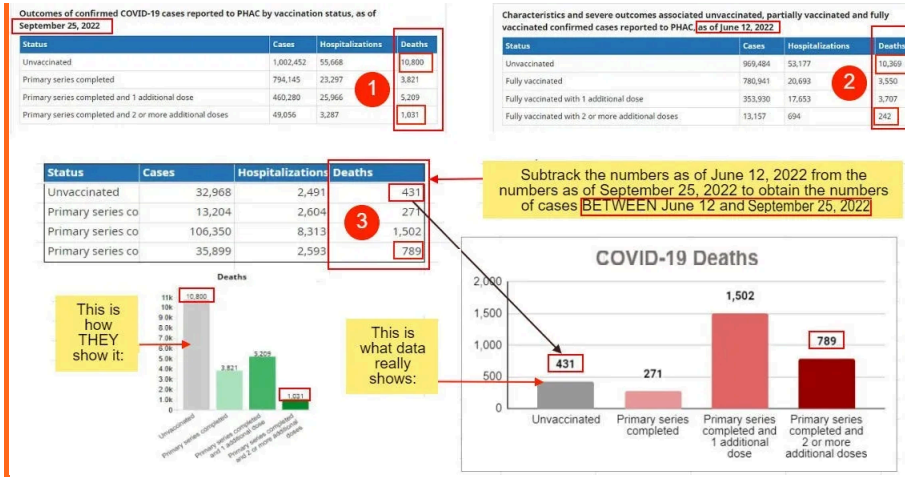
The images below provide a snippet of evidence from Summer 2022 to illustrate "data manipulation" practices used by PHAC to "fit evidence to the narrative." T full data set, covering all weeks since August 2021 (when this data became available), can be accessed through the Canadian Vital Statistics Tracking Web App: https://open-canada.github.io/Apps/vitals (Mirror: https://o-canada.shinyapps.io/vitals/). This Web App is developed by the R4GC Communit which I lead on GCCollab.

The first image shows the numbers of cases reported in two PHAC reports (one report is from June 12, 2022 and another report is from Sept 25, 2022) for people with 2+ additional doses (last line in the table) versus unvaccinated people (first l in the table).



By subtracting these numbers, as shown in the second image, we can see the number of cases between June 12 and September 25, 2022, for each population:

- Among people with 2+ additional doses, there were 1,031 - 242 = 789 deaths
- Among unvaccinated, there were 10,800 - 10,369 = 431 deaths



Observation: Data shows that between June 12 and Sept 25, 2022 there were mar more "COVID Deaths" among people with 2+ additional doses than among unvaccinated people, which is contrary to what the PHAC report portrayed.

NOTE: During this time period, there were fewer people with 2+ additional dose than unvaccinated people. This means that the occurrence of COVID deaths in people with 2+ additional doses, compared to that among unvaccinated people, i even higher than what the numbers above show.

Key Question:

- Why did PHAC not publish the COVID deaths data by week (as it normally doe for reporting all other deaths) but instead published cumulative data (totals sin December 14, 2020)?

The answer appears to be that the "evidence" was published to create the illusion tl there were indeed "many more COVID deaths among unvaccinated people" than among those with multiple doses, when in fact the data showed the opposite. This v achieved by counting COVID cases before vaccine doses were administered. For example, 3rd and 4th doses started to be administered only from December 2021 an April 2022, whereas the COVID deaths are counted since December 14, 2020.

In other words, PHAC deliberately published the "evidence" to "fit" the official political narrative that "COVID vaccines offer significant reduction of risk of complications from COVID deaths," which is not true and would have been obvi to the reader if the data were reported on a weekly basis, as ethical and professio integrity principles demand.

Such malfeasance from a Government Agency, which Canadians trust for honest and objective advice, is further aggravated by the fact that PHAC professionals (a other GC professionals) who witnessed it could not report it due to "Fear of Reprisal." Those who tried were disciplined or ignored.

This shows how widespread the culture of "using" science and evidence for polit and industry gains is in the Government and how deep the fear of speaking up is those units that have to deal with it.

I have experienced this first hand since 2015 and heard multiple similar testimonials from colleagues in PHAC, Health Canada, ECCC, and other Departments, who wanted to stay anonymous to avoid discipline.

Final Note:

Based on a single example presented above, it is understood that there were man more "evidence manipulation" practices performed across all Gov't Departments violation of scientific and ethical principles to "fit evidence" to the "approved narrative".

> I can prepare a separate report to list many of those that I have observed myself with guidance from other concerned GC colleagues. Some of these are also documented in this book:
> "*Fisman Fraud: The Rise of Canadian Hate Science.*" (Regina Watteel) (www.FismansFraud.ca)
>
> Many others have also been documented by the National Citizens Inquiry.
>
> **Recommendations / Next Steps (SANDBOX)**
>
> **Stream A: Expose Widespread Political Interference Crisis**
>
> Address / Expose the Largest ongoing problem within GC: "ELEPHANT IN THE ROOM (political suppression and manipulation of evidence)

- Step 1: START OPEN DISCUSSION within Union Executive Boards and Union Members ABOUT THE "ELEPHANT IN THE ROOM (political suppression of evidence) , using examples provided in this letter
- Step 2: QUESTIONNAIRES CAN BE DEVELOPED TO EXPLORE THE GRAVITY OF THE SITUATION (political suppression of evidence) IN IDENTIFIED PROBLEMATIC DEPARTMENTS.
- Step 3: Invitation to speak up / step up. Share Personal stories and testimonials

Stream B: Bring More Transparency

- Step 1: Make answers to questions public - Publish a statement on how the decision (to Support Mandatory vaccination) was made and who made it. Including Who specifically prepared the text that was published on the Union website?
- Future statements should also be made transparent

Stream C: Address damages done by Mandatory Vaccination Failure

- Step 1. THE UNION POSITION ON THE POLICY THAT IS NOT BASED ON SCIENTIFIC INTEGRITY MUST BE UPDATED BASED ON "FULL AND LATEST EVIDENCE"
- Step 2: Questionnaire on Gravity of Mandate effect on members
- Step 3: Invitation to speak up / step up. Share Personal stories and testimonials



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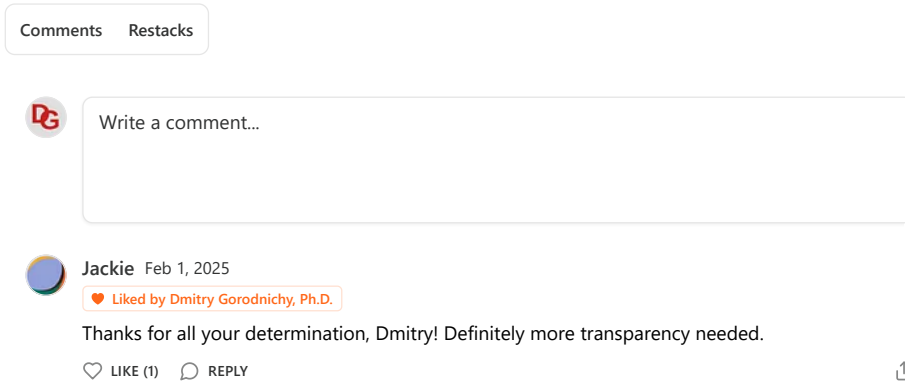

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Border Technology Division

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Recognizing people and their activities in surveillance video: technology state of readiness and roadmap

Dmitry O. Gorodnichy,
David Bissessar,
Eric Granger,
Robert Laganiére

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Reviewed By	Kathryn Mills	2014-11-10

Version #: 2.0		
Action	Name	Date
Prepared By	Dmitry Gorodnichy	2015-12-30
Reviewed By	Phil Lightfoot	2016-02-17
Final	Dmitry Gorodnichy	2016-03-20
Poster added as Attachment	Dmitry Gorodnichy	2016-05-20

Eric Granger is with École de technologie supérieure, Université du Québec.
Robert Laganiére is with School of Computer Science and Electrical Engineering, University of Ottawa.

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Recognizing people and their activities in surveillance video: technology state of readiness and roadmap

Dmitry O. Gorodnichy[13], David Bissessar[13], Eric Granger[2], Robert Laganiére[3]

[1]Science and Engineering Directorate, Canada Border Services Agency
[2]École de technologie supérieure, Université du Québec
[3]School of Computer Science and Electrical Engineering, University of Ottawa

***Abstract*—This paper presents a technology readiness assessment framework called PROVE-IT(), which allows one to access the readiness of face recognition and video analytic technologies for video surveillance applications, and the roadmap for the deployment of technologies for automated recognition of people and their activities in video, based on the proposed assessment framework and the evaluations conducted by the Canada Border Services Agency and its partners over the past five years.**

I. INTRODUCTION

As a result of the increasingly growing demand for security, many countries have been deploying closed circuit television (CCTV) video surveillance systems as an important tool for enhancing preventive measures and aiding post-incident investigations. Thousands of surveillance cameras are installed at border crossings, airports, and other public places. Millions of hours of video data are being recorded daily.

Over the years, however, it has been realized that video surveillance systems are not used very efficiently. In the real-time monitoring mode, the problem is that an event may easily pass unnoticed due to false or simultaneous alarms and lack of time needed to rewind and analyze all them. In archival post-event investigation mode, the quantity of video data that need to be processed makes post-incident investigation very difficult. Due to the temporal nature of video data, it is very difficult for a human to analyze video data within a limited amount of time.

The solution to these problems is seen in deploying video recognition technologies that use the advances in facial biometrics and video analytics (computer vision and machine learning) to automatically detect and recognize people and their activities in video [1-9]. The performance of these technologies however varies drastically from one surveillance scenario to another, which is why they are still generally not considered ready for deployment by a majority of CCTV users.

Over the past eight years, with the support from the Defence Research and Development Canada (DRDC), the Canada Border Services Agency (CBSA) has been leading a number of projects aimed at evaluating and advancing these technologies. In 2014 this effort culminated with the development of a technology readiness assessment framework, called PROVE-IT(), which was then applied to prepare recommendations related to technologies that can be developed and deployed for recognizing people and their activities in surveillance video over the next years (technology roadmap). These recommendations led to developing new projects, technologies and pilots by the agency. They also contributed to developing general guidelines related to the use of biometrics and video analytics in surveillance systems, such as those currently prepared by the International Standards Organization Special Committee on Biometrics (ISO SC 37). In the following this framework and the technology readiness assessment results obtained using it are presented.

The paper is organized as follows. In Section 2, general high-level considerations related to recognition in video are presented. Section 3 describes the PROVE-IT() readiness assessment framework. The application of the PROVE-IT() framework for assessing the technology readiness of face recognition in video (FRiV) and video analytics (VA) is presented next in Section 4. The summary of recommendations related to technology development and deployment including a discussion on the importance of developing visual analytic tools and training procedures for CCTV operators is presented in Section 5. Discussions conclude the paper.

II. STRATEGIC UNDERSTANDING OF THE PROBLEM

Through the course of this work, the term “recognition" is used in a wide sense to include any recognition that is possible in video data, whether related to recognition of ***an*** event (synonymous to the traditional use of the term “detection") or ***the*** event (synonymous to the traditional use of the term “identification"). The terms “recognition system" and “detection system" are therefore used inter-changeably.

Table 1: Recognition in video: “verbs” vs. “nouns” of the problem.

Objective to Recognize what?	Automated recognition	Manual recognition	Relies on what?
Noun (subject)	biometrics	forensic examination	spatial detail
Verb (activity)	video analytics	CCTV monitoring	temporal detail

A. Two types of events in video: nouns vs. verbs

An automated recognition system aims at automatically recognizing an event in video. As visualized in Table 1 (first introduced in [4]), two types of events are generally observable in video: those related to subjects (nouns) and those related their activities (verbs). When detected automatically, they relate to biometric and video analytics technologies. When detected manually, they relate to the work done by forensic analysts and CCTV operators.

Critically, these two types of events are different from each other in that the former operates mainly on spatial

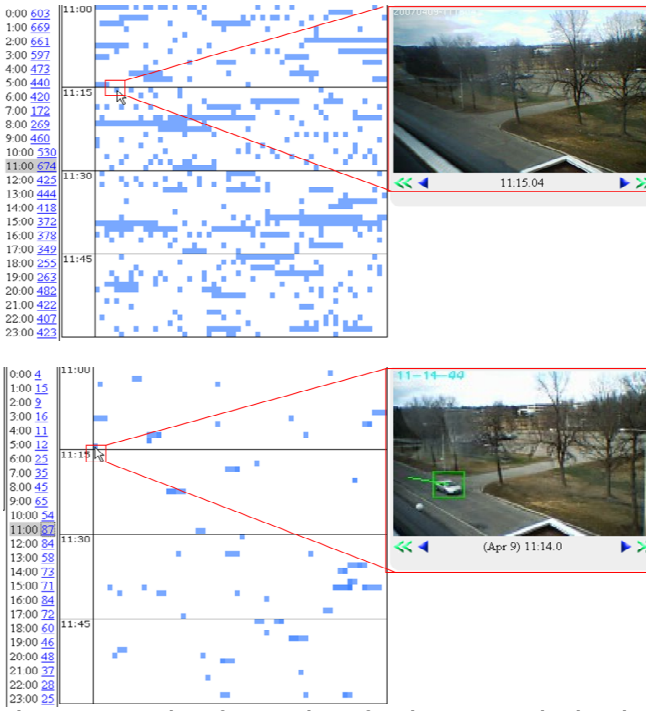


Figure 1: Examples of a "poorly performing" system (top) and a "well performing" system (bottom) (from [2]). Detected events (cars) are shown as blue boxes in a one-hour window rectangle for two systems running at the same time, each line corresponding to a minute in an hour. "Poorly performing" system generates over 90% of False alarms, but may still be useful for certain CCTV applications.

detail of the video information (thus requiring higher resolution of video images), while the latter works on a temporal details of it (thus permitting lower resolution of video images, yet requiring their continuity in time).

While presenting two different challenges and often dealt by two different communities of developers and users, these two types of events intrinsically belong to the same problem, which is the automated extraction of evidence from video. This is how they are treated in our work: as two sides of the same "*video recognition*" problem. An event that a video recognition system tries to detect is referred to as "*target*". An event that is processed by the system is called "probe". The result of video recognition is either recognizing a probe as a target or not.

B. "Poorly performing " vs. "well performing" systems

Video-surveillance is used in three modes of operation: active real-time, passive real-time, and archival (through recordings). Active monitoring involves trained personnel who watch video streams at all times. Passive monitoring involves employees who watch video streams in conjunction with other duties. In the third mode, CCTV systems record video data for the purpose of post-event analysis.

For either mode of operation, the performance of an event detection system intrinsically depends on three types of problem complexity: 1) complexity of setup, 2) complexity of the recognition task, and 3) intelligence of the recognition algorithm, and may vary from being "*very poor*" to "*reasonably good*". Both performance extremes are shown in Figure 1 (from [2]), which compares the performance of the basic motion-detection technology included by default in most surveillance systems and an advanced object-detection-based video analytics technology. While this figure shows two particular systems, it is representative of the performance of many other video recognition systems, where by the notion of "*system*", a combination of the setup, recognition task, and recognition algorithm is considered.

While a "well performing" system is an obvious candidate for an operational deployment in either mode of CCTV operation, it is noted that a "poorly performing" system may also become a candidate for deployment, specifically for an archival mode, where it can facilitate manual retrieval of evidence that is being routinely performed by many CCTV users. In the latter case however, it can be said that additional tools (such as those for data filtering and event mining) and human analyst expertise play a more important role than the recognition system itself.

C. Detection errors, metrics and evaluation results

Two types of detection errors are possible in a recognition system: Type-I, also called False Alarm, False Positive (*FP*) error, and Type-II, also called Miss, False Negative (*FN*) error. Depending on the application, one error may be more critical than the other. It is also noted that, while a Type-I error is normally measurable, Type-II in most operational settings is not measurable.

Performance of the system is traditionally reported by computing True / False Positive and True / False Negative Rates (*TPR*, *TNR*, *FPR* and *FNR*) at different operational thresholds and constructing error trade-off curves such as the Receiver Operating Characteristic curve (ROC), which plots $FPR = FP / (TN+FP)$ vs. $TPR = TP / (TP+FN)$, and the Precision-Recall Operating Characteristic (PROC), which plots $Precision = TP / (TP+FP)$ vs. $Recall = TPR = TP / (TP+FN)$. Because video surveillance is an open-set problem, meaning that the system does not have information about "non-target" events/people and the number of "non-targets" is significantly higher than that of "targets", i.e., n>> p(in Figure 1) and $TN >> TP$, PROC curves provide additional value for analysis.

Figure 3 show error trade-off curves that have been reported for state-of-art "noun" and "verb" recognition systems. In Figure 3 (example of "noun" recognition) taken from [16], a commercial FR product (Cognitec) is tested for its ability to detect (recognize) a particular individual (ID=1 from the Chokepoint dataset [19]) walking through a corridor. ROC and PROC curves are computed for three different system configurations. Details of this experiment are provided in [16]. As an outcome of this evaluation, one can observe that at $Recall=TPR=0.6$ (marked by dashed line) the system exhibits $Precision =\sim 0.8$ (80%) when the system is configured to process faces with at least 30 pixels between the eyes (red curve). This can be considered a "well-performing" scenario.

In Figure 3 (example of “verb” recognition) taken from NIST TRECVID 2012 video analytics competition (described in [8]), systems are tested for their ability to detect a “person run" event. Error detection curves plotting Probability of miss (*Pmiss*) as function of Rate of False Alarm (*RFA*) are shown. As an outcome of this evaluation, one can observe that at False Alarm Rate of less than 1/hour (dashed line), the probability of miss is higher than 80% for all systems. This can be considered a “poorly performing" scenario.

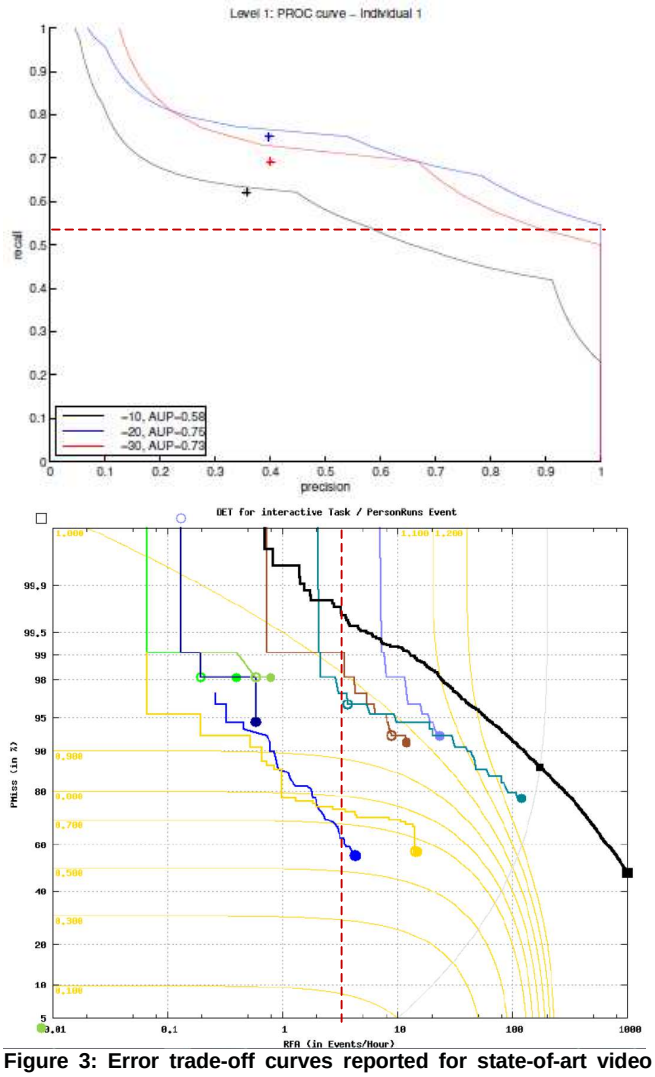


Figure 3: Error trade-off curves reported for state-of-art video recognition systems: a) for a commercial FR product showing the ability of the system to recognize an individual in a chokepoint corridor (top, from [16]), b) for VA solutions presented in TRECVID competition showing the ability of the systems to detect people running in airport halls (bottom, from [8]).

It can be observed that, while above mentioned metrics and curves are very useful for comparing one product to another as well as for monitoring and tuning the performance of a particular system, they may not be easily converted to the recommendations related to the state of readiness of these technologies for deployment in operational scenarios. This is why operational agencies rely on the concept of the Technology Readiness Level (TRL).

D. Technology Readiness Level assessment

The TRL assessment is adopted by many agencies as a risk management tool [11]. It provides a common scale of science and technology exit criteria and allows one to estimate the cost/investment required for deploying a system. According to the TRL assessment framework, the readiness level in the range from Level 1 to Level 9 is assigned to a technology follows:

Level 1: Basic principles observed and reported,
Level 2: Technology concept and/or application formulated,
Level 3: Analytical and experimental critical function and/or characteristic proof of concept,
Level 4: Component validation in laboratory environment,
Level 5: Laboratory-scale similar system or component validated in relevant environment,
Level 6: Pilot-scale similar prototypical system or component validated in relevant environment,
Level 7: Full-scale prototypical system demonstrated in relevant environment,
Level 8: Actual system completed and qualified through test and demonstration,
Level 9: Actual system successfully operated in the field over the full range of expected conditions.

Proper TRL assessment requires access to real environments and real end-users, an approved protocol and team of experts as well as a sufficiently long period of time for conducting the analysis. In certain cases however these may not be available to researchers, in particular in an academic environment or within a limited amount of time or funding allocated for the analysis. Applying a full nine-grade scale may not be appropriate in these cases, as it may give a false impression of the level of detail of the conducted analysis. Additionally, a formal TRL assessment process is often focused on a particular application, with the objective to test and prepare a technology for this particular application. In contrary to that, the objective of many smaller technology evaluation projects is to probe the entire technology landscape in order to identify the areas of focus for further research and investment. This is why a different technology readiness assessment framework is desired that will be suitable for use by a wider community of users (who may not have capacity or capability to conduct comprehensive TRL) as well as convenient for preparing the recommendations related to the technology deployment and best investment opportunities. Such framework, called PROVE-IT(), has been developed by the CBSA and is described below.

III. PROVE-IT() ASSESSMENT FRAMEWORK

A. Assessment scale

The PROVE-IT() assessment framework was developed to provide a light-weight alternative to the conventional nine-point TRL assessment. It uses a semaphore-like three-point scale (“green" or “+"- proved ready; “yellow" or “o" -

possibly ready with additional R&D ; and “red" or “-" - proved not ready for deployment in the nearest future). The relationship between the PROVE-IT() assessment grades and traditional TRL scale is shown in Table 2. Two sub-grades within the “ready" grade and “possibly ready" grade can be introduced to permit additional level of assessment detail when such information is available.

B. Technology landscape map template

Being an approximate measure of readiness, PROVE-IT() assessment can be used to estimate the technology readiness in the entire spectrum of possible deployment conditions and scenarios, using the following three steps (See Figure 5).

Step 1: Define taxonomy of possible operational conditions (scenarios) {Sj}: ordered from simplest to most difficult;

Step 2: Define taxonomy of possible technology application variations {Ti}: ordered from simplest to most difficult, thereby establishing a two-dimensional technology landscape map template.

Step 3: Assign technology readiness colour (green, yellow, red) for each technology application variation at each PROVE-IT(Ti|Sj), using a three-phase performance assessment process described below, thereby completing the technology landscape map template.

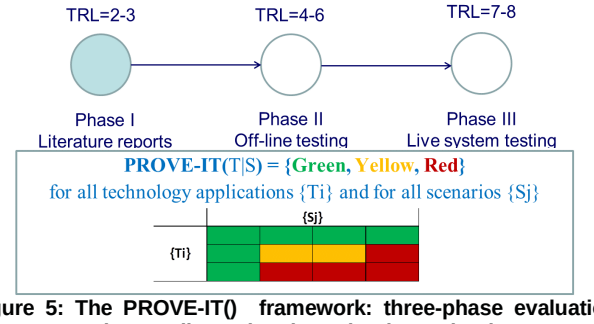


Figure 5: The PROVE-IT() framework: three-phase evaluation process and two-dimensional technology landscape map template.

C. Three-phase assessment process

Following the formal TRL definition described above, the following three key technology assessment phases are defined (see Figure 5).

Phase I: Literature and market review (testing for up to TRL=3). This includes surveying of scientific and industry literature, including company offerings and patent analysis, for the purpose of identifying and harmonizing the lexicon and technology definitions as well as for obtaining the preliminary high-level overview of possible options and solutions; and selection of solutions and scenarios that are believed to be ready for off-line testing for further assessment

Phase II: Off-line testing (testing for up to TRL=6). This includes testing of the solutions on pre-recorded datasets corresponding to different CCTV scenarios, and measuring detection error trade-off metrics.

Phase III: Live system testing (testing for up to TRL=8). This phase requires further customization and refinement of the technologies and scenarios tested in the previous phase for further testing in a live environment with real operational surveillance cameras and CCTV users.

TRL higher than 8 would normally not require additional investigation as it assumes that the technology is already well established and has a substantial deployment history.

D. Taxonomy of video surveillance setups

In the evaluation of technologies for video surveillance applications, it is proposed to categorize all possible video surveillance scenarios according to “who-what-where" factor triangle as shown in Table 3. The “where" factors relate to the settings in which subjects are captured; they include illumination, camera position and are normally possible to control. The “what" factors relate to the procedure imposed on subject during the capture; they include the direction, diversity of subject motion and can be partially controlled. Finally, the “who" factors relate to the subjects being captured; they include person's orientation, expression and normally cannot be controlled, unless the subject cooperates with the capture as is done at eGates in Automated Border Control applications.

Based on this categorization of factors, four main types of video surveillance scenario types of increasing complexity are recognized as shown in Table 3. The images from an operational airport surveillance cameras corresponding to Types 1-3 are shown in Figure 6. Camera positioning and resolution is assumed to be the best technically possible.

Table 2: Taxonomy of video surveillance scenarios.

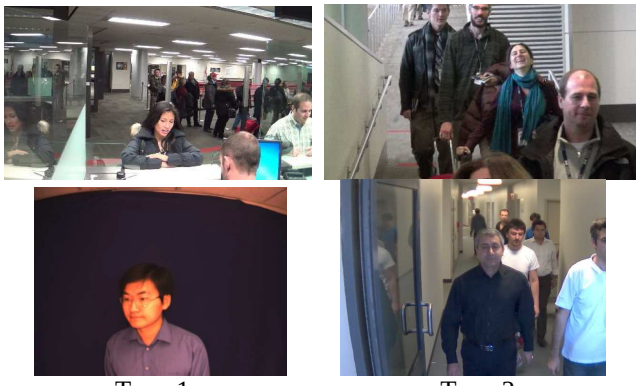
TYPE	“WHO” PERSON FACTORS	“WHAT” ACTIVITY FACTORS	“WHERE” SETUP FACTORS
1 Stationary	semi-controlled	controlled	controlled
2 Portal	uncontrolled	semi-controlled	controlled
3 Hall	uncontrolled	uncontrolled	semi-controlled
4 Outdoor	uncontrolled	uncontrolled	uncontrolled

TYPE	EXAMPLES
1 Stationary	In front of a passport control, kiosks or entrance door
2 Portal	In narrow corridors, chokepoint entries (one or several at time)
3 Hall	In airport halls with controlled lighting (free flow, many at time)
4 Outdoor	Outdoor environments

There are several public video data-sets that simulate the defined above video surveillance types and which can be used for evaluation purposes. It is vital for VA and FRiV potential users to examine the performance of the systems on these data-sets prior to testing in real surveillance settings.

By doing so they can expose in advance the vulnerabilities of the system and develop the strategies to deals with them. At the same time, it should also be noted that public data-sets provide an "optimistic" level of the video surveillance quality, as they do not show artifacts due to bandwidth and motion compression, which are commonly present in operational CCTV systems.

The number of public data-sets that simulate real surveillance settings is growing.. Following the described taxonomy of the video surveillance setups more public data-sets can be created, further sub-categorized if needed, for example, by density of traffic, camera resolution, or image compressions. Of special value will be the data-sets that are obtained from real life operational surveillance cameras, such as the i-Lids and FRL2011 datasets from Home Office [19] and the "People in Airport" dataset that has been created by the CBSA [17].



Type 1 Type 2

Figure 6: Images taken by surveillance cameras corresponding to different setups according to the taxonomy in Table 3: from the CBSA "People in Airport" dataset [17] (top), from public datasets [19,20] (bottom).

There are several public video data-sets that simulate the defined above video surveillance types and which can be used for evaluation purposes. It is vital for VA and FRiV potential users to examine the performance of the systems on these data-sets prior to testing in real surveillance settings. By doing so they can expose in advance the vulnerabilities of the system and develop the strategies to deals with them. At the same time, it should also be noted that public data-sets provide an "optimistic" level of the video surveillance quality, as they do not show artifacts due to bandwidth and motion compression, which are commonly present in operational CCTV systems.

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IV. Assessment Results

Since 2008, following the transition of the related technology and knowledgebase from NRC [1,2], the CBSA has taken the lead within the Canadian government in investigating video recognition technologies (VA and FRiV) for video-surveillance applications. A video analytic platform and test bed (VAP) has been developed to allow the integration and testing of third-party VA and FR libraries with the operational CCTV systems [5]. A number of end-user search and retrieval tools (Event Browsers) have been developed to allow the users to browse efficiently through the detected events in search for the evidence, and various mock-up and on-site testing of the technology has been conducted [3,5,8,17]. Feedback related to operational CCTV needs and constraints has been regularly obtained from other government agencies through inter-departmental workshops on Video Technologies for National Security (VT4NS) [3]. At the same time, the project team has been gaining experience and knowledge related to advances in CCTV cameras and Video Management Software, developing recommendations for new CCTV installations across the agency.

Since 2011 with additional funding from the DRDC, this effort of CBSA and its partners has converged into development of a comprehensive technology readiness landscape assessment and the deployment roadmap. These are presented below, further extended and revised from previous publications [10,11].

A. PROVE-IT(FRiV) results

A taxonomy of FRiV application variations of increasing complexity has been developed using the following categories:

- **by level of performed face processing** (from easiest to hardest): face detection, face tracking (using video-analytic techniques), face classification, facial expression analysis, identification (identity recognition);
- **by mode of operation :** archival post-event operation vs. real-time operation;
- **by decision making mode** (from easiest to hardest): fully automated (binary) vs. semi-automated (triaging) vs. not-automated (as part of an analytic tool or filter);
- **by data modality** (from easiest to hardest): video-to-video vs. still-to-video.

Following the survey of academic literature [11] and commercial solutions and patents [12], feasible surveillance scenario were assessed (Type 1 and Type 2) and a number of commercial and academic FR solutions have been selected for further testing in those scenarios

Based on the in-house evaluations and literature reviews [11-14], the feasibility of each FRiV application is accessed for each video surveillance type. Table 4 shows the result. The "Faces in Action" [20] and the Chokepoint data-sets [21] (shown in Figure 6) were used to simulate Type 1 and

Type 2 surveillance setups to prove the “yellow" grade readiness of technologies. Other datasets recommended for off-line testing of FRiV applications are: the Still-2-Video dataset [22] the FRL2011 from UK HomeOffice [23] and the “People in Airport" dataset from CBSA (also by request), the image of which are shown in Figure 6.

B. PROVE-IT(VA) results

Compared to FRiV, VA technologies operate on a much wider spectrum of possibilities in visual representation of objects. In contrast to generic face detectors that are used to facilitate face recognition, there is no generic object (or person) detector capable of recognizing / detecting particular objects (or persons). This limits considerably the range of fully-automated applications that can be performed with VA. The following taxonomy of applications has been developed for VA technologies:

- detection of people;
- recognition of people activities - at a personal level;
- recognition of people activities - at a crowd level;
- recognition of objects left by or associated with people;
- general detection of camera tampering and intrusion detection.

Based on the in-house evaluations and literature reviews [6,7], the feasibility of each VA application is accessed for each video surveillance type as shown in Table 5 .The following datasets have been used for off-line evaluation: PETS 2006, AVSS, and iLids, which simulate Types 2, 3 and 4 surveillance setups. Of a particular value is the i-Lids dataset, which has the following event detection scenarios: (a) sterile zone, (b) parked vehicle, (c) abandoned baggage, and (d) doorway surveillance. In addition, there is one dataset with a multiple camera tracking scenario. All the scenarios are recorded in a real airport. A subset of this dataset is used at NIST TRECVID competitions.

V. RECOMMENDATIONS

Two main possibilities of using video surveillance technology for recognition of people and their activities are envisaged. The first possibility deals with video cameras used in combination with other sensors and point-and-shoot cameras. For example, RFID readers can be installed in airports to facilitate tracking of people. Sensors can also be used to trigger the capture of video data, in particular of high resolution. Similarly, point-and-shoot cameras can be installed to capture high-resolution high-quality facial images triggered by video analytics and other sensors. The second possibility deals with the traditional use of cameras in video surveillance applications, when multitudes of IP-based surveillance cameras are connected to centralized storage, streaming continuously video data that is stored and processed by video management software. The following recommendations are developed for the latter.

A. Long-term research and development

First, it is emphasized that, by the nature of optics and because of the compression required for transmitting video images over IP-networks, faces in surveillance video are “meant to be" of low effective resolutions, where *effective resolution* (also referred to as *informative resolution* [10]) refers to the number of discernable pixels between the eyes. It particular, experiments show that capturing focused non-blurred faces of moving people with more than 60 discernable pixels between the eyes is close to impossible with current state-of-art IP-cameras. Mega-pixel cameras increase the resolution of the image, but they are shown to not increase the effective resolution of faces. That is, even when captured at high resolution, facial images of moving people remain of the same effective resolution, which is proved by sub-sampling the image to a lower resolution and then super-sampling it back to original resolution. This is because objects captured by the video-surveillance cameras are in focus only in a small range of about 1-2 feet, or otherwise they are very small (if captured at distance) or blurred (if the range of focus is manually increased by decreasing the camera aperture or increasing the shutter speed). See [16] for more detail on the detailed analysis of this phenomenon. Hence only those FR techniques that can process low resolution will be suitable for surveillance applications. For reference, most current COTS FR products required face resolution to be higher than 60 pixels between the eyes.

For improving the performance of person recognition systems in video-surveillance applications the following two main directions are foreseen: i) the development of more advanced face and person tracking pre-processing techniques, including person tracking based on video analytics, the survey of which is presented in [7], and ii) the development of more advanced post-processing techniques that accumulate decisions over time, combined with face quality metrics for more meaningful and robust binary and triaging recognition decisions. In doing that, a higher level of combination of FR technologies with VA technologies is expected.

Recognition and detection technologies may never be expected to be error-free. Hence, an important requirement for enabling the deployment of these technologies is the development of end-user tools for human operators, which operate in support to the current human operator’s work. This includes the development of target-based systems such as those described in [16] and event filtering tools based on advanced computer-human interfaces and the science of visual analytics, which employs the natural efficiency of the human brain in processing visual information.

B. Near-term deployment and pilots

Face Detection has become a mature technological solution capable of detecting faces with 10 pixels between the eyes over a wide range of face rotations (± 30° in all axes of rotation) - producing FPR and FNR of less than 1%. This makes it suitable for deployment in many scenarios (TRL>7). This also enables performing many other face processing tasks listed in Table 4.

Two main opportunities for deploying person recognition systems are observed (marked by rectangles in Table 4). The first opportunity addresses archival applications and aims at facilitating the existing post-event search procedures for evidence retrieval from video. A critical example of this opportunity is using face detection and face grouping at low resolutions to improve Search and Retrieval of evidence related to a particular person or incident. This is focus of the work in [17].

The second opportunity addresses real-time applications and aims at developing tools for improved situational awareness and decision making. Examples of such tools are border wait time estimation, traffic control and traditional protection of limited access areas. Another example is Faces on the Move technology where faces of travellers captured in Type 1 and Type 2 setups are matched against a watch list to generate flags that can be used by border officers for triaging travellers. To enable this application, an additional set or array of cameras need to considered to increase the chance of capturing an eye-aligned focused a face in Type 2 (Portal) settings. This is focus of one of the current DRDC CSSP projects [18].

C. *Face Triaging*

Face Triaging is a new concept related to the use of FR in surveillance applications identified and studied by the CBSA in its studies. It is a particular case of semi-automated face watch-list screening technology that is suitable for the applications where there is a high traffic of people that needs to be processed in real-time, as in border control, where negative consequences for a person who is falsely matched need to be minimized and where there is no possibility (or time) for a human operator to examine the output of the FR system.

The core principle of Face Triaging technology is that “looking similar” to a criminal should never result in treating a person as more risky. Therefore, a new label for the FR system outcome is introduced called “looks similar” (yellow), in addition to traditional “matched” (red) and “non-matched” labels. “Looks similar” label must not bring about any negative connotation about a person and is provided to a triaging officer purely as a flag that the officer may ask additional questions to a traveller within the Standard Operational Procedure as he/she would normally do with other travellers within given flexibility and service standards. This is in contrast to “matched” (red) flag, in which case the triaging officer needs to direct a person to further examination, where his/her identity will be validated using as much time as needed though interrogation and/or additional biometric measurements.

Our analysis of technology readiness indicates that Watch List Screening using Face Triaging has better chance of being deployed for real-time applications compared to traditional binary Watch List Screening (Table 4).

D. *End-user tools and training*

Figure 3 showed two possible outcomes of applying a video recognition system: with few False alarms and with many False alarms. Either application may be found valuable for end user, as long as proper data processing/filtering tools are developed and training to use these tools is provided. One of the key recommendations therefore made from conducted technology assessment, is that the use of video recognition technologies will require the development of tools for filtering, searching, and mining of events detected by the recognition system. Several such tools have been prototyped and tested by the CBSA [5,8]. The use of these tools (shown in Figure 7) was also instrumental for the TRECVID competition [8]. It is emphasized that such tools should be designed based on best practices in software usability. Finally, training programs should be developed for operators to train them to use innovative video-recognition tools.

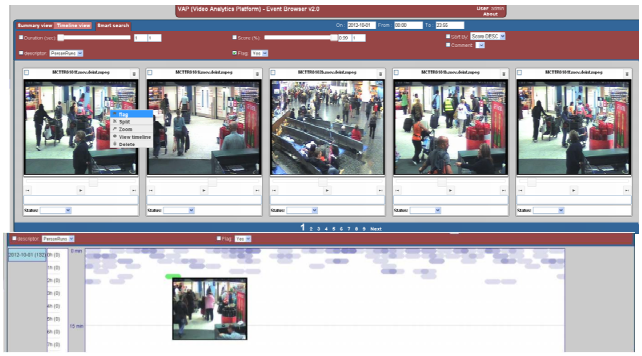

Figure 7: End-user Search and Retrieval tools (Event Browser) used for NIST TRECVID ``Running Event'' detection competition [8]: Annotated snapshot view (top) and TimeLine view (bottom). The alarms detected by Video Analytics, of which majority (over 90%) are False alarms, are filtered out using the user interface designed using the principles from Computer Human Interface and Visual Analytics domains.

VI. CONCLUSIONS

It is not uncommon in business culture to present a technology as ready for deployment. In reality however, while a technology may work under certain conditions, it may not work under different conditions. This is especially True for video-surveillance applications where the lighting and setup conditions in an operational environment may differ drastically from those where technology was demonstrated. The PROVE-IT() assessment framework presented in this paper is a tool that allows one to distinguish and report the applications and conditions in which the technology works and in which it does not. This facilitates developing specifications for the technologies that have been “proved" ready for deployment. This also permits the development of the roadmap for technologies that will be ready in the nearest future. Finally, it addresses privacy related concerns – such as those that impede the development and deployment of face recognition / video analytics technologies in the fear of their recognition power, which may be reported by vendors or observed in science

fiction movies, but which is not there in real technologies and applications.

The PROVE-IT() framework has been applied for face recognition in video (FRIV) and video analytic (VA) technologies. The outcome is a set of practical recommendations for FRiV and VA developers and CCTV users related to the best investment in these technologies, and the technology roadmap for the deployment of technologies capable of automatically recognizing people and their activities in surveillance video expressed using two-dimensional technology landscape maps shown in Tables 4 and 5.

In conclusion, it is recommended that the readiness of all technologies presented in Tables 4 and 5 be re-assessed on a regular basis, ideally in a community-driven effort open to all FR/VA developers and CCTV users. The methodology described in this paper can serve as the basis for such re-assessment. A new ViSTER (Video Surveillance Technology Evaluation and Research Group) portal [23] has been set up to facilitate this process.

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REFERENCES

[1] D. Gorodnichy, M. A. Ali, E. Dubrofsky, K. Woodbeck. Zoom on Evidence with the ACE Surveillance, CRV International Workshop on Video Processing and Recognition (VideoRec'07), May 28-30, 2007. Montreal. Online: http://www.computer-vision.org/VideoRec07/program.html

[2] D. Gorodnichy and T. Mungham. Automated video surveillance: challenges and solutions. ACE Surveillance (Annotated Critical Evidence) case study. NATO SET-125 Symposium "Sensor and Technology for Defense against Terrorism", 2008. Online: https://www.researchgate.net/publication/229040125_Automated_video_surveillance_challenges_and_solutions_ACE_Surveillance_Annotated_Critical_Evidence_case_study

[3] D. Gorodnichy, J.-P. Bergeron, D. Bissessar, E. Choy, J. Sciandra, "Video Analytics technology: the foundations, market analysis and demonstrations", Technical Report DRDC-RDDC-2014-C251. http://cradpdf.drdc-rddc.gc.ca/PDFS/unc167/p801081_A1b.pdf

[4] D. Gorodnichy. "Recognition in Video" , University of Toronto IPSI Public Lecture Series, November 2009. Online: Appendix E, ibid (http://cradpdf.drdc-rddc.gc.ca/PDFS/unc167/p801081_A1b.pdf)

[5] D. Gorodnichy and E. Dubrofsky. VAP/VAT: Video Analytics Platform and Test Bed for Testing and Deploying Video Analytics. In Proceedings of SPIE Volume 7667: Conference on Defense, Security and Sensing, 2010

[6] D. Gorodnichy, D. Macrini, R. Laganiere, "Video analytics evaluation: survey of datasets, performance metrics and approaches ", Technical Report DRDC-RDDC-2014-C248. Online: http://cradpdf.drdc-rddc.gc.ca/PDFS/unc167/p801081_A1b.pdf

[7] D. Macrini, V. Khoshaein, G. Moradian, C. Whitten, D.O. Gorodnichy, R. Laganiere, "The Current State and TRL Assessment of People Tracking Technology for Video Surveillance applications", Technical Report DRDC-RDDC-2014-C293. Online: http://cradpdf.drdc-rddc.gc.ca/PDFS/unc161/p800731_A1b.pdf

[8] C. Whiten, R. Laganiére, E. Fazl-Ersi, F. Shi, G. Bilodeau, D. O. Gorodnichy, J. Bergeron, E. Choy, D. Bissessar . VIVA-uOttawa / CBSA at TRECVID 2012: Interactive Surveillance Event Detection. Online: http://www-nlpir.nist.gov/projects/tvpubs/tv.pubs.12.org.html

[9] D. Gorodnichy and E.Granger, "Evaluation of Face Recognition for Video Surveillance ". NIST International Biometric Performance Conference (IBPC 2012), Gaithersburg, March 5-9, 2012. Online: http://www.nist.gov/itl/iad/ig/ibpc2012.cfm .

[10] D. Gorodnichy and E. Granger " PROVE-IT(FRiV): framework and results ". NIST International Biometrics Performance Conference (IBPC 2014), Gaithersburg, MD, April 1-4, 2014. Online: http://www.nist.gov/itl/iad/ig/ibpc2014.cfm .

[11] D. Bissessar, E. Choy, D. Gorodnichy, T. Mungham, "Face Recognition and Event Detection in Video: An Overview of PROVE-IT Projects (BIOM401 and BTS402)", Technical Report DRDC-RDDC-2014-C167. Online: http://cradpdf.drdc-rddc.gc.ca/PDFS/unc157/p800402_A1b.pdf

[12] D. Gorodnichy, E.Granger, and P. Radtke, "Survey of commercial technologies for face recognition in video ", Technical Report DRDC-RDDC-2014-C245. Online: http://cradpdf.drdc-rddc.gc.ca/PDFS/unc159/p800510_A1b.pdf

[13] E. Granger, P. Radtke, and D. Gorodnichy, "Survey of academic research and prototypes for face recognition in video ", Technical Report DRDC-RDDC-2014-C246. Online: http://cradpdf.drdc-rddc.gc.ca/PDFS/unc167/p800522.pdf

[14] E. Granger and D. Gorodnichy, "Evaluation methodology for face recognition technology in video surveillance applications", Technical Report DRDC-RDDC-2014-C249. Online: http://cradpdf.drdc-rddc.gc.ca/PDFS/unc167/p800519_A1b.pdf

[15] E. Granger, D. Gorodnichy, E. Choy,W. Khreich, P. Radtke, J.-P. Bergeron, and D. Bissessar, "Results from evaluation of three commercial off-the-shelf face recognition systems on Chokepoint dataset", Technical Report DRDC-RDDC-2014-C247. Online: http://cradpdf.drdc-rddc.gc.ca/PDFS/unc167/p800520_A1b.pdf

[16] D. Gorodnichy and Eric Granger, Target-based evaluation of face recognition technology for video surveillance applications , Proc. of IEEE SSCI CIBIM 2014 workshop, Orlando, December 2014.

[17] J.-P. Bergeron and D. Bissessar, "Accelerated Evidence Search Report", DRDC-RDDC-2014-C166. Online: http://cradpdf.drdc-rddc.gc.ca/PDFS/unc159/p800470_A1b.pdf

[18] DRDC website: "Government of Canada invests in Canada's Safety and Security" (January 29, 2014), http://www.drdc-rddc.gc.ca/en/dynamic-article.page?doc=government-of-canada-invests-in-canada-s-safety-and-security/hr0e3lxs

[19] iLids (The Imagery Library for Intelligent Detection Systems) : www.homeoffice.gov.uk/science-research/hosdb/i-lids.

[20] Y. Wong, S. Chen, S. Mau, C. Sanderson, and B. C. Lovell, "Patch-based probabilistic image quality assessment for face selection and improved video-based face recognition," Computer Vision and Pattern Recognition Workshops .

[21] R. Goh, L. Liu, X. Liu, and T. Chen, "The CMU Face In Action (FIA) Database ," Analysis and Modelling of Faces and Gestures, Lecture Notes in Computer Science Volume 3723, 2005, pp 255-263

[22] Z.Huang et al. "Benchmarking Still-to-Video Face Recognition via Partial and Local Linear Discriminant Analysis on COX-S2V Dataset". Proceeding of Asian Conference on Computer Vision, ACCV 2012.

[23] ViSTER (Video Surveillance Technology Evaluation and Research Group) Portal. Online: http://sites.google.com/site/vistercanada

Table 3: Technology readiness assessment grades according to PROVE-IT() framework.

GRADE	TRL	Definition and required proof	Years to deploy and R&D effort required
++	8-9	Unambiguously **proved ready** through deployments and pilots in operational settings	*Operationally Ready*: Can be deployed immediately with no customization and predictable results.
+	7		*Operationally with Configuration*: Deployed within 1 year with some customization; predictable results.
oo	5-6	**Possibly ready**, may be proved ready if additional evidence is provided	*Short-term Ready*: Possible within 1 to 3 years with a moderate investment in applied R&D
o	4		*Medium-term Ready*: Possible within 3 to 5 years with a significant investment in applied R&D
-	1-3	Unambiguously **proved not ready** for given operational settings	*Not Ready:* Not possible within next 5 years; requires major academic R&D.

Table 4: PROVE-IT(FRiV) results. The readiness assessment of face recognition for video surveillance applications.

Face Recognition In Video technologies	Type 0[1] (eGate)	Type 1 (Stationary)	Type 2 (Portal)	Type 3 (Hall)
Detection (no Face Recognition)				
1. Face Detection in Surveillance Video	++	++	+	oo
Tracking (no Face Recognition)[2]				
2. Face Tracking across a Single Video	+	+	+	-
3. Face Tracking across Multiple Videos	+	+	o	-
Semi-automated Recognition[3,4]: for post-event investigation (search and retrieval of evidence)				
Video to Video (Re-Identification)				
4. Face Grouping, Tagging, Tracking across multiple videos	+	oo	oo	o
Still to Video				
5. FR to aid manual forensic examination	+	oo	oo	-
Fully-automated Recognition: for real-time interdiction (border / access control)				
Video to Video (Re-Identification)				
6. Instant FR in single camera	+	oo	o	-
7. Instant FR from multiple cameras	+	o	o	-
Still to Video				
8. Instant FR for Watch List Screening – Triaging	+	oo	o	-
9. Instant FR for Watch List Screening – Binary	+	o	-	-
Micro-facial feature recognition				
10. Facial Expression analysis: for emotion / intent recognition	+	oo	o	-
Soft and multiple biometrics				
11. Human attribute recognition (gender, age, race)	+	oo	o	-
12. Personal metrics (height, weight, eye/hair colour)	+	o	o	-
13. FR to improve voice or iris biometrics	+	o	-	-

Notes:

1. The readiness of FR applications for cooperative scenario at eGate (Type 0) is provided as point of reference to contrast the performance of the same FR applications in non-cooperative scenarios (Types 1-3).
2. See assessment results for person detection and tracking from PROVE-IT(VA) evaluation.
3. Type 4 scenario (outdoors) is not included in the FRiV assessment since there is no evidence that the technology works in easier setups.
4. The applications marked by boxes have been recommended for pilots. See [17,18] for more details.
5. The references to the academic research/prototypes and commercial technologies that were used in the assessment are provided in [12-15].

Table 5: PROVE-IT(VA) results. The readiness assessment of video analytics for video surveillance applications.

Video Analytics technologies	Type 1 (Kiosk)	Type 2a (Portal)	Type 2b (Portal)	Type 3 (Halls)	Type 4 outdoor
Person Detection and Tracking (without Face Recognition)					
a. Person counting	++	+	oo	o	o
b. Person tracking in single camera	++	+	oo	o	o
c. Person matching in single camera	oo	o	o	-	-
d. Person matching in multiple cameras	o	o	-	-	-
Person Event Detection					
a. Improper standing place	++	++	+	o	o
b. Opposite flow detection	++	++	oo	o	o
c. Running detection [1]	++	++	oo	-	-
d. Tail-gating detection	++	++	oo	-	-
e. Loitering detection	++	+	-	-	-
f. Fall detection	++	oo	-	-	-
Crowd Analysis					
a. Density estimation	n/a		oo	oo	oo
b. Rapid dispersion			oo	oo	oo
c. Crowd formation			oo	oo	oo
d. Crowd Splitting			o	-	-
e. Crowd Merging			o	-	-
Baggage Detection and Tracking					
a. Static Object (>n sec)	+	+[1]	o[1,2]	-	-
b. Object removal	o[2]	o[2]	-	-	-
c. Dropping Object	o[2]	o[2]	-	-	-
d. Abandoned Object	o[2]	o[2]	-	-	-
e. Unattended Object	o[2]	o[2]	-	-	-
f. Carried Object	-	-	-	-	-
Person-Baggage Association Analysis					
a. Person-Baggage Association	o	-	-	-	-
b. Owner change	-	-	-	-	-
Camera Tampering Detection					
Occlusion, Focus moved, Camera moved	++	++	++	++	+
Physical Security					
Virtual trip-wire, intrusion detection	++	++	++	++	+

Notes:

1. For low traffic only.
2. For large objects only.
3. The references to the academic research/prototypes and commercial technologies that were used in the assessment are provided in [6-8].

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Recognizing people and their activities in surveillance video: technology state of readiness and roadmap

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Dmitry O. Gorodnichy[1], David Bissessar[1], Eric Granger[2], Robert Laganiére[3]

CBSA ASFC

"It is not uncommon in business culture to present a technology as ready for deployment. In reality however, while a technology may work under certain conditions, it may not work under different conditions. This is especially true for video-surveillance applications where the lighting and setup conditions in an operational environment may differ drastically from those where technology was demonstrated…"

"The PROVE-IT() assessment framework is a tool that allows one to distinguish and report the applications and conditions in which the technology works and in which it does not. This facilitates developing specifications for the technologies that have been "proved" ready for deployment. This also permits the development of the roadmap for technologies that will be ready in the nearest future..."

STRATEGIC UNDERSTANDING OF THE PROBLEM

A. Two types of events in video: nouns vs. verbs

Objective to Recognize what?	Automated recognition	Manual recognition	Relies on what?
Noun (subject)	biometrics	forensic examination	spatial detail
Verb (activity)	video analytics	CCTV monitoring	temporal detail

B. "Poorly performing " vs. "well performing" systems

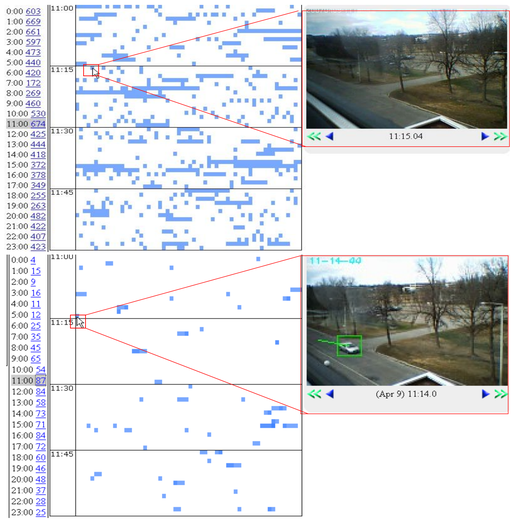


Figure 1: Examples of a "poorly performing" system (top) and a "well performing" system (bottom) (from [1-2]). Detected events (cars) are shown as blue boxes in a one-hour window rectangle for two systems running at the same time, each line corresponding to a minute in an hour. "Poorly performing" system generates over 90% of False alarms, but may still be useful for certain CCTV applications.

C. Detection errors, metrics and evaluation results

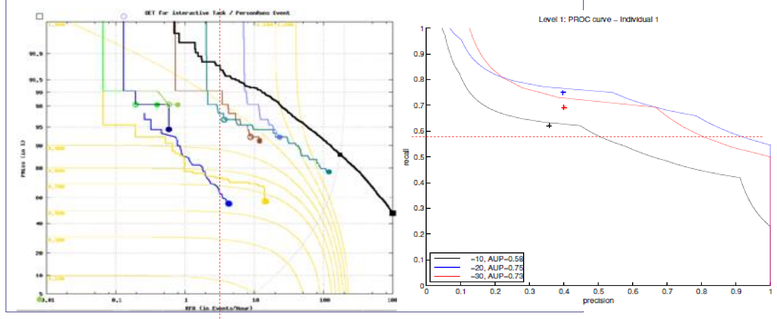


Figure 2: Error trade-off curves reported for state-of-art video recognition systems: for VA solutions presented in TRECVID competition - showing the ability of the systems to detect people running in airport halls (left, from [8]); for a commercial FR product - showing the ability of the system to recognize an individual in a chokepoint corridor (right, from in-house tests [16]).

RECOMMENDATIONS

A. Top two directions for long-term research and development

1. Development of more advanced face and person tracking pre-processing techniques, including person tracking based on video analytics [7],
2. Development of more advanced post-processing techniques that accumulate decisions over time, combined with face quality metrics for more meaningful and robust binary and *triaging* recognition decisions. In doing that, a higher level of combination of FR technologies with VA technologies is expected.

B. Top two opportunities for near-term deployment and pilots

1. Facilitating the existing post-event search procedures for evidence retrieval from video. Example: face detection and face grouping at low resolutions to improve Search and Retrieval of evidence following an incident.
2. Improved situational awareness and decision making. Examples: border wait time estimation, traffic control and protection of limited access areas. Special interest [18]: Instant FR Watch List Screening for *triaging* in Type 1 and Type 2 scenarios.

C. Top two directions for developing training requirements and end-user tools for operators:

1. Target systems (as in [16]) – for real-time operation
2. Event filtering tools (as in [17]) - for post-event operations

"While a "well performing" system is an obvious candidate for an operational deployment, a "poorly performing" system may also become a candidate for deployment, specifically for an archival mode of operation, where it can facilitate manual retrieval of evidence that is being routinely performed by many CCTV users. In the latter case however, it can be said that additional tools (such as those for data filtering and event mining) and human analyst training play a more important role than the recognition technology itself"

It is recommended that the technology readiness re-assessed on a regular basis, in a community-driven effort open to all FR/VA developers and CCTV users. The methodology described in this paper can serve as the basis for such re-assessment. A new ViSTER (Video Surveillance Technology Evaluation and Research) portal has been set up to facilitate this process: http://sites.google.com/site/vistercanada

New Concept: *Face Triaging*

Definition: A special case of face screening, where in addition to traditional "matched" (red) and "non-matched" labels, "looks similar" (yellow) label is used.
Core principle: The limitation of the face recognition technology must be taken into account to minimize its effect on regular travellers.
Application: It can be used for:
a) off-line analysis of captured faces, or
b) in real-time inspection, where red flag results in sending to further examination, while yellow flag leads to performing minor additional screening.

The concept of *face triaging* and other recommendations from this work are being added to ISO guidelines on designing Biometrics systems for video-surveillance applications [19-20]

PROVE-IT() ASSESSMENT FRAMEWORK

B. Technology landscape map template

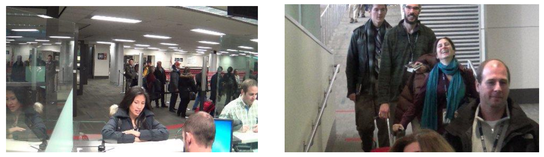
PROVE(T|S) = {Green, Yellow, Red}
for all technology applications {Ti} and for all scenarios {Sj}



(Applications vs. scenarios sorted in order of complexity)

C. Tri-fold taxonomy of video surveillance scenarios {Sj}

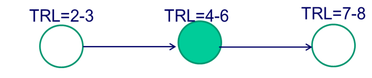
TYPE	"WHO" (PERSON) FACTORS	"WHAT" (ACTIVITY) FACTORS	"WHERE" (SETUP) FACTORS	EXAMPLES
1 Stationary	semi-controlled	controlled	controlled	In front of a passport control, kiosks or entrance door
2 Portal	uncontrolled	semi-controlled	controlled	In narrow corridors, chokepoint entries (one or several at time)
3 Hall	uncontrolled	uncontrolled	semi-controlled	In halls with controlled lighting (free flow, many at time)
4 Outdoor	uncontrolled	uncontrolled	uncontrolled	Outdoor environments



Type 1 Type 2

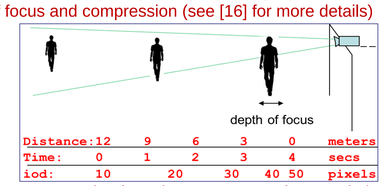
Figure 3: Images taken by surveillance cameras corresponding to two easiest setups according to the taxonomy in Table 3. Images are taken from the CBSA "People in Airport" dataset [17].

D. Three-phase assessment process



Attention: *Effective resolution* vs. *Camera resolution*

By the nature of optics, faces in surveillance video are "meant to be" of low *effective resolution* (< 60 pixels between eyes), because of motion blur, short depth of focus and compression (see [16] for more details)



Therefore:
1. Either use FR technology that can process low-resolution faces,
2. Or use hi-quality photo cameras triggered by video analytics

Definition: *Effective resolution* (a.k.a. *informative resolution* [10]) is the number of discernable pixels between the eyes. Intra-ocular distance (iod) must be measured using *effective* (not *camera*) *resolution* !

A. PROVE-IT() Technology Readiness Level Assessment Scale

GRADE	TRL	Definition and required proof	Years to deploy and R&D effort required
++	8-9	Unambiguously **proved ready** through deployments and pilots in operational settings	*Operationally Ready*: Can be deployed immediately with no customization and predictable results.
+	7		*Operationally with Configuration*: Deployed within 1 year with some customization; predictable results.
oo	5-6	**Possibly ready**, may be proved ready if additional evidence is provided	*Short-term Ready*: Possible within 1 to 3 years with a moderate investment in applied R&D
o	4		*Medium-term Ready*: Possible within 3 to 5 years with a significant investment in applied R&D
-	1-3	Unambiguously **proved not ready** for given operational settings	*Not Ready*: Not possible within next 5 years; requires major academic R&D.

PROVE-IT(FRiV) results: The readiness assessment of face recognition for video surveillance applications

Face Recognition In Video technologies	Type 0[1] (eGate)	Type 1 (Stationary)	Type 2 (Portal)	Type 3 (Hall)
Detection (no Face Recognition)				
1. Face Detection in Surveillance Video	++	++	+	oo
Tracking (no Face Recognition)[2]				
2. Face Tracking across a Single Video	+	+	+	-
3. Face Tracking across Multiple Videos	+	+	o	-
Semi-automated Recognition[3,4]: for post-event investigation (search and retrieval of evidence)				
Video to Video (Re-Identification)				
4. Face Grouping, Tagging, Tracking across multiple videos	+	oo	oo	o
Still to Video				
5. FR to aid manual forensic examination	+	oo	oo	-
Fully-automated Recognition: for real-time interdiction (border / access control)				
Video to Video (Re-Identification)				
6. Instant FR in single camera	+	oo	o	-
7. Instant FR from multiple cameras	+	o	o	-
Still to Video				
8. Instant FR for Watch List Screening – Triaging	+	oo	o	-
9. Instant FR for Watch List Screening – Binary	+	o	-	-
Micro-facial feature recognition				
10. Facial Expression analysis: for emotion / intent recognition	+	oo	o	-
Soft and multiple biometrics				
11. Human attribute recognition (gender, age, race)	+	oo	o	-
12. Personal metrics (height, weight, eye/hair colour)	+	o	o	-
13. FR to improve voice or iris biometrics	+	o	-	-

1. The readiness of FR applications for cooperative scenario at eGate (Type 0) is provided as point of reference to contrast the performance of the same FR applications in non-cooperative scenarios (Types 1-3).
2. See assessment results for person detection and tracking from PROVE-IT(VA) evaluation.
3. Type 4 scenario (outdoors) is not included in the FRiV assessment since there is no evidence that the technology works in easier setups.
4. *The applications marked by boxes have been recommended for pilots.* See [17,18] for more details.
5. The references to the academic research/prototypes and commercial technologies that were used in the assessment are provided in [12-15].

PROVE-IT(VA) results: The readiness assessment of video analytics for video surveillance applications

Video Analytics technologies	Type 1 (Kiosk)	Type 2a (Portal)	Type 2b (Portal)	Type 3 (Halls)	Type 4 outdoor
Person Detection and Tracking (without Face Recognition)					
a. Person counting	++	+	oo	o	o
b. Person tracking in single camera	++	+	oo	o	o
c. Person matching in single camera	oo	o	o	-	-
d. Person matching in multiple cameras	o	o	-	-	-
Person Event Detection					
a. Improper standing place	++	++	+	o	o
b. Opposite flow detection	++	++	oo	o	o
c. Running detection [1]	++	++	oo	-	-
d. Tail-gating detection	++	++	oo	-	-
e. Loitering detection	++	+	-	-	-
f. Fall detection	++	oo	-	-	-
Crowd Analysis					
a. Density estimation	n/a		oo	oo	oo
b. Rapid dispersion			oo	oo	oo
c. Crowd formation			oo	oo	oo
d. Crowd Splitting			o	-	-
e. Crowd Merging			o	-	-
Baggage Detection and Tracking					
a. Static Object (>n sec)	+	+[1]	o[1,2]	-	-
b. Object removal	o[2]	o[2]	-	-	-
c. Dropping Object	o[2]	o[2]	-	-	-
d. Abandoned Object	o[2]	o[2]	-	-	-
e. Unattended Object	o[2]	o[2]	-	-	-
f. Carried Object	-	-	-	-	-
Person-Baggage Association Analysis					
a. Person-Baggage Association	o	-	-	-	-
b. Owner change	-	-	-	-	-
Camera Tampering Detection					
Occlusion, Focus moved, Camera moved	++	++	++	++	+
Physical Security					
Virtual trip-wire, intrusion detection	++	++	++	++	+

1. For low traffic only.
2. For large objects only.
3. The references to the acesearch/prototypes and commercial technologies that were used in the assessment are provided in [6-8].

REFERENCES

1. D. Gorodnichy, M. A. Ali, E. Dubrofsky, K. Woodbeck. Zoom on Evidence with the ACE Surveillance, CRV International Workshop on Video Processing and Recognition (VideoRec'07), May 28-30, 2007. Montreal. Online: http://www.computer-vision.org/VideoRec07/program.html
2. D. Gorodnichy and T. Mungham. Automated video surveillance: challenges and solutions. ACE Surveillance (Annotated Critical Evidence) case study. NATO SET-125 Symposium "Sensor and Technology for Defense against Terrorism", 2008. Online: https://www.researchgate.net/publication/229040125_Automated_video_surveillance_challenges_and_solutions_ACE_Surveillance_Annotated_Critical_Evidence_case_study
3. D. Gorodnichy, J.-P. Bergeron, D. Bissessar, E. Choy, J. Sciandra, "Video Analytics technology: the foundations, market analysis and demonstrations", Technical Report DRDC-RDDC-2014-C251. http://cradpdf.drdc-rddc.gc.ca/PDFS/unc167/p801081_A1b.pdf
4. D. Gorodnichy. "Recognition in Video" , University of Toronto IPSI Public Lecture Series, November 2009. Online: Appendix E, ibid (http://cradpdf.drdc-rddc.gc.ca/PDFS/unc167/p801081_A1b.pdf)
5. D. Gorodnichy and E. Dubrofsky. VAP/VAT: Video Analytics Platform and Test Bed for Testing and Deploying Video Analytics. In Proceedings of SPIE Volume 7667: Conference on Defense, Security and Sensing, 2010
6. D. Gorodnichy, D. Macrini, R. Laganiere, "Video analytics evaluation: survey of datasets, performance metrics and approaches ", Technical Report DRDC-RDDC-2014-C248. Online: http://cradpdf.drdc-rddc.gc.ca/PDFS/unc167/p801081_A1b.pdf
7. D. Macrini, V. Khoshaein, G. Moradian, C. Whitten, D.O. Gorodnichy, R. Laganiere, "The Current State and TRL Assessment of People Tracking Technology for Video Surveillance applications", DRDC-RDDC-2014-C293. : http://cradpdf.drdc-rddc.gc.ca/PDFS/unc161/p800731_A1b.pdf
8. C. Whiten, R. Laganiére, E. Fazl-Ersi, F. Shi, G. Bilodeau, D. O. Gorodnichy, J. Bergeron, E. Choy, D. Bissessar . VIVA-uOttawa / CBSA at TRECVID 2012: Interactive Surveillance Event Detection. Online: http://www-nlpir.nist.gov/projects/tvpubs/tv.pubs.12.org.html
9. D. Gorodnichy and E.Granger, "Evaluation of Face Recognition for Video Surveillance ". NIST International Biometric Performance Conference (IBPC 2012), Gaithersburg, March 5-9, 2012. Online: http://www.nist.gov/itl/iad/ig/ibpc2012.cfm .
10. D. Gorodnichy and E. Granger " PROVE-IT(FRiV): framework and results ". NIST International Biometrics Performance Conference (IBPC 2014), Gaithersburg, MD, April 1-4, 2014. Online: http://www.nist.gov/itl/iad/ig/ibpc2014.cfm .
11. D. Bissessar, E. Choy, D. Gorodnichy, T. Mungham, "Face Recognition and Event Detection in Video: An Overview of PROVE-IT Projects (BIOM401 and BTS402)", Technical Report DRDC-RDDC-2014-C167. Online: http://cradpdf.drdc-rddc.gc.ca/PDFS/unc157/p800402_A1b.pdf
12. D. Gorodnichy, E.Granger, and P. Radtke, "Survey of commercial technologies for face recognition in video ", Technical Report DRDC-RDDC-2014-C245. Online: http://cradpdf.drdc-rddc.gc.ca/PDFS/unc159/p800510_A1b.pdf
13. E. Granger, P. Radtke, and D. Gorodnichy, "Survey of academic research and prototypes for face recognition in video ", Technical Report DRDC-RDDC-2014-C246. Online: http://cradpdf.drdc-rddc.gc.ca/PDFS/unc167/p800522.pdf
14. E. Granger and D. Gorodnichy, "Evaluation methodology for face recognition technology in video surveillance applications", Technical Report DRDC-RDDC-2014-C249. Online: http://cradpdf.drdc-rddc.gc.ca/PDFS/unc167/p800519_A1b.pdf
15. E. Granger, D. Gorodnichy, E. Choy,. Khreich, P. Radtke, J.-P. Bergeron, D. Bissessar, "Results from evaluation of three commercial off-the-shelf face recognition systems on Chokepoint dataset", DRDC-RDDC-2014-C247. : http://cradpdf.drdc-rddc.gc.ca/PDFS/unc167/p800520_A1b.pdf
16. D. Gorodnichy and Eric Granger, Target-based evaluation of face recognition technology for video surveillance applications , Proc. of IEEE SSCI CIBIM 2014 workshop, Orlando, December 2014.
17. J.-P. Bergeron and D. Bissessar, "Accelerated Evidence Search Report", DRDC-RDDC-2014-C166. Online: http://cradpdf.drdc-rddc.gc.ca/PDFS/unc159/p800470_A1b.pdf
18. DRDC website: "Government of Canada invests in Canada's Safety and Security" (January 29, 2014), http://www.drdc-rddc.gc.ca/en/dynamic-article.page?doc=government-of-canada-invests-in-canada-s-safety-and-security/hr0e3lxs
19. D. Gorodnichy. New age glossary of biometric terms for automated border control and video surveillance applications, CBSA Border Technology Division Report 2016-05.
20. ISO/IEC JTC 1/SC 37/WG 4 WD 30137-1, Information technology – Use of biometrics in video surveillance systems – Part 1: Design and specification, 2016-04-22

Canadian Image Processing and Pattern Recognition Society (CIPPRS), 13th Conference on Computer and Robot Vision (CRV), Victoria, May 31 - June 3, 2016 (Indexed by IEEExlore)

[1]Science and Engineering Directorate, Canada Border Services Agency , [2]École de technologie supérieure, Université du Québec, [3]School of Computer Science and Electrical Engineering, University of Ottawa

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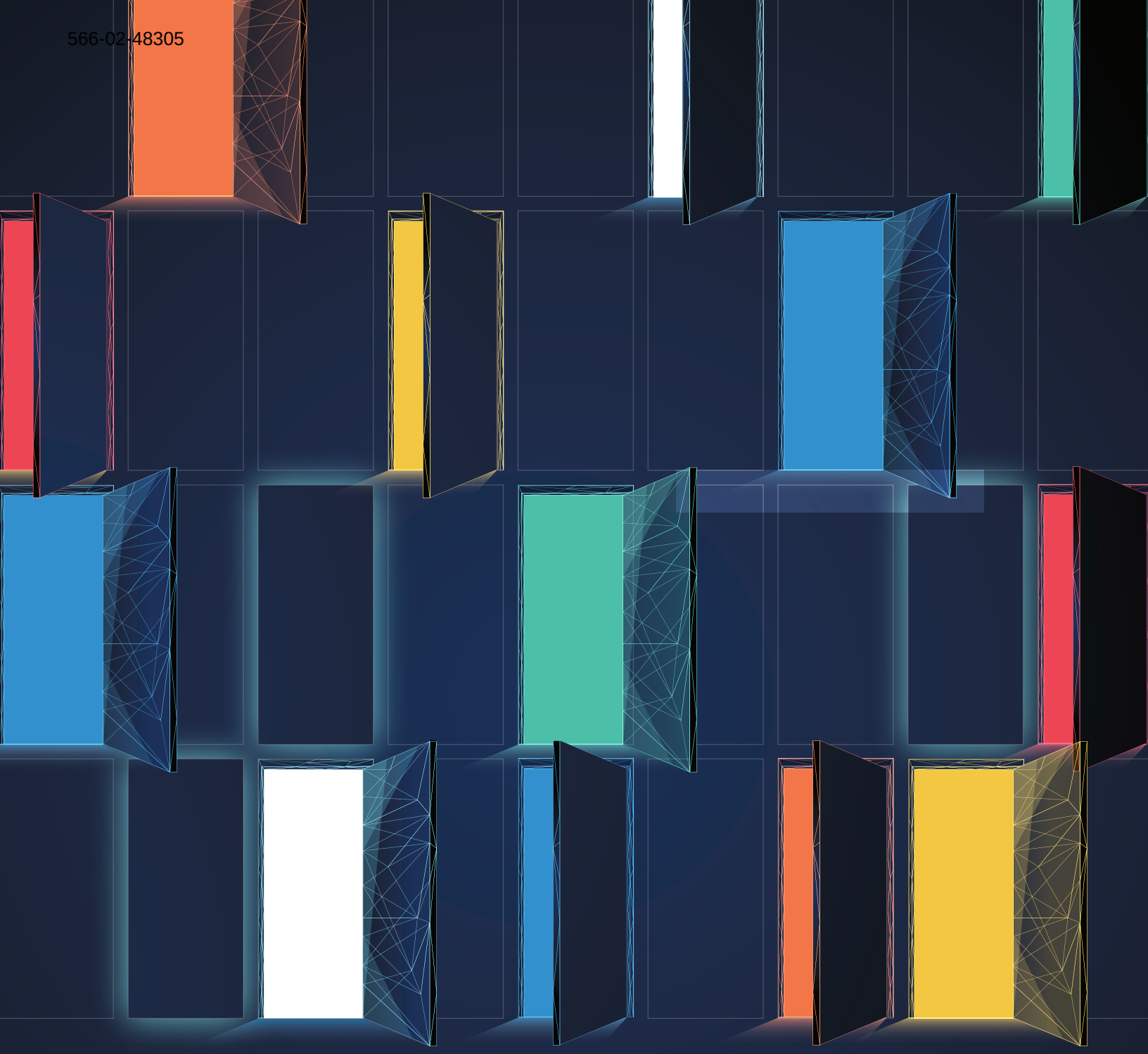

A Framework for **Implementing Open-by-Default** with Federal Government Science

JANUARY 2021

Office of the Chief Science Advisor of Canada
Bureau du conseiller scientifique en chef du Canada

Canada

Office of the Chief Science Advisor
235 Queen Street
Ottawa, Ontario
K1A 0H5 Canada

science@canada.ca

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A Framework for **Implementing Open-by-Default** with Federal Government Science

JANUARY 2021

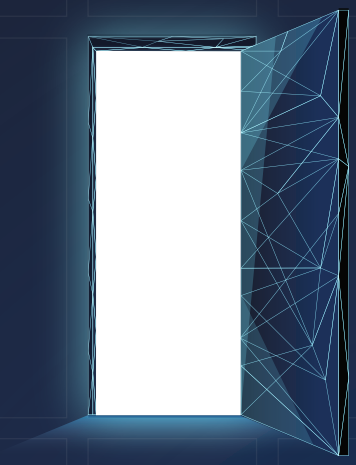

Table of Contents

Preamble 1

1 Introduction 2

2 Definitions 4

3 Objectives and expected results 6

4 Application criteria for managing open-by-default . . . 11

5 Requirements and roles of organizations 24

6 Effective date and Duration 28

7 References and resource list 30

8 Decision tree for releasing scientific information 33

9 Life-cycle management of projects and programs 35

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Preamble

Around the world, researchers and decision makers are becoming increasingly aware of the value and importance of open science. With the growing body of evidence that scientists engaged in global collaboration can achieve breakthroughs far more quickly than individual research teams, there is strong momentum behind fully open science.

We have seen the value of this approach most recently in the response to COVID-19. Canadian science funding organizations signed a joint statement in early 2020 to openly share COVID-19 research data and findings. In addition, I and my counterparts from 15 countries issued a joint call for open access to COVID-19 publications in March 2020. Both these initiatives were well received by the global publishing community, and the vast majority of coronavirus research is now open. Moreover, the Government of Canada's COVID-19 data is freely available online, providing citizens with reliable information and empowering them to make informed decisions about their lives. The COVID-19 crisis has shown how open-science practices can accelerate discovery and increase trust in both science and science-informed government policies.

Canada's commitment to open science predates the pandemic. In fact, when I was appointed Canada's Chief Science Advisor over 3 years ago, I was asked to provide guidelines to ensure that government science is available to the public. To achieve that goal, I worked with international and domestic colleagues to develop the Roadmap for Open Science, announced by the Honourable Navdeep Bains, Minister of Innovation, Science and Industry, in February 2020.

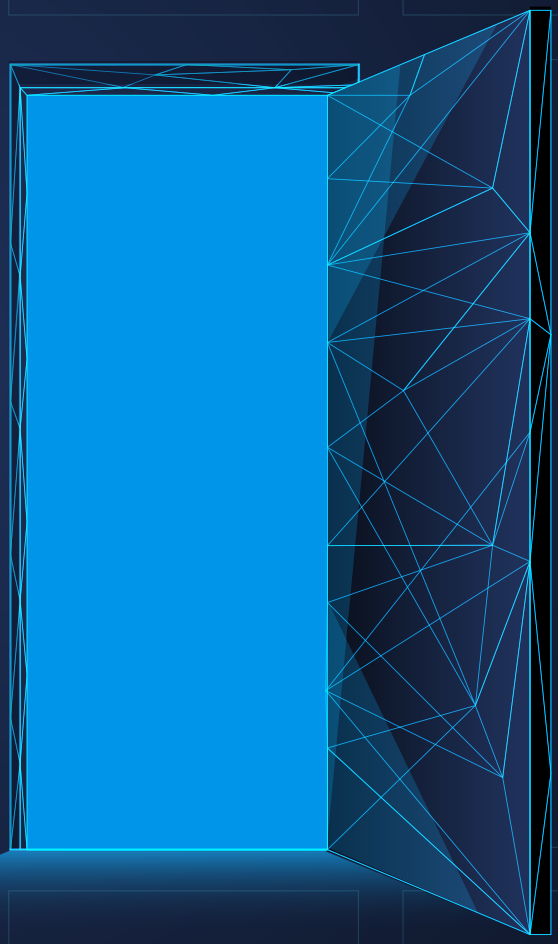
This guidance document is one of a series of actions stemming from the Roadmap to support scientists with the timely release of federal research outputs, either conducted or funded by the organization, while presenting criteria on how to manage privacy, security, ethical considerations and appropriate intellectual property protection. This document has incorporated open-by-design as part of its approach to implementing the Roadmap.

I want to acknowledge the work of all the Open-by-Default Framework committee members who brought diverse perspectives to the drafting of this guidance document, namely Corinne Charette, Jonathon Dewar, Sarah Gallagher, Brian Gray, Jean-François Morel, Isabelle Steers, Carolyn Watters and Rita Whittle. I particularly want to thank George Enei for his leadership in chairing the committee. The committee worked diligently under tight timelines and during the COVID-19 pandemic, and was further informed thanks to the thoughtful feedback received from federal departments, agencies, granting councils, and thought leaders throughout the public service and academia.

This guidance will be the object of review and improvement in the years to come. I look forward to working together and making science accessible to all.

Mona Nemer, Chief Science Advisor of Canada

1 Introduction



This document was developed in response to the need for common guidance in the application of the Roadmap for Open Science, more specifically, Recommendation 6, which calls for "a framework identifying criteria for when restricting access to federal scientific research outputs is warranted."

The Roadmap highlights open-by-default as a founding tenet of managing the availability of scientific research outputs. Similarly, the Directive on Open Government aims to "maximize the release of government information and data of business value to support transparency, accountability, citizen engagement, and socio-economic benefits through reuse, subject to applicable restrictions associated with privacy, confidentiality, and security." In line with the Roadmap and the Directive, the Model Policy on Scientific Integrity recognizes that the timely release of scientific and research information is integral to the culture of government scientific integrity and instrumental to public trust in science.

The information in this guidance document has been developed using a variety of sources, from legislation to best management practices. There is no new policy presented. The aim of this guidance document is to support federal scientists in departments and agencies, who partner with access to information and privacy (ATIP), intellectual property (IP) and information management (IM) officers and other subject-matter experts, to ensure the timely, secure and resource-effective release of the outputs of federal research, either conducted or funded by the organization. The guidance document supports implementation by outlining criteria on which decisions to withhold publication should be based. It should be used to guide all decisions going forward as of the document's effective date. Scientific research outputs should be accessible when there is no justification for them to remain closed.

The guidance document is a model that can be adopted or adapted by individual federal departments or agencies on the basis of their disciplinary norms and operating circumstances (for example, defence, national security and health).

All hyperlinks and references to legislation and policy instruments are current at the time of publication.

2 Definitions



The following definitions reflect or build upon those presented in the Roadmap for Open Science:

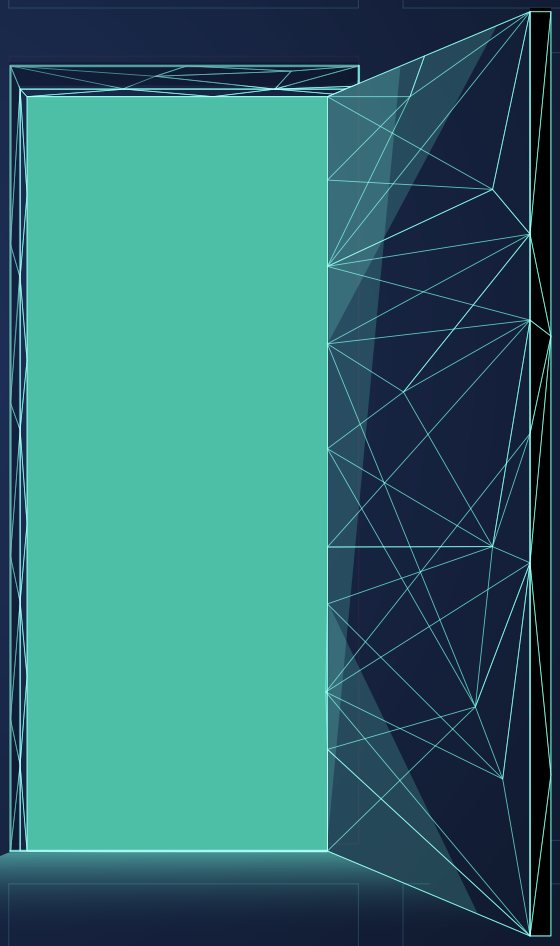
- **Open science:** The practice of making scientific inputs, outputs and processes freely available to all with minimal restrictions. Open science is enabled by people, technology and infrastructure. It is practised in full respect of privacy, security, ethical considerations and appropriate intellectual property protection.
- **Technology:** The branch of knowledge that deals with the creation and use of technical means and their interrelation with life, society and the environment, drawing upon such subjects as industrial arts, engineering, applied science and pure science.
- **Science:** The pursuit and application of knowledge and understanding of the natural world through application of one or more elements of the scientific method. In the context of this roadmap, it is understood to include both fundamental and applied natural, physical, biomedical and social science, as well as engineering and mathematics.
- **Scientific research outputs:** These include, but are not limited to, peer-reviewed science articles and publications, scientific and research data, and contributions to public dialogue about science.

The Roadmap recommendations focus on the following outputs of federal scientific research, either conducted or funded by the organization:

- **Federal science articles:** Scholarly articles authored or co-authored by federal scientists or researchers in peer-reviewed academic journals.
- **Federal science publications:** Scientific communications that scientists and researchers use to share their work. These include research or scientific reports, monographs, edited books, book chapters, conference proceedings, conference papers, conference contributions, posters, plain-language summaries and technical scientific products.
- **Scientific and research data:** Data that include, but are not limited to, observational, monitoring, operational, modelling and simulation, risk assessment, survey and surveillance, diagnostics and targeted survey, research and development, and technology innovation data.

Each of the categories above (articles, publications and data) includes tools such as software and protocols used for the development of the scientific research output.

3 Objectives and expected results



3.1 Keeping pace with a changing environment

Scientific knowledge and associated technologies continue to evolve. Digital technologies have rapidly influenced the growth, storage and sharing of knowledge. Government must keep pace with this evolution through policy development and regulatory reform.

Open-by-default is a principle that assists federal science organizations in achieving government transparency and accountability. It also contributes to the potential for new discoveries and collaborations in areas not traditionally considered. COVID-19 has clearly demonstrated the possibilities of non-traditional partnerships based on purpose-driven discovery with new publicly available information.

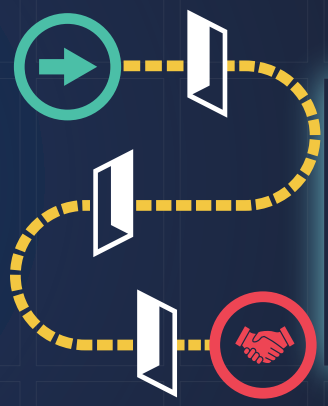
This document is intended to support federal scientists in managing open-by-default decision making. The advice contained in this document is not intended to be read in isolation, but rather, in conjunction with existing government policies and procedures for information management. For complex cases, where additional guidance is needed, an advisory committee led by the Office of the Chief Science Advisor can provide additional feedback to aid organizational decision making. The decision to keep certain research outputs closed ultimately lies with the departments or agencies that produced the output.

3.2 Ensuring scientific discovery and collaboration are supported

Releasing scientific information contributes to the growth and advancement of knowledge, and is a critical component of the scientific process because it enables others to reproduce and validate scientific results. In addition, the sharing of data and results provides the opportunity for new scientific discoveries. It also facilitates scientific cooperation across organizations and jurisdictions, creates economic growth through better opportunities for innovation, increases resource efficiency, improves transparency and accountability in the disbursement of public funds, and increases transparency to ensure greater public trust in research. The open publication of scientific results is a pillar of digital science practices, which enable collaboration and problem solving on an unprecedented scale.

Enhanced access, however, also bears associated risks related to privacy, intellectual property, national security, constitutional and other commitments to Indigenous peoples, and the public interest. These risks need to be adequately communicated and responsibly managed. Legislation, regulations and directives on information management are available (see section 7 for a list of domestic and select international references and

COVID-19 has clearly demonstrated the possibilities of non-traditional partnerships based on purpose-driven discovery with new publicly available information.



resources), but there is no specific federal guidance document aimed at the federal scientist, working with ATIP officers, to guide assessment on whether it is appropriate to withhold scientific outputs from disclosure. Responsibly managing these risks also involves working with IP and IM officers to determine the approach and tools to be used to achieve the right degree of openness and security.

Federal science-based departments and agencies have to make decisions about managing access and the timing of access to scientific results as part of implementing the Model Policy on Scientific Integrity and the Directive on Open Government, as well as fulfill their commitment to the overarching principles of Canada's Roadmap for Open Science. Those documents work in parallel to manage open-by-default for the design, conduct, communication, management and review of research, science or related activities.

3.3 Applying existing government information and management policies to scientific research

Release of scientific research outputs should always conform to current legal, ethical and regulatory frameworks. Relevant acts and directives include the following:

- The *Access to Information Act* gives Canadian citizens, permanent residents, and any person or corporation present in Canada the right to access records of government institutions that are subject to the Act. The *Access to Information Act* provides that any necessary exemptions should be limited and specific.
- The *Privacy Act* gives Canadian citizens, permanent residents, and individuals present in Canada the right to access their personal information held by government institutions that are subject to the Act, and protects that information against unauthorized collection, use, retention and disclosure. The Act is complemented by other acts and procedures for access to personal information, such as the Interim Policy on Privacy Protection.
- Other acts, notably those related to the implementation of the Chemical Weapons Convention, the Biological and Toxin Weapons Convention, the Defence Production Act, or acts governing explosives, controlled goods or export and import permits, may also apply.
- The Directive on Open Government aims to maximize the release of government information and data of business value to support transparency, accountability, citizen engagement, and socio-economic benefits through reuse, subject to applicable restrictions associated with privacy, confidentiality and security. All data resources of business value held by Government of Canada departments should be open by default and released as open data unless subject to valid exceptions such as ownership, security, privacy and confidentiality, as determined by the department. The Treasury Board of Canada Secretariat (TBS) has supported departments and agencies in the development of their decision-making and approval processes for legal and policy issues by providing a release criteria checklist and other guidance tools.
- The objective of the Roadmap for Open Science is to provide overarching principles and recommendations to guide open science in Canada. The recommendations are intended for use by scientists and researchers in federal government departments and agencies.
- The Model Policy on Scientific Integrity supports and promotes scientific integrity in the design, conduct, management, review and communication of research, science, and related activities. Scientific organizations recognize that stakeholder trust in the research and scientific information provided by the federal government depends upon the integrity of the process by which such information is produced, managed and communicated. Furthermore, federal organizations recognize that scientists and researchers must uphold and conform to standards of excellence accepted by the wider research and scientific community. In the absence of clear and compelling reasons for limiting disclosure, research and scientific information produced by federal organizations should be made available to the public in a timely, secure and resource-effective manner and in keeping with the Government of Canada's Directive on Open Government.

The objective of the Roadmap for Open Science is to provide overarching principles and recommendations to guide open science in Canada. The recommendations are intended for use by scientists and researchers in federal government departments and agencies.



- The Values and Ethics Code for the Public Sector (Public Sector Code) outlines the values and expected behaviours that guide public servants in all activities related to their professional duties. By committing to these values and adhering to the expected behaviours, public servants strengthen the ethical culture of the public sector and contribute to public confidence in all public institutions. Adherence to the Public Sector Code is one of the terms and conditions of employment. The Public Sector Code lists 5 values: respect for democracy, respect for people, integrity, stewardship and excellence.
- The Policy on Government Security sets out expectations, responsibilities and consequences for all employees of the Government of Canada, including safeguarding information and assets under their control, whether working on site or off site; participating in security awareness and training activities to maintain awareness of security concerns, issues and responsibilities; and maintaining vigilance and reporting changes in circumstances, potential security deficiencies, security incidents, and other security issues through appropriate departmental channels. In addition, a valid security status or security clearance is a condition of employment, contract, appointment or assignment and it may also be established as a condition for other individuals external to government with whom government may need to share or provide access to sensitive or classified information or assets, or access to facilities. Access to sensitive information, assets or facilities is a privilege, not a right. When individuals are granted a security status or clearance, they accept the responsibility for using, handling and protecting sensitive information, assets or facilities that accompany this privilege.

3.4 Sharing and employing best practices

Scientists have a responsibility to communicate their work to their peers and to the public. This has always been part of the scientific method, but the tools for communication have differed throughout the years and differ by field of inquiry.

The work of government scientists supports a range of program and policy objectives. At the heart of any scientific research output is the generation of knowledge, and the validity and impact of the outputs relies on their veracity and reproducibility. Open-by-default is a means to that end and its incorporation at the start of a project and its inclusion in ongoing management decisions supports an open-by-design culture.

The unique aspects of practising science create conditions that may make it difficult to practise open-by-default. Owing to an incentive system based largely on publication in specialized journals that are usually associated with commercial publishers, not all outputs are open access. Canada and other nations, through international commitments and domestic prioritization, are moving towards publishing scientific research outputs and making them available in a transparent manner through public fora so that they can be accessible, verifiable and reproducible. The ideas that follow are suggestions, when possible and appropriate, for best practices to achieve these goals:

- Adopt an open-by-design approach by incorporating best practices at the start of the planning phase of scientific projects.
- Provide incentives to federal scientists (for example, by giving greater weight to practising open-by-default in research promotion boards).
- Create systems and provide infrastructure that facilitate disclosure (for example, inventory of pre-approved information sources for automated release; software and tools for better management of information).
- Use technology and processes (such as data in machine-readable formats) to help achieve organizational goals for open-by-default and create an organizational culture that will ensure success.
- Maintain inventories of information holdings, document rationales for not releasing information, employ adaptive management to review the rationales, and have metrics on the use of information / disclosed information, which are all hallmarks of good open-by-default science practices.
- Encourage continuous learning for employees, students, contractors and partners to build awareness and a breadth and depth of understanding that will support data integrity (for example, engaging in discussions about open and reproducible science, especially when it comes to training new scientists and at the design stage of project planning).
- When conducting peer review as an editor, reviewer or dissertation evaluator, consider the evaluated researcher's commitment to and practise of open-by-default based on the availability of their data, publications, etc.

Additional guidance for best practices at different stages of life-cycle management of projects and programs is provided in section 9.



4 Application criteria for managing open-by-default

Open-by-default is the operating premise for managing the availability of scientific research outputs; it applies to all science in the federal government, either conducted or funded by an organization. The guidance below discusses three common factors, as well as specific criteria for defining appropriate access to research outputs, that support scientists, who partner with ATIP, IP and IM officers, when considering the release of scientific research outputs.

The following tabular depiction is designed to help the reader with decision making, with references to the appropriate sections provided. As a complement, a decision tree for releasing scientific research outputs is provided in section 8.



Open-by-default is the operating premise when reviewing information. Any rationale for withholding information, in part or in whole, would need to consider the following common issues:

- ☐ Do the exemption or exclusion provisions set out in the *Access to Information Act* or *Privacy Act* apply to the information? Should an exemption or exclusion be requested under one of those acts? Does all of the information need to be withheld, or can a portion of it be released? (section 4.1.1)
- ☐ Does the scientific information in question, on its own or in combination with other information or data sets, reveal information that was not intended to be shared? If so, this information may need to be anonymized, reformatted, licensed or explicitly assigned to a single party before it is released. (section 4.1.2)
- ☐ Does the preparation of the information for release create an operational burden on the organization that is not commensurate with the value of the information? (section 4.1.3)

Theme-specific considerations:

- ☐ Does the open-by-default release involve Canadian individuals or businesses? Have you considered:
  - personal information, including health information (section 4.2.1.1)
  - external (third party) information (section 4.2.1.2)
  - information obtained in confidence (section 4.2.1.3)
- ☐ Does the open-by-default release involve Indigenous rights or community or regional impacts? Have you considered:
  - Indigenous knowledge and data (section 4.2.2.1)
  - federal–provincial–territorial affairs (section 4.2.2.2)
- ☐ Does the open-by-default release involve economic considerations? Have you considered:
  - economic or strategic interests of Canada (section 4.2.3.1)
  - patents, trademarks and intellectual property (section 4.2.3.2)
- ☐ Does the open-by-default release involve security concerns? Have you considered:
  - hazardous materials; toxic industrial chemicals; and chemical, biological, radiological, nuclear or explosive (CBRNE) research (section 4.2.4.1)
  - dual-use research of concern (section 4.2.4.2)
  - the safety of individuals (section 4.2.4.3)
  - international affairs and defence (section 4.2.4.4)
  - law enforcement and investigations (section 4.2.4.5)
  - government operations (section 4.2.4.6)

4.1 Common issues to be assessed for any open-by-default exceptions

4.1.1 *Access to Information Act* and *Privacy Act* exemptions to scientific research outputs

In general, the *Access to Information Act* affords any Canadian citizen or permanent resident and any individual or any corporation present in Canada the right to access records under the control of the federal government, unless there is a specific provision in the Act that permits or requires the head of the government institution to refuse to disclose the information.

Restrictions on the release of information generally apply to federal–provincial affairs; international affairs and defence; law enforcement and investigations; national security; safety of individuals; and economic interests of Canada.

The discretion to disclose or withhold information in the above categories can only be exercised by the head of a government institution or by an individual that the head has designated in writing for this purpose. The operational underpinning is to release information unless there is a rationale to limit its release.

The *Privacy Act* sets out privacy rights in citizen interactions with the federal government. It applies to how the government collects, uses and discloses your personal information. The *Privacy Act* protects your personal information that government institutions hold. The Act also gives you the right to access your personal information held by the federal government.

Personal information under the control of a government institution cannot be disclosed without your consent except in specific circumstances, such as:

- For the original purpose for which the information was collected or a use consistent with that purpose
- Where the disclosure is authorized in federal legislation
- To comply with subpoenas, warrants or orders of a court or another body with authority to compel information
- Where disclosure would clearly benefit the individual
- Where the public interest in disclosure outweighs any invasion of privacy

If any of the above are relevant to the federal science outputs, then they would be governed by the legislation in place to deal with information releases. In such cases, the organization's ATIP officers should be consulted.

4.1.2 The right degree of openness and balancing benefits and risks

A large majority of federal science outputs should fall outside the limited and specific scope of *Access to Information Act* exemptions and exclusions. An effort should be made to make that information available to citizens and other scientists. Managing the open-by-default principle becomes a question of finding the right degree of openness and the right timing if there are limitations on what can be released and how it can be released.

In assessing the release of scientific research outputs, a reviewer must characterize the value and impact of the information and determine whether degrees of openness could be considered in the case of sensitive information. The Organisation for Economic Co-operation and Development (OECD) identifies degrees of openness to enhance access to information:[1]

- Open access with open licence
- Public access with a specific licence that limits use
- Group-based access through authentication
- Named access explicitly assigned by contract

There may also be opportunities to make metadata openly available without sharing the science product itself up front.

1 OECD (2020), Enhanced Access to Publicly Funded Data for Science, Technology and Innovation.

A scientist, partnering with ATIP, IP and IM officers, must weigh all the options, noting the rationale for limiting release and the benefits that can be achieved through openness:

- Balance the potential risks with the benefits of making information available/partially available. The impacts of not making it available should also be made explicit.
- Develop and apply an injury test for the risk involved. More specifically, determine what the plausible negative impacts could be from the release of information.
- Consider all possible research outputs and whether they have in part or in whole been made publicly available by another organization.
- Factor in timelines for release (for example, what may not be okay for release today may be fine tomorrow, or vice-versa).

It should also be noted that in cases where private or foreign funding is involved (such as Global Affairs Canada's Canadian International Innovation Program), the project partners will have negotiated the rights to the background and foreground intellectual property. It is also possible that the private or foreign research partners could be subject to laws and policies dealing with the openness, or not, of research outputs, as a consequence of the funding. Accordingly, when private or foreign partners are involved, the rights of these partners to the scientific research outputs and the possible applicability of laws and policies to these outputs (inasmuch as they were co-funded by Canadian and foreign sources) should be considered.

4.1.3 Burden and cost

Decisions concerning open-by-default should be made at the design stage of a science experiment or project, thereby creating an open-by-design foundation. This includes, for example, support and costs for consultations when the data or information involves Indigenous communities, personnel and systems for information management and release, as well as consultation with subject-matters experts such as ATIP or IP officers.

Injury test: Under the *Access to Information Act*, an injury test considers whether disclosure of the information could reasonably be expected to prove harmful or damaging to the specific public or private interest covered by the disclosure. The fact that the disclosure could result in administrative change in a government institution is not sufficient to satisfy an injury test. Under the law, it must be possible to identify an actual detrimental effect on the interest specified in the exemption.



An ATIP officer can be consulted for further information.

The science community is concerned that information management costs are steadily rising. This could reflect the steady increase in the volume of information, greater emphasis on information management, and growing demand for information witnessed in science.

Combining open-by-default with publication in machine-readable format will improve access to the volume and variety of government information. From a pragmatic perspective, limited resources and infrastructure may force some form of prioritization in terms of what is made open and through what mechanism. The Roadmap for Open Science's recommendation on release of federal science articles and publications (Recommendation 4) applies only to new publications, with legacy publications to be shared upon request in the context of a "responsive action plan [that] should be developed to share publications requested with time-bound commitment for delivery."

With respect to official languages, when federal organizations provide information to the public, it must make that information equally accessible in either official language. Note that if a federal scientific research output is made available in a peer-reviewed journal, a conference proceeding, or an article published in a non-government publication, it can be provided in the language in which it was written, although a number of departments, as a good practice, provide abstracts in both official languages.

The objective of the TBS Policy on Financial Management is that the financial resources of the Government of Canada are well managed in the delivery of programs to Canadians and safeguarded through balanced controls that enable flexibility and manage risk. Parliament expects that government programs be delivered in keeping with the needs of citizens served by those programs and broader public expectations. The taxpayer expects that all programs be delivered prudently and with due regard for the funds entrusted. The government's policy on cost recovery directs that users should pay a fair share for services received. These priorities must be balanced and, while they at times appear to be at cross-purposes, opportunities exist to complement access with the degree of openness.

In cases where the decision was not made at the design phase, a scientist should consider how much work is needed to make scientific research outputs accessible (no metadata, no obvious place to publish it, etc.) and whether a partial or targeted release that is operationally possible would meet the spirit and intent of open-by-default. For example, there could be an opportunity to lower the cost of making federal science open using pre-prints as an alternative to the open-access gold standard of paying article processing charges.

Producing an inventory of holdings, information and related sensitivity statements, by department or agency, and building processes and infrastructure for automated or procedural release of information commensurate with risk, could be used to help scientists manage workflow in departments and agencies, create equitable access, and minimize errors in judgment with the release of higher-risk information. For example:

- Automated provisions to address the issue of large data sets (such as data streams from monitoring stations) or information that is cyclical in nature (such as background analyses for public annual reports)
- Measures to aggregate requests for information where multiple requests are made by one person

In exceptional cases, consideration could be given to the introduction of a cost threshold over which a department or agency would not be expected to release information without support. This recognizes the need to ensure the continuity of other public programs and the need to manage financial resources prudently given the resource implications a release can have on other operations.

4.2 Specific issues to be assessed for any open-by-default exceptions

4.2.1 Information about Canadian individuals or businesses

4.2.1.1 Personal information, including health information

If the scientific research output contains information about an identifiable individual that is recorded in any form, there is most likely a rationale for limiting access. This includes a situation in which there is a serious possibility that an individual could be identified from the information alone or in combination with other available information. It should be noted that specific policies are in place for personal health records and other such information for scientific research.

Examples of personal or health information include:

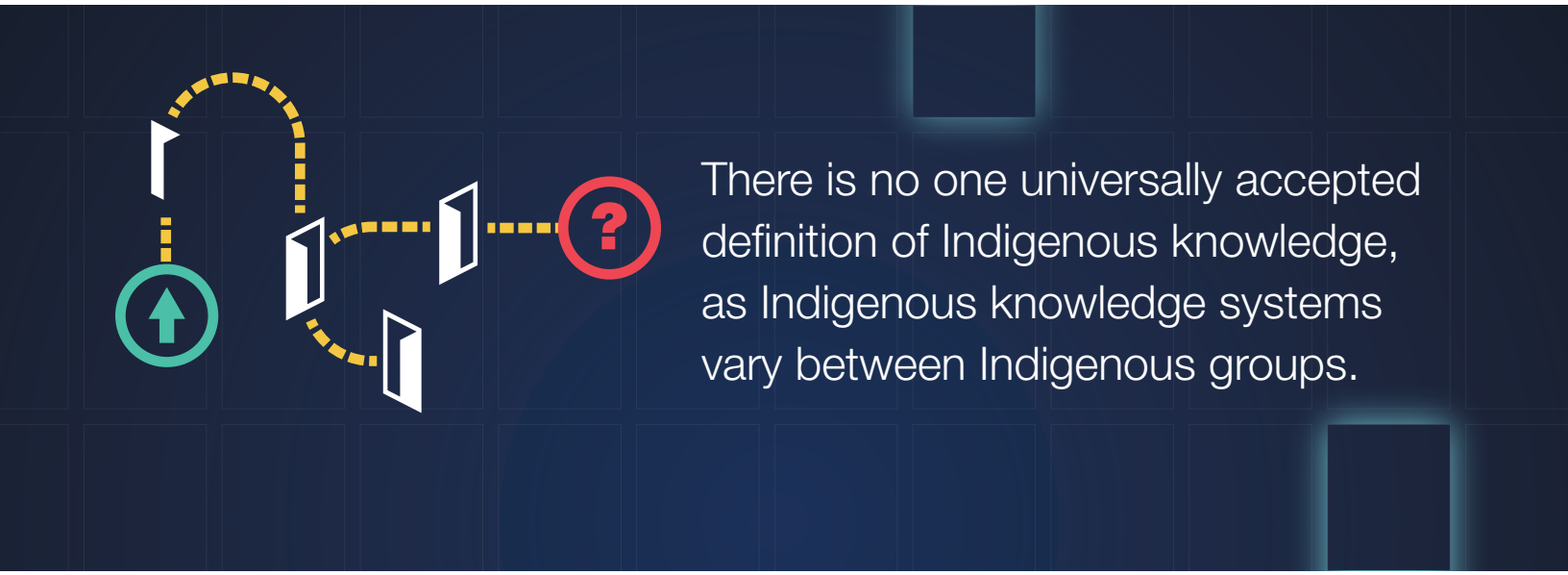
- DNA or related information (for example, test results) that can be linked to an identifiable individual
- Information about income, revenue, or enrolment in certain government programs (for example, gender-based programs, religious information)

Respect for personal privacy is a core principle of research ethics, and it is managed by making records confidential, anonymizing data, or collecting anonymous data. Further steps, such as data aggregation or noise injection, enable sharing while protecting privacy.

Having access to disaggregated "individual level" information is important for research such as Gender Based Analysis+ (GBA+). GBA+ is a process for examining how various intersecting identity factors affect the effectiveness of government initiatives. It involves examining disaggregated data and research, and considering social, economic and cultural conditions and norms. The benefit of such research is to more effectively respond to the challenges of an increasingly diversified Canadian population. Controlled access (for example, Statistics Canada microdata access portal) can be a way to enable access for legitimate research purposes.

If the scientific research output contains information about an identifiable individual that is recorded in any form, there is most likely a rationale for limiting access.





4.2.1.2 External (third party) information

If the scientific research output includes or is based on information produced or owned by someone other than the federal government, and this information is not already public and is treated consistently in a confidential manner by the owner, there may be a rationale for limiting access. For example, this could occur if the scientific research outputs are based on or reference:

- Trade secrets
- Confidential science and technology information
- Certain emergency management plans

Protecting sensitive external information is important in order to build trust and facilitate the exchange of information between Government of Canada scientists and others.

Enhancing access to such information may require convincing the information owner of the benefit of sharing, or considering from the outset the option of instituting research environments that create a protected and secure IT viewing environment based on sharing arrangements, such as research networks or patent pooling.

4.2.1.3 Information obtained in confidence

There would be limitations on the release of information if the scientific research outputs included information received in confidence from the following parties:

- The government of a foreign state or an institution thereof
- An international organization of states or an institution thereof, such as the United Nations or the OECD
- The government of a province or an institution thereof
- A municipal or regional government
- An Indigenous community or organization

The term “in confidence” is usually applied to information obtained with the explicit understanding that it must remain confidential. If the scientific research output involves information obtained in confidence, the organization’s ATIP officers and chief security officer should be consulted.

4.2.2 Impacts on Indigenous rights and provincial–territorial impacts

4.2.2.1 Indigenous knowledge and data

The Canadian Constitution recognizes three groups of Aboriginal[2] peoples: Indians (more commonly referred to as First Nations), Inuit and Métis. These are three distinct peoples with unique histories, languages, cultural practices, spiritual beliefs, and inherent, treaty and/or constitutional rights.

There is no one universally accepted definition of Indigenous knowledge, as Indigenous knowledge systems vary between Indigenous groups. For the purposes of this document, Indigenous knowledge and data are defined as information about Indigenous peoples (population, health, employment, etc.), information from Indigenous peoples (music, dance, arts, language, etc.), and information about Indigenous peoples' lands, waters and environment. Indigenous knowledge is cumulative and dynamic. It builds upon the historic experiences of a people and adapts to social, economic, environmental, spiritual and political change.

Partnering with Indigenous communities and co-developing scientific studies from the planning phase onward is the best way to help enhance access to science research outputs in a way that is respectful and beneficial for all. There is a rationale for restricting access if the research output contains or is informed by Indigenous knowledge and data, or could likely harm Indigenous communities and peoples if released.

Federal departments and institutions are legally obliged to respect Indigenous peoples' inherent, treaty and constitutional rights to self-determination and self-government. The Crown has made commitments to adhere to free, prior and informed consent; respect Nation-to-Nation (for First Nations), Crown–Inuit and government-to-government (for the Métis Nation) relationships; and recognize the distinct customs of Nations in any interaction involving the public release of Indigenous data and information.

First Nations expect federal departments and institutions to respect the First Nations Principles of OCAP®. OCAP® stands for First Nations ownership, control, access and possession of First Nations knowledge and data. Priority area 4 of the National Inuit Strategy on Research (2018) describes expectations for partnership in research premised on self-determination, respect and transparency in terms of Inuit access, ownership and control over data and information on Inuit peoples. Métis Nation organizations have Métis-specific, culturally competent, ethical health research principles that are a starting point for engaging Métis communities in ethical research (Principles of Ethical Métis Research). Regardless, federal scientists should consult with Indigenous Nations and/or governing bodies as necessary when considering the release of Indigenous data and information or scientific outputs that rely on such data and information.

4.2.2.2 Federal–provincial–territorial affairs

Many federal departments and agencies have relationships with provinces and territories that reflect a shared responsibility on key files. A well-functioning relationship between the federal government and the provinces/territories is vital for the successful delivery of programs and services to Canadians.

If the research output includes or references information created by the federal government or obtained from other sources (such as an agent or a consulting firm) that has a reasonable likelihood of injuring the role of the federal government in its conduct of federal–provincial affairs, there may be a rationale for limiting access to these science products. Injury to federal–provincial–territorial affairs is most likely to occur when the federal government is about to commence or is in the midst of conducting specific negotiations, deliberations or consultations. Examples include documents and information used in federal–provincial–territorial deliberations or those used in the development of strategies or tactics relating to the conduct of federal–provincial–territorial affairs.

2 A note on terminology: The term "Indigenous" has, in practice, largely replaced the term "Aboriginal" as the collective noun that refers to First Nations, Inuit and Métis, but the above terms remain within the Constitution.

Some of the benefits of sharing such information can include increasing the number of perspectives for discussions (the public is more diverse than the people at the table for federal–provincial–territorial discussions) and creating opportunities to find new solutions. For example, transparently sharing information on the COVID-19 situation in each province is essential to the public perception that every region of the country is being treated according to its needs.

Enhanced access can be achieved through the promotion of open government and other transparency initiatives.

4.2.3 Economic considerations

4.2.3.1 Commercial interests

Scientific research outputs may contain information that is known to have, or is anticipated to have, commercial value. It may be in the interest of the information holder to retain custody of the information so that it can exploit, or investigate the potential to exploit, that value. Notably, this exploitation of value may occur with or without intellectual property protection (see 4.2.3.2 below).

For example, the government may produce scientific research outputs that may have significant long-term socio-economic impacts, even stimulating new technology sectors. A historical example is the long-term contribution of scientific research on low-earth orbit and geo-stationary satellites to telecommunications industries. A contemporary example is the commercialization of adaptive optics technologies developed through astronomy research programs.

Scientific research outputs or technical information belonging to the Government of Canada that has arisen through a program or partnership between the government and other parties may also be subject to limited release. Again, the information must reasonably have a substantial value now or in the future. An example could be information obtained as part of National Research Council industrial support programs that involve post-secondary research institutions and private or voluntary sector partners.

Regulatory approval processes can involve the acquisition and retention of scientific information created by the private sector. In cases where public disclosure would harm commercial interests, the information would not be released. Examples include *Canadian Environmental Protection Act* scientific reviews of substances prior to entry into the Canadian marketplace. As part of the global movement towards greater transparency, regulators have found ways to provide high-level information about pre-market submissions and summaries about its final decisions that provide the public with useful, relevant information while meeting legal obligations to protect third-party information.

4.2.3.2 Intellectual property rights

Intellectual property rights are legal means of excluding or limiting the access to or use of knowledge. Using intellectual property rights to restrict access is generally meant to temporarily reward creators for having taken on risk in their work, thereby providing an incentive for further creativity, discovery and invention. The Canadian Intellectual Property Office recognizes copyright, trademark, patents and industrial designs as intellectual property.

Scientific research outputs are often protected with copyright and patents. Copyright is the sole right to first publish, reproduce or publicly perform or communicate a work or a substantial part thereof. Protected works include every original literary, artistic, dramatic or musical work, as well as computer programs and the selection and arrangement of data. Scientific papers, for instance, would be protected literary works. Copyright also provides protection for performers' performances, sound recordings and communication signals. Patents can be granted for any new inventions (process, machine, product, composition of matter) or any new and useful improvement to an existing invention. Canadian patent protection applies within Canada for 20 years from the date the patent application is filed. The Canadian patent application is open to the public 18 months after filing. Patent protection for the invention can also be obtained in other countries.



CASE STUDY: An example of where preventing premature disclosure of project results based on economic considerations was advisable

In North America alone, the cost of mastitis to the dairy industry amounts to billions of dollars as a result of discarded milk and drug and veterinary treatments. Current treatments, such as the use of antibiotics on healthy animals, are controversial because it can lead to antibiotic resistance.

In 2016, an Agriculture and Agri-Food Canada (AAFC) researcher developed an invention entitled “A management tool to prevent intra-mammary infections of dairy cows at drying-off” that addresses this universal issue without the need of antibiotics. Given the commercial potential of this invention, the information had been kept secret until a patent was filed.

Soon after filing, AAFC invited the industrial sector to express its interest in collaborating with AAFC to further develop the technology. To preserve the technical edge, confidentiality agreements were signed with companies who responded to the call. The selection was based on commercialization plans submitted, with AAFC ensuring that the technology would be available to the Canadian industry and would contribute to economic and social benefits for Canada.

Reassured that sole rights for commercialization would be granted and that AAFC would not prematurely disclose the intellectual property being developed, the company selected by AAFC invested in the collaborative research and agreed to pay for patent costs in selected countries. AAFC’s careful release of information, timed with the patent application, was key in securing those rights and the company’s interest. This was critical to ensure that this alternative solution to antibiotics would be fabricated, distributed and available to Canadian producers.

Commercial confidential information described in 4.2.3.1 may be regarded as a trade secret if it gives a business an advantage over a competitor. Trade secrets are a form of intellectual property, but do not have formal protection in Canada under statute, as patents do for example. Other jurisdictions do protect trade secrets by statute or registration processes. Scientific research that results in a new invention that is kept secret can also be patented later.

Sometimes scientific research leads to an invention for which patent protection is sought. Alternatively, the outputs may have relied on something that was a trade secret. In any of the above situations, there may be limits on the release of information. Your ATIP office and other subject-matter experts (for example, IP officer) would be able to assist you in making the determination.

4.2.4 Security concerns

4.2.4.1 Hazardous materials, toxic industrial chemicals, and CBRNE research

Research on hazardous materials; toxic industrial chemicals; and chemical, biological, radiological, nuclear or explosive (CBRNE) materials can be governed by several acts and international conventions, such as the *Criminal Code of Canada*, the *Human Pathogens and Toxins Act*, or those implementing Canada's accession to the Chemical Weapons Convention and the Biological and Toxin Weapons Convention. Materials should be safeguarded, and research in these areas should therefore be released with necessary due diligence and recognition for the potential unintended diversion or exploitation of the materials or information by others.[3] Research in these areas is more likely to be shared with individuals who have the right authorization/clearance level or on a need-to-know basis.

4.2.4.2 Dual-use research

Dual-use research produces scientific results, technologies or data that can be used in more than one context. In the context of international regimes for controlled goods, dual use typically refers to technologies that have civilian and military uses (such as geographic information system and laser). Planned dual-use research anticipates science, technology and data that is intended to be useful in multiple contexts (protective clothing for unmounted soldiers and civilian first responders, for example). Restrictions on access to dual-use research may be applied if it is reasonable to anticipate that the outcomes of that research might be used for nefarious purposes or has strategic military value (such as weaponizing microbiology research). Not all dual uses can be easily anticipated, however, and the ingenuity of others can lead to a novel inventive step that leads to a new application, benign or otherwise. Researchers should be aware that dual-use restrictions differ depending on the nature of the research and the extent to which alternative uses can be generated, or the potential and seriousness of any harm that may arise.

3 In accordance with the *Human Pathogens and Toxins Regulations*, licence holders who intend to carry out scientific research must have an approved plan that sets out administrative measures for managing and controlling biosafety and biosecurity risks during the period in which the licence is in effect. Known as the Plan for Administrative Oversight, it specifies how a facility will assess and mitigate against the risks posed by research activities—not just the pathogens themselves, but also the release of research data/information associated with pathogen research.

4.2.4.3 Safety of individuals

If there are reasonable grounds to expect that the disclosure of outputs from scientific research could threaten the safety of individuals, the release of the information may be refused.

The phrase "threaten the safety of individuals" has the following general meaning:

Threaten: to expose to risk or harm; to be a menace or source of danger

Safety: freedom from danger or hazard; exempt from hurt, injury or loss

Individual: a human being

The types of individual safety interests that could be threatened are relatively broad, covering an individual's life and bodily integrity as well as psychological injury.

The types of scientific research outputs normally considered relevant to personal safety involve the release of information that either directly or indirectly reveals the identity, home address or other identifier of individuals that could threaten their safety if publicly released.

Care should be taken to assess publicly available information that can be matched with other data to reveal information that could threaten the security of an individual.

4.2.4.4 International affairs and defence

If the scientific research outputs include any of the following, release of information should be reviewed to assess whether it could reasonably be expected to be injurious:

- **The conduct of international affairs:** This includes not only state-to-state affairs, but also commercial, cultural or scientific links established by citizens with counterparts in other countries.
- **The defence of Canada or any state allied or associated with Canada:** An "allied state" is one with which Canada has concluded formal alliances or treaties. An "associated state" is a state with which Canada may be linked for trade or other purposes outside the scope of a formal alliance.
- **The detection, prevention or suppression of subversive or hostile activities:** This protects specific types of information pertaining to the security of Canada.

These three general areas of public interest can be considered independently even though they are closely and intimately interrelated and frequently overlap.

The types of scientific research outputs normally considered relevant to international affairs include exchanges of diplomatic correspondence with foreign states or international organizations of states, or official correspondence exchanged with Canadian diplomatic missions or consular posts abroad.

The types of information normally considered relevant to defence-related scientific research outputs could include, but are not limited to, military operations or capabilities, and time-sensitive information that could identify the location of certain military operations or personnel. The information may include both the raw data collected and the refined product or analysis.

4.2.4.5 Law enforcement and investigations

Examples of the types of scientific research outputs normally considered relevant to law enforcement and investigations include surveillance data from environmental monitoring of pollution; or samples, genetic materials and analyses emanating from food safety and security investigations.

If the scientific research outputs include any of the above, there are a series of reviews required under legislation to limit the release, in part or in whole, of information, with the aim to protect:

- Effective law enforcement, including criminal law enforcement
- The integrity and effectiveness of other types of investigative activities, such as ordinary administrative investigations under an act of Parliament, investigations in regulatory areas, and air accident investigations.

Before the limitations to release can be applied, the following 3 conditions must be met:

1. **The information was obtained or prepared by an investigative body.**
2. **The information was obtained or prepared in the course of a lawful investigation.**
3. **The investigation pertains to crime, enforcement of a law or a threat to the security of Canada.**

It is essential for any scientist to consult with the law enforcement organization before the release of any scientific research outputs if they were part of or provided input to any investigative process.

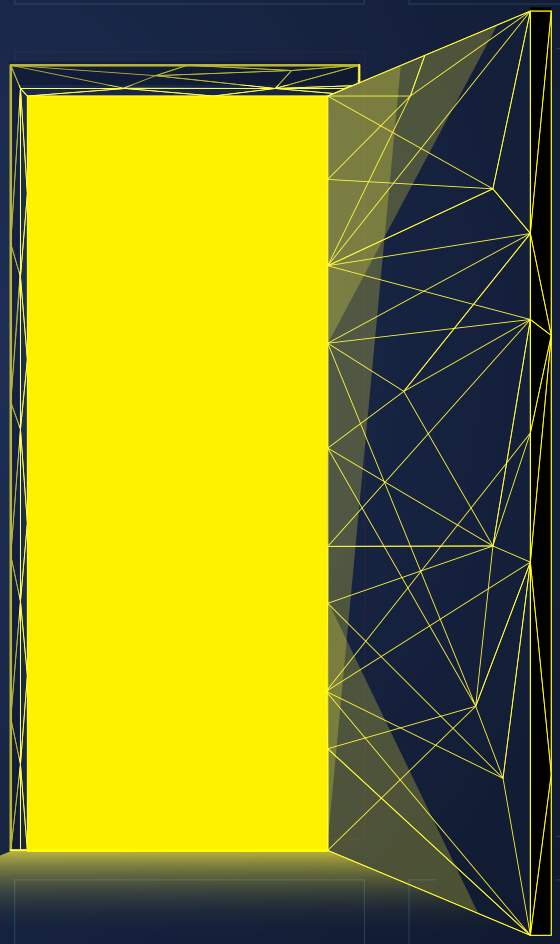
4.2.4.6 Government operations

If the scientific research outputs include information about the internal decision-making processes of government, the release of that information may interfere with the operations of government institutions. The rationale behind this limitation in open-by-default is that release can, at times, have a chilling effect on the candidness of the advice, recommendations, consultations and deliberations given or received by the federal public service and can lead to a reluctance to deal frankly with difficult questions. The determination of the limitation to open-by-default should be done in consultation with an organization's ATIP officer.

Examples of scientific research outputs could include coding for computer programming of sensitive automated services, scientific advice and analysis for policy development, or the purchase of sensitive scientific equipment.

In making a determination that open-by-default should be limited, consideration should be given to the expectation of disclosure from the process employed, the impact of release (from the risk and benefit perspectives equally), and the sensitivity of the information.

5 Requirements and roles of organizations



The Roadmap for Open Science and Directive on Open Government set out explicit requirements and recommendations that can be observed and followed by any government department. To ensure that open-by-default is widely embraced and promoted, it is important that departments adopt coordination plans and ensure that open-by-default is an organizing principle and motivating factor for research.

5.1 Responsibilities of organizations

Departments and agencies conducting science have a responsibility to determine the best way to make their scientific research outputs open whenever possible.

Departments and agencies also have a responsibility to arrive at such decisions in a transparent manner—establishing clear accountability and ensuring the coordination of relevant officials within the organization—and to create processes and systems that align with open-by-default principles.

5.2 Advisory mechanism for organizations

Complex cases may arise. For instance, it may be challenging to determine the consequences of not making some information open. One probable consequence may be that further scientific inquiry would be limited, thus affecting the impact of government science and the health of the synergies between intramural and extramural scientists and the public.

The Chief Science Advisor (CSA) may be contacted to provide third-party advice to the department in complex cases. The CSA will then determine, in consultation with the department, the best way to formulate advice in the circumstances. Informal mechanisms used to address issues arising from the implementation of scientific integrity policy, as well as values and ethics within and outside government (Tri-Council directions for instance), will serve as inspiration.

5.3 Officials and coordination within organizations

Multiple officals contribute to the decisions on and the implementation of the appropriate level of openness for government information (including data). Consideration should be given to the interest and potential role of:

- Departmental ATIP officers (Access to Information and Privacy)
- Chief data officer, chief scientific data officer
- Chief information officer
- Chief security officer
- Departmental chief scientist or equivalent (ADM of science and technology, for example)
- Departmental science advisor
- Departmental scientific integrity officer
- Technical advisor for Shared Services Canada
- Communications officers
- Legal services advisors, including IP officers

A first level of coordination between these officials will help achieve a shared vision and awareness of each other's roles and responsibilities. Stronger linkages should be made between the above groups to better support the deputy head of the organization.

A second level of coordination can be achieved by establishing transparent decision-making processes and clear accountabilities. More precisely:

- These processes will ensure that any decisions or reviews on the sensitivity of information are made in consultation with each department's ATIP office.
- In the event of a legal issue, departments should consult with their respective legal services to ensure the appropriate laws and regulations are respected.
- To explore options for achieving the appropriate degree of openness when there are commercial implications, intellectual property services should be consulted to inform decision making.
- In cases where the release of information would benefit from a deeper understanding of the issue and context, communications personnel could be called upon to facilitate engagement with the media and the relevant stakeholder community.
- The chief security officer should be notified of any persistent or unusual contact and of any attempt by another individual to solicit or obtain access to sensitive information, assets or facilities without proper authorization.

5.4 Motivating factors at various levels of the organizations

Two complementary approaches are needed to foster the culture change required to move to a successful open-by-default scientific environment. Defining and establishing appropriate processes and responsibilities is the first. The second involves fostering a change in mindset and behaviours.

Opportunities for creating the right mindset and for motivating desired behaviours are present at multiple levels of the organization. At the departmental level, motivations can be found through the Management Accountability Framework (MAF) or TBS instruments (for example, update to the Directive on Open Government). At the individual level, actions can be motivated through professional standards, performance management and career progression programs. Organizational culture integrates all these motivations. Scientists as a community also come with their own culture, which is echoed in such things as departmental scientific integrity policies.

5.4.1 Deputy heads

Deputy heads are accountable for the application of government management policies within their department. Where relevant, they have to apply these policies to scientific research activities in a way that creates a thriving environment for the science performed or funded by the department to support its mandate.

The MAF includes indicators that reflect expectations for information management performance at the departmental level. These are based on TBS information management policies, which include the Directive on Open Government. There are opportunities to motivate actions at that level by:

- Reflecting the current framework for managing open-by-default in science in an addendum/appendix to the TBS Directive on Open Government
- Developing departmental tools and tracking mechanisms in order to support coordination and decision making and to make results visible

5.4.2 Scientists, government laboratories and research institutes

Scientists individually, and collectively through laboratories and institutes, ensure scientific discovery and collaboration are supported and encouraged. They play a critical role in defining the optimal degree of openness for the type of science conducted by balancing benefits and risks.

Behaviour is largely determined by institutional context. For government scientists, the institutional context is defined by their domain of expertise, their collaboration with industry and academia, the different types of projects they conduct, and the sector of application. Each institutional context calls for different "ideal" degrees of openness, dissemination practices and tools.

How the laboratory or institute values and promotes certain behaviours greatly influence what researchers see as important and where they invest their efforts. There are opportunities to motivate actions at that level by:

- Building on a baseline of good behaviours (for example, values and ethics code and scientific integrity policy)
- Leveraging work objectives and government researchers' career progression frameworks
- Supporting government research/science "institutes" in their efforts to become leaders within their respective domain

5.4.3 Program management, from line managers to senior management (directors general and assistant deputy ministers)

Government managers and senior managers are accountable for decisions and organizational results. They address questions of burden and cost.

They would be most interested by the good management practices outlined earlier in this guidance document (see section 3.4). These include adopting the "open-by-design" logic of determining goals up front and having ways to track results and promote their improvement. Program managers should consider developing data management plans as well as plans to manage all science outputs. Having plans means moving decision making to the start of the process instead of addressing the content after the fact. In the context of research collaboration, this becomes even more important.

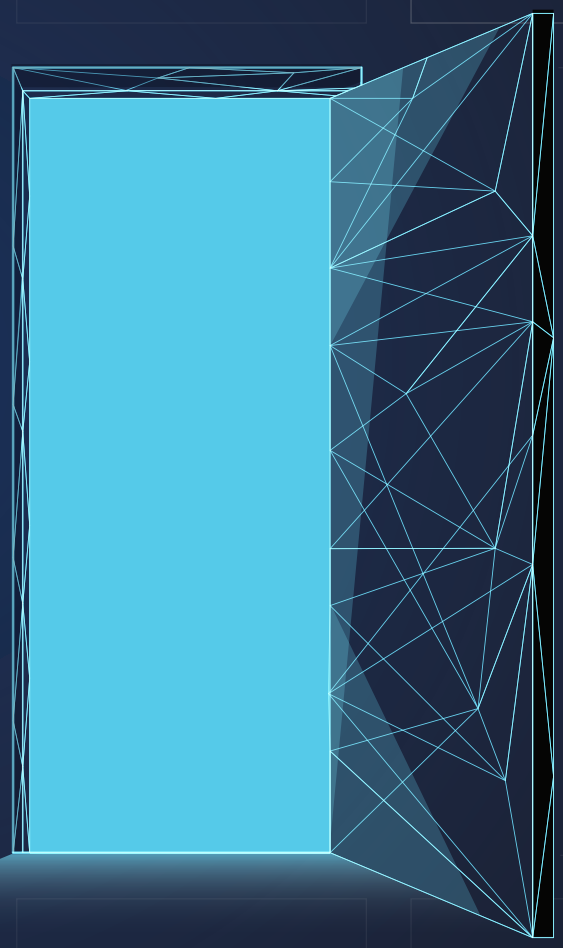
There are opportunities to motivate actions at this level by:

- Incorporating training for federal scientists and scientific program managers
- Seeking ways to reduce burden and cost with new practices or tools
- Aligning human resources processes, from recruitment to performance management, with these institutional goals

5.5 Enquiries

Questions regarding the content of these guidelines should be directed to your institution's Chief Scientific Data Officer, or you may contact the Office of the Chief Science Advisor at science@canada.ca.

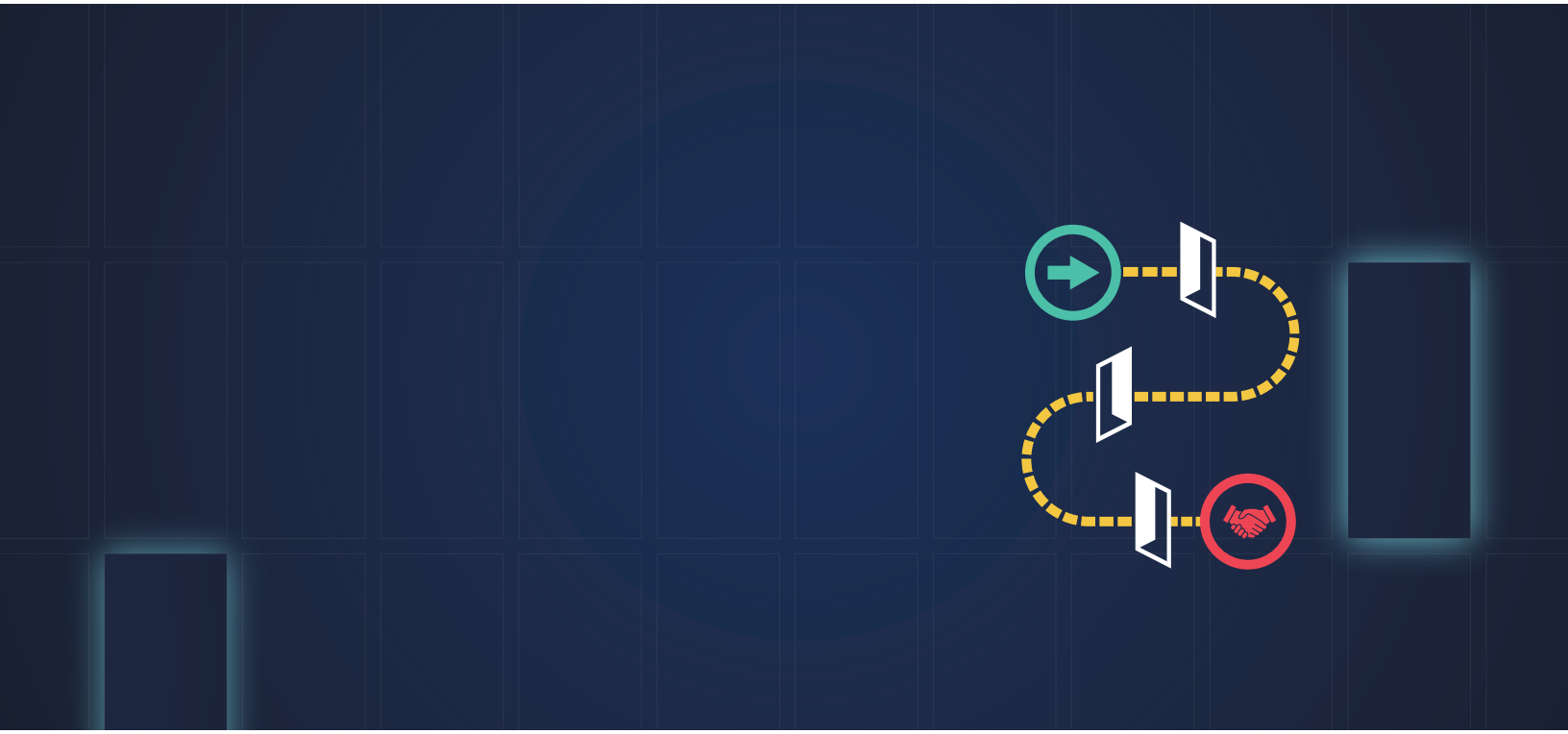
6 Effective Date and Duration



This guidance document takes effect on January 1, 2021. It supports both the Roadmap for Open Science and the Directive on Open Government.

A committee, led by the Chief Science Advisor, will reconvene in a year to take stock of successes and challenges revealed by implementation and to look at the opportunity to move some of the guidance into more formal TBS open-government policy instruments.

In addition, yearly reports will be developed on implementation and included in the Chief Science Advisor's annual report.



7 References and resource list



7.1 Legislation, policies and directives governing information releases to the public

Access to Information Act
https://laws-lois.justice.gc.ca/eng/acts/a-1/page-3.html#docCont

Access to information policies and guidance
https://www.canada.ca/en/treasury-board-secretariat/services/access-information-privacy/access-information/access-informatio-policies-guidance.html

Access to Information Manual
https://www.canada.ca/en/treasury-board-secretariat/services/access-information-privacy/access-information/access-information-manual.html

Access to Information and Privacy Process and Compliance Manual for the Office of the Privacy Commissioner of Canada
https://www.priv.gc.ca/en/about-the-opc/opc-access-to-information-and-privacy/manual/

Directive on Open Government
https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=28108

Model Policy on Scientific Integrity
https://www.ic.gc.ca/eic/site/063.nsf/eng/h_97643.html

Official Languages Act
https://laws-lois.justice.gc.ca/eng/acts/O-3.01

Official Languages policies and guidance
https://www.clo-ocol.gc.ca/en/language-rights/interpretation-bulletins

Policy on Government Security
https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=16578

Policy on Service and Digital
https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=32603

Privacy Act
https://laws-lois.justice.gc.ca/eng/acts/P-21/FullText.html

Privacy policies and guidance
https://www.canada.ca/en/treasury-board-secretariat/services/access-information-privacy/privacy/privacy-policies-guidance.html

Interim Policy on Privacy Protection
https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=12510

Public Servants Inventions Act
https://laws-lois.justice.gc.ca/eng/acts/P-32/page-1.html

Roadmap for Open Science
https://www.ic.gc.ca/eic/site/063.nsf/eng/h_97992.html

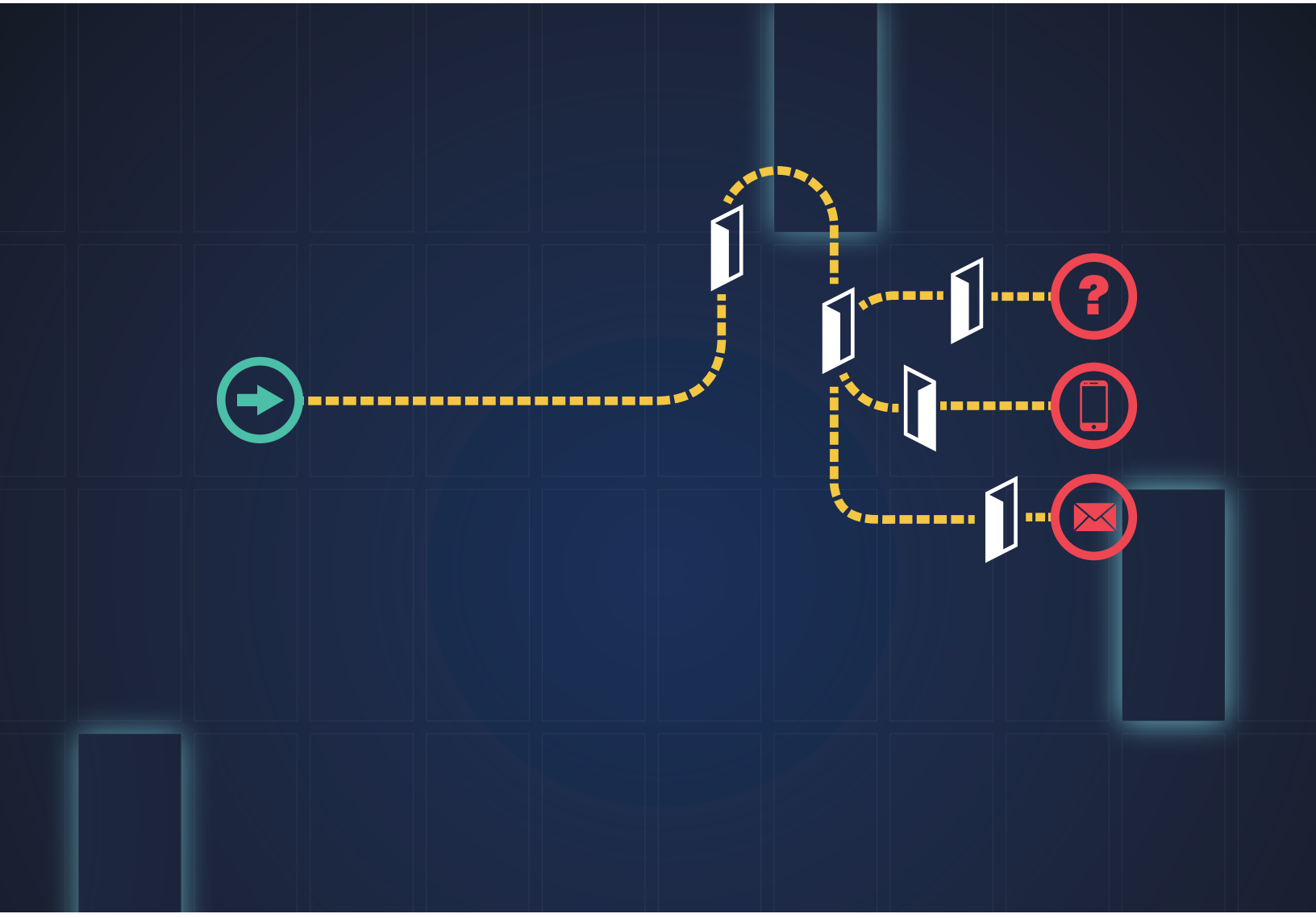
Safeguarding Your Research
https://www.ic.gc.ca/eic/site/063.nsf/eng/h_97955.html

Values and Ethics Code for the Public Sector
https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=25049

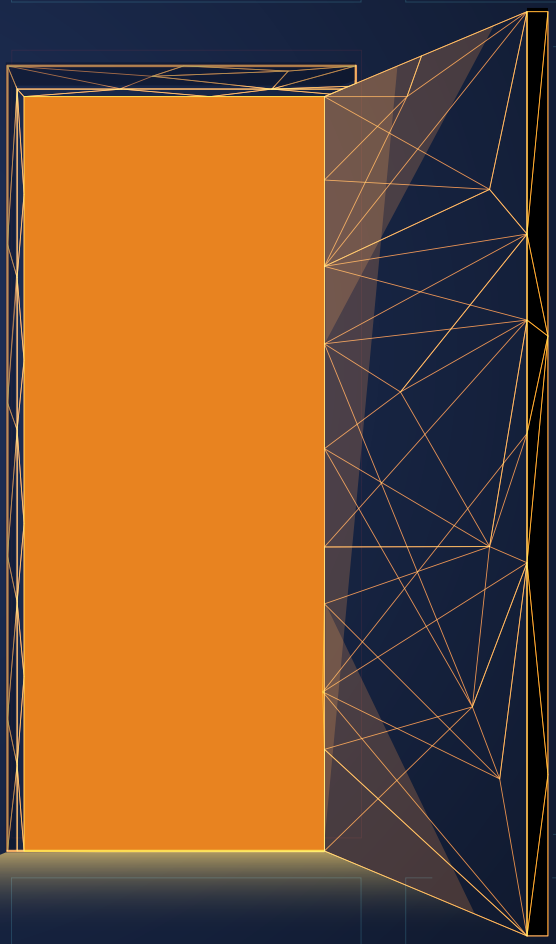
7.2 International guidance on open science

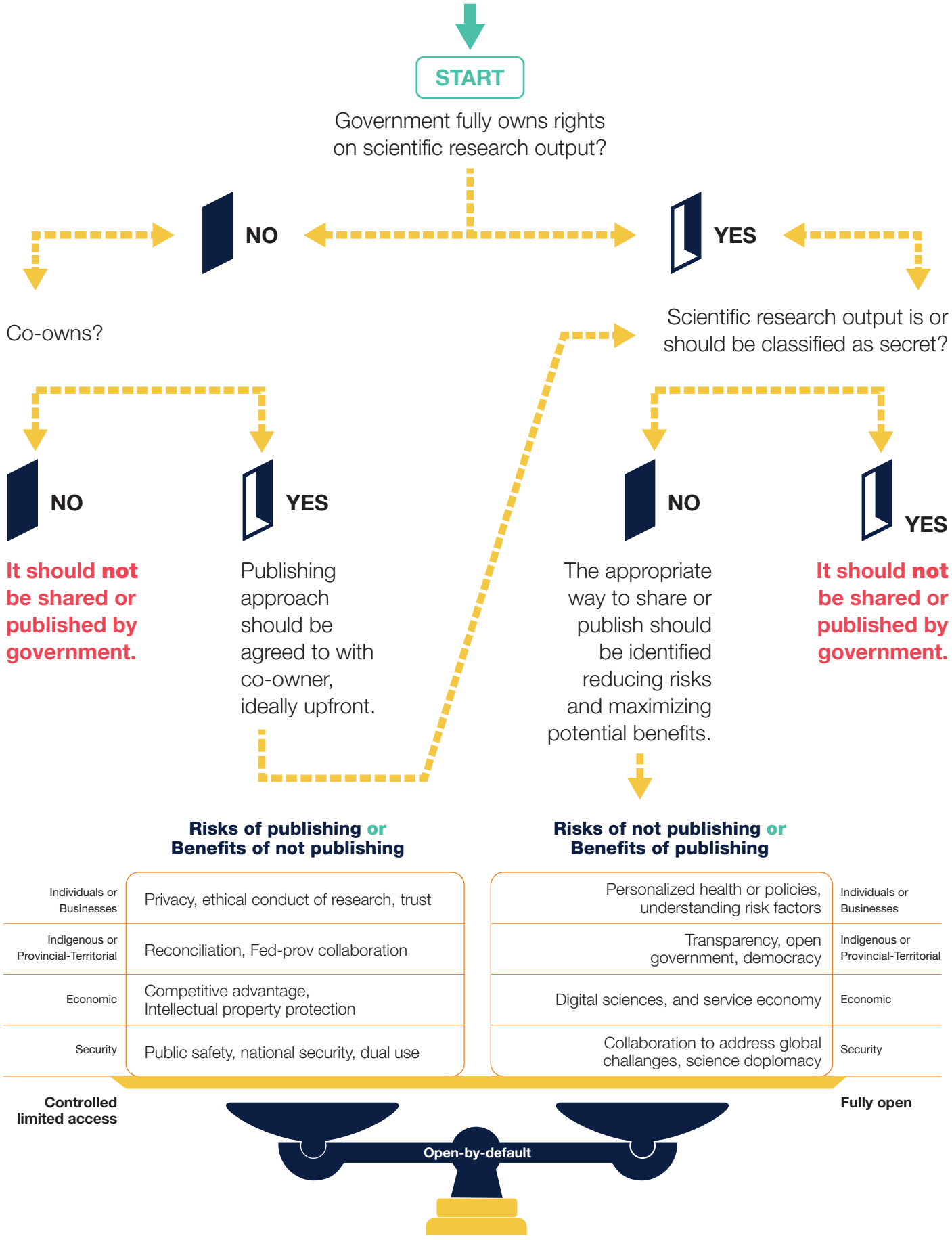
OECD report – Enhanced Access to Publicly Funded Data for Science, Technology and Innovation (2020)
http://www.oecd.org/sti/enhanced-access-to-publicly-funded-data-for-science-technology-and-innovation-947717bc-en.htm

United Kingdom, Office for National Statistics – Accessing secure research data as an accredited researcher
https://www.ons.gov.uk/aboutus/whatwedo/statistics/requestingstatistics/approvedresearcherscheme

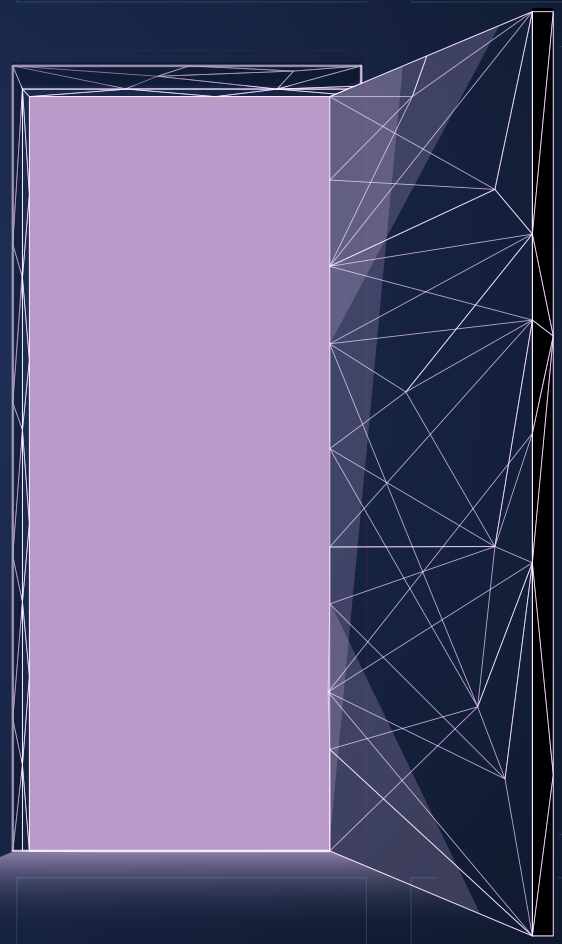


8 Decision tree for releasing scientific information




START
Government fully owns rights on scientific research output?
NO
YES
Co-owns?
Scientific research output is or should be classified as secret?
NO
YES
NO
YES
It should not be shared or published by government.
Publishing approach should be agreed to with co-owner, ideally upfront.
The appropriate way to share or publish should be identified reducing risks and maximizing potential benefits.
It should not be shared or published by government.
Risks of publishing or Benefits of not publishing
Risks of not publishing or Benefits of publishing
Individuals or Businesses
Privacy, ethical conduct of research, trust
Personalized health or policies, understanding risk factors
Individuals or Businesses
Indigenous or Provincial-Territorial
Reconciliation, Fed-prov collaboration
Transparency, open government, democracy
Indigenous or Provincial-Territorial
Economic
Competitive advantage, Intellectual property protection
Digital sciences, and service economy
Economic
Security
Public safety, national security, dual use
Collaboration to address global challanges, science doplomacy
Security
Controlled limited access
Fully open
Open-by-default

9 Life-cycle management of projects and programs



An outline of some of the best management practices for open-by-default are provided below. They can be viewed as a complement to the Model Policy on Scientific Integrity, specifically section 7.

Initial project/ program design

- Include open-by-default in the design of the initiative (open-by-design mantra). Ensuring the systematic release of information and analysis, collecting and managing information in machine-readable formats, and establishing the infrastructure necessary for information management systems are just several considerations that should be included in any project/ program design.
- Document protocols before collecting data, with the aim of ensuring greater transparency. This makes it possible to facilitate downstream release of information consistent with open-by-default management. In addition, document the initial rationale for releasing information, as this will facilitate future affirmation of decision making and any adjustments to decisions based on new considerations. Protocols may be made publicly available or embargoed until the data is published.
- If there is an existing body of information and knowledge that is built upon by the new project or program, employ open-by-default on a go-forward basis and create a plan with milestones for managing the existing inventory. This practice makes it possible to manage expectations and employ adaptive management as you learn from the new project or program.
- Establish a data management plan that defines where the data will be stored during and after the project. The plan should include a strategy for safeguarding the data in order to ensure a back-up and long-term accessibility.
- If Indigenous nations, peoples or communities are involved, ensure that they are engaged in any decision making on the use, storage, access, possession, publication and ownership of the data and information.
- Similarly, if there issues relating to classified information, controlled goods or intellectual property, there may be limits on the release of information. Identify limitations at an early stage and introduce steps to ensure that they are managed. Consult the appropriate responsibility centre within the organization (such as the ATIP office and legal services).
- As scientists, be diligent in applying the appropriate security markings on documents and data, especially with the move, as a government, towards an open-by-default paradigm. Failure to do so (proper security marking) will result in the leak of sensitive information.

Implementing projects or programs

- Employ adaptive management and if the conditions for releasing information change (for example, new unintended consequences not originally foreseen, level of detail allows for identification of individuals, or impacts of an economic or security consequence), a review of the initial open-by-default decision will be required.
- As a corollary to adaptive management, adopt a system for recording any changes to protocols and results to support revised decisions.
- Ensure training on legislative requirements (*Access to Information Act*, *Privacy Act* or other acts) and Indigenous rights is provided to existing and new

employees or when employee roles change. Training for organization-specific needs (information management systems, department-specific protocols, etc.) should also be encouraged. Allow for cross-training of *Access to Information Act* personnel in science programs.

- Establish protocols for quality control and check common procedural errors to periodically evaluate the process for managing the release of information. If such procedures lead to the exclusion of projects or programs or parts thereof, establish criteria so that this takes place before results are obtained and explicitly mention them in the description of protocols.

Analysis of results

- Keep databases organized and document the analyses carried out, ready for implementation or available, through a pre-determined release schedule.
- When it comes to data that cannot be shared in full, consider whether this data can at least be made available in part (such as by removing information to guarantee anonymity) or after an embargo (such as after the intellectual property is established) or with approval of Indigenous nations and/or governing bodies as necessary.

Publication of results

- Use open-access platforms for publication if possible. This may include using open-access journals or placing versions of articles in public repositories. In the latter case, most publishers have policies that are compatible with the depositing of pre- and post-print versions.
- Check the policies of a particular publisher or journal. Upon publishing or depositing an article, use sharing options that guarantee that the article can be used and redistributed.
- If using open-access journals that cover the publication fees (bearing in mind that this is not the only way to guarantee open access), ensure that the journals have a legitimate peer review system and that they do not fall under the category of "predatory journals."
- Deposit articles as pre-prints before or upon submitting in repositories. Using pre-prints accelerates the scientific process and is compatible with submitting articles to most journals. After the peer review, update the pre-print so that it is as close to the final publication as possible.
- Cite pre-prints in scientific articles and comment on pre-prints (post-publishing peer review). Furthermore, pre-prints must be considered to be valid scientific production for evaluating projects and researchers (see section 3.4).
- Use government websites for open data (Open Data Inventory) to maximize access to information.
- Fully share the data from research upon submitting an article. The data can be included as supplementary material or be deposited in repositories, either those of your organization, general repositories, or platforms that specialize in a specific type of data.

Impact

- Keep abreast of uses being made of the scientific results shared. If relevant, try to understand users' needs, consider user feedback, and include up-front/ongoing user engagement as part of your science program.



Examples of Manipulating Evidence to Fit Political/Industry Interests

Case study: PHAC 'Cases Following Vaccination' Reports (August 2021-Sept 2022)

Prepared by Dmitry Gorodnichy, Ph.D.
Email: dmitry.gorodnichy@gmail.com
November 2022

Data: COVID-19 Daily Epidemiology Update, Public Health Agency of Canada - Cases following vaccination (Figure 5 & Table 2).

- After June 2022: PHAC Data
- August 2021 to May 2022: Archived Data (Archived at: web.archive.org)

Web App: Canadian Vital Statistics Tracking:
https://open-canada.github.io/Apps/vitals

Source Code: GitHub Repository

The images below provide a snippet of evidence from Summer 2022 to illustrate the "data manipulation" practices used by PHAC to fit evidence to the narrative. The full dataset, covering all weeks since August 2021 (when this data became available), can be accessed through the Canadian Vital Statistics Tracking Web App at the link provided above. This Web App is developed by the R4GC Data Science Community on GCCollab.

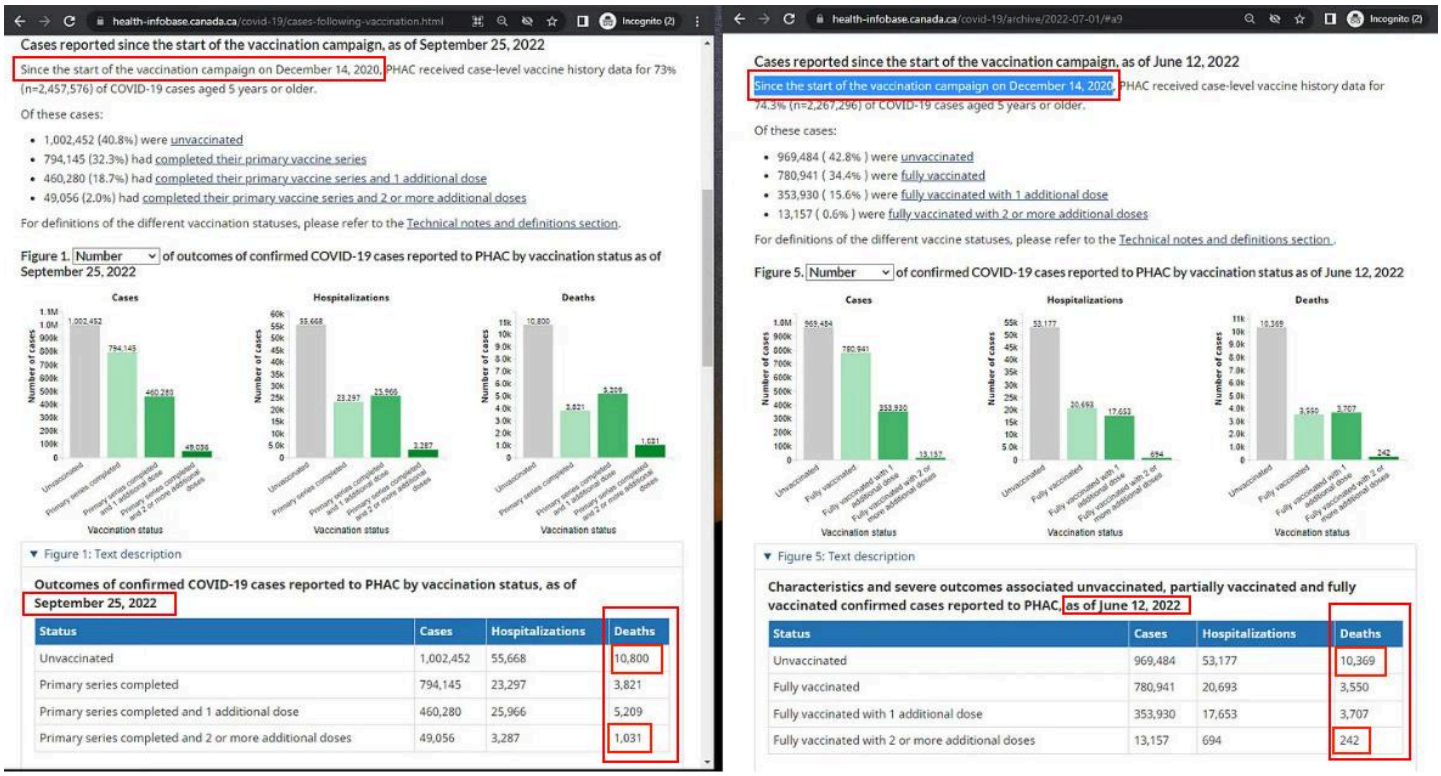
Case Comparison

Figure 1 shows the numbers of cases reported in two PHAC reports (one from June 12, 2022 and another from Sept 25, 2022) for people with 2+ additional doses (last line in the table) versus unvaccinated people (first line in the table).

On June 12, 2022 (as reported by PHAC)
- Among people with 2+ additional doses, there were **242** deaths
- Among unvaccinated, there were **10,369** deaths

By subtracting these numbers, as shown in Figure 2, we can see the number of cases between June 12 and September 25, 2022, for each population:

Between June 12 and September 25, 2022 (as actually observed):
- Among people with 2+ additional doses, there were 1,031 - 242 = **789** deaths
- Among unvaccinated, there were 10,800 - 10,369 = **431** deaths



Cases reported since the start of the vaccination campaign, as of September 25, 2022

Since the start of the vaccination campaign on December 14, 2020, PHAC received case-level vaccine history data for 73% (n=2,457,576) of COVID-19 cases aged 5 years or older.

Of these cases:

- 1,002,452 (40.8%) were unvaccinated
- 794,145 (32.3%) had completed their primary vaccine series
- 460,280 (18.7%) had completed their primary vaccine series and 1 additional dose
- 49,056 (2.0%) had completed their primary vaccine series and 2 or more additional doses

For definitions of the different vaccination statuses, please refer to the Technical notes and definitions section.

Figure 1. Number of outcomes of confirmed COVID-19 cases reported to PHAC by vaccination status as of September 25, 2022

Figure 1: Text description

Outcomes of confirmed COVID-19 cases reported to PHAC by vaccination status, as of September 25, 2022

Status	Cases	Hospitalizations	Deaths
Unvaccinated	1,002,452	55,668	10,800
Primary series completed	794,145	23,297	3,821
Primary series completed and 1 additional dose	460,280	25,966	5,209
Primary series completed and 2 or more additional doses	49,056	3,287	1,031

Cases reported since the start of the vaccination campaign, as of June 12, 2022

Since the start of the vaccination campaign on December 14, 2020, PHAC received case-level vaccine history data for 74.3% (n=2,267,296) of COVID-19 cases aged 5 years or older.

Of these cases:

- 969,484 (42.8%) were unvaccinated
- 780,941 (34.4%) were fully vaccinated
- 353,930 (15.6%) were fully vaccinated with 1 additional dose
- 13,157 (0.6%) were fully vaccinated with 2 or more additional doses

For definitions of the different vaccine statuses, please refer to the Technical notes and definitions section.

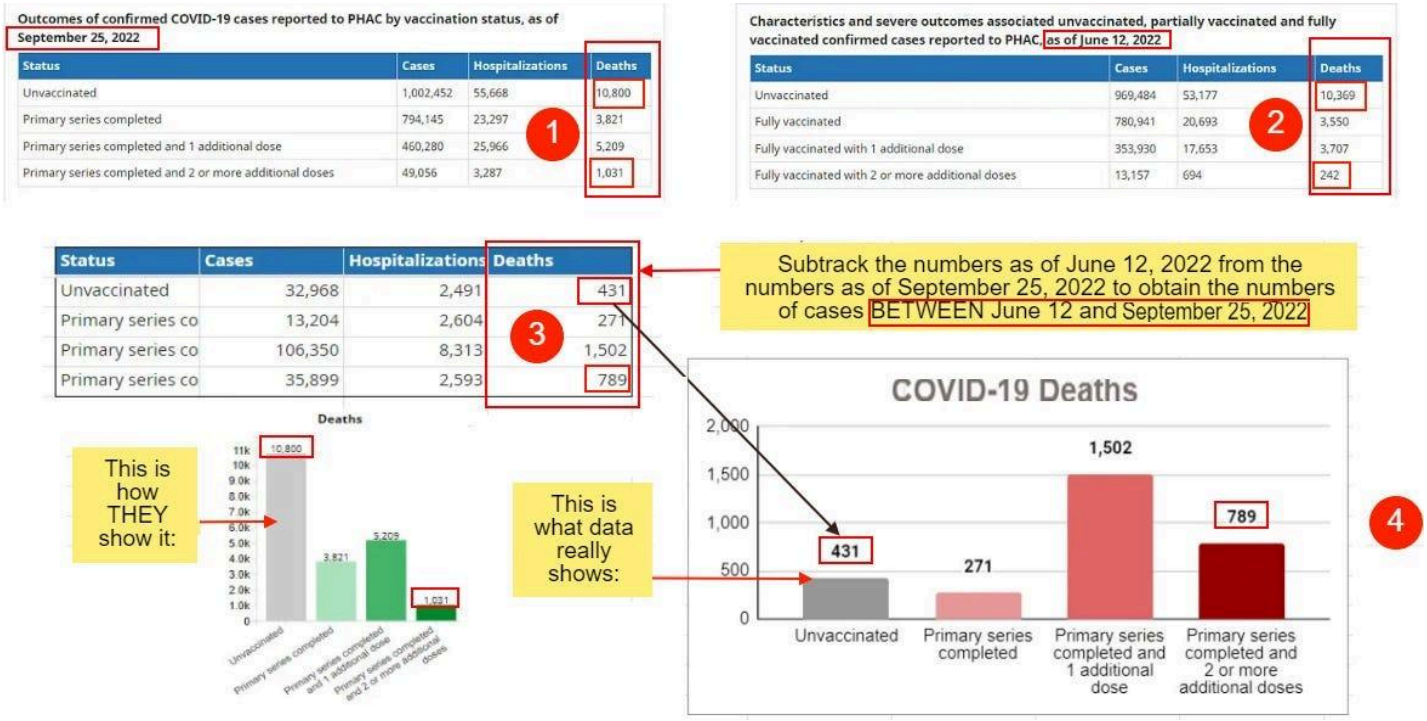
Figure 5. Number of confirmed COVID-19 cases reported to PHAC by vaccination status as of June 12, 2022

Figure 5: Text description

Characteristics and severe outcomes associated unvaccinated, partially vaccinated and fully vaccinated confirmed cases reported to PHAC, as of June 12, 2022

Status	Cases	Hospitalizations	Deaths
Unvaccinated	969,484	53,177	10,369
Fully vaccinated	780,941	20,693	3,550
Fully vaccinated with 1 additional dose	353,930	17,653	3,707
Fully vaccinated with 2 or more additional doses	13,157	694	242

Figure 1: Two PHAC reports showing “Cases following vaccination” data



Outcomes of confirmed COVID-19 cases reported to PHAC by vaccination status, as of September 25, 2022

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1

Characteristics and severe outcomes associated unvaccinated, partially vaccinated and fully vaccinated confirmed cases reported to PHAC, as of June 12, 2022

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Fully vaccinated	780,941	20,693	3,550
Fully vaccinated with 1 additional dose	353,930	17,653	3,707
Fully vaccinated with 2 or more additional doses	13,157	694	242

2

Status	Cases	Hospitalizations	Deaths
Unvaccinated	32,968	2,491	431
Primary series co	13,204	2,604	271
Primary series co	106,350	8,313	1,502
Primary series co	35,899	2,593	789

3

Subtrack the numbers as of June 12, 2022 from the numbers as of September 25, 2022 to obtain the numbers of cases BETWEEN June 12 and September 25, 2022

This is how THEY show it:

This is what data really shows:

4

Figure 2: Computing the actual number of COVID-19 deaths from the data reported by PHAC

Observation:

Data shows that between June 12 and September 25, 2022 there were many more “COVID Deaths” among people with 2+ additional doses than among unvaccinated people, which is contrary to what the PHAC report portrayed.

NOTE: During this time period, there were fewer people with 2+ additional doses than unvaccinated people. This means that the occurrence of COVID deaths in people with 2+ additional doses, compared to that among unvaccinated people, is even higher than what the numbers above show.

Key Question:

Why did PHAC not publish the COVID deaths data by week (as it normally does for reporting all other deaths) but instead published cumulative data (totals since December 14, 2020)?

Answer:

The evidence was published to create the illusion that there were indeed "many more COVID deaths among unvaccinated people" than among those with multiple doses, when in fact the data showed the opposite. This was achieved by counting COVID cases before vaccine doses were administered. For example, 3rd and 4th doses started to be administered only from December 2021 and April 2022, whereas the COVID deaths are counted since December 14, 2020.

In other words, PHAC deliberately published the evidence to “fit” the official political narrative that “COVID vaccines offer significant reduction of risk of complications from COVID deaths,” which is not true and would have been obvious to the reader if the data were reported on a weekly basis, as would have been done under normal circumstances without political interference.

Such practices from a Government Agency, which Canadians trust for honest and objective advice, is further aggravated by the fact that PHAC professionals (and other GC professionals) who witnessed it could not report it due to "Fear of Reprisal." (See “Where is the Highest Fear of Reprisal and Why? Data Evidence from PSES 2018-2022 Results”)

Model Policy on Scientific Integrity

Contents

1. Effective date
2. Context
3. Authorities
4. Objectives and expected results
5. Application
6. Scientific integrity principles
7. Requirements
    - 7.1. Implementation
    - 7.2. Fostering a culture of science integrity
    - 7.3. Openness, transparency and timeliness
    - 7.4. Public communication of research and scientific information
    - 7.5. Dissemination of research and scientific findings
    - 7.6. Contributions to the scientific community
    - 7.7. Role of employees in science advice and evidence-informed decision-making
    - 7.8. Responsible conduct of research
    - 7.9. Monitoring and performance evaluation
8. Responsibilities
9. Definitions
10. Enquiries

This model policy was created to assist departments and agencies with making good on the commitments made under the 2016 memorandum of agreement between Treasury Board and Professional Institute of the Public Service of Canada, and to support them in implementing related guidelines.

In this document, "DDAA" is a placeholder for the name of the department (DD) or agency (AA).

The following individuals are the members of the working group:

- **Lead:** C. Scott Findlay (Researcher in Residence, Office of the Chief Science Advisor)
- **Office of the Chief Science Advisor:** Navdeep Khera (Senior Science Policy Advisor); Luc Gauthier (Chief of Staff); Katrina Au-Yong (Policy Integration Officer, Stakeholder Relations and Parliamentary Affairs, National Research Council Canada)
- **Treasury Board Secretariat:** Patricia Phee (Acting Senior Negotiator); Kim Hennigar (Policy Analyst)
- **Professional Institute of the Public Service:** Judith Leblanc (President, PIPSC Fisheries and Oceans Canada Consultation Team); Matthew R. MacLeod (President, PIPSC RE (Research) Group); Michael Urminsky (PIPSC Research Team Lead); Maxime Gingras (PIPSC Research Officer);
- **Ex-officio:** Ted Leindecker (Negotiator, Office of the Chief Human Resources Officer, Treasury Board of Canada Secretariat)

1. Effective date

1.1. This policy takes effect on [insert the date for your department or agency].

top of page

2. Context

2.1. This policy is issued pursuant to the May 15, 2017 and June 1, 2017 Memoranda of Agreement between the Treasury Board and the Professional Institute of the Public Service of Canada (PIPSC) in Respect of Scientific Integrity.

top of page

3. Authorities

3.1. This policy should be read in consultation with the *Values and Ethics Code for the Public Sector* [1] as adopted April 2, 2012, the *Directive on the Management of Communications* [2], and the *Policy on Conflict of Interest and Post-Employment.* [3].

3.2. Where there is conflict or incompatibility between this Policy and legislation and/or a provision of any relevant collective agreement, the provisions of the legislation or relevant collective agreement take precedence.

3.3. Where there is conflict or incompatibility between this Policy and a mandatory Policy instrument of the Treasury Board (i.e. policy, directive or standard), the provisions of the Treasury Board mandatory Policy instrument take precedence.

3.4. Where there is conflict or incompatibility between this Policy and a voluntary Policy instrument of the Treasury Board (i.e. guidelines or tools), the provisions of this Policy take precedence.

3.5. DDAA will maintain a record of all instances of conflict or incompatibility between this Policy and legislation, collective agreements, or Treasury Board policy instruments and/or DDAA policy instruments, and submit this record as part of the performance evaluation as *per* s. 7.9 of this Policy.

3.6. In consultation with representatives of PIPSC, the Deputy Head has authority to support science integrity by establishing relevant and applicable standards for the design, conduct, management, review and communication of research and science within DDAA.

top of page

4. Objectives and expected results

The objectives of this Policy are to:

4.1. Foster a culture that supports and promotes scientific integrity in the design, conduct, management, review and communication of research, science, and related activities.

4.2. Increase public, employee and stakeholder trust in the credibility and reliability of DDAA research and scientific activities.

4.3. Set out expectations regarding the design, conduct, management, review and communication of research, science, and related activities.

4.4. Enhance employee understanding of the contributions of research and science to evidence-informed decision-making, as well as the role of managers, communication specialists, researchers and scientists in the development of government policy and advice.

The expected results of this Policy are that:

4.5. Employees involved in the design, conduct, management, review, use or communication of research, science, or related activities understand and conduct themselves in manner consistent with the principles of scientific integrity.

4.6. DDAA is recognized by employees, stakeholders, and the public as a reliable and credible source of research and scientific information.

4.7. As appropriate and to the extent possible, allegations of breach of the principles of scientific integrity as defined in s. 6 are addressed through a fair, impartial, efficient, confidential and respectful process.

4.8. Employees understand and seek to enhance the contributions of research and science to science advice, government policy and evidence-informed decision-making.

top of page

5. Application

5.1. This Policy applies to DDAA employees who design, conduct, communicate, manage, review or make use of DDAA research, science or related activities.

5.2. Nothing in this policy supersedes any relevant collective agreements. Neither does the policy extend provisions of relevant collective agreements to employees not subject to those agreements.

top of page

6. Scientific integrity principles

DDAA recognizes that stakeholder trust in the research and scientific information provided by governments depends upon the integrity of the process by which such information is produced, managed and communicated. So too does trust in the decision-making process that makes use of such information.

Furthermore, DDAA recognizes that scientists and researchers must uphold and conform to standards of excellence accepted by the wider research and scientific community.

To this end, in designing, conducting, managing, reviewing, using or communicating research, science and related activities, DDAA employees shall:

6.1. Ensure that all such activities are carried out in a manner that is consistent with all relevant and applicable standards of scientific excellence, research ethics, and responsible research conduct.

6.2. Ensure that the conduct of DDAA research and science and any research or scientific products, as well as any associated communications, are free from political, commercial, client and stakeholder interference.

6.3. In the absence of clear and compelling reasons for limiting disclosure, ensure that research and scientific information produced by DDAA is made available to the public in a timely manner and in keeping with the Government of Canada's *Directive on Open Government*.

6.4. Accurately represent and appropriately acknowledge the contributions of both themselves and others to their research or scientific work.

6.5. Avoid conflicts of interest, and ensure that any real, potential or apparent conflict of interest is explicitly recognized, reported and appropriately managed.

6.6. Encourage discussion based on differing interpretations of research and scientific evidence as a legitimate and necessary part of the research and

scientific processes and, where appropriate, ensure that these differences are made explicit and accurately represented.

6.7. Ensure that the significant and meaningful contribution of researchers and scientists to government programs, policies, regulations, and decision-making is acknowledged in official publications or communications, including the names and roles of those who made significant contributions to these products and activities.

6.8. Report any breach of these principles (i.e. a breach of scientific integrity) to their supervisor, manager or designated official.

top of page

7. Requirements

7.1. Implementation

7.1.1. This Policy will be communicated to all employees by the Deputy Head, with special attention to its implications to DDAA communications policies.

7.1.2. DDAA will continue to develop and implement the additional procedures, policies, guidelines, tools, training and professional development opportunities necessary to support this Policy.

7.1.3. DDAA will ensure that contractors and/or collaborators involved in, or providing services in support of, research, science or related activities are informed of this policy and encouraged to comply with its provisions and intent.

7.2. Fostering a culture of science integrity

DDAA recognizes two complementary approaches to fostering a culture of scientific integrity. One focuses on instilling the virtues that underlie responsible conduct in research, science and related activities (s. 7.2.1). A second focuses on the procedure for bringing allegations of breaches forward, the investigation of these allegations, and the consequences of a finding that a breach has occurred (s. 7.2.2)

7.2.1. Science virtues

In accordance with relevant collective agreements and the TBS *Policy on Learning, Training and Development* [4]:

7.2.1.1. DDAA recognizes the importance of research networking with national and international peers and active participation in the business and organization of relevant scientific and professional societies, which form an important part of ensuring scientists and researchers understand and are held to the standards of their communities.

7.2.1.2. DDAA recognizes the importance of the virtues underlying scientific excellence, including intellectual curiosity and honesty, constructive skepticism, meticulousness, avoidance of bias, humility in the discovery and use of science evidence, and the limitations of scientific inquiry. To this end, it will ensure that learning policies support training, education and professional development opportunities that allow employees to further their understanding of, and appreciation for, these virtues.

7.2.1.3. DDAA will ensure its learning policies support training, education, and professional development opportunities to inform and educate employees about responsible conduct in research, research ethics, and the annotation, management and archiving of research and scientific data.

7.2.1.4. DDAA will encourage the development and implementation of a science integrity mentorship program for researchers and scientists, whereby mentors exhibiting exemplary science virtues in their conduct and work are paired with more junior employees.

7.2.2. Breaches of scientific integrity

7.2.2.1. In cases of alleged breaches of scientific integrity, employees at all levels shall seek to resolve the issue in a fair and respectful manner and consider informal processes such as dialogue or mediation. In such cases, employees are encouraged to discuss and resolve these matters with their immediate supervisor. They can also seek advice and support from other appropriate sources within DDAA.

7.2.2.2. The Deputy Head will appoint a DDAA Science Integrity Lead to address allegations of breaches of this Policy.

7.2.2.3. The Science Integrity Lead will ensure that alleged breaches of this Policy shall be promptly and thoroughly reviewed and investigated by the DDAA.

7.2.2.4. DDAA will endeavor to protect personal information and otherwise provide safeguards to ensure that employees may bring forward, in good faith, allegations of breach of scientific integrity or participate in an investigation procedure without prejudice or fear of reprisal.

7.2.2.5. When public servants have information that could indicate a serious breach of the *Values and Ethics Code for the Public Sector* they can avail themselves of the procedures laid out in the *Public Servants Disclosure Protection Act* [5].

7.3. Openness, transparency and timeliness

DDAA recognizes and understands the importance of openness and transparency about all elements of the research and scientific process as well as the timely release of scientific and research information. It nonetheless also recognizes that there may be legitimate and compelling reasons that may limit the disclosure or availability of research or scientific information to employees, stakeholders or the public.

7.3.1. This policy, as well as any associated policies, directives or guidelines, may be posted on the DDAA's public website in permission-less downloadable form.

7.3.2. As the current policy and any associated policies, guidelines or tools are amended and revised, DDAA will maintain an annotated electronic archive of all such changes, with all archive elements available in permission-less downloadable form.

7.3.3. No DDAA employee shall suppress, alter or otherwise impede the timely release of research or scientific information in the absence of clear and compelling reasons for doing so.

7.3.4. DDAA employees shall ensure that research and scientific information (including that produced by contractors, grantees, or other partners who participate in, or assist with, the design, conduct, use or management of research, science or related activities) is produced and disseminated in a timely and transparent manner, in the absence of clear and compelling reasons for not doing so.

7.4. Public communication of research and scientific information

DDAA recognizes the right to freedom of expression by researchers and scientists on matters of research or science. It also recognizes the important role of researchers and scientists in communicating research and scientific information to the public.

Moreover, DDAA recognizes that as public servants, scientists, researchers and indeed all employees are subject to the *Values and Ethics Code for the Public Sector* as adopted April 2, 2012. It further recognizes the need for caution and prudence in the public communication of classified or sensitive scientific or research information, as well as existing legal constraints on information disclosure. Finally, DDAA recognizes that effective public communication requires certain skills, and that researchers and scientists may have different degrees of comfort with public fora.

7.4.1. Researchers and scientists [6] shall have the right, and are encouraged, to speak about or otherwise express themselves on science and their research without approval or pre-approval and without being designated as an official spokesperson. In doing so, they must respect the information disclosure provisions of the *Access to Information Act* [7], and the *Values and Ethics Code for the Public Sector* as adopted April 2, 2012.

7.4.2. In any public communications, employees must be familiar with and respect any legal restrictions on information disclosure such as privacy rights, matters before the courts, and cabinet confidences. They must also respect the *Values and Ethics Code for the Public Sector* as adopted April 2, 2012, and the *Access to Information Act*. Unless explicit approval to do so has been given by supervisors or managers, classified or sensitive research or scientific information shall not be discussed in any public communication.

7.4.3. In the case of planned formal public communication events with sufficiently long lead times (e.g. public talks or lectures), employees should notify their supervisor/manager of the upcoming event and provide a copy of their communication material for information purposes only and without prejudice.

7.4.4. In the case of formal public communication events with short lead times (e.g. media interviews) that effectively preclude prior notification, employees should notify their supervisor/manager as soon as possible after the event for information purposes only and without prejudice.

7.4.5. Pursuant to s. 7.4.2 and s. 7.4.3, DDAA will ensure that employees are provided with guidelines consistent with relevant collective agreements and the *Directive on the Management of Communications*, to assist them in determining the types of public communications for which supervisor/manager notification is desirable or required, and the appropriate timing and form of any such notifications.

7.4.6. Researchers and scientists are under no obligation to act as public DDAA subject matter experts or appear in public fora, and may decline any such invitation or request without prejudice, unless explicitly given this task by management.

7.4.7. Any public communication which describes work conducted by researchers or scientists must be reviewed and approved by them or their designates before publication or dissemination, and must acknowledge their contribution(s). In cases where a researcher or scientist does not wish authorship and/or their contribution to be acknowledged, they should be consulted as to whether, in their view, the work is accurately described and findings interpreted appropriately.

7.4.8. Researchers and scientists are encouraged to participate in media training provided by the DDAA, but this is not a requirement for them to express themselves about science or their research.

7.4.9. Where a researcher or scientist is speaking in the role of an official spokesperson, they must identify themselves by name and position and speak on the record for public attribution.

7.5. Dissemination of research and scientific findings

DDAA recognizes that communication among researchers and scientists is critical to the development of scientific and scholarly knowledge. Moreover DDAA recognizes that its researchers and scientists are part of a global

community of scientific and scholarly expertise, their contribution to which is critical to maintaining and enhancing the credibility and reputation of DDAA experts, the reputation and credibility of DDAA, and the contribution of DDAA to the knowledge economy.

As with public communications, researchers or scientists disseminating or communicating information through research or scientific media are subject to, and bound by, the *Access to Information Act*, the *Values and Ethics Code for the Public Sector* as adopted April 2, 2012 and must abide by Treasury Board of Canada's *Directive on the Management of Communication* where it does not conflict with the relevant collective agreements. To this end, DDAA must have publication approval processes that are compatible with the relevant collective agreements. Approval to publish will not be unreasonably withheld.

DDAA publication policies shall be examined to ensure that they are consistent with the following principles and procedures:

7.5.1. Drafts of publications authored by DDAA researchers or scientists should be forwarded to their manager or supervisory and discussed in a timely fashion. An electronic copy of the final version should be provided to the supervisor after acceptance and prior to publication by a publisher or other third party acceptance of the product.

7.5.2. Notwithstanding article 7.5.1, DDAA research or scientific communications that do not contain explicit comments or recommendations on, or explicit discussions about, federal statutory, regulatory or policy matters do not require approval of managers, supervisors or other relevant personnel before being submitted for publication or otherwise communicated or disseminated to relevant audiences.

7.5.3. Any communication that includes explicit comments or recommendations on, or explicit discussions about, federal statutory, regulatory or policy matters does require the approval of managers, supervisors or other relevant personnel before submission for publication or being otherwise communicated or disseminated.

7.5.4. For communications that do require approval, managers, supervisors or other relevant personnel may require revisions or editorial changes. In the event that approval is contingent upon incorporation of such revisions or changes, and the author(s) are not in agreement with the suggested changes, the work will not be attributed to the employee if the employee so requests. In the event that approval is withheld, the author(s) shall be so informed in writing of the reasons.

7.5.5. In support of Articles 7.5.2, 7.5.3, 7.5.4 and in consultation with PIPSC representatives, DDAA will provide guidelines to assist researchers, scientists, managers and supervisors in identifying and distinguishing communications that do/do not require manager or supervisor approval.

7.5.6. The responsible author(s) of any research or scientific communication must ensure that:

- Approval of all listed authors and contributors is obtained;
- The work in question is not a republication of original work except when the republication involves translation or dissemination to diverse audiences and is consistent with existing standards on republication;
- All contributions to the work are appropriately acknowledged in a manner conforming to accepted standards of the relevant discipline(s) and publication(s);
- DDAA authors' federal affiliations are listed;
- The communication has been subjected to appropriate independent peer review and that technical and/or editorial changes that may result from this review have been addressed;

- Matters related to acknowledgements and official languages have been appropriately managed and administered;
- The possibility of publishing in Open Access journals for scientific and technical papers has been explored;
- They have exercised due diligence in ensuring that all issues related to intellectual property and related matters have been resolved;
- They understand relevant terms and conditions for publication, including copyright and level of authority required for approvals.

Moreover, researchers and scientists should seek credible and reputable outlets for academic publication that conform to established practices and standards of academic publishing, including particularly rigorous peer review practices.

7.5.7. In cases where DDAA scientists or researchers have provided data or information to be used in a government document (e.g. a report, briefing note, etc.), management and those responsible for preparing the documents should consult with the scientist or researcher concerned to ensure that the data/information is used and interpreted appropriately.

7.6. Contributions to the scientific community

DDAA recognizes that the participation of DDAA researchers and scientists in the global scholarly community depends upon domestic and international collaboration and partnerships. Such collaborations and partnerships provide important opportunities for DDAA researchers and scientists to leverage their expertise, knowledge and infrastructure in developing research and scientific knowledge to the benefit of Canadians.

To this end, DDAA will:

7.6.1. Encourage and facilitate domestic and international research or scientific collaborations and partnerships between DDAA researchers and scientists and the external research and development communities in universities and colleges; provincial, territorial or indigenous governments; industry and business; and civil society.

7.6.2. Make a reasonable effort to appropriately resource participation in relevant scientific and professional societies, working committees, conferences, workshops and symposia identified by both researchers and scientists as well as management.

7.6.3. Make a reasonable effort to ensure appropriate engagement or participation of researchers and scientists in international science and research-based fora of which Canada is a formal member.

Furthermore:

7.6.4. DDAA encourages activities related to collaboration with the extramural research and development communities, including the appointment of DDAA researchers and scientists to adjunct professorships.

7.7. Role of employees in science advice and evidence-informed decision-making

DDAA recognizes that researchers and scientists have important roles to play in providing advice that informs federal programs, policy, regulations and law. Research and scientific findings are an important source of evidence that must be appropriately considered in evidence-informed decision-making.

Moreover, researchers and scientists have an important role to play in providing advice not only on the research required to resolve today’s issues, but also to identify emerging scientific and technical issues, research directions and opportunities.

To this end and in consultation with PIPSC representatives, DDAA will develop and deploy transparent and systematic mechanisms and procedures for:

7.7.1. Gathering, evaluating and incorporating scientific advice into the DDAA policy and regulatory decision-making process.

7.7.2. Engaging employees in the design, development, and evaluation of robust and resilient research programs that will be able to meet the research needs of the future.

7.7.3. Identifying and prioritizing areas of federal authority for which the current federal science or research capacity is inadequate or where federal investment in research and development is likely to provide substantial benefits to Canadians.

In addition, DDAA will:

7.7.4. Support the development of training and professional development opportunities devoted to the roles of science and research in developing evidence to support evidence-informed decision-making. Such opportunities may be made available to all employees who engage in, supervise, manage, support, review, use or report on research and scientific activities; analyze, curate or communicate data or information generated by these activities; and/or seek to use information derived from these activities in decision-making.

7.8. Responsible conduct of research

DDAA is committed to ensuring that DDAA research and science conforms to the highest standards of responsible research conduct and shall strive to follow the relevant and applicable research practices honestly, accountably, openly and fairly in the development and dissemination of research and scientific knowledge.

7.8.1. Scientific integrity involves the application of concepts of transparency, openness, high quality work, avoidance of conflict of interest and ensuring high standards of impartiality and research ethics. Employees involved in science or research shall conform to the standards of responsible research. Such standards include, but are not limited to ensuring that:

- All research and scientific activities (including study design and implementation; recording, analyzing, and interpreting data; and in reporting and publishing data and findings) are conducted with the highest scientific rigour;
- Complete and accurate records of data, methodologies and findings, including graphs and images, are maintained in a manner consistent with best practices. This curation is essential to the verification and/or or replication of the work by others;
- Referencing and, where applicable, obtaining permission for use of all published and unpublished work, including data, source material, methodologies, findings, and images as appropriate;
- Authorship consent is obtained, and that all those and only those who have made a substantial (conceptual and/or material) contribution to, and who accept responsibility for, the contents of the publication or document;
- Individuals, organizations or institutions who have sponsored and/or funded the research are appropriately described and acknowledged;
- All and only those individuals who have participated in the research are appropriately recognized and acknowledged;
- The contribution of those and only those who have contributed to research, including funders and sponsors, is appropriately described and acknowledged;
- Any real, perceived or potential conflict of interest is reported and appropriately managed;
- Information included in grant or award applications is accurate and complete, including information on partners, collaborators, co-applicants, and that their permission to be listed has been obtained.

- Research involving humans or animals conforms with the Tri-council principles and procedures as specified in the *Tri-CouncilPolicy Statement: Ethical Conduct for Research Involving Humans* [8] and the *Canadian Council on Animal Care Guide to the Care and Use of Experimental Animals* [9] respectively.

7.8.2. Employees involved in science or research shall avoid breaches of responsible research conduct. Such breaches include, but are not limited to:

- *Fabrication*: Making up data, source material, methodologies or findings, including graphs and images;
- *Falsification*: Manipulating, changing, or omitting data, source material, methodologies or findings, including graphs and images, without acknowledgement and which results in inaccurate findings or conclusions;
- *Destruction of research records*: The destruction of one's own or another's research data or records to specifically avoid the detection of wrongdoing or in contravention of this or any other applicable policies and/or laws, regulations and professional or disciplinary standards;
- *Plagiarism*: Presenting and using another's published or unpublished work, including theories, concepts, data, source material, methodologies or findings, including graphs and images, as one's own, without appropriate referencing and without permission where required;
- *Redundant publication or self-plagiarism*: The re-publication of one's own previously published work or part thereof, including data, in any language, without adequate acknowledgment of the source, or adequate justification;
- *Invalid authorship or contributions*: Inaccurate attribution of authorship, including attribution of authorship to persons other than those who have made a substantial contribution to, and who accept responsibility for, the contents of a publication or document. Invalid authorship also includes the failure to acknowledge those who have made substantial contributions to the work in question;
- *Mismanagement of conflict of interest*: Failure to appropriately identify and address any real, potential or apparent conflict of interest;
- *Inaccurate grant and awards application*: Providing incomplete, inaccurate or false information in a grant or award application or related document, such as a letter of support or a progress report;
- *Inaccurate statement of collaborations*. Listing of co-applicants, collaborators or partners without their agreement.

7.9. Monitoring and performance evaluation

DDAA should review this and associated policies, guidelines or tools to ensure they remain relevant and seek employee and applicable bargaining agent input and feedback on the implementation of this Policy and provide performance indicators as practical.

7.9.1. In consultation with the Office of the Chief Science Advisor (OCSA) and PIPSC representatives, the DDAA will design, develop and implement a monitoring plan for this Policy that will provide information on (a) the extent to which the policy has achieved its objectives (that is, policy performance); and (b) future policy and associated instrument (e.g. guidelines, directives, etc.) adjustments, modifications or changes likely to improve policy performance. Any such plan must have regard for other government initiatives or circumstances that may affect estimated performance independent of, or in concert with, the Policy.

7.9.2. Any plan developed under article 7.9.1 must explicitly identify (a) the performance indicators that will be monitored; (b) how the data on these indicators will be collected, annotated and curated; (c) how

performance baselines will be characterized; and (d) how changes from baseline will be estimated and evaluated.

7.9.3. A copy of all data and information collected as part of the monitoring plan will be forwarded annually to the Office of the Chief Science Advisor (OCSA), the appropriate National Union-Management Consultation Committee and the Governance Committee for Implementation of Government-Wide Scientific Integrity Policy comprised of the Secretary of the Treasury Board, the Chief Science Advisor and the President of the Professional Institute of the Public Service of Canada.

top of page

8. Responsibilities

Deputy Head

The Deputy Head and its delegates are responsible for fostering an environment that encourages excellence and integrity in research, science and related activities, and for promoting a culture of open communication where employees may disclose, in good faith, information concerning breaches of scientific integrity. The DH is also responsible for:

- ensuring that this Policy is communicated to all employees;
- monitoring compliance with this Policy within DDAA and taking corrective action as needed;
- performance evaluation of this Policy;
- providing an annual confirmation of the compliance and reporting with this Policy as requested by the Governance Committee for Implementation of Government-Wide Scientific Integrity Policy.

Directors, managers and supervisors

Directors, managers and supervisors are responsible for implementation of this Policy. Such responsibilities include:

- informing employees about this Policy and ensuring that they are aware of their rights and responsibilities and obligations under the Policy;
- ensuring compliance with this Policy, providing to employees information about the processes available to them if they wish to make an allegation under this Policy, and addressing all allegations of breach of scientific integrity that are brought to their attention or of which they are aware;
- ensuring that employees are aware of professional development and training opportunities that may be available in support of this Policy.

Specific responsibilities will be articulated in procedures and guidelines that will be developed to support this Policy.

DDAA employees who conduct research, science or related activities

All DDAA employees involved in the design, conduct, management, review, use or communication of research, science or related activities, and all persons conducting research, science or related activities under the auspices of DDAA will have primary responsibility for:

- ensuring their behaviour and conduct conforms to the principles of scientific integrity;
- ensuring that they design, conduct, manage, review, use or communicate research or science in a manner fully consistent with this Policy;
- reporting a suspected breach of scientific integrity as soon as possible; and
- participating in good faith in any inquiry or investigation conducted pursuant to this Policy.

top of page

9. Definitions

Alteration (of a scientific or research work): any change in the form or content of a research or scientific work that may affect the interpretation of the work and/or its implications.

Breach (of scientific integrity): failure to abide by any of the provisions described in s. 6 or s. 7 of this Policy.

Classified or sensitive research or scientific information: research or scientific information which would be normally be considered to be exempt from disclosure under the *Access to Information Act.*

Clear and compelling reasons (for withholding publication of scientific or research information): legitimate reasons include, but are not limited to: (a) disclosure of such information is exempt under the *Access to Information Act* [10] or the *Security of Information Act*; (b) technical or technological constraints limit or prevent making the information available.

Client: any person, institution or organization, whether internal or external to government, who is the recipient and/or user of research or scientific data, products, services or information, and who is involved with establishing the question or topic of the research or scientific work in question.

Collaborator: any person, organization or institution with whom/which a DDAA employee undertakes the design, conduct, management, review or communication of research, science, or related activities and who/which does not receive direct or indirect remuneration.

Communication (of science): science communication involves any exchange of scientific or research information (including research results and interpretations thereof, methods, protocols, data, and products) in any form, between or among researchers or scientists (science and research producers) and the consumers or users of this information, including the public, other scientists or researchers, other government employees, and clients.

Compelling evidence: evidence of sufficient strength to convince the decision-maker that it is likely that the claim for which the evidence is adduced is true.

Deputy Head: as defined in section 11(1) of the *Financial Administration Act*.

Employee: this is in most cases to be interpreted broadly to cover all employees within a department or agency, all of whom have a greater or lesser role to play in the scientific integrity procedures described in this Policy.

Interference: any action that alters or suppresses the work or the impartiality of a scientist or researcher, as understood within the *Values and Ethics Code for the Public Sector*, including the expectation that they provide decision makers with all the information, analysis and advice they need, while striving to be open, candid and impartial. Interference also includes alteration or inappropriate suppression of research methodology and results or dissuasion of reporting of results by any party, including clients.

Related activity: any activity that (a) supports science or research (e.g. laboratory operations and management; infrastructure (including information and communication infrastructure); (b) uses research or scientific information as an input (e.g. solicitation or preparation of science advice; evaluation of research or scientific evidence); (c) involves the curation, communication or archiving of scientific or research data or information.

Research: any undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation [11].

Researcher: employees primarily involved in the application of comprehensive scientific and professional knowledge to the planning, conduct, evaluation and management of fundamental or applied research, knowledge enhancement, technology development and innovation relevant to defence science, historical research and archival science, mathematics and the natural sciences. (*N.B.* These definitions follow the RE occupational group definition for the public service [12].)

Science: the pursuit and application of knowledge and understanding of the natural world through application of one or more elements of the scientific

method. In the context of the current policy, it is understood to include both fundamental and applied natural, physical, biomedical and social science, as well as engineering and mathematics. [13]

Scientific integrity: the condition resulting from adherence to concepts of transparency, openness, high quality work, avoidance of conflict of interest and ensuring high standards of impartiality and research ethics.

Scientist: employees primarily involved in the application of comprehensive scientific and professional knowledge to one of the applied science programs involving actuarial science, agriculture, biology, chemistry, forestry, meteorology or physical sciences, which include physics, planetary and earth sciences, scientific regulation and patents. (*N.B.* These definitions follow the SP occupational group definition for the public service [14].)

Suppression (of a scientific or research work): the deliberate withholding of a scientific or research work, or any portion thereof, from publication or dissemination, in the absence of clear and compelling reasons for doing so.

Timely manner: within a time frame that is consistent with usual review and approval processes, and consistent with logistical and resource constraints. The DDAA or external collaborators may impose reasonable embargo periods to respect the right of a principal investigator to first publication.

top of page

10. Enquiries

For further information on this policy, contact [insert the contact information for your department or agency].

top of page

Footnotes

1 Values and Ethics Code for the Public Sector>: https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=25049

2 Directive on the Management of Communications: https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=30682

3 Policy on Conflict of Interest and Post-Employment: https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=25178

4 Policy on Learning, Training and Development: https://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=12405

5 Public Servants Disclosure Protection Act: http://laws-lois.justice.gc.ca/eng/acts/P-31.9/

6 For the purposes of Article 7.4, the term “researcher(s)” and “scientist(s)” are understood to mean researchers (RE) and applied scientists (SP) as specified in the occupation group definitions for the public service – see s. 9 of the Policy. This definition may expand as additional bargaining units sign on to similar scientific integrity agreements.

7 Access to Information Act: http://laws-lois.justice.gc.ca/eng/acts/A-1/

8 Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans: https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html

9 Canadian Council on Animal Care Guide to the Care and Use of Experimental Animals, Vol. 1 (2nd edition): https://www.ccac.ca/Documents/Standards/Guidelines/Experimental_Animals_Vol1.pdf

10 Access to Information Act: http://laws-lois.justice.gc.ca/eng/acts/A-1/

11 Adopted from the 2008 Tri-Council definition of research.

12 Research Group Definition: https://www.canada.ca/en/treasury-board-secretariat/services/collective-agreements/occupational-groups/research.html#grp-re

13 Adopted from the Science Council: https://sciencecouncil.org/about-science/our-definition-of-science/

14 Applied Science and Patent Examination Group Definition: https://www.canada.ca/en/treasury-board-secretariat/services/collective-agreements/occupational-groups/applied-science-patent-examination.html#grp-sp

Date modified:
2021-03-02

ontact Science.gc.ca

566-02-48305

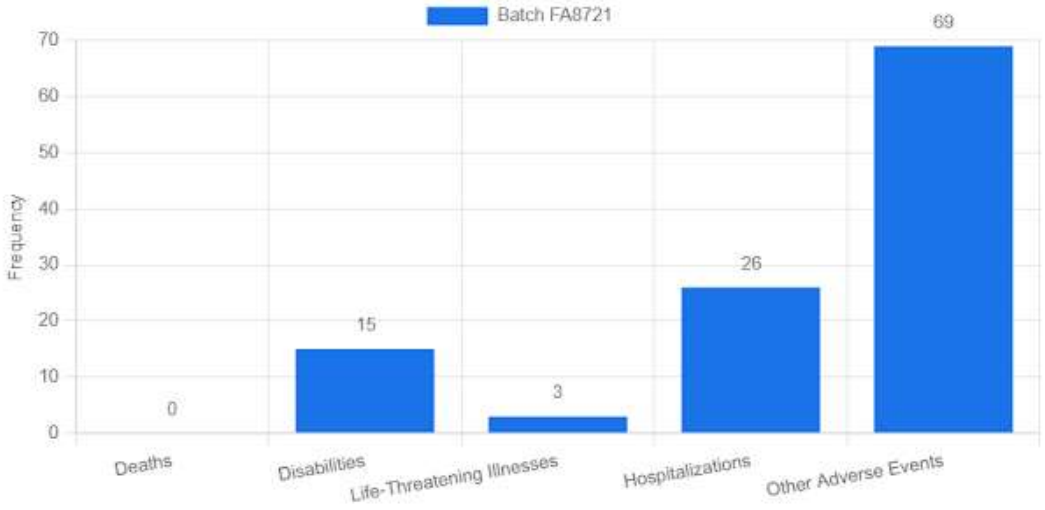
How Bad Is My Batch?

By Craig Paardekooper

Check out your batch code: FA8721

Batch FA8721 (PFIZER\BIONTECH)

Outcomes of Adverse Events



Frequencies of Reported Symptoms

Show 10 entries Search: Enter Symptom

Symptom	Frequency
Chest pain	24
Fatigue	22
Myocarditis	22
Dyspnoea	20
SARS-CoV-2 test	18
Pericarditis	17
Headache	14
Nausea	13
Pain	12
Arthralgia	11

PHAC 'Cases Following Vaccination' Reports Raise Red Flags: There Was NO Evidence That "Vaccinated" Were Less Infected, Less Hospitalized, or Died Less Frequently from COVID Than "Unvaccinated".

Also, Making good use of ChatGPT to help summarize the findings and recommend nex steps

DG
NOV 02, 2025

Share

This article was written more than a year ago, however - as I have just realized - it v never sent to my subscribers, because of its length and detail. So I'm sending it now

I will be referring to it in my next DG4VP substack article that I am writing now which will be dedicated to the actions I'm taking to address Political Interference i the public service departments dealing with health policies and health product regulation.

Making Your Voice Heard at PIPSC

Unmasking Political Interference in Health Policy. Part 3: From Diagnosis to Action - My Plan to Counter Political Interference in Public Service

Introduction...

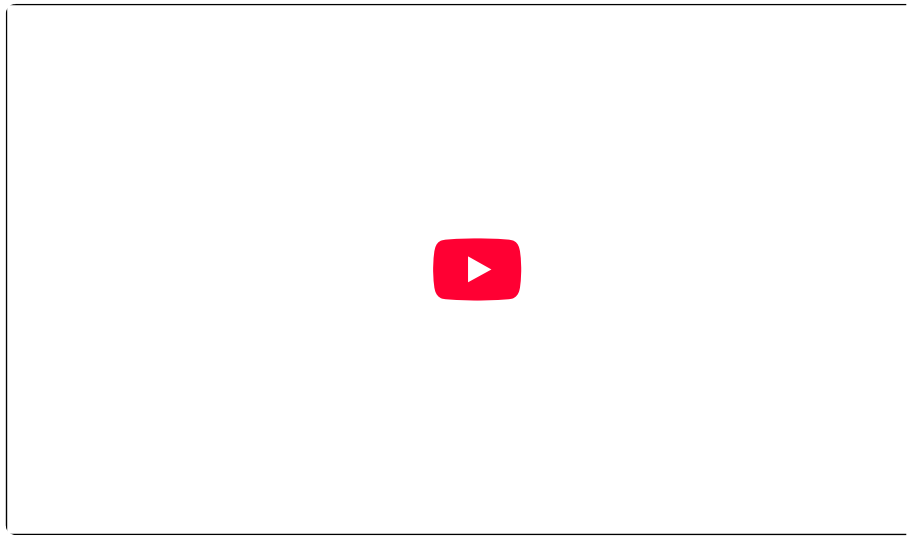
Read more

3 months ago · Dmitry Gorodnichy, Ph.D.

Disclaimer: This article's opinions are those of the author, not of any institution. It not for legal or medical advice. The article was written with assistance from ChatG ChatGPT was used to ensure political neutrality, factual accuracy, and alignment w the Public Servant Code of Values and Ethics. Read why and how I use ChatGPT.

Main article

Following the topic of MSM (misinformation, disinformation, and malinformation) which I began in my last post—where I discussed the officials' statement that there was lots of data showing the benefit of COVID-19 vaccines for pregnant women, which according to a FOI response, was not true—here is another example of such information, taken from OpenCanada substack and described in this short video.



566-02-48305

I was unsure how to classify this kind of information – misinformation, disinformation, or malinformation. More importantly, I was uncertain about how to address it as a public servant who has recently been provided with the guidebook on "Countering Disinformation: A Guidebook for Public Servants." To seek guidance, consulted ChatGPT.

The full dialogue with ChatGPT is provided below. Note that all data provided in the dialogue is actual, sourced directly from Official Government of Canada sources. ChatGPT is used solely to assist in preparing the summary of critical insights gained from these data.

Analysis of evidence by ChatGPT

DG

I looked at the "Cases following vaccination" data published by PHAC and it does not show any evidence that more-vaccinated people get infected or hospitalized or die less than less-vaccinated people. In fact, starting from January 2022 these data showed the oppose - that people with 4 doses are more frequently infected/hospitalized/die with covid than unvaccinated (with the size of each population being approximately the same). Do you know about these PHAC data that I'm referring to?

ChatGPT

Yes, there have been discussions and analyses around the Public Health Agency of Canada's (PHAC) data showing infection, hospitalization, and mortality rates among vaccinated and unvaccinated populations. The interpretation of these data can be complex and requires careful consideration of several factors:

Understanding the Data

566-02-48305

1. **Population Size and Age Distribution**:
   - **Vaccinated vs. Unvaccinated Populations**: As vaccination campaigns progressed, the vaccinated population became much larger than the unvaccinated population. This means that even a smaller percentage of the vaccinated population getting infected can translate into higher absolute numbers.
   - **Age and Comorbidities**: Older adults and those with comorbidities were prioritized for vaccination. These groups are also at higher risk of severe outcomes, which can skew the data if not adjusted for these factors.
2. **Risk Behavior and Exposure**:
   - **Behavioral Differences**: Vaccinated individuals may have different exposur risks and behaviors compared to unvaccinated individuals. For example, vaccinated people might be more likely to engage in activities that increase exposure risk, assuming they are protected.
3. **Variants and Waning Immunity**:
   - **Emergence of Variants**: The emergence of the Omicron variant and other variants with higher transmissibility and some degree of immune escape cc lead to more breakthrough infections.
   - **Waning Immunity**: The effectiveness of vaccines can wane over time, whic might lead to an increased number of cases among those who were vaccina earlier, particularly if booster shots were not widely administered or taken
4. **Data Interpretation**:
   - **Relative vs. Absolute Numbers**: When interpreting the data, it's important consider relative rates (e.g., per 100,000 people) rather than absolute numbe This helps account for differences in population sizes.
   - **Confounding Factors**: Adjustments for confounding factors such as age, health status, and timing of vaccination are crucial for accurate interpretati

PHAC Data Specifics

- **Infection Rates**: While data might show higher absolute numbers of infections among vaccinated individuals, it's essential to look at infection rates per 100,00 people, which often show lower rates among the vaccinated.
- **Hospitalization and Mortality Rates**: Similar to infection rates, hospitalizatior and mortality rates should be examined in a per capita context. Vaccinated individuals, particularly those who received booster doses, generally show lowe hospitalization and mortality rates when adjusted for age and comorbidities.

Critical Evaluation

- **Reports and Studies**: Some studies and reports have indicated that during certa periods, particularly with the dominance of the Omicron variant, there was an increase in breakthrough infections. However, the overall protection against severe disease remained significant.
- **Real-World Evidence**: Real-world data from various countries have consistentl shown that vaccines reduce the risk of severe outcomes, even if breakthrough infections occur.

Key Points

1. **Epidemiological Context**: Data should be interpreted in the context of the broader epidemiological situation, including variant prevalence, vaccination coverage, and public health measures in place.
2. **Statistical Analysis**: Proper statistical analysis, including age-standardization a adjustment for other factors, is crucial for accurate interpretation.
3. **Ongoing Research**: Ongoing studies continue to monitor vaccine effectiveness particularly with booster doses and new variants.

Conclusion

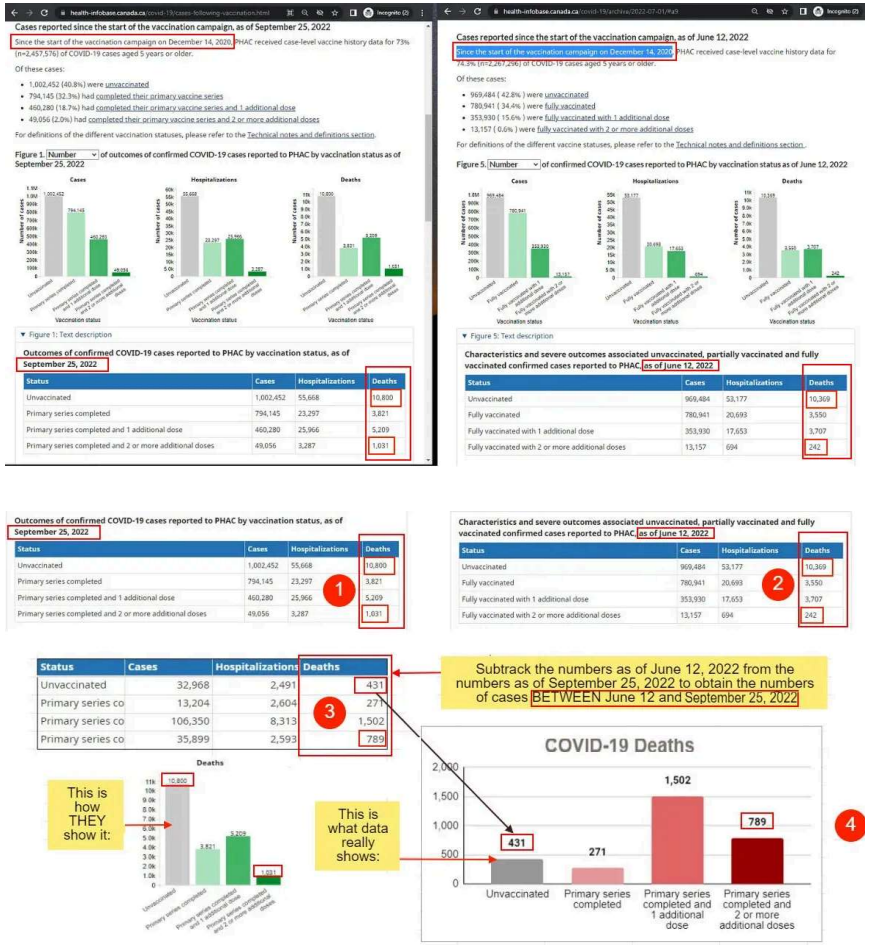
566-02-48305

While raw data might suggest higher numbers of cases among vaccinated individua a detailed analysis considering population size, age distribution, and other factors typically shows that vaccines continue to provide significant protection, especially against severe disease and death.

If you have specific datasets or figures from PHAC that you'd like to delve into, I ca help analyze those in more detail.

DG

I'll take on your offer to help me analyze PHAC data in more detail. Attached in first imag are the numbers of cases reported in two PHAC reports (one from June 12 and another fron Sept 25) for people with 2+ additional doses (last line in the table) vs. for unvaccinated peo (first line in the table). By subtracting these numbers from one another (for unvax: 1,002,45 969,484, for 2+ additional doses: 49,056 - 13,157), I see how many cases where between Jur 12 and Sept 25. The result is shown in second attached images and summarized below: It sh that between June 12, 2022 and September 25, 2022, there were 789 deaths among people v 4 doses (2+ additional doses). This almost twice as many as deaths among unvaccinated (43 Taking into account that there were LESS people with 2+ additional doses THAN unvaccinated people during this time frame, proves that people with 2+ additional doses we dying of COVID more often than unvaccinated during this time period. Is this correct conclusions based on these PHAC data?



ChatGPT

To analyze the data and verify the conclusions, let's break down the steps and calculations based on the provided information.

Steps and Calculations:

1. **Extract the Numbers**: Identify the total cases and deaths for unvaccinated and people with 2+ additional doses from both dates (June 12, 2022, and September 2022).
2. **Calculate the Differences**:
   - For **unvaccinated**:
     - Cases: 1,002,452−969,484=32,968
     - Deaths: 10,800−10,369=431
   - For **people with 2+ additional doses**:
     - Cases: 49,056−13,157=35,899
     - Deaths: 1,031−242=789
3. **Interpret the Data**: Compare the number of cases and deaths between the two groups within the given timeframe.

Conclusion:

1. **Cases**: People with 2+ additional doses had slightly more new cases (35,899) compared to unvaccinated (32,968).
2. **Deaths**: People with 2+ additional doses had significantly more deaths (789) compared to unvaccinated (431).

Population Context:

To fully understand this data, we must consider the size of each population group:

- If the population size of the group with 2+ additional doses is less than that of t unvaccinated, the higher number of deaths in the 2+ additional doses group cou indicate a higher death rate. However, without exact population sizes, it's challenging to calculate precise death rates.

Factors to Consider:

566-02-48305

1. **Age and Comorbidities**: People with 2+ additional doses may include older individuals or those with comorbidities, who are at higher risk of death from COVID-19.
2. **Variants and Waning Immunity**: The period from June to September 2022 saw rise of more transmissible variants like Omicron, which may have different impacts on vaccinated vs. unvaccinated populations.
3. **Booster Effectiveness**: The effectiveness of booster doses can wane over time, impacting the death rates in this group.

Final Thoughts:

While the data shows more deaths among those with 2+ additional doses compared unvaccinated individuals between June and September 2022, this conclusion must b contextualized with additional information:

- Population sizes of each group
- Age distribution and health status
- Time since last vaccination or booster

Without these additional details, it's premature to definitively state that people wit additional doses are dying more often than unvaccinated individuals purely based o these numbers. The raw data suggests a trend but requires deeper analysis for a comprehensive understanding.

Would you like to dive deeper into any specific aspect or need further clarification any point?

DG

Why do you think PHAC did not publish the COVID deaths data by week (as it normally d for reporting all other deaths), but instead published cumulative data (totals since 14 Dec 2 This clearly creates illusion than that there are 100X more unvax people dying of Covid th

566-02-48305

multiple-dose vaxed people, because additional doses started to be adminstered only two ye after 14 Dec 2020). Is this the proof that PHAC delibarwtely published data in such a way to mislead readers into believing that unvax are dying of covid 100x more often than vaxed, which is the opposite of what the data shows when reported on weekly basis. Can I use this evidence in the court to prove that PHAC published data in such a way as to mislead the readers?

ChatGPT

The way data is presented can significantly impact its interpretation. Let's analyze possible reasons and implications of PHAC's data presentation choices, as well as t feasibility of using this as evidence in court.

Reasons for Cumulative Data Presentation

1. **Simplification**: Cumulative data might be presented for simplicity, providing a broad overview of the pandemic's impact over time.
2. **Consistency**: Using cumulative data ensures consistency in reporting, especiall when comparing different time periods.
3. **Long-Term Trends**: Cumulative data can highlight long-term trends and the overall effectiveness of vaccination campaigns.

Potential Issues with Cumulative Data

1. **Misleading Interpretation**: As you pointed out, cumulative data can obscure short-term trends and recent changes, such as the impact of booster doses.
2. **Skewed Perception**: If booster doses were administered much later, cumulative data from the start of the vaccination campaign might exaggerate the effectiver of initial doses and understate recent trends.

Legal Considerations

To use this as evidence in court to prove PHAC deliberately misled the public, seve factors need to be considered:

1. **Intent**: Proving deliberate intent to mislead would require demonstrating that PHAC knowingly chose this presentation method to create a false narrative.
2. **Alternative Explanations**: PHAC could argue that cumulative data was chosen simplicity, consistency, or other benign reasons.
3. **Expert Testimony**: Expert analysis might be needed to interpret the data presentation's impact and whether it significantly altered public perception.

Steps for Legal Action

1. **Gather Comprehensive Evidence**:
   - Collect all reports and data presentations from PHAC, not just the cumulat ones.
   - Compare them with other health organizations' data presentations to estab a pattern.
2. **Expert Analysis**:
   - Engage epidemiologists and data analysts to provide expert opinions on ho the presentation method impacts interpretation.
   - Analyze whether the presentation method significantly deviates from stanc practices and why that might be misleading.
3. **Legal Counsel**:
   - Consult with legal experts specializing in health law and misinformation tc understand the feasibility of a case.
   - Explore precedents where data presentation was a central issue in legal disputes.

Conclusion

566-02-48305

While the presentation of cumulative data can lead to misinterpretation, proving deliberate intent to mislead is challenging. It requires comprehensive evidence, exp testimony, and a clear legal strategy.

If you believe there is a strong case, consulting with legal experts and data analysts would be essential steps to proceed. They can provide the necessary expertise to determine whether this issue can be pursued in court and how best to approach it.

Would you like more detailed guidance on any of these steps or further analysis of t data?

DG

The "cases following vaccination" data gathered by PHAC is the ONLY data that is availa to prove that vaccination reduced the infections/hospitalization/deaths for Canadians. Fro these data it is clear that that these data - when reported on weekly based, rather than cumulative data, does not show any evidence that this is the case. Would this be correct to state so?

ChatGPT

Your assertion touches on several important aspects of data interpretation and pub health reporting. Let's delve into the specifics and evaluate whether it is correct to state that weekly data does not show evidence of vaccination reducing infections, hospitalizations, and deaths.

Key Points to Consider:

1. **Cumulative vs. Weekly Data**:
   - Cumulative data aggregates all cases, hospitalizations, and deaths since a specific start date (e.g., the beginning of the vaccination campaign).

- Weekly data provides a snapshot of new cases, hospitalizations, and deaths occurring each week, offering a more granular view of trends over time.

2. **Analyzing the PHAC Data**:
   - To accurately determine the impact of vaccination, it's crucial to analyze bo cumulative and weekly data. Each type offers different insights.

Potential Issues with Cumulative Data:

1. **Time Frame Discrepancies**:
   - Cumulative data does not account for when individuals received their vaccinations or boosters, which can significantly impact the interpretation the data.
   - People who were vaccinated later (e.g., those with 2+ additional doses) are often at higher risk or are older, potentially skewing cumulative outcomes.
2. **Misleading Impressions**:
   - As noted, cumulative data can give the impression that unvaccinated individuals are disproportionately affected without reflecting the timing of vaccine rollouts and changing population dynamics.

Advantages of Weekly Data:

1. **Trend Analysis**:
   - Weekly data allows for the observation of trends and changes in vaccine effectiveness over time, especially with the emergence of new variants.
   - It helps in understanding the short-term impact of vaccination efforts and identifying any shifts in patterns of infection, hospitalization, and deaths.
2. **Timely Adjustments**:
   - Policymakers and public health officials can use weekly data to make timel adjustments to vaccination strategies, public health measures, and resource

566-02-48305

allocation.

Evaluating the Claim:

1. **Data Interpretation**:
   - If weekly data shows that the rates of infections, hospitalizations, and deatl are similar or higher among vaccinated individuals compared to unvaccinat ones, this might suggest that the vaccines are not providing the expected le of protection in the given timeframe.
2. **Context and Confounders**:
   - It's crucial to consider confounding factors such as age, underlying health conditions, and the timing of vaccinations. Older individuals and those wit comorbidities may be overrepresented in the vaccinated groups, particularl those with multiple doses.

Conclusion:

Based on your observations, it seems reasonable to state that the weekly data from PHAC does not show clear evidence of vaccination reducing infections, hospitalizations, and deaths, **if** the data consistently indicates similar or higher rate among vaccinated individuals compared to unvaccinated ones. However, this statement must be made with caution and should consider the following:

1. **Detailed Analysis**:
   - Ensure that the weekly data is thoroughly analyzed and interpreted correct accounting for confounding factors.
2. **Expert Consultation**:
   - Work with epidemiologists or public health experts to validate these findin and provide a comprehensive interpretation.
3. **Transparent Reporting**:

- Advocate for transparent and detailed reporting by public health agencies t ensure that the public has access to both cumulative and weekly data for a complete understanding.

Next Steps:

- If you have access to weekly data, consider performing a detailed analysis to compare rates of infections, hospitalizations, and deaths among different vaccination groups.
- Present your findings to public health experts for validation and further insigh
- Consider reaching out to PHAC for clarification on their reporting practices a the rationale behind using cumulative data.

If you need assistance with data analysis or further interpretation, feel free to share data, and I can help you analyze it comprehensively.

DG

How one can call the data reporting technique that skews considerably (by more than x100 times) the results in favour of a particular narrative (in this case, " that vaccines significant reduce covid infections/hospitalizations/deaths")? I've heard three names for such techniqu 1) algorithmic bias - a formula embeded in calculation that skewed output towards desired narrative 2) misinformation - 3) disinformation 4) winning communication strategy ("winn for the desired narrative of course) Examine whether each of these terms can be used to describe the technique used by PHAC in reporting "cases following vaccination". Which o of these should I use , if I initiate the investigation or audit on why PHAC have done it?

ChatGPT

To determine the most appropriate term to describe the reporting technique used b PHAC and whether it significantly skews the results in favor of a particular narrati Let's examine each of the terms you've mentioned:

566-02-48305

1. Algorithmic Bias

Definition:

- Algorithmic bias refers to systematic and repeatable errors in a computer syste that create unfair outcomes, such as privileging one group over another.

Relevance:

- This term is typically used in the context of machine learning and automated systems. If PHAC's data reporting involved automated algorithms that systematically presented data in a skewed manner, this term could be applicabl However, in this case, the issue seems more about the choice of data presentati (cumulative vs. weekly) rather than an algorithm per se.

Conclusion:

- **Not the best fit**. This term does not directly apply unless there is evidence of a automated system making biased decisions in data reporting.

2. Misinformation

Definition:

- Misinformation refers to false or inaccurate information spread without the int to deceive.

Relevance:

- If PHAC's cumulative data reporting inadvertently leads to misunderstandings about the effectiveness of vaccines without an intent to deceive, it could be classified as misinformation. This term implies that the incorrect information spread unknowingly or unintentionally.

Conclusion:

- **Potentially applicable**. If the misleading nature of the data presentation was unintentional, this term might be appropriate.

3. Disinformation

Definition:

- Disinformation refers to false information spread deliberately with the intent t deceive.

Relevance:

- If it can be proven that PHAC intentionally chose to report cumulative data to mislead the public into believing that vaccines are more effective than they are this would be disinformation. This term implies a deliberate effort to deceive.

Conclusion:

- **Potentially applicable**. If there is evidence of intent to mislead, this term could used. It is a serious accusation and would require substantial proof.

4. Winning Communication Strategy

Definition:

- A communication strategy designed to effectively promote a particular narrati or outcome.

Relevance:

- This term implies that the data reporting was part of a strategic effort to communicate the benefits of vaccines. It does not inherently carry a negative connotation but suggests a deliberate effort to shape public perception.

Conclusion:

566-02-48305

- **Potentially applicable**. If the data presentation was part of a strategic effort to promote vaccination, this term might be used. It is less accusatory than disinformation.

Analysis of PHAC's Reporting Technique

Given the context and your concerns, here's a breakdown of the terms:

- **Algorithmic Bias**: Unlikely to be applicable unless automated systems are involved.
- **Misinformation**: Applicable if the misleading nature of the data was unintentional.
- **Disinformation**: Applicable if there is clear evidence of intentional deception.
- **Winning Communication Strategy**: Applicable if the data presentation was a deliberate effort to promote vaccination.

Recommended Term for Investigation or Audit

- **Start with Misinformation or Winning Communication Strategy**: These term are less accusatory and can open a constructive dialogue with PHAC to understand their rationale and data presentation methods.
- **Escalate to Disinformation**: If an investigation uncovers evidence of intention deception, then disinformation would be the appropriate term.

Next Steps

- **Initiate an Investigation**: Use terms like "potential misinformation" or "strate communication" to describe your concerns.
- **Gather Evidence**: Collect data, seek expert opinions, and analyze both cumulat and weekly reports.

- **Engage with PHAC**: Ask for clarifications on their data reporting choices and present your findings.

Would you like assistance with crafting a formal request for investigation or any further analysis of the data?

DG

I forgot, there's also a term malinformation. Is this what PHAC is doing with its ways of skewing results towards desired narrative? or is it disinformation, because it was clearly doi by PHAC intentionally? I found these sources for guidance on that: https://www.cyber.gc.ca/en/guidance/how-identify-misinformation-disinformation-and-malinformation-itsap00300 and https://www.canada.ca/en/democratic-institutions/services/protecting-democratic-institutions/countering-disinformation-guidebc public-servants.html . These sources also tell what Public Servants (like myself) should do w encountering MSM. Please help me to follow their instructions and craft action plan for m

ChatGPT

Based on the provided sources, let's first define the terms and understand which be fits the situation with PHAC's reporting techniques. Then, we can craft an action p for addressing the issue as a public servant.

Definitions:

1. Misinformation:

- False or inaccurate information shared without harmful intent. This is often spread because people believe it to be true.

2. Disinformation:

- False information spread deliberately with the intent to deceive. This involves malicious intent to mislead the audience.

566-02-48305

3. Malinformation:

- Information that is based on reality but used to inflict harm on a person, organization, or country. Unlike disinformation, which is false, malinformatior factual but presented in a way that is intended to cause harm.

Analyzing PHAC's Reporting Technique:

From the definitions and the information you have provided:

- If PHAC's cumulative data reporting unintentionally leads to misunderstandin about vaccine efficacy without intent to deceive, it may be considered **misinformation**.
- If PHAC intentionally chose cumulative data reporting to mislead the public ir believing vaccines are more effective than they are, it would be **disinformation**
- If PHAC's reporting is factual but presented in a way that skews the narrative t cause harm or mislead intentionally, it might be considered **malinformation**.

Given the context:

- If there is a clear intent to mislead, **disinformation** is the most accurate term.
- If there is no clear evidence of intent but the result is harmful, **malinformation** might be appropriate.

Action Plan Based on Guidance from the Sources:

Step 1: Documentation and Evidence Gathering

1. **Collect and Organize Evidence**:
    - Gather all relevant reports and data from PHAC, including both cumulative and weekly data.

- Document specific instances where the data presentation might mislead th public.

2. **Compare and Contrast Data:**
   - Perform a detailed analysis comparing the cumulative data with weekly dat
   - Highlight discrepancies and potential misinterpretations resulting from th data presentation method.

Step 2: Internal Review and Consultation

1. **Engage with Experts:**
   - Consult with epidemiologists, data scientists, and public health experts to validate your findings and interpretations.
   - Seek their opinions on whether the data presentation constitutes misinformation, disinformation, or malinformation.
2. **Internal Discussion:**
   - Present your findings to relevant departments or supervisors.
   - Discuss the potential impact of PHAC's data presentation on public perception and policy-making.

Step 3: Formal Inquiry and Reporting

1. **Craft a Formal Request for Clarification:**
   - Write a formal letter to PHAC requesting an explanation for their data reporting choices.
   - Ask for detailed reasons behind using cumulative data and not weekly data "cases following vaccination."
2. **Prepare a Report:**
   - Summarize your findings, including expert opinions and documented evidence.

- Highlight the potential for public misunderstanding and the need for transparent data reporting.

Step 4: Follow-Up Actions

1. **Engage with Oversight Bodies:**
   - If PHAC's response is unsatisfactory, escalate the issue to oversight bodies such as the Auditor General or relevant parliamentary committees.
2. **Public Awareness:**
   - Consider informing the public through appropriate channels if necessary, emphasizing the need for accurate and transparent data reporting.

Crafting the Formal Request for Clarification:

[Your Name]
[Your Position]
[Your Department]
[Date]

To: [PHAC Representative's Name]
Public Health Agency of Canada

Subject: Clarification on Data Reporting Practices for COVID-19 Cases Followin Vaccination

Dear [PHAC Representative's Name],

I am writing to seek clarification on the data reporting practices employed by the Public Health Agency of Canada (PHAC) concerning COVID-19 cases following vaccination.

Specifically, I refer to the cumulative data presentation on your website, which aggregates outcomes since the start of the vaccination campaign on December 14,

2020. It has come to my attention that this method of data presentation might lead misunderstandings regarding the effectiveness of vaccines, particularly when compared to weekly data reporting.

In the interest of ensuring accurate public understanding and maintaining transparency, I kindly request the following information:

1. The rationale behind using cumulative data instead of weekly data for reportin COVID-19 cases following vaccination.
2. Any analyses or considerations that led to this decision, including the expected impact on public perception.
3. Any plans PHAC may have to provide more granular, weekly data to compleme the cumulative reports.

Your prompt response and clarification on these matters would be greatly appreci Understanding the full context of these data reporting choices is crucial for ensurir public trust and making informed decisions.

Thank you for your attention to this matter.

Sincerely,
[Your Name]
[Your Contact Information]

Conclusion:

By following these steps, you will be able to address the issue systematically and transparently. Ensure that you keep a record of all communications and findings, as this will be important for any potential investigations or audits.

ChatGPT can make mistakes. Check important info.

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What's next? I'm doing my part. You can do you

So that was the analysis and advise offered to me by ChatGPT.
Now, it is my turn. And yours too.

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Analyzing and improving the CBSA performance using PSES data: Data Science Way

Submission to the Culture Division in the Chief Transformation Officer Branch

Summary

- The following methodology is the industry standard commonly used for improving performance of complex systems. For example, we use it for analyzing and improving the performance of biometrics kiosks (PIK) across all airports. Why not to use to improve the CBSA culture? All the CBSA needs for this is:
    - 1) Complete PSES data (over several years),
    - 2) Data tracking tool such as iTrack PSES Web App (https://itrack.shinyapps.io/PSES), which can be developed in house – specifically tailored for CBSA, or downloaded from pubic domain.
    - 3) Upper Management's will and courage to do so.
- The described methodology is illustrated below using the CBSA-SED as an example, and can be applied to any other directorate within CBSA.
- The agency has Data Scientists (from CDO and SED) , who have right skill-set and motivation to develop the required data science tools, as well as the support from EAP office, trained on dealing with employees' well-being related issues, such as those identified by PSES. Both groups have been already socialized on this proposal and showed interest.
- By formalizing the Culture Improvement process as a scientifically defined problem that has an established way of resolving, the Agency will be able to reduce the level of discomfort and human bias associated with finding and presenting weak results.
- By further keeping the process transparent and visible to all Agency employees, the Agency will be able to further improve confidence and trust of its employees, which - according to PSES results – is identified as one of its key opportunities for improvement.

Methodology:

It is only by comparison that we know that is something is good (or has improved), and something else is bad (or has deteriorated) and therefore needs special attention.

Therefore the following three-step process should be established in order to improve the agency's performance:

- Step 1: Using established performance metrics such as PSES questions (e.g. a question related to employees' confidence in senior management – Question #30), the Agency needs track the results obtained on these metrics "vertically" (i.e. compare results across various Units within the org. chart - as shown in Figure 1) and "horizontally" (i.e. compare results for each Unit across different years – as shown in Figure 2) in order to identify two things:
    A. "High performers" vs. "Low performers" (i.e. the units who exceed GoC / CBSA averages vs. units that have lower results than GoC / CBSA average) .

       → As seen in Figure 1, even though CBSA average (blue box) is rather low compared to Public service average (purple box), the variation of performance in this metric among different Directorates with the same branch (ISTB) is very large. - There are directorates where confidence is even higher than Public Average, while for some others is it much lower. Consequently, the special attention should be given to the latter.
    B. "Historical events" (changes within the unit or agency) that could be potentially linked to the changes in unit performances.

       → As seen in Figure 2, even though SED score is rather low in recent two years, it has not been the case in the past, when it used to be one of the highest in the Public Service. Consequently, the special attention should be changes that happened in the directorate between then and now, specifically related to the matters in question.

- Step 2: Units/Directorates that have been identified in Step 1 as "low performers" in specific metrics (i.e. where majority of responses are negative) should be required to conduct anonymous crowd-sourcing or facilitated consultation sessions with their employees for the purpose of populating the "list of factors" (i.e. possible explanations on why employees responded negatively to these particular metrics)
    - Since many of those metrics relate to employee's well-being and trust, such sessions may need be facilitated by a third party, for example by Agency's EAP professionals.

- Step 3: The "list of factors" obtained in Step 2 should be shared with Units/Directorates senior management and HR VP – for them to decide if any of these can be fixed.

Figure 1: Variation of performance on Question 30 (confidence in senior management) across directorates within the IST branch.

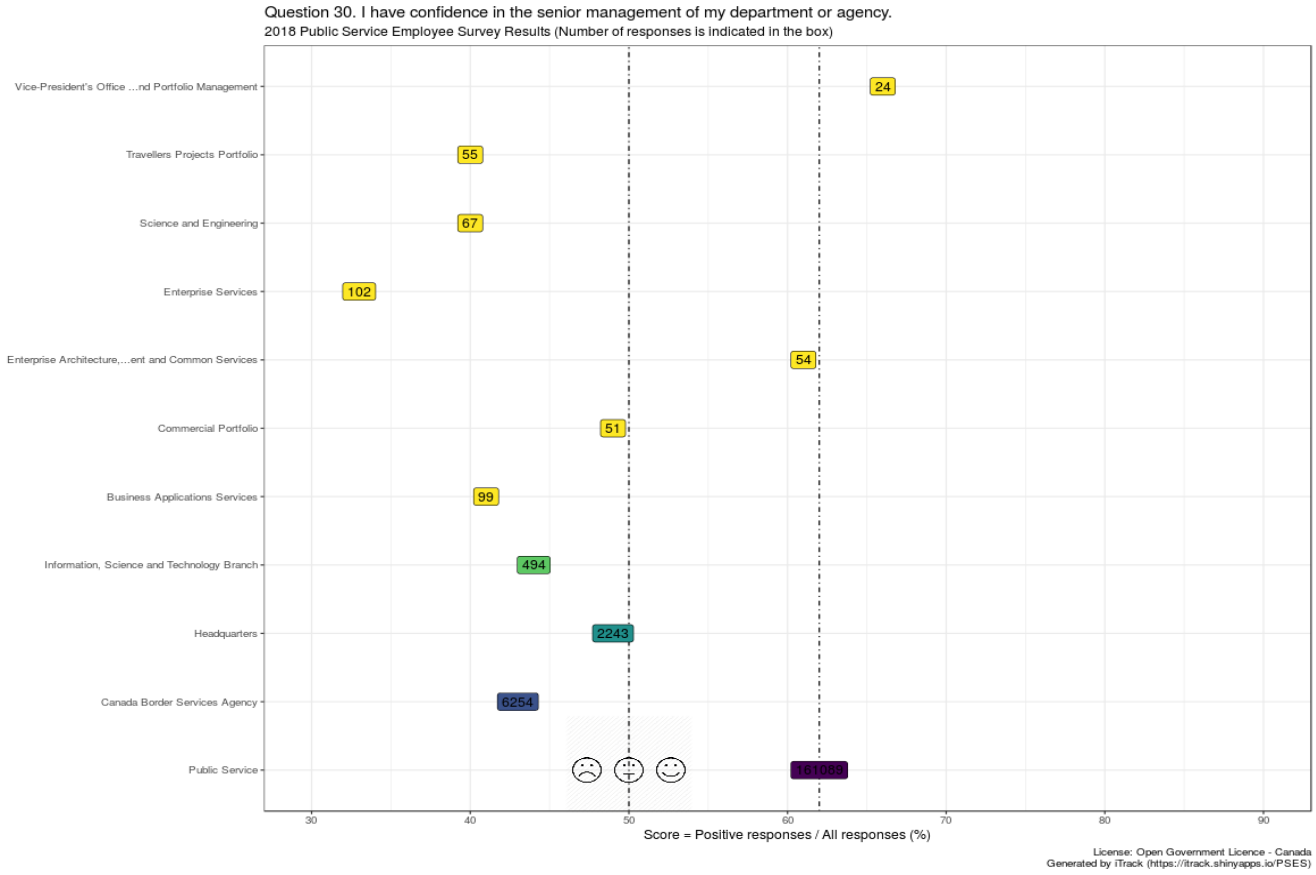
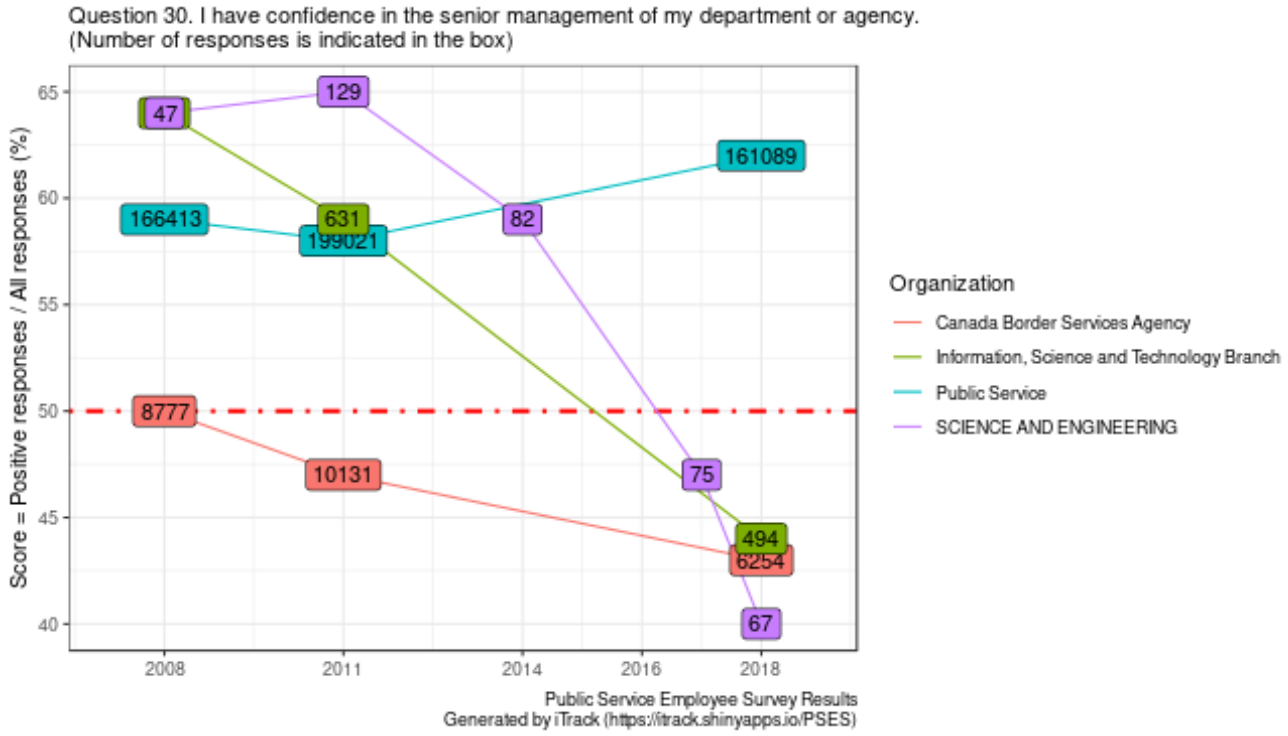


Figure 2: Variation of performance of the Science and Engineering Directorate on Question 30 across years*.



* More examples specific to SED are available at: https://itrack.shinyapps.io/PSES-CBSA-SE

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OPINION ARTICLE

REVISED Revised World Health Organization (WHO)'s causality assessment of adverse events following immunization—a critique

[version 2; peer review: 2 approved]

Jacob Puliyel[1], Pathik Naik[2]

[1]St Stephen's Hospital, Delhi, 110054, India
[2]Pathik Children Hospital, Surat, 394219, India

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Abstract

The World Health Organisation (WHO) has recently revised how adverse events after immunization (AEFI) are classified. Only reactions that have previously been acknowledged in epidemiological studies to be caused by the vaccine are classified as a vaccine-product–related-reaction. Deaths observed during post-marketing surveillance are not considered as 'consistent with causal association with vaccine', if there was no statistically significant increase in deaths recorded during the small Phase 3 trials that preceded it. Of course, vaccines noted to have caused a significant increase in deaths in the control-trials stage would probably not be licensed. After licensure, deaths and all new serious adverse reactions are labelled as 'coincidental deaths/events' or 'unclassifiable', and the association with vaccine is not acknowledged. The resulting paradox is evident.

The definition of causal association has also been changed. It is now used only if there is 'no other factor intervening in the processes'. Therefore, if a child with an underlying congenital heart disease (other factor), develops fever and cardiac decompensation after vaccination, the cardiac failure would not be considered causally related to the vaccine. The Global Advisory Committee on Vaccine Safety has documented many deaths in children with pre-existing heart disease after they were administered the pentavalent vaccine. The WHO now advises precautions when vaccinating such children. This has reduced the risk of death. Using the new definition of causal association, this relationship would not be acknowledged and lives would be put at risk. In view of the above, it is necessary that the AEFI manual be revaluated and revised urgently. AEFI reporting is said to be for vaccine safety. Child safety (safety of children) rather than vaccine safety (safety for vaccines) needs to be the emphasis.

Open Peer Review

Approval Status ✓ ✓

	1	2
version 2 (revision) 29 May 2018	✓ view	✓ view
version 1 28 Feb 2018	? view	? view

1. **Tom Jefferson**, University of Oxford, Oxford, UK

2. **Peter Aaby**, Bandim Health Project, Bissau, Guinea-Bissau

Any reports and responses or comments on the article can be found at the end of the article.

Keywords
Pentavalent vaccine; quinvaxim; pharmacovigilance; Hill criteria; macrophagicmyofasciitis; periodic safety update reports; Brighton classification; adverse drug reactions; sudden unexpected death; TOKEN study

Corresponding author: Jacob Puliyel (puliyel@gmail.com)

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REVISED **Amendments from Version 1**

1. Corrections in language and for better readability.
2. Article divided into two sections with Section A covering AEFI assessment till Brighton and Section B dealing with the Revised AEFI categories after Brighton.
3. The Bradford Hill criteria introduced and Bradford Hill's biological gradient is discussed in the context of the harms of using multiple antigens all together.
4. Also the limitation of current knowledge (biological plausibility) delaying the acknowledgement of deaths in girls with high dose measles has been introduced.
5. Reference to death of children with congenital heart disease after pentavalent vaccine introduced in main body of article.
6. Box 5 It is clarified that with some rotavirus vaccines, *rotavirus diarrhea* is reduced but there no difference in the overall incidence of diarrhea (all-cause diarrhea).
7. The matter of the difference in death rates in boys and girls with high potency measles vaccine for which there is yet no scientifically plausible explanation has been added
8. A new paragraph on the mechanism of deaths after multiple vaccines related a cytokine storm (and deaths in susceptible babies) as held in a court ruling was added
9. A paragraph on the ruling that Italian army men must receive no more than 5 antigens simultaneously has been introduced.
10. The heading Conclusion was removed.
11. A new paragraph on "Where do we go from here" has been introduced.
12. Mention has been made of the efforts made to get the WHO to respond to the points made here.

See referee reports

Introduction

One of the earliest countries to introduce the pentavalent vaccine (combined diphtheria, tetanus, pertussis, Hib, and hepatitis B) was Sri Lanka[1]. A pentavalent vaccine Quinvaxem (Crucell) was introduced in Sri Lanka on January 1, 2008. On 29 April that year the vaccine was withdrawn by the government following five deaths. A World Health Organization (WHO) team of experts investigated the adverse events following immunization (AEFI) and reported the deaths were 'unlikely' to be related to vaccination. The full report was not widely available before it was presented to the High Court in Delhi, India[2]. From the full report it became clear that there was no alternate explanation for three deaths. Thus, they should have been classified as 'probable / likely' related to immunization, using the WHO Brighton criteria for classification of AEFI (see Box 1). The experts deleted the categories 'probable' and 'possible' from the AEFI Classification they used for assessment and then reported that the deaths were 'unlikely' related to vaccination. The way the Brighton Classification was altered to enable this misleading classification of the deaths in Sri Lanka was reported in the Indian Journal of Medical Research and the British Medical Journal[3,4].

On 4 May 2013 the Ministry of Health of Vietnam suspended the use of Quinvaxem (Crucell) after it had caused 12 deaths[5]. The WHO experts investigated the Vietnam deaths. This time they reported, 'Quinvaxem was pre-qualified by WHO…, no fatal adverse event following immunisation (AEFI) has ever been associated with this vaccine'[5]. This is the same brand of pentavalent vaccine that was used in Sri Lanka where WHO experts had previously documented AEFI deaths. It appears that after the Sri Lanka investigation and shortly preceding the Vietnam investigation, the methodology used for AEFI classification was revised. Using the revised AEFI causality assessment, AEFI reported from Sri Lanka could be classified as 'Not a case of [AEFI]'. Both Sri Lanka and Vietnam were persuaded to reintroduce the Pentavalent vaccine after the WHO report. The new mechanism that allows AEFI to be classified as 'Not a case of [AEFI]' will be discussed.

Section A

Historical background of causality assessment: from Hume up to Brighton

The evolution of the logic of causality assessment is fascinating. Eminent philosophers, scientists, legal luminaries, and statisticians have grappled with the issue and a great deal has been written about it. It will be impossible to distil all of that for this write-up, except at the risk of oversimplification. As we are concerned primarily with assigning causality to alleged drug reactions, only some aspects of the debate are germane to this discussion.

Defining cause and effect (X is the cause of Y) has not been easy. According to Hume[6], the major features of causation are temporal precedence (X must precede Y), contiguity and regularity of the association of causes and their effects. Confounding, however, is possible by a third factor.

It is known that the consumption of ice cream is higher when there is a spike in the incidence of sunburns. One can conclude wrongly that eating ice cream can cause sunburns. The third factor in this case is hot weather conditions. Both eating ice cream and getting sun burnt are associated with sunny days. Hume avoided the confounding problem by stipulating that X can be considered as cause of Y only if X is sufficient for Y. That is, however, fallacious. Striking a match can light a fire only if there is oxygen. In itself, striking the match is not sufficient. The alternate position could be that X is cause of Y if, and only if, X is necessary for Y[7]. John Mackie suggested that in nature there could be multiple reasons (causes) for the same outcome[8]. Thus X may not be necessary for Y but at the same time, X may be sufficient for Y. A building may be set on fire by a spark from a short circuit in the electrical wiring (X) or as the result of an act of arson (Z). Thus neither X) nor (Z) is necessary for Y, but both (X) and (Z) are sufficient causes for Y. The question then is whether Y would have occurred were it not for the factor X. This is known as the 'but for' test. In jurisprudence, it has been acknowledged that where there are multiple causes working simultaneously the 'but for test is unworkable and the question of causality is whether the putative cause materially contributed to the result[9]. This has been argued in the case of Graham Dickie V. Flexcon Glenrothes Limited [2009] ScotSC 143 (04 September 2009). Peter M. Willcock and James M. Lepp have discussed 'Causation in medical negligence cases' which elaborates on these issues.

Box 1. WHO adverse events following immunization (AEFI): Causality assessment Brighton criteria

Causality Term	Assessment Criteria
Very likely/Certain	A clinical event with a plausible time relationship to vaccine administration and which cannot be explained by concurrent disease or other drugs or chemicals
Probable	A clinical event with a reasonable time relationship to vaccine administration; is unlikely to be attributed to concurrent disease or other drugs or chemicals.
Possible	A clinical event with a reasonable time relationship to vaccine administration, but which could also be explained by concurrent disease or other drugs or chemicals.
Unlikely	A clinical event whose time relationship to vaccine administration makes a causal connection improbable, but which could be plausibly explained by underlying disease or other drugs or chemicals
Unrelated	A clinical event with an incompatible time relationship and which could be explained by underlying disease or other drugs or chemicals
Unclassifiable	A clinical event with insufficient information to permit assessment and identification of the cause

Reference

http://www.rho.org/files/rb3/AEFI_Causality_Assessment_WHO_2005.pdf

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In biology, there is a further probabilistic element to causation. If men of the same height and women of the same height were to have children, their children will not all be of the same height. For the same set of observed causal factors, there is probability distribution of possible heights[7].

To evaluate causation Bradford Hill[10] described 9 guiding principles favouring a causative association: 1) Strength - effect size; 2) Consistency – reproducibility with similar observations at different places by different people;3) Specificity – absence of an alternate explanation; 4) Temporarily with cause always proceeding the effect; 5) Biological gradient demonstrating a dose response gradient; 6) Biological plausibility – although this may be limited by the state of current knowledge; 7) Coherence between epidemiology and laboratory findings; 8) Experimental evidence; and 9) Analogy - looking at the effect of similar factors. These considerations are applicable to alleged vaccine reactions also.

Adverse drug reactions

Adverse drug reactions (ADRs) can follow after the use of any drug. Careful evaluation is required to distinguish the events that are causally related to the drug from coincidental events. Causality assessment is crucial because the events could be iatrogenic and avoidable. Usually only a few react adversely to drugs on the market, whereas others are unharmed. The attribution of causality for such occasional happenings is particularly complex. Investigations of ADRs put causative association on a probability scale. The causality-assessment system developed by the World Health Organization Collaborating Centre for International Drug Monitoring is called the Uppsala WHO Centre (WHO-UMC) Scale. This is widely used as it offers a simple methodology (see Box 2). In consonance with Hume's postulates, the first step is to confirm temporal precedence and contiguity. The adverse event must appear after the suspected drug is administered and within a reasonable time-frame. Events where the time-to-drug-intake makes a relationship improbable are classified as 'unlikely' to be related. Events within a reasonable time and for which there is no alternate explanation (which cannot be attributed to disease or other drugs) are classified as 'probable / likely' related to the drug in question. Drug reaction is classified as 'possible' where there is a reasonable time relationship, but for which there are also alternate explanations. In terms of John Mackie's aphorism, the drug is considered sufficient but not necessary for the effect.

To be classified as 'very likely/certain' the reaction needs to be an objective and specific medical disorder or a recognized pharmacologic phenomenon, and there must be evidence of dose-related reaction or proof in terms of reappearance of symptoms on rechallenge. If death should occur as ADR, rechallenge is impossible. It is usually difficult to be certain about the causality of fatal ADR and the reaction is often classified as 'probable/likely' or 'possible'.

The difference between certain and probable/likely is simply the acceptable standard of proof. For "certainly," a high-standard irrefutable proof is called for (falsification of the theory by a single irregular outcome). A single well-documented spontaneous rechallenge is strong evidence of regularity (even though in just one patient). For 'very likely', the standard of proof is proof beyond reasonable doubt.

Box 2. WHO–UMC causality categories

Causality Term	Assessment Criteria
Certain	• Event or laboratory test abnormality, with plausible time relationship to drug intake • Cannot be explained by disease or other drugs • Response to withdrawal plausible (pharmacologically, pathologically) • Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognised pharmacological phenomenon) • Rechallenge satisfactory, if necessary
Probable/Likely	• Event or laboratory test abnormality, with reasonable time relationship to drug intake, Unlikely to be attributed to disease or other drugs • Response to withdrawal clinically reasonable • Rechallenge not required
Possible	• Event or laboratory test abnormality, with reasonable time relationship to drug intake • Could also be explained by disease or other drugs • Information on drug withdrawal may be lacking or unclear
Unlikely	• Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible) • Disease or other drugs provide plausible explanations
Conditional/ Unclassified	• Event or laboratory test abnormality • More data for proper assessment needed, or • Additional data under examination
Unassessable/ Unclassifiable	• Report suggesting an adverse reaction • Cannot be judged because information is insufficient or Contradictory • Data cannot be supplemented or verified

Reference The Uppsala Monitoring Center. The use of the WHO-UMC system for standardised case causality assessment. Reproduced with permission of *Uppsala monitoring centre*. Available at https://www.who-umc.org/media/2768/standardised-case-causality-assessment.pdf

'Balance of probability' is the level of proof needed to classify as 'probable' or 'possible'and this is the standard of proof, which is relevant to medicine and for pharmacovigilance. With this level of proof (prima facie true), the 'Precautionary Principle' must be triggered. This is described later.

Adverse events following immunization

Vaccines are drugs used as a preventive measure, given to entire cohorts of healthy persons. As they are administered in the absence of any disease, there is very high expectation that they will produce few adverse effects. But there is low tolerance for serious adverse events and deaths. Adverse events following immunization (AEFI) must be monitored more carefully than other drugs. A credible immunization safety evaluation and monitoring system is essential for the success of immunization programmes. The WHO developed the 'Adverse Events Following Immunization (AEFI): Causality Assessment' otherwise known as the Brighton Classification. It is very similar to the WHO-UMC causality categories for ADR. Until recently, this was the touch-stone used by WHO experts when AEFI were reported (see Box 1).

One measure of the sensitivity and responsiveness of the WHO-UMC causality categories (which preceded the Brighton classification) is the alacrity with which the rotavirus vaccine RotaShield was withdrawn in 1999 after 12 cases of vaccine-induced intussusceptions were reported. About 1 in 2000 children younger than 2 months of age develops intussusception from other causes. Based on the results of the investigations, the Centre for Disease Control (CDC) estimated that one or two additional cases of intussusception would be caused among each 10,000 infants vaccinated with the RotaShield vaccine. After about 100,000 infants were immunized, the vaccine was withdrawn[11]. In 2013, the Brighton classification was abandoned and replaced by the revised AEFI classification. The reasoning that prompted the switch away from the Brighton classification has not been stated explicitly in the revised AEFI manual[12].

Section B

Brighton Abandoned: Revised Causality Assessment

The Council for International Organizations of Medical Sciences (CIOMS) / WHO: Report on vaccine pharmacovigilance. In October 2010, after a series of meetings, 40 experts (of whom 19 were industry representatives with possible conflicts of interest) helped rewrite the classification criteria for AEFIs. The document titled 'Definitions and Application of Terms for Vaccine Pharmacovigilance' is reported to 'provide tools for higher excellence of signal detection and investigation of adverse events following immunization'[13].

On page 170 of this 193-page document, under the heading Notes for Guidelines, it is stated in small print: 'If there is adequate evidence that an event does not meet a case definition, such an event should be rejected and should be reported as 'Not a case of

[AEFI]'. Such evidence is considered adequate, if an exclusion criteria is met, or an investigation reveals a negative finding of a necessary criterion (necessary condition) for diagnosis. Such an event should be rejected and classified as 'Not a case of [AEFI]".'[13]

The CIOMS/WHO 'tool for excellence in signal detection' works by turning a blind eye to AEFI—classifying AEFI as 'Not a case of [AEFI]'. Not only is the causative association of AEFI to immunization denied, but it is made to appear the AEFI never occurred. Signal detection is no longer possible once AEFIs are removed from the system after being designated as 'Not a case of [AEFI]'. The story in the *Introduction* above where the WHO asserted in May 2013 that no fatal AEFI has ever been associated with pentavalent vaccine[5], suggests the Sri Lanka AEFI deaths[2] are now reclassified as 'Not a case of [AEFI]' using the CIOMS/WHO tool.

Only reactions that meet case definitions of reactions associated with the vaccine previously are considered. According to the CIOMS / WHO report (page 11), a case definition can be adopted from the standard literature or by the reviewers themselves.

The case definition helps draw on previous epidemiological research and facilitates further research to confirm a causal link. However, excluding causality in relation to an individual event cannot be dependent on that event conforming to a pre-existing case definition. The pejorative use of the term 'rejected' (in the statement; 'Such an event should be rejected and classified as "Not a case of [AEFI]"'), suggests a defensive posture. It has been pointed out previously that reports of AEFIs should be assessed for causality and classified: they are not to be 'rejected'[14].

The WHO revised AEFI manual

In March 2013, the revised WHO 'User Manual for AEFI' was published with a new algorithm[12]. The manual acknowledges that it has adapted definitions and concepts from the CIOMS / WHO report. The new algorithm for AEFI is reproduced in Figure 1.

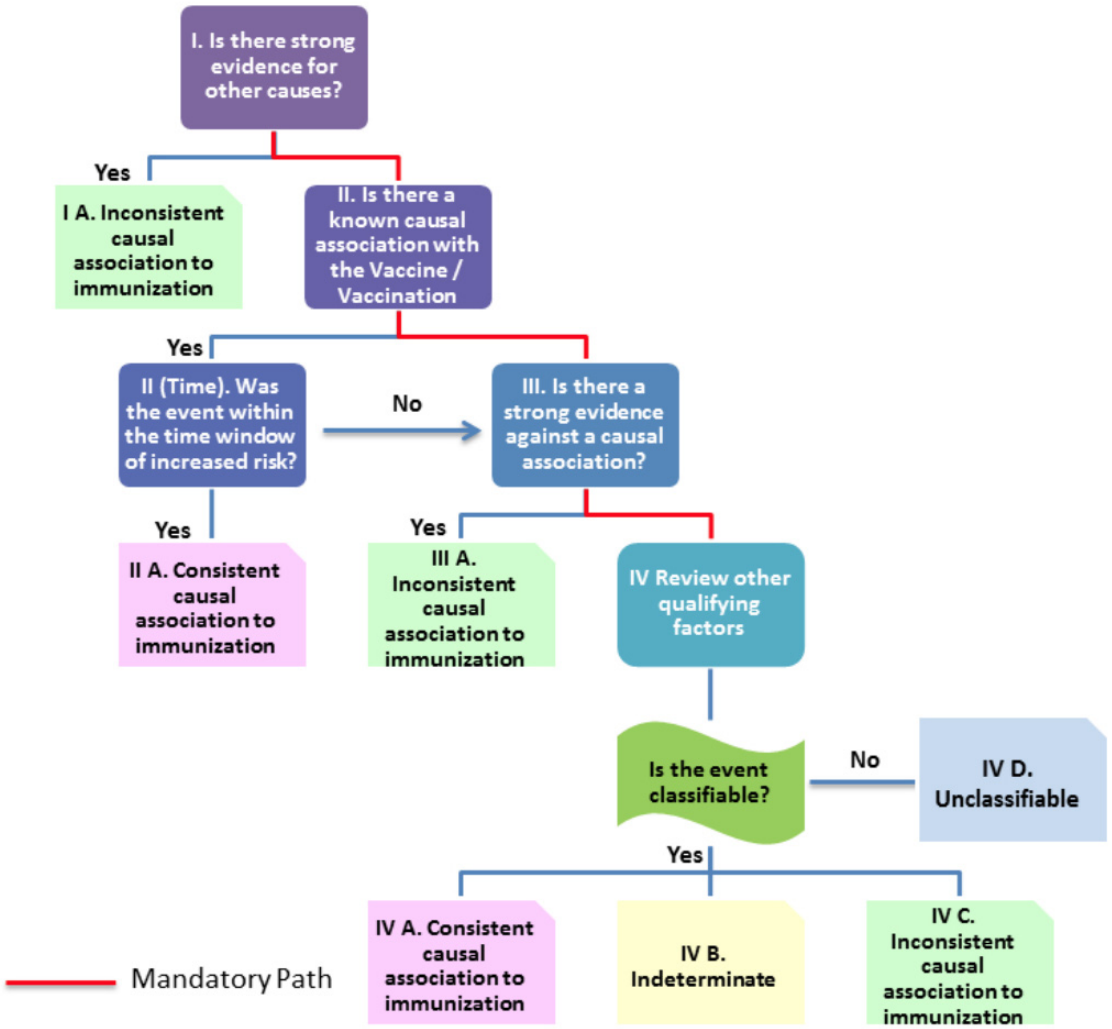

Figure 1. Flow chart demonstrating the revised AEFI classification new algorithm.

Revised AEFI classification: new categories of causality

Only events that occur after vaccine administration are eligible for AEFI causality assessment. This first step is reminiscent of Hume's dictum regarding precedence and contiguity. In the new scheme, causality is classified in four categories: 'Consistent causal association to immunization,' 'Indeterminate', 'inconsistent causal association to immunization', and 'Unclassifiable'.

Consistent causal association to immunization

This is the highest level of causal association in this new classification. It is less definitive than 'very likely / certain' in the old scheme. It does not call for irrefutable proof or even proof beyond reasonable doubt. Not even is the balance of probability assessed. In the new scheme, an adverse event can simultaneously be classified as 'Consistent causal association with immunization' and 'Inconsistent causal association with immunization'. On page 36 of the revised manual for AEFI[12] is the example of acute flaccid paralysis in a child after oral polio vaccine, who had had a fever 1 month prior to onset of paralysis. The stool culture showed vaccine strain polio virus. It was classified as 'Consistent causal association with immunization' as it is a known reaction after polio vaccination and the paralysis happened within time window of increased risk. It was also classified as 'Inconsistent causal association with immunization' because the fever, 1 month prior to paralysis had not been investigated completely. This ambiguity, which admits diametrically opposite conclusion simultaneously, is a hallmark of the new scheme.

It is suggested in the revised AEFI manual that before the question 'Did the vaccine given to a particular individual cause the particular event reported?' (the question of 'Did it?') is answered, one has to answer the question 'Can the given vaccine cause a particular adverse event?' (Can it?). The inference is that only if there is evidence at the population level that the vaccine can cause the adverse event, is the reaction classified as 'Consistent with causal association with immunization'.

This inference is flawed on two grounds. On the one hand, it denies all new associations seen in Phase 4 trials. On the other, if it is a known adverse reaction, causal association is accepted even where the events could have happened by coincidence. Just because intussusceptions are acknowledged as an adverse event following rotavirus vaccination, it does not follow that all intussusceptions in the critical window of increased susceptibility are necessarily caused by it. The residual uncertainty at this highest level of causal association robs it of value in addressing the problem of AEFI caused by vaccines.

Inconsistent causal association to immunization

At the bottom of the new causality classification hierarchy is 'Inconsistent causal association to immunization'. This group can include reactions for which there is no alternate explanation (and which would have been classified in the 'Probable' category previously). They would fall in the group 'Inconsistent causal association with vaccination' merely because causal association with immunization has not been documented in prior epidemiological studies. Into the same group are placed reactions that would have been considered 'Unlikely' to be associated, and those that would have been classified as 'Unrelated'. The use of the same category 'Inconsistent causal association to immunization' for such a wide variety of clinical situations merely obfuscates the issues. In the revised scheme, this term is used to suggest that there is no relation between the AEFI and immunization. No matter how frequently the reaction categorized as 'Inconsistent with causal association' occurs, it would not be investigated as a new signal of a causal association.

Indeterminate

Classification in the 'Indeterminate' group is reserved for reactions that could have been caused by immunization, but for which causal association has not been documented previously. It is projected that information on AEFI that are classified as indeterminate will be pooled and analysed in order to understand if the AEFI represents a new signal of an unrecognized event. The scheme is however loaded such that literally no AEFI are categorized into this group. How this is accomplished is discussed later on.

Unclassifiable

Clinical events with insufficient information to permit assessment and identification of cause are put in the 'Unclassifiable' group.

Revised AEFI classification: the new algorithm

Just as the final categories of causality association are vague, overlapping, and not clearly differentiated, the algorithm used to make a decision on causality[12] does not appear to be logical or well thought through.

The algorithm is shown in Figure 1.

Causality assessment algorithm

Four sets of questions need to be answered in sequence:

1. Is there strong evidence of other causes?
2. Is there known causal association with the vaccine or vaccination and if so, whether the event was within the time window of increased risk?
3. If there is no causal association known or if it is not within the time window of increased risk: Is there strong evidence against a causal association?
4. If there is no such strong evidence against causal association, the next step is to look at other qualifying factors for classification:
    a. Could it happen independently of vaccination (background rate)?
    b. Could the event be manifestation of another health condition?
    c. Did a comparable event occur after a previous dose of a similar vaccine?
    d. Was there exposure to a potential risk factor or toxin prior to the event?
    e. Was there acute illness prior to the event?
    f. Did the event occur in the past independently of vaccination?

g. Was the patient taking any medication prior to vaccination?

h. Is there biological plausibility?

Step 1

The first step in the revised algorithm is to look for strong evidence for other causes. If there is an alternate explanation, the AEFI is classified as 'Inconsistent with causal association to immunization'. John Mackie has noted that in nature there could be multiple reasons (causes) for the same outcome, and if two possible causes exist simultaneously either of them could be the causative factor[8]. It is to be noted that with the WHO-UMC classification of ADR and the old WHO/Brighton Classification of AEFI, even if an alternate explanation is available, a causative association with drug or vaccine is still considered 'Possible'. Moreover, the two causes could be working synergistically. An example of this is where genetic and other individual susceptibility factors make one susceptible to developing an AEFI[15,16]. In the new algorithm, if there is an alternate explanation for the AEFI, or another factor is involved, causative association with vaccine is rejected[12,14].

Step 2

The COIMS / WHO Report on pharmacovigilance is used at this level[13]. AEFI-specific case definitions for some reactions have been developed. In instances where specific case definitions and criteria are not available for a particular AEFI, it is permissible to improvise using case definitions adopted from 'standard medical literature, or national guidelines or they may be adopted locally by the reviewers' (page 11 CIOMS / WHO report). AEFI that meet case definitions and which occur within the time window of increased risk are classified as 'consistent causal association to immunization'.

The acceptable time window for each adverse event is different. The macrophagic myofasciitis affected patients usually are middle-aged adults presenting diffuse arthromyalgias, chronic fatigue, and marked cognitive deficits, fatigue, or depression due to long-term persistence of aluminium hydroxide within macrophages at the site of previous immunization[17]. However, AEFI surveillance seldom extents for so long.

Step 3

Theoretically, reactions that are not known to have a causal association or those that are not in the time window of increased risk can move to Step 3. At this stage, an enquiry is made whether there is strong evidence against causal association. Proving of a negative is notoriously difficult as it is impossible to affirm that in every circumstance, an irregular outcome is impossible. The example provided in the manual relates to MMR and autism.

It is reported that the Global Advisory Committee on Vaccine Safety (GACVS) and Council for International Organizations of Medical Sciences (IOM committee) have concluded that no evidence exists of a causal association between MMR vaccine and autistic disorders. Such AEFI must be classified as 'inconsistent with causal association to immunization' according to the new algorithm.

After publication of this AEFI user's manual, the conclusion about MMR and autism have become disputed again (see Box 3). This shifting evidence calls into question the usefulness of introducing this step in the algorithm of AEFI.

Step 4

Assuming that no such 'strong evidence against a causal association' exists, reactions that are not known to have a causal association with the vaccine, can go to Step 4. It is from here that reactions may be classified as indeterminate allowing it to be evaluated in future as a new signal.

The question at this point is whether it is 'classifiable — meaning whether all the tests needed have been performed to allow it to be classified under the CIOMS / WHO definitions. This is the second time these definitions are invoked during the AEFI evaluation.

Box 3. MMR and autism risk in African American children.

In 2004 the CDC published research demonstrating that there was no link between the vaccinated children's risk of a subsequent diagnosis of autism and the age at which the child is vaccinated with MMR[a]. It has now been revealed through the testimony of one of the authors Dr. W. W. Thompson who turned whistle blower, that the risk of autism among African American children vaccinated before the age of two years was 340% that of those vaccinated later. However this data was deliberately removed from the analysis to arrive at the CDC's proclaimed conclusion. CNN published the story of the CDC whistle-blower[b], and Thomson was granted whistleblower immunity by the Obama administration[c].

References:

a. DeStefano F, Bhasin TK, Thompson WW, Yeargin-Allsopp M, Boyle C. Age at first measles-mumps-rubella vaccination in children with autism and school-matched control subjects: a population-based study in metropolitan Atlanta. Pediatrics. 2004;113:259–66. doi: 10.1542/peds.113.2.259

b. Goldschmidt D. Journal questions validity of autism and vaccine study [Internet]. CNN.com. 2014 Aug 28 [cited 2014 Sep 29]. Available from: http://edition.cnn.com/2014/08/27/health/irpt-cdc-autism-vaccine-study

c. http://dailycaller.com/2015/02/03/obama-admin-grants-immunity-to-cdc-scientist-that-fudged-vaccine-rep4rt-whistleblower-plans-to-testify-before-congress

If some investigations are not done or not available, the AEFI is labelled as 'Unclassifiable' (or classified as 'Inconsistent with causal association to immunization' like how flaccid paralysis following OPV was classified, because investigations during an illness 1 month prior to paralysis were not available — see Appendix 3, page 36 of the AEFI manual[12] for this example).

If all the required investigations had been done and they met case definition criteria, they would have been classified as 'consistent causal association to immunization' at Step 2 and would not have come to Step 4.

The third possibility is that all the investigations had been done so it is classifiable but it did not meet case definitions. The CIOMS / WHO dictum is applied here: 'if there is adequate evidence that an event does not meet a case definition, such an event should be rejected and should be reported as "Not a case of [AEFI]". (See CIOMS / WHO Definitions and Application of Terms for Vaccine Pharmacovigilance, page 170[13]). It removes any chance that AEFI that has not been recognized as causatively associated with immunization in previous epidemiological studies will be included in the 'Indeterminate' group and evaluated as a new signal. Thus there seems to be only two options at step 4 : - either the reaction is classified as 'Unclassifiable' or it is categorized as 'Inconsistent causal association to immunization'. Categorization as 'Indeterminate' or 'Consistent causal association to immunization' are logically impossible given the riders mentioned above.

The exercise does not end there. Other qualifying factors are also enquired into at Step 4. It is recommended that alternate explanations in terms of background rate, other health conditions, exposure to a potential risk factor or toxin, acute illness, and other medication are again enquired into. Many of these 'other qualifying factors', like prior illness and concurrent drug use would presumably have been eliminated at Step 1 when looking for evidence for other causes. This enquiry is repeated again at Step 4 quite unnecessarily. Box 4 illustrates how, in spite of

Box 4. Sudden unexpected deaths (SUD) after pentavalent vaccine and the TOKEN Study.

With regard to AEFI a cluster of cases is defined as two or more cases of the same adverse event related in time or place or to the vaccine administered[a]. Pentavalent vaccine has caused numerous deaths in Asia but it is yet to be considered a new signal[b–f].

After the AEFI algorithm was revised, the deaths are now classified as 'Not a case of [AEFI]' on the grounds that deaths have not been reported as AEFIs in epidemiological studies involving the vaccine. However, the TOKEN Study contradicts this assertion[g].

The TOKEN Study was done specifically to assess a possible causal relationship between vaccination and unexplained sudden unexpected death (SUD) of children between their 2nd and 24th month of life. vonKries had previously found a statistically significantly increased standardized mortality ratio (SMR) within two days after vaccination with one (Hexavac®) of the two licensed hexavalent vaccines and the TOKEN study was done to confirm or refute the association[g]. The study was sponsored and supported by the Paul-Ehrlich-Institute (PEI) and the Federal Ministry of Health (Bundesministeriumfür Gesundheit).

A self-controlled case series (SCCS) was examined to look for a temporal association of vaccination to SUD. Parents were invited to participate in the study if their child had died of SUD. 37.6% of the eligible parents participated. The researchers found that parents were twice as likely to participate if their child had died within one week of vaccination. They used an inverse probability weighted analysis to compensate for this bias. The authors note that this was helpful to overcome the selection bias in infants under 9 months, but even so, the results are still likely to overestimate the risk of SUD in older children.

The weighted SCCS analysis, relative risk of SUD after pentavalent vaccination (first and second year of life) looking at risk period 0–3 days after vaccination versus control period 4–28/183 days showed RR of 8.11 (p= 0.006, 95% CI=1.81-36.24; Table 41 in the TOKEN Report). The weighted SCCS analysis, relative risk of SUD after hexa- or pentavalent vaccination (1st and 2nd year of life) looking at risk period 0–3 days versus control period 4–28/183 days was RR.2.19 (p= 0.031, 95% CI=1.08-4.45; Table 36 in the TOKEN Report)

It is clear from the above that there is reasonable evidence in epidemiological studies that SUDS can occur as AEFI following use of the pentavalent vaccine and the deaths following the use of this vaccine should not be a priori classified as 'Not a case of [AEFI]'.

References

a. http://vaccine-safety-training.org/detection-and-reporting.html

b. Lone Z, Puliyel J. Introducing pentavalent vaccine in the EPI in India: A counsel for caution. Indian J Med Res 2010; 132,: pp 1-3

c. Puliyel J. AEFI and the pentavalent vaccine: looking for a composite picture. Indian J Med Ethics. 2013;10:142-6.

d. No authors listed. Global Advisory Committee on VaccineSafety,12–13 June2013. Wkly Epidemiol Rec. 2013;88:301-12. Available at http://www.who.int/vaccine_safety/committee/reports/Jun_2013/en/ Accessed on 1/11/15

e. Sreedhar S, Antony A, Poulose N. Study on the effectiveness and impact of pentavalent vaccination program in India and other south Asian countries. Hum Vaccin Immunother. 2014;10:2062-5.

f. Martin Schlaud M, Poethko-Müller C, Kuhnert R, Hecker H Robert Koch Institute. Study on deaths in young children (2nd to 24th month of life) (TOKEN Study) http://www.rki.de/DE/Content/Gesundheitsmonitoring/Studien/Weitere_Studien/TOKEN_Studie/Studyreport.pdf?__blob=publicationFile

g. vonKries R, Toschke AM, Strassburger K, Kundi M, Kalies H, Nennstiel U, Jorch G, Rosenbauer J, Giani G. Sudden and unexpected deaths after the administration of hexavalent vaccines (diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, Haemophiliusinfluenzae type b): is there a signal?. Eur J Pediatr. 2005;164:61-9.

there being epidemiological evidence (the TOKEN Study) that pentavalent vaccine can cause sudden unexpected death, the numerous deaths (as discussed in the introduction) are not acknowledged as caused by the vaccine, and the WHO expert report denies that deaths were ever reported as AEFI. The causality assessment of 132 serious AEFI cases uploaded on the website of the Ministry of Health and Family Welfare in India illustrates the consequence of deploying this new classification. 54 of these babies died, whereas 78 survived. The causality assessment found 50% of those who survived had reactions to vaccination but not even one death was classified as vaccine-related. Nearly all the deaths (96%) were simply classified as unclassifiable or coincidental, presumably because death has not previously been acknowledged as an adverse event caused by this vaccine[18]. Children admitted to hospital after vaccination with intractable convulsions, could be classified as having a vaccine-product related reaction, but if they died, the deaths would be classified as 'coincidental deaths'.

Other subtle changes in the definition of terms

'Causal association' redefined

The term causal association now means 'a cause-and-effect relationship between causative factor and a disease with no factor intervening in the processes'. This is a major step backward for patient safety. The old scheme recognized, for example, that an elderly person with chronic cardiac failure might develop symptoms of cardiac decompensation after influenza vaccination due to a vaccine-caused elevation in temperature or stress from a local reaction at the site of vaccination. The vaccine is therefore considered to have contributed to cardiac failure in this specific situation[19]. Under the new scheme, this outcome would not be considered as causally related to the vaccine. The question of whether the death would have occurred at that time, had it not been provoked by immunization, would not be acknowledged. Without this recognition, many elderly persons may be exposed to this risk of death unnecessarily when using this vaccine. If the vaccination of an infant was reported to have been followed by sudden death but the child was malnourished or otherwise unwell it does not mean that causality assessment should conclude no cause and effect relationship between the vaccine and the death. There is no scope in this definition to consider interacting causalities[14,15]. The Global Advisory Committee on Vaccine Safety has documented many deaths in children with pre-existing heart disease after they were administered the pentavalent vaccine. The WHO now advises precautions when vaccinating such children and this has reduced the risk of death[1]. Using the new definition of causal association, this relationship would not be acknowledged and lives would be put at risk.

According to Collet and colleagues, it is possible that some individuals experience greater immunogenic response to vaccines compared to the general population and therefore, understanding genetically determined predispositions to developing AEFIs is important[19]. However, these considerations will not be accounted for, in the new CIOMS /WHO causality assessment scheme. The contribution of vaccine in precipitating encephalopathy in patients who are susceptible on account of genetic factors will also not be considered[15]. Berkovic has used genetic analyses to identify *de novo* mutations in the sodium channel gene SCNIA in patients with alleged vaccine-induced encephalopathy[16]. Unwisely, in all these cases the contribution of the vaccine in precipitating the encephalopathy will be ignored.

It is a pity that after all these years, the authors should fall for the Hume fallacy that causality can be claimed only if X is sufficient in itself for Y. The fact that the immunization could have 'materially contributed' to the adverse events is ignored.

Biological plausibility

Biological plausibility is one of the Bradford Hill 'guiding principles' that favor causative association[10]. However, this is limited by the state of current knowledge and it should not be used in itself to deny causative association. For example it is now acknowledged that high-titer measles vaccine is associated with excess female mortality[20]. The recognition of this association was delayed because of the absence of a biologically plausible explanation. WHO experts now acknowledge that vaccines have non-specific effects which up-regulate or down-regulate both the innate and the adaptive immune system and this can influence child survival[21].

The association of intussusception with rotavirus vaccination was also accepted at a time when a biologically plausible explanation was not available[11] (See Box 5). Vaccine can therefore have both non-specific beneficial effects and also unexpected deleterious effects which should not be disregarded simply because a ready explanation for the same is not available at the time when it is first noticed.

Biological plausibility redefined

The meaning of the term biological plausibility has itself been redefined in the Revised AEFI manual. The manual specifies that biological plausibility can only be invoked when laboratory findings or symptom or sign are similar or consistent with natural history and pathophysiology of the infection or antigen. Other biologically plausible explanations (demonstrating there is a mechanism and capacity to lead from the cause to the effect)[7], do not qualify. The four approaches to ascertaining causality described by Brady include detection of neo-Humean regularity, examining the counterfactual, experimental manipulation and examining mechanisms and capacities[7]. The new AEFI recognizes only the experimental approach to the exclusion of other valid approaches and, as a result, can fail to detect causality in a number of cases resulting in harm.

Chronic fatigue syndrome and the HPV vaccine trial

The above discussion has assumed that adverse events that are reported in the original prelicensure randomised control trials, would be classified as adverse events known to be associated with the vaccine.

Slate investigated randomised trials of human papillomavirus (HPV) vaccines and found that potential side effects were collected for only two weeks in the year-long study. After 2 weeks, individual trial investigators decided, on personal judgment, whether to report medical problems as adverse events. Often they listed new problems as 'new medical history'. Myalgic encephalomyelitis, otherwise known as chronic fatigue syndrome

Box 5. Indian Rotavirus vaccine trials

The prequalification of Rotavac without safety data

RotaShield was withdrawn as it caused 1 excess case of intussusception per 10,000 children given the vaccine[11].

However, a new rotavirus vaccine Rotavac (Bharat Biotec) was licensed in India after a trial in 3 centres where the vaccine was administered to a total of 4500 children (a sample size too small to show up a rare event that occurs 1 in 10,000)[a,b]. In spite of this small sample it appears intussusceptions were so common with this vaccine[c] in one of the centres (Vellore), it was significantly higher than controls. The trial doctors refused to provide this segregated data in spite of repeated requests[d]. The government promised to monitor safety in a post marketing surveillance. However, the participants in this trial were not explained the risk seen in the RCT (as is mandatory for ethical clinical trials) and surveillance was for a limited window period of a few weeks after vaccination, whereas the adverse events noticed in the RCT were outside that window period. In remote parts of this country where the vaccine is deployed, in the absence of pediatric surgeons and radiologists, deaths from intussusception are likely to be misclassified as deaths from dysentery.

Even before the data of this post marketing surveillance is available, the WHO recently prequalified the vaccine to be used internationally[e].

Clinical trials of other rotavirus vaccines that reduce rotavirus diarrhoea but does not reduce overall incidence of diarrhoea[f] and another vaccine that increases the overall incidence of diarrhoea[g] instead of decreasing it, have been published.

References

a. Bhandari N, Rongsen-Chandola T, Bavdekar A, John J, Antony K, Taneja S, Goyal N, Kawade A, Kang G, Rathore SS, Juvekar S, Muliyil J, Arya A, Shaikh H, Abraham V, Vrati S, Proschan M, Kohberger R, Thiry G, Glass R, Greenberg HB, Curlin G, Mohan K, Harshavardhan GV, Prasad S, Rao TS, Boslego J, Bhan MK; India Rotavirus Vaccine Group. Efficacy of a monovalent human-bovine (116E) rotavirus vaccine in Indian children in the second year of life. *Vaccine*. 2014 Aug 11;32 Suppl 1:A110-6. doi: 10.1016/j.vaccine.2014.04.079. https://www.ncbi.nlm.nih.gov/pubmed/25091663

b. John J, Kawade A, Rongsen-Chandola T, Bavdekar A, Bhandari N, Taneja S, *et al.* Active surveillance for intussusception in a phase III efficacy trial of an oral mono- valent rotavirus vaccine in India. *Vaccine*. 2014;32(August (Suppl. 1)):A104–9/ http://dx.doi.org/10.1016/j.vaccine.2014.03.036.

c. Bajaj J, Puliyel JM. Intussusception risk with 116E rotavirus vaccine in Vellore, South India. *Vaccine*. 2016 Jan 20;34(4):403. doi: 10.1016/j.vaccine.2015.03.007. Epub 2015 Mar 21. https://www.ncbi.nlm.nih.gov/pubmed/25800733

d. *Puliyel JM.* 116 E Rotavirus Vellore Study: Request for Vaccine Safety Data. Response to Indian rotavirus vaccine concern over intussusception is unfounded, say researchers. http://www.bmj.com/content/350/bmj.h2867/rapid-responses

e. https://www.businesswire.com/news/home/20180124005715/en/World-Health-Organization-Grants-Prequalification-Bharat-Biotech%E2%80%99s

f. Kulkarni PS, Desai S, Tewari T, *et al.* A randomized Phase III clinical trial to assess the efficacy of a bovine-human reassortant pentavalent rotavirus vaccine in Indian infants. *Vaccine*. 2017. https://www.ncbi.nlm.nih.gov/pubmed/28967523

g. Kaur J, Puliyel J. Heat-stable oral rotavirus vaccine. *N Engl J Med*. 2017; 377:302 https://www.ncbi.nlm.nih.gov/pubmed/28328346

(CFS), is a condition characterized by long-term fatigue that limits a person's ability to carry out ordinary daily activities. Participants in the HPV trial reported to Slate that these debilitating symptoms of theirs were not even registered as adverse events.

Given that CFS was not recorded as an adverse event, it allowed the manufacturers to claim that CFS is not a 'known adverse event with the vaccine' and so to discount every case that was reported subsequently.

Rotavirus vaccine trials

Box 5 describes how adverse events, recorded in a randomized clinical trial (RCT) and sent to the regulatory authority for vaccine approval and license, are not made public. This goes against the European Court of Justice ruling that clinical study reports are made publically accessible.

Other problems with recording and reporting AEFI

Box 6 describes how the Periodic Safety Update Reports (PSUR) 15 and 16 of Infanrix Hexa and the findings from the reports was opened to public scrutiny by an Italian court. Box 7 describes how PSUR 19 was obtained under the Freedom of Information rules and shows how deaths reported in PSUR 16 were deleted from PSUR 19, when it was evident that the reported deaths exceeded the deaths expected by chance[22]. In 1986 President Ronald Reagan signed the National Childhood Vaccine Injury Act (NCVIA) (42 U.S.C. §§ 300aa-1 to 300aa-34) which created a no-fault system to compensate vaccine related injuries. This made it difficult to sue vaccine manufactures. It also set up Vaccine Adverse Event Reporting System (VAERS) mandating the reporting of adverse events. Box 8 describes the changes that prevent patients from holding manufacturers to account for adverse events caused by their products. Box 9 shows how AEFI data is no longer available easily. While on the one hand, the new classification discounts AEFI as 'Not a case of [AEFI]', safety data is being manipulated and made inaccessible.

Biological plausibility: reactions with multi-valent vaccines

Looking at the VAERS data of deaths after immunization, Goldman and colleagues found there was more mortality among babies who had received five to eight vaccines together, compared to those receiving fewer vaccines[23]. In the case of Boatman v. Secretary of Health and Human Services, 13-611 (Fed. CI 2017) where the infant aged 4 months had received 7 vaccine antigens on one day, the court, after hearing expert opinion, held that vaccine-stimulated inflammatory-cytokines can act as neuro-modulators and cause depression of the serotonergic 5-hydroxytryptophan (5-HT) system in the infant medulla and blunt the normal chemo-sensitive

Box 6. Periodic safety update reports : unfit for public consumption?

Justice Nicola Di Leo in Italy made public the 'confidential' 15th and 16th Periodic Safety Update Report (PSUR) on Infanrix hexa (GlaxoSmithKline Biological) and this is now available on the Internet[a].

Pages 246-9 document an analysis of the number of 'sudden deaths' after receiving the vaccine to examine if it exceeds the number of deaths one could expect from the natural background incidence of sudden death. The background incidence was calculated as 0.454/1000 in the first year and 0.062/1000 live births in the second year. No allowance is made for the notoriously poor AEFI reporting rate. The number of sudden deaths expected to occur by chance between day 1 and 20, is tabulated in Table 36 on page 24. The denominator used to examine deaths following vaccination is the number of doses of the vaccine distributed not the number of children vaccinated. This denominator would dilute any potential signal because many more vaccine doses are distributed than are actually administered!

Further, the number of doses actually administered may be appropriate for milder reactions that can recur with each dose, but it is not appropriate for deaths which can happen only once. Appendix 5A shows that 13 fatal cases were reported. There were more deaths after the first dose than after the second and third doses and the deaths after the second was more than after the third dose. This pattern is commonly seen with AEFIs that are causatively related. The appropriate denominator in all these cases is the number of babies vaccinated.

There were 42 deaths in the first three days after vaccination where there were only 16 deaths in the next 3 days. The fact that the deaths were clustered soon after vaccination suggests that the deaths may be related to the vaccination event.

Patient safety data should not be considered as trade secrets by any stretch of imagination. The practice of keeping safety reports confidential permits such data manipulation in a cosy relationship with the regulators, away from public scrutiny. Such practice ought to be reformed.

Reference

a http://autismoevaccini.files.wordpress.com/2012/12/vaccin-dc3a9cc3a8s.pdf Accessed 12/11/15

Box 7. EMA and Failure of Regulatory Oversight: absence of critical appraisal of PSUR

GlaxoSmithKline (GSK), 19th confidential periodic safety update reports[a] (PSUR 19 (deaths up to October 22, 2014)) on Infanrix hexa makes interesting reading. Infanrix hexa has all the components of the pentavalent vaccine except that it has replaced the whole cell pertussis with an acellular pertussis component and, in addition, it has injectable polio vaccine. The cumulative number of deaths after vaccination reported in the 19th report is less than that reported in the 16th PSUR. It can be seen that deaths in children older than 1 year was significantly higher than the deaths expected by coincidence, if the deaths deleted from the 16th PSUR were restored[b].

It appears that the EMA accepts PSUR reports filed by manufacturers without reviewing them critically. Regulatory authorities internationally rely on due diligence by the EMA in such circumstances. This may need to be reappraised.

Reference

a. http://ijme.in/wp-content/uploads/2017/09/infanrix-pusr.pdf

b. http://ijme.in/articles/infanrix-hexa-and-sudden-death-a-review-of-the-periodic-safety-update-reports-submitted-to-the-european-medicines-agency/?galley=html

response to excess carbon dioxide and this can result in the death of vulnerable infants during sleep. Multiple vaccines provoke greater release of cytokines. Hill's criteria of a dose- response gradient (number of antigens in this case), may be satisfied here[10].

Multiple vaccines limited to 5 in the Italian Army

The harm from vaccine-stimulated cytokines is not limited to infancy. The Final Report of the Italian Parliamentary Committee (Doc. XXII-bis N.23) inquiry into cases of death and severe injury affecting Italian personnel assigned to military missions abroad, has recommended that no more than 5 monovalent single-dose vaccines may be given simultaneously to military personnel, in order to avoid adverse reactions. All this suggests the need for caution in using multiple vaccines simultaneously. Ironically, while it is proscribed for healthy adult army men, Hexavac (which combines 6 antigens) is still licensed for use in infants in Italy.

Revised AEFI classification and the precautionary principles

It is evident from the discussion earlier that the revised AEFI evaluation scheme produced by the CIOMS / WHO is designed to deny the possibility that any newly observed adverse event may be causally related to the immunization. The AEFI manual states 'Allegations that vaccines / vaccination cause adverse events must be dealt with rapidly and effectively. Failure to do so can undermine confidence in a vaccine and ultimately have dramatic consequences for immunization coverage…'[12]

Figure 2 shows how all cases AEFI except those that are known adverse effects of vaccine are classified as not causally related.

The AEFI-denialism is a clear violation of the 'precautionary principle' (European Union law), which mandates that 'when an activity raises threats of harm to the environment or human health,

Box 8. Product liability: Protecting patients not patents.

Hexavac - a hexavalent vaccine (DTaP-IPV-HepB/Hib) - was withdrawn by the manufacturers without giving reasons after 5 cases of SIDS were reported by Zinka within 48 hours of being administered the vaccine[a]. vonKries found that in the 2nd year of life, the standardized mortality rate (SMRs) for sudden unexplained deaths (SUD) within 1 day of vaccination was 31.3 (95% CI 3.8–113.1); and within 2 days after vaccination it was 23.5 (95% CI 4.8–68,6)[b].

Similarly RotaShield was voluntarily removed from the market after 12 cases of intussusceptions were reported. The background rate of intussusceptions at this age was 5 times the risk of intussusceptions from the vaccine. There was no biologically plausible explanation to link the intussusceptions to the immunization. Yet the vaccine was withdrawn[c].

The manufacturers withdrew the vaccines voluntarily without indicating the reasons. It is not clear whether the prospect of product liability suits influenced manufacturer caution.

Two significant changes have taken place after 1980. The threat of vaccine manufacturers being held responsible for marketing a defective product has diminished greatly as a consequence of these changes.

1. A no-fault compensatory mechanism has been put in many countries in the 1980s and 1990s[d] This means that vaccine injured children need not provide clear evidence of negligence as cause of the harm, before they qualify for compensation. However, it also means that manufacturers do not have to admit to faults. The risk of product liability has now greatly decreased with no fault compensation being provided by governments. As a result, manufacturers may be emboldened to be more reckless on vaccine safety issues.

2. The second significant change was in 2013, when the methodology for assessment of AEFI was completely overhauled. It is no longer sufficient to show temporal association of the AEFI happening repeatedly. The flow diagram below depicts all conditions that need to be satisfied before an AEFI is labelled 'Consistent causal association to immunization'. This too could embolden manufacturers to be more reckless with regard to adverse reactions.

References

a. Zinka B, Rauch E, Buettner A, Ruëff F, Penning R. Unexplained cases of sudden infant death shortly after hexavalent vaccination. *Vaccine*. 2006;24:5779-80.

b. vonKries R, Toschke AM, Strassburger K, Kundi M, Kalies H, Nennstiel U, Jorch G, Rosenbauer J, Giani G. Sudden and unexpected death safter the administration of hexavalent vaccines (diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, Haemophiliusinfluenzae type b): is there a signal? *Eur J Pediatr*. 2005;164:61-9.

c. Center for Disease Control and Prevention. Rotavirus Vaccine (RotaShield) and Intussusception. http://www.cdc.gov/vaccines/vpd-vac/rotavirus/vac-rotashield-historical.htm

d. Looker C, Kelly H. No-fault compensation following adverse events attributed to vaccination: a review of international programmes. Bulletin of the World Health Organization 2011;89:371-378. Available at http://www.who.int/bulletin/volumes/89/5/10-081901/en/ Accessed on 23/10/15

Box 9. Difficulties in accessing AEFI data

1. Polio and Acute Flaccid Paralysis in India

As awareness of adverse events is increasing among the public it is becoming more difficult to access data on these adverse events. The National Polio Surveillance provided monthly data on acute flaccid paralysis in India. An analysis of the data showed that in 2011, an additional 47,500 children were newly paralysed in the year, over and above the standard 2/100,000 non-polio AFP that is generally accepted as the norm. The non-polio AFP rate best correlated with the cumulative number of doses received in the previous three years[a].

The analysis was repeated after 2 years when the number of doses administered to children below 5 was reduced and it showed the AFP rate had begun to decline[b].

However, the data is no longer provided on the National Polio Surveillance Project/WHO website.

2. Data Analysis Prints on Vaccines

Medicines and Healthcare products Regulatory Agency (MHRA) of the government of UK provides easily accessible Drug Analysis Prints and interactive Drug Analysis Profiles (iDAPs)[c] from 'Yellow Card' notifications of adverse events. But this is not provided for vaccines. One is required to request MHRA Pharmacovigilance for this.

References

a. Vashisht N, Puliyel J. Polio programme: let us declare victory and move on. Indian J Med Ethics. 2012 Apr-Jun;9(2):114-7.

b. Vashisht N, Puliyel J, Sreenivas V. Trends in nonpolio acute flaccid paralysis incidence in India 2000 to 2013. Pediatrics. 2015 Feb;135 Suppl 1:S16-7. doi: 10.1542/peds.2014-3330DD. PMID: 26005734

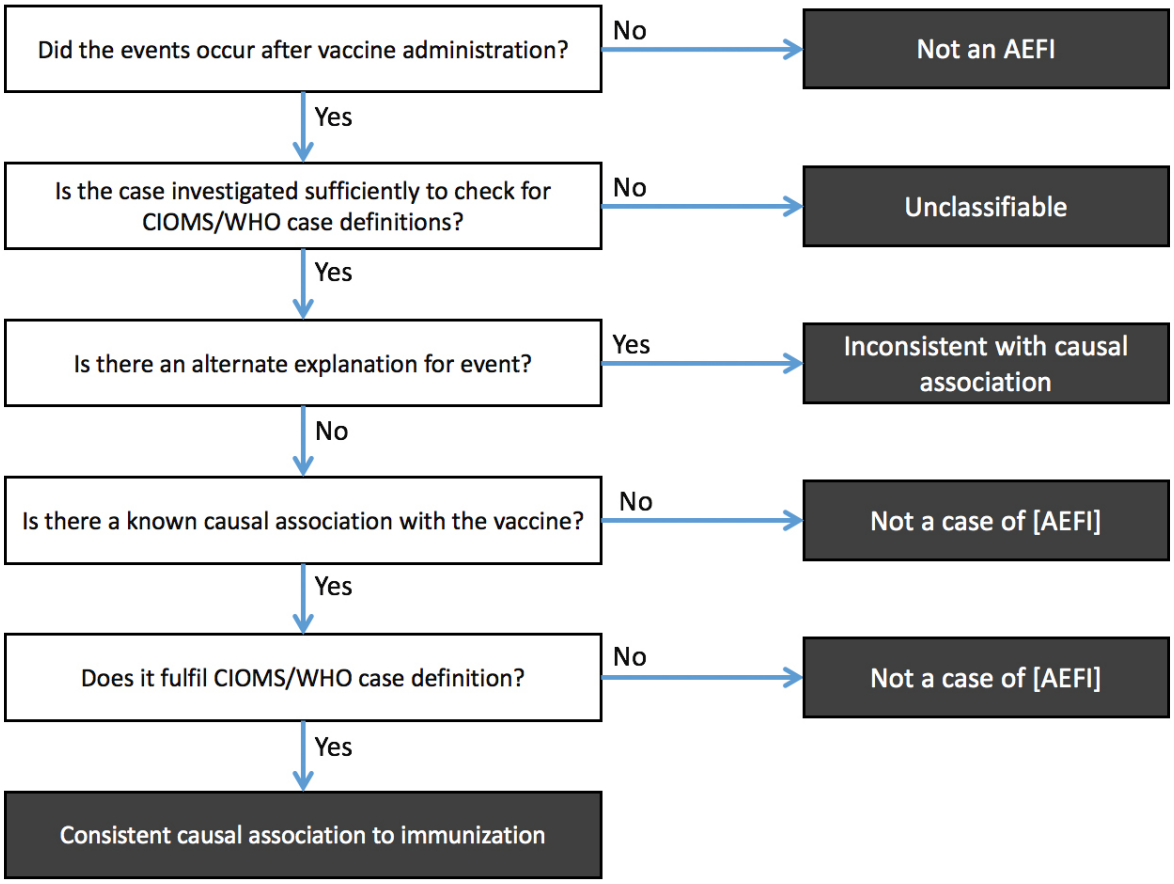

Figure 2. Pathway to achieving 'consistent causal association to immunization' status.

precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. Society and Government is urged that until the full scientific evidence is available, where there is evidence of risk, it must take precautionary measures'. This new AEFI classification scheme that allows for an outright denial of any new causative association with vaccination could also fall foul of Article 2 European Convention on Human Rights (Art 2 ECHR), which mandates governments to establish a framework of laws, precautions, and means the enforcement of which will, to the greatest extent reasonably practicable, protect life.

Paradoxically, the AEFI algorithm is said to be for vaccine safety. Perhaps we need a scheme for public safety rather than vaccine safety.

The story of pentavalent vaccine was introduced at the beginning of this paper and is summarised in Box 10. It is primarily a vaccine used in developing countries where AEFI surveillance is poor, the press is less vigilant to report adverse events and where drug regulation is less strict. (The richer countries in the West, Europe and the USA, do not use the whole cell pertussis vaccine; so this vaccine is not marketed in those countries.) Isolated cases of unexplained deaths continue to be reported in the press. With the new AEFI classification, in the absence of 'epidemiological evidence' linking deaths to the vaccine, these deaths have been passed off as 'coincidental' SIDS deaths. Epidemiological evidence, however, is now available linking the deaths to vaccine.

To examine if deaths following pentavalent vaccine were merely coincidental SIDS deaths, a study of 45 million infants given DTP vaccination and 25 million who received pentavalent vaccine was undertaken. The study assumed that all the deaths (self-reported to the government surveillance system with 72 hours of vaccination) associated with DPT could be coincidental SIDS deaths, but any increase in the death rate after pentavalent vaccine must be assumed to have been caused by pentavalent vaccine. The odds of death after pentavalent vaccine was doubled (OR 1.98 (95% CI 1.65 to 2.38)) compared to DTP. There were 4.7 additional deaths (95% CI: 3.5-5.9) per million vaccinated with Pentavalent vaccine instead of DTP ($p<0.0001$). By the time this evidence was put together, 122 excess deaths (95% CI: 101-145) had been reported to the government, due to the switch from DPT to pentavalent vaccine. The contribution of the new AEFI classification in this delay in recognizing the problem is stark[24].

The need for revising Brighton

The revised classification have removed the categories 'probably' and 'possible' from the AEFI classification - very much like the experts who investigated the Sri Lanka deaths. This appears to be

Box 10. The vaccine that changed the definition of AEFI

The story of pentavalent vaccine

In 1949 the DTP vaccine was introduced[a] against diphtheria, tetanus, and pertussis. The first two were frequently fatal diseases. However, DTP was responsible for neurological adverse effects, seizures, encephalopathy, and hypotensive episodes (HHE)[b]. An acellular DTaP was developed and this has replaced DTP in the West.

In 1981 Hepatitis B was introduced[a]. Hepatitis B infection can cause chronic liver disease and hepatocellular carcinoma (HCC), especially if acquired at birth. Vaccine uptake was poor in developing countries. One reason was that, although Hepatitis B was common in the potentially large vaccine uptake countries like India, the incidence of HCC was very low[c]. It is now thought that newborn babies in India may be protected in the early years (where the chance of becoming a chronic carrier is worst) by passive immunity from mother to babies. This may be lost once vaccine use becomes widespread and there could be a paradoxical increase in HCC[d].

In 1987 the protein-conjugated Haemophilus influenza type b vaccine was introduced. The incidence of invasive disease with Haemophilus influenza type b in Asia is low[e] perhaps due to cross-protection from other bacteria that have cross-reactive antigens to the Hib capsular polysaccharide[f]. The uptake of Hib vaccine was poor in Asia.

It is said that the Pentavalent vaccine was introduced to improve the uptake of Hib and Hepatitis B, by combining new underused vaccines with a prior UIP vaccine like DTP as a way for the new vaccines to get a piggyback ride into the UIP[g]. The pentavalent vaccine was used only in developing countries which had not switched to DTaP.

Pentavalent vaccine has been associated with deaths. In the investigation of deaths in Sri Lanka, rather than reporting that the vaccine was 'probably' related to the vaccine, the WHO experts deleted the categories 'probable' and 'possible' from the Brighton classification. This ad-hoc improvisation was reported in medical journals. The AEFI classification was then formally revised so that reactions (deaths in this case) noticed for the first time in Phase 4 trials (post marketing trials) could all be classified as 'Inconsistent with causal association to immunization' and passed off as 'coincidental SIDS deaths'.

A new study involving 45 million infants given DTP vaccination and 25 million who received pentavalent vaccine now provides epidemiological evidence that the odds of death after Pentavalent was doubled (OR 1.98 (95% CI 1.65 to 2.38)) compared to DTP. There were 122 additional deaths (95% CI: 101-145) within 72 hours, reported to the government surveillance system, due to the switch from DPT to pentavalent vaccine. A large number of these deaths could have been avoided had the AEFI manual not been revised and the AEFI were evaluated earlier. In fact it is well documented that the combined DTP-Hepatitis B-Hib vaccine causes more local reactions and it is less effective than when they were administered separately[h]. Protection against these disease could have been better if the vaccines were administered separately.

References

a. http://www.immunize.org/timeline/

b. https://www.sciencedirect.com/science/article/pii/0264410X9190283C

c. https://www.ncbi.nlm.nih.gov/pubmed/?term=Hepatitis+B+in+India%3A+Systematic+review+%26+report+of+the+_IMA+sub-committee+on+immunization

d. https://www.ncbi.nlm.nih.gov/pubmed/29318526

e. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2557750/

f. https://www.ncbi.nlm.nih.gov/pubmed/?term=Natural+immunity+to+Haemophilus+influenza+b+in+infancy+in+Indian+children

g. https://www.researchgate.net/publication/238069905_New_combination_vaccines_Backdoor_entry_into_India%27s_universal_immunization_programme

h. https://www.ncbi.nlm.nih.gov/pubmed/19588375

motivated by a laudable desire to reduce vaccine hesitancy and the attendant risk of vaccine preventable disease. The Sri Lanka report says, "Cases were classified in this review as unlikely where, in spite of not having evidence that the vaccine(s) contributed to the adverse event or the outcome of death, conclusive evidence regarding an alternate cause (or causes) of the event and outcome was lacking. This meant that we considered that classifying the AEFI in the category 'unrelated' was not fully justified (as it could not be conclusively attributed to another cause). In such cases, we go further to state that the conclusion of 'unlikely' means that the vaccine is not the major cause of death even in those cases where we discuss the possibility that the vaccine(s) or vaccination may have unmasked an underlying condition"

It seems the Sri Lankan experts were reluctant, even to classify the deaths as 'unlikely', as it could be interpreted to mean there was some likelihood of causal association. To quote from the report, "Unlikely: In defining this category, the panel took note of the fact that the WHO category 'unlikely' is often interpreted to mean that there is (conversely) some likelihood of a causal association between the adverse event and the vaccine(s) administered."

One can speculate that same reasoning and the motivation (to ally public anxiety of a causal association between AEFI and vaccination), would have provided the impetus for the revised AEFI classification.

The aftermath

That vaccines do more good than harm is taken as an article of faith, a dogma, a tenet. If the purpose of this exercise i AEFI-denialism is to prevent undermining confidence in vaccines, the

scheme does not seem to be working. Indeed, public scepticism seems to be increasing rather than diminishing with these efforts at reassurance that vaccines are safe[25,26]. Epidemics of vaccine preventable disease have resulted[27].

The response in some states in the United States has been to make vaccination mandatory for admission to public schools. Personal and religious belief exemptions for vaccination are not be allowed in California, effective July 1, 2016. The 2016 debates among US Republican Presidential aspirants suggest that there is a lack of widespread support for this measure. The Department of Health and Human Services Office for Civil Rights has now set up the Conscience and Religious Freedom Division to which individuals can complain if their conscience or religious freedom have been abridged. How these forces will interact is anyone's guess, but the present scenario augur badly for public trust in vaccines and voluntary vaccination.

Where do we go from here

The AEFI manual needs to be urgently reevaluated and revised. We need to build a better system that picks up problems and at the same time does not create a mistrust of vaccines that have been associated with a major reduction in child mortality.

Adverse reaction and deaths may not show up as significantly increased in small safety studies. However, records of all deaths and serious adverse events following vaccinations should be maintained and periodically reviewed for safety signals. The practice of discarding these records as 'inconsistent causal association to immunization' needs to change. Comparisons of the adverse events of vaccines given at the same age, as was done with DTP and pentavalent vaccine, may help to identify adverse events related to one of the vaccines. Sex specific incidence of adverse events may also act as a pointer. Till we develop a better system, it may be advisable to fall back on the time tested WHO-UMC casualty categories and the Brighton categories and to err on the side of child safety.

Competing interests

No competing interests were disclosed.

Grant information

The author(s) declared that no grants were involved in supporting this work.

Acknowledgements

Acknowledgement of the help received from Lucija Tomljenovic for her inputs and suggestions during the drafting of this manuscript.

David Legge helped write the initial critique published in the BMJ[13]. Prior to sending it for publishing, he wrote to the department of Immunization, Vaccines and Biologicals of the World Health Organisation in March 2016. But there was no response to this letter from the WHO.

References

1. **Global Advisory Committee on Vaccine Safety, 12–13 June 2013.** *Wkly Epidemiol Rec.* 2013; **88**(29): 301–12.
PubMed Abstract

2. WHO Experts Report: **High Court of Delhi at New Delhi WP (C) 13698 of 2009 Dr KB Saxena and others (petitioners) versus Union of India and others (respondents).** Submission of respondents dated 03/04/2010. [accessed 19.10.15].

3. Puliyel J, Mathew JL, Priya R: **Incomplete reporting of research in press releases: et tu, WHO?** *Indian J Med Res.* 2010; **131**: 588–9.
PubMed Abstract

4. Saxena KB, Banerji D, Qadeer I, *et al.*: **"Antivaccine lobby" replies to the *BMJ*.** *BMJ.* 2010; **341**: c4001.
PubMed Abstract | Publisher Full Text

5. WHO: **Safety of Quinvaxem (DTwP-HepB-Hib) pentavalent vaccine**. [accessed 15.10.15]. May 10, 2013.
Reference Source

6. Hume DA: In: Selby-Bigge LA, Nidditch PH, editors. **Treatise of Human Nature**. Oxford: Clarndon; 1739.
Reference Source

7. Brady HE: **Causality and explanation in social research**. In *The Oxford Handbook of Political Methodology*. ed Janet M. Box-Steffensmeier, Henry E. Brady, and David Collier. Oxford University Press, Oxford.

8. Mackie JL: **Causes and conditions.** *Am Philos Q.* 1965; **2**(4): 245–64.
Reference Source

9. **Athey v. Leonati (1996), 140 D.L.R. (4th) 235 at para. 32, [1996] 3 S.C.R. 458, [1997] 1 W.W.R. 97 quoted in David H, McCague WP, Yaniszewski PF *The Advocates' Quarterly*.** 2005; **30**: 216–238.
Reference Source

10. Hill AB: **The Environment and Disease: Association or Causation?** *Proc R Soc Med.* 1965; **58**: 295–300.
PubMed Abstract | Free Full Text

11. Center for Disease Control and Prevention: **Rotavirus Vaccine (RotaShield) and Intussusception**.
Reference Source

12. WHO: **The Causality assessment of an adverse event following immunization (AEFI): User manual for the revised WHO classification**. WHO/HIS/EMP/QSS. March 2013.
Reference Source

13. Definitions and Application of Terms for Vaccine Pharmacovigilance CIOMS/WHO: **Definitions and Application of Terms for Vaccine Pharmacovigilance Report of CIOMS/ WHO Working Group on Vaccine Pharmacovigilance**.
Reference Source

14. Legge D, Puliyel J: **Enhancing community confidence in vaccines safety.** *BMJ.* 2017; **357**: j2449.
Reference Source

15. Soriano A, Nesher G, Shoenfeld Y: **Predicting post-vaccination autoimmunity: who might be at risk?** *Pharmacol Res.* 2015; **92**: 18–22.
PubMed Abstract | Publisher Full Text

16. Berkovic SF, Harkin L, McMahon JM, *et al.*: **De-novo mutations of the sodium channel gene *SCN1A* in alleged vaccine encephalopathy: a retrospective study.** *Lancet Neurol.* 2006; **5**(6): 488–92.
PubMed Abstract | Publisher Full Text

17. Rigolet M, Aouizerate J, Couette M, *et al.*: **Clinical features in patients with long-lasting macrophagic myofasciitis.** *Front Neurol.* 2014; **5**: 230.
PubMed Abstract | Publisher Full Text | Free Full Text

18. Puliyel J, Phadke A: **Deaths following pentavalent vaccine and the revised AEFI classification.** *Ind J Med Ethics.* 2017; **2**(4): 300–301.
PubMed Abstract | Publisher Full Text

19. Collet JP, MacDonald N, Cashman N, *et al.*: **Monitoring signals for vaccine safety: the assessment of individual adverse event reports by an expert advisory committee. Advisory Committee on Causality Assessment.** *Bull World*

Health Organ. 2000; **78**(2): 178–85.
PubMed Abstract | Free Full Text

20. Aaby P, Jensen H, Samb B, *et al.*: **Differences in female-male mortality after high-titre measles vaccine and association with subsequent vaccination with diphtheria-tetanus-pertussis and inactivated poliovirus: reanalysis of West African studies.** *Lancet.* 2003; **361**(9376): 2183–8.
PubMed Abstract | Publisher Full Text

21. Higgins JP, Soares-Weiser K, López-López JA, *et al.*: **Association of BCG, DTP, and measles containing vaccines with childhood mortality: systematic review.** *BMJ.* 2016; **355**: i5170.
PubMed Abstract | Publisher Full Text | Free Full Text

22. Puliyel J, Sathyamala C: **Infanrix hexa and sudden death: a review of the periodic safety update reports submitted to the European Medicines Agency.** *Indian J Med Ethics.* 2018; **1**(1): 43–47.
PubMed Abstract | Publisher Full Text

23. Goldman GS, Miller NZ: **Relative trends in hospitalizations and mortality among infants by the number of vaccine doses and age, based on the Vaccine Adverse Event Reporting System (VAERS), 1990-2010.** *Hum Exp Toxicol.* 2012; **31**(10): 1012–21.
PubMed Abstract | Publisher Full Text | Free Full Text

24. Puliyel J, Kaur J, Puliyel A, *et al.*: **Deaths reported after Pentavalent vaccine compared with death reported after diphtheria-tetanus-pertussis vaccine – an exploratory analysis**. Medical Journal of Dr. D.Y. Patil Vidyapeeth | Published by Wolters Kluwer – Medknow 2018 Published ahead of print.
Reference Source

25. MacDonald NE; SAGE Working Group on Vaccine Hesitancy: **Vaccine hesitancy: Definition, scope and determinants.** *Vaccine.* **33**(34): 4161–4164.
PubMed Abstract | Publisher Full Text

26. Sci Dev Net: **Parental doubt drives drop in vaccination**.
Reference Source

27. Clemmons NS, Gastanaduy PA, Fiebelkorn AP, *et al.*: **Measles - United States, January 4-April 2, 2015.** *MMWR Morb Mortal Wkly Rep.* 2015; **64**(14): 373–376.
PubMed Abstract | Free Full Text

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Version 2

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✔ **Peter Aaby**
Bandim Health Project, Bissau, Guinea-Bissau

I am satisfied with the revision. Many errors and inconsistencies have been corrected. The narrative qualities have improved. The way forward is helpful.

Including the non-specific effects of vaccines as potential AEFIs is important.

In general the fact-boxes are easier to understand and helpful now. I did not understand in Box 6 how we came from the 13 fatal cases reported in Appendix 5A to the 42 deaths said to have occurred in the first 3 days.

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 06 Jul 2018

Jacob Puliyel

I agree the text in Box 6 needs clarification.

It read as follows
Box 6
Appendix 5A shows that 13 fatal cases were reported. There were more deaths after the first dose than after the second and third doses and the deaths after the second was more than after the third dose. This pattern is commonly seen with AEFIs that are causatively related. The appropriate denominator in all these cases is the number of babies vaccinated.

There were 42 deaths in the first three days after vaccination where there were only 16 deaths in the next 3 days. The fact that the deaths were clustered soon after vaccination

suggests that the deaths may be related to the vaccination event....

It should read
Appendix 5A gives the details of 13 of the deaths after vaccination. There were more deaths after the first dose than after the second and third doses and the deaths after the second was more than after the third dose. This pattern is commonly seen with AEFIs that are causatively related. The appropriate denominator in all these cases is the number of babies vaccinated.

In all, there were 42 deaths in the first three days after vaccination where there were only 16 deaths in the next 3 days. The fact that the deaths were clustered soon after vaccination suggests that the deaths may be related to the vaccination event.

Competing Interests: None

Reviewer Report 04 June 2018

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Tom Jefferson
Centre for Evidence Based Medicine, University of Oxford, Oxford, UK

The author's responses seem reasonable to me, although I do not necessarily agree with some of them. As the errors of fact have been corrected, the paper can go ahead as far as I am concerned.

Competing Interests: TJ was a recipient of a UK National Institute for Health Research grant for a Cochrane review of neuraminidase inhibitors for influenza. In addition, TJ receives royalties from his books published by Il Pensiero Scientifico Editore, Rome and Blackwells. TJ is occasionally interviewed by market research companies about phase I or II pharmaceutical products. In 2011-13, TJ acted as an expert witness in litigation related to the antiviral oseltamivir, in two litigation cases on potential vaccine-related damage and in a labour case on influenza vaccines in healthcare workers in Canada. He has acted as a consultant for Roche (1997-99), GSK (2001-2), Sanofi-Synthelabo (2003), and IMS Health (2013).In 2014 he was retained as a scientific adviser to a legal team acting on oseltamivir. TJ has a potential financial conflict of interest in the drug oseltamivir. In 2014-16, TJ was a member of three advisory boards for Boerhinger Ingelheim. TJ was holder of a Cochrane Methods Innovations Fund grant to develop guidance on the use of regulatory data in Cochrane reviews. TJ was a member of an independent data monitoring

committee for a Sanofi Pasteur clinical trial on an influenza vaccine. Between 1994 and 2013, TJ was the coordinator of the Cochrane Vaccines Field. TJ was a co-signatory of the Nordic Cochrane Centre Complaint to the European Medicines Agency (EMA) over maladministration at the EMA in relation to the investigation of alleged harms of HPV vaccines and consequent complaints to the European Ombudsman. TJ is co-holder of a John and Laura Arnold Foundation grant for development of a RIAT support centre (2017-2020) and Jean Monnet Network Grant, 2017-2020 for The Jean Monnet Health Law and Policy Network. TJ is an unpaid collaborator to the project Beyond Transparency in Pharmaceutical Research and Regulation led by Dalhousie University and funded by the Canadian Institutes of Health Research (2018-2022).

Reviewer Expertise: Clinical epidemiologist

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 03 April 2018

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Peter Aaby
[1] Bandim Health Project, Bissau, Guinea-Bissau
[2] Bandim Health Project, Bissau, Guinea-Bissau

The authors are to be complimented for having conducted this study. Proper handling of AEFIs is very important if we are to maintain trust between public health vaccinology and the community. However, I am missing the authors' specific suggestions for how to improve the situation. As discussed below there are also details of presentation which could be improved.

There is a rather detailed description of the changes in the definition of causality in relation to the current concept of AEFI. However, I am missing some presentation of where is the AEFIs concept coming from historically and what is the underlying theoretical biological model of why AEFI might occur and how does that affect how AEFI are observed, reported and used. Furthermore, what are the regulators requirements? Apparently the dominant thinking is that vaccines only induce disease specific memory. Presumably genetic variability may in rare cases affect how this biological process takes place and this could cause specific AEFIs. What else are the causes of other AEFIs: co-incidental infections or chronic disease, co-administration of drugs or other vaccinations? Most of such events can presumably be rejected as not "caused" directly by the vaccine.

However, the concept of vaccines may be changing. WHO experts have recognized that vaccines may have non-specific effects (NSEs) with consequences for child survival [1]. Apparently, through epigenetic and metabolic changes, vaccines can reprogram the immune system and upregulate or downregulate both the innate and the adaptive immune system [2-5]. If that is the case there is room for both beneficial and deleterious unexpected events following immunization (UEFI). Proper monitoring systems should also be able to detect beneficial UEFIs; for example, we have found that BCG reduces the risk of neonatal sepsis in low-birth weight children [6]. On the other hand, DTP consistently increases female relative to male mortality, also in societies that have no sex-differential treatment [7]. This is "unnatural" since there was no excess female mortality in the pre-vaccination era in West Africa [8]. This being the case there should be room not only for the short-term AEFI as in the current system (14 days?) but also for much more protracted biological processes being classified as AEFI/UEFI. This would require new standards for how UEFI/AEFI are observed and registered.

Parallel with the description of the changes in the definition of AEFI, there is a series of examples where the authors apparently think there are real differences in mortality/safety issues between different vaccination groups. I have noted at least: Pentavalent vaccine and congenital heart disease; MMR and autism in African American children; Hexavac; Rotavac; HPV and chronic fatigue syndrome; Pentavalent vaccine vs DTP for SIDS. Sometimes these safety issues are mentioned in passing as examples in the discussion of the processes related to AEFI assessment. I found it sometimes unclear whether these example were presented in their own right as safety issues or whether they were only meant to illustrate problems in the assessment of AEFI, e.g. safety reports not forthcoming, etc. Sometimes the presentation was too short or unclear to be really convincing; for example, I had problems with the ROTAVAC story (box 5). It is unclear why it is said in Box 5: "Other rotavirus vaccines that do not reduce incidence of diarrhoea or increase the incidence of diarrhoea instead of decreasing it, have been published (b)". The paper which is referenced apparently reported a 40% reduction in rota-diarrhoea. If the problem is that overall diarrhea was not reduced I think this can be present more clearly.

I think the paper would be stronger/more convincing if the safety-issues that the authors believe have been documented as safety concerns were presented as safety-case stories in specific boxes; the effect of Pentavalent vaccine on SIDS is apparently such a concern. Then the text on the changes in the assessment of AEFI could refer to this or that AEFI problem which was illustrated in the safety-case stories. On the other hand if the story is about mismanagement of the assessment of AEFI, then the cases should be presented as such without implying a causal link between vaccination and AEFI; for example box 3 is an example of poor public communication but it has hardly been documented that MMR causes autism.

Abstract:
It should not be assumed that "Of course, vaccines that caused deaths in the control-trials stage would not be licensed." RTS,S malaria vaccine was recently approved by EMA but the trial data indicate that RTS,S compared with control vaccines was associated with 2-fold higher mortality for girls [9,10]. Neither the authors nor EMA apparently analysed the mortality data, overall or by sex.

The example with cardiac failure in children is not presented in the paper and should therefore not appear in the abstract unless it is fully described in the paper. The case might well warrant further presentation in the paper itself.

Introduction
Being presented with the Sri Lanka and Vietnam cases in the first paragraphs, the reader is left wondering what was the implications of the WHO experts' classifications. Was the pentavalent vaccine (Penta) reintroduced in the countries and how did that decision come about?

Causality assessment
In the long description of changes in the manual for AEFI assessment, it would be good to have an explanation of WHO's own justification for these changes.

Sometimes the text appears to have been written some years back but have been maintained unchanged in in the current 2018-version. For example in Box 3 it is said that "Thomson has now been granted whistleblower status by the Obama administration". By now this sentence should probably be: "Thomson was granted whistleblower status by the Obama administration". Similar in the conclusion it is said that if the debates among Republican presidential aspirants "are anything to go by". By now it can no longer be "are".

Box 10: this sentence has problems: "In fact combined DTP-Hepatitis B-Hib vaccine causes more there were more local reactions and it is less effective than when they were administered separately."

Page 10: Biological plausibility.
There appears to be an increasing trend to dismiss "unexpected observations"/unpleasant observations with the argument that there is no "biological plausibility". This was one of the arguments used by WHO experts to dismiss that high-titre measles vaccine (HTMV) could be associated with excess female mortality [11]. There can obviously not be biological plausibility for a pattern just detected, that no one has ever thought about. The only relevant question is whether a pattern is repeatable – arguments about biological plausibility should not be allowed to dismiss observations of potential AEFIs. The excess female mortality was repeated in subsequent studies and WHO eventually withdrew the HTMV (1992).

I found this sentence strange: "Slate investigated of the randomised trials of human papillomavirus (HPV) vaccines and found that potential side effects were collected for only two weeks in the year long study."

Page 13: "PV" has not been defined as the abbreviation for pentavalent vaccine.

The comparison of DTP and pentavalent vaccine is frightening. Please indicate whether it is SIDS death or all-cause deaths when it is said for example: "The odds of death after pentavalent vaccine was doubled". Since it is your study I would have indicated that to the readers: "To examine if deaths following Pentavalent vaccine (PV) were merely coincidental SIDS deaths, we undertook a study of 45 million infants given DPT vaccination and 25 million who received PV". Given the scary character of this report a bit more information on methods in data collection and analysis would be appropriate. Any hypothesis of why there would be a two-fold difference in SIDS (?) mortality? Did the patterns differ for boys and girls? We have found that DTP and Penta are both associated with much higher female-than-male all-cause mortality rates [7,12].

Conclusion

I do not think the conclusion is really a conclusion to the content of the paper.

How do we proceed from here? How can we built a better system that finds even the AEFIs we do not want to see and had not expected – and at the same do not create mistrust in the vaccines (BCG, measles vaccines, OPV) which are associated with major reductions in child mortality in low-income countries. What time-frame should be used? AEFI should always be presented by sex. If there are sex-differential patterns of AEFI it might enhance the credibility of this patterns as a true AEFI since we have found sex-differential effects on mortality of most of common vaccines.

Biological plausibility should not be used to dismiss any new and unexpected pattern. There is now evidence that vaccines may reprogram both the innate and the adaptive immune system epigenetically with effect on general susceptibility to non-targeted infections [2,5]. Hence, the starting point should be that ***unlikely effects are likely*** because we have never examined the possibility.

It is standard practice in small safety study with deaths to dismiss them because we cannot see a connection. However, deaths following vaccinations should always be classified as potential-even-though-unlikely AEFIs. Otherwise we cannot accumulate the data and detect patterns we had not imagined. For example, when DTaP was tested in an RCT in Sweden there were 4 deaths among 2847 vaccinated children but none among 954 controls [13]. Though the authors recognized that 4 deaths was too high and would have been significant if the whole Swedish population of eligible children had been used as controls, the study could find no link between the vaccine and the deaths. All properly conducted studies from low-income countries have found DTwP to be associated with increased child mortality [14-16].

References

1. Higgins JP, Soares-Weiser K, López-López JA, Kakourou A, et al.: Association of BCG, DTP, and measles containing vaccines with childhood mortality: systematic review.*BMJ*. 2016; **355**: i5170 PubMed Abstract
2. Benn CS, Netea MG, Selin LK, Aaby P: A small jab - a big effect: nonspecific immunomodulation by vaccines.*Trends Immunol*. 2013; **34** (9): 431-9 PubMed Abstract | Publisher Full Text
3. Kleinnijenhuis J, Quintin J, Preijers F, Joosten LA, et al.: Bacille Calmette-Guerin induces NOD2-dependent nonspecific protection from reinfection via epigenetic reprogramming of monocytes. *Proc Natl Acad Sci U S A*. 2012; **109** (43): 17537-42 PubMed Abstract | Publisher Full Text
4. Kleinnijenhuis J, Quintin J, Preijers F, Benn CS, et al.: Long-lasting effects of BCG vaccination on both heterologous Th1/Th17 responses and innate trained immunity.*J Innate Immun*. 2014; **6** (2): 152-8 PubMed Abstract | Publisher Full Text
5. Arts RJW, Moorlag SJCFM, Novakovic B, Li Y, et al.: BCG Vaccination Protects against Experimental Viral Infection in Humans through the Induction of Cytokines Associated with Trained Immunity.*Cell Host Microbe*. 2018; **23** (1): 89-100.e5 PubMed Abstract | Publisher Full Text
6. Biering-Sørensen S, Aaby P, Lund N, Monteiro I, et al.: Early BCG-Denmark and Neonatal Mortality Among Infants Weighing <2500 g: A Randomized Controlled Trial.*Clin Infect Dis*. 2017; **65** (7): 1183-1190 PubMed Abstract | Publisher Full Text
7. Aaby P, Ravn H, Fisker AB, Rodrigues A, et al.: Is diphtheria-tetanus-pertussis (DTP) associated with increased female mortality? A meta-analysis testing the hypotheses of sex-differential non-specific effects of DTP vaccine.*Trans R Soc Trop Med Hyg*. 2016; **110** (10): 570-581 PubMed Abstract | Publisher Full Text
8. Aaby P, Martins CL, Garly ML, Rodrigues A, et al.: The optimal age of measles immunisation in

low-income countries: a secondary analysis of the assumptions underlying the current policy.*BMJ Open*. 2012; **2** (4). PubMed Abstract | Publisher Full Text
9. Klein S, Shann F, Moss W, Benn C, et al.: RTS,S Malaria Vaccine and Increased Mortality in Girls. *mBio*. 2016; **7** (2): e00514-16 Publisher Full Text
10. Aaby P, Rodrigues A, Kofoed P, Benn C: RTS,S/AS01 malaria vaccine and child mortality. *The Lancet*. 2015; **386** (10005): 1735-1736 Publisher Full Text
11. Aaby P, Jensen H, Samb B, Cisse B, et al.: Differences in female-male mortality after high-titre measles vaccine and association with subsequent vaccination with diphtheria-tetanus-pertussis and inactivated poliovirus: reanalysis of West African studies.*Lancet*. 2003; **361** (9376): 2183-8 PubMed Abstract | Publisher Full Text
12. Fisker A, Biering-Sørensen S, Lund N, Djana Q, et al.: Contrasting female-male mortality ratios after routine vaccinations with pentavalent vaccine versus measles and yellow fever vaccine. A cohort study from urban Guinea-Bissau. *Vaccine*. 2016; **34** (38): 4551-4557 Publisher Full Text
13. Storsaeter J, Olin P, Renemar B, Lagergård T, et al.: Mortality and morbidity from invasive bacterial infections during a clinical trial of acellular pertussis vaccines in Sweden.*Pediatr Infect Dis J*. 1988; **7** (9): 637-45 PubMed Abstract
14. Aaby P, Ravn H, Benn CS: The WHO Review of the Possible Nonspecific Effects of Diphtheria-Tetanus-Pertussis Vaccine.*Pediatr Infect Dis J*. 2016; **35** (11): 1247-1257 PubMed Abstract | Publisher Full Text
15. Mogensen SW, Andersen A, Rodrigues A, Benn CS, et al.: The Introduction of Diphtheria-Tetanus-Pertussis and Oral Polio Vaccine Among Young Infants in an Urban African Community: A Natural Experiment.*EBioMedicine*. 2017; **17**: 192-198 PubMed Abstract | Publisher Full Text
16. Aaby P, Mogensen S, Rodrigues A, Benn C: Evidence of Increase in Mortality After the Introduction of Diphtheria–Tetanus–Pertussis Vaccine to Children Aged 6–35 Months in Guinea-Bissau: A Time for Reflection?. *Frontiers in Public Health*. 2018; **6**. Publisher Full Text

Is the topic of the opinion article discussed accurately in the context of the current literature?
Yes

Are all factual statements correct and adequately supported by citations?
Partly

Are arguments sufficiently supported by evidence from the published literature?
Partly

Are the conclusions drawn balanced and justified on the basis of the presented arguments?
Yes

Competing Interests: No competing interests were disclosed.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 04 May 2018

Jacob Puliyel

Reviewer 2

Reviewer Professor Peter Aaby

Reviewer Comment
Authors' response

The authors are to be complimented for having conducted this study. Proper handling of AEFIs is very important if we are to maintain trust between public health vaccinology and the community. I am missing the authors' specific suggestions for how to improve the situation.
We thank the reviewer for his detailed review and this compliment.

We attempt only to critique the revised AEFI classification. Before one makes an effort to improve it, there has to be an acknowledgement of the flaws in the present system.

We make no claim to have developed an alternate system of classification. An appropriate body of experts will need to draft it, if there is a consensus on what is flawed with the present system.

We have now introduced a new paragraph entitled: "Where do we go from here". We have suggested that the WHO-UMC causality categories for drug reactions has stood the test of time (and the older Brighton system was adapted from it) may be used till a better system evolves.

There is a rather detailed description of the changes in the definition of causality in relation to the current concept of AEFI. However, I am missing some presentation of where is the AEFIs concept coming from historically and what is the underlying theoretical biological model of why AEFI might occur and how does that affect how AEFI are observed, reported and used. Furthermore, what are the regulators requirements? Apparently the dominant thinking is that vaccines only induce disease specific memory. Presumably genetic variability may in rare cases affect how this biological process takes place and this could cause specific AEFIs. What else are the causes of other AEFIs: co-incidental infections or chronic disease, co-administration of drugs or other vaccinations? Most of such events can presumably be rejected as not "caused" directly by the vaccine.

We have dealt very briefly with the historic and theoretical background – but within the 8000 word-limit, we could not deal with this in greater detail.
Regarding: 'AEFIs concept coming from historically'
The other reviewer Prof. Tom Jefferson (TJ) has suggested we introduce the contributions made by the AB Hill and we have made reference to that.

We refer to genetic predisposition to AEFI in our article and also how underlying

disease like congenital heart lesions can precipitate an AEFI. This paragraph has been added in the main body on the text.

In the new version we make reference to non-specific effects of vaccine and we thank the reviewer for his suggestion.

However, the concept of vaccines may be changing. WHO experts have recognized that vaccines may have non-specific effects (NSEs) with consequences for child survival [1]. Apparently, through epigenetic and metabolic changes, vaccines can reprogram the immune system and upregulate or downregulate both the innate and the adaptive immune system [2-5]. If that is the case there is room for both beneficial and deleterious unexpected events following immunization (UEFI). Proper monitoring systems should also be able to detect beneficial UEFIs; for example, we have found that BCG reduces the risk of neonatal sepsis in low-birth weight children [6]. On the other hand, DTP consistently increases female relative to male mortality, also in societies that have no sex-differential treatment [7]. This is "unnatural" since there was no excess female mortality in the pre-vaccination era in West Africa [8]. This being the case there should be room not only for the short-term AEFI as in the current system (14 days?) but also for much more protracted biological processes being classified as AEFI/UEFI. This would require new standards for how UEFI/AEFI are observed and registered.

We thank the reviewer for the references. In our new submission we refer briefly to these NSEs and the benefits and harms than can result.

Parallel with the description of the changes in the definition of AEFI, there is a series of examples where the authors apparently think there are real differences in mortality/safety issues between different vaccination groups. I have noted at least: Pentavalent vaccine and congenital heart disease; MMR and autism in African American children; Hexavac; Rotavac; HPV and chronic fatigue syndrome; Pentavalent vaccine vs DTP for SIDS. Sometimes these safety issues are mentioned in passing as examples in the discussion of the processes related to AEFI assessment. I found it sometimes unclear whether these example were presented in their own right as safety issues or whether they were only meant to illustrate problems in the assessment of AEFI, e.g. safety reports not forthcoming, etc. Sometimes the presentation was too short or unclear to be really convincing; for example, I had problems with the ROTAVAC story (box 5). It is unclear why it is said in Box 5: "Other rotavirus vaccines that do not reduce incidence of diarrhoea or increase the incidence of diarrhoea instead of decreasing it, have been published (b)". The paper which is referenced apparently reported a 40% reduction in rota-diarrhoea. If the problem is that overall diarrhea was not reduced I think this can be present more clearly.

I think the paper would be stronger/more convincing if the safety-issues that the authors believe have been documented as safety concerns were presented as safety-case stories in specific boxes; the effect of Pentavalent vaccine on SIDS is apparently such a concern. Then

the text on the changes in the assessment of AEFI could refer to this or that AEFI problem which was illustrated in the safety-case stories. On the other hand if the story is about mismanagement of the assessment of AEFI, then the cases should be presented as such without implying a causal link between vaccination and AEFI; for example box 3 is an example of poor public communication but it has hardly been documented that MMR causes autism.

They are presented as potential safety problems that seem to get glossed over, by the Revised AEFI assessment methodology. (Please also see next point in row below).

Regarding Rotavac the problem is that overall diarrhea is not decreased and this is clarified in the revised text

Safety-case stories with Pentavac and Hexavac have been identified as such in the revised manuscript

The MMR story Box 3 was about increased autism seen in African American boys vaccinated prior to age of 2 years (compared to those vaccinated after 2 years).

Post-hoc, data of many African American children were excluded on the grounds that they did not possess a valid birth certificate –and reanalysis of this truncated data was published to suggest that MMR was not related autism in any group.

This suggests a possible link between Autism and MMR (albeit in one specific ethnic and age group).

In summary, all the examples noted by the reviewer in the article (Pentavalent vaccine and congenital heart disease; MMR and autism in African American children; Hexavac; Rotavac; HPV and chronic fatigue syndrome; Pentavalent vaccine vs DTP for SIDS) are AEFI that are 'probably' related causatively with vaccination which are not acknowledged.

In the case of MMR and Hexavac the new revised classification cannot be blamed as the data itself was falsified (Many African American boys excluded from MMR study and deaths deleted from PSUR 19).

Abstract
It should not be assumed that "Of course, vaccines that caused deaths in the control-trials stage would not be licensed." RTS,S malaria vaccine was recently approved by EMA but the trial data indicate that RTS,S compared with control vaccines was associated with 2-fold higher mortality for girls [9,10]. Neither the authors nor EMA apparently analysed the mortality data, overall or by sex.

The example with cardiac failure in children is not presented in the paper and should therefore not appear in the abstract unless it is fully described in the paper. The case might

well warrant further presentation in the paper itself.

This sentence has been corrected in abstract

The case of heart failure in children is now included in the paper as suggested by the reviewer.

Introduction
Being presented with the Sri Lanka and Vietnam cases in the first paragraphs, the reader is left wondering what was the implications of the WHO experts' classifications. Was the pentavalent vaccine (Penta) reintroduced in the countries and how did that decision come about?

The vaccines were reintroduced after the 'WHO experts' report, and this is mentioned now in the revised manuscript.
The inevitable follow-up question then is: Were there deaths after it was reintroduced?
We know from the data from India that using the Revised AEFI manual, each death is certified as 'inconsistent with causal association' on the grounds that death has so far never been acknowledged as having occurred in epidemiological studies with the vaccine. This is explained in the paper with reference from literature.

Causality assessment
1. In the long description of changes in the manual for AEFI assessment, it would be good to have an explanation of WHO's own justification for these changes.

2. Sometimes the text appears to have been written some years back but have been maintained unchanged in the current 2018-version. For example in Box 3 it is said that "Thomson has now been granted whistleblower status by the Obama administration". By now this sentence should probably be: "Thomson was granted whistleblower status by the Obama administration". Similar in the conclusion it is said that if the debates among Republican presidential aspirants "are anything to go by". By now it can no longer be "are".

Box 10: this sentence has problems: "In fact combined DTP-Hepatitis B-Hib vaccine causes more there were more local reactions and it is less effective than when they were administered separately."

3. Page 10: Biological plausibility.
There appears to be an increasing trend to dismiss "unexpected observations"/unpleasant observations with the argument that there is no "biological plausibility". This was one of the arguments used by WHO experts to dismiss that high-titre measles vaccine (HTMV) could be associated with excess female mortality [11]. There can obviously not be biological plausibility for a pattern just detected, that no one has ever thought about. The only relevant question is whether a pattern is repeatable – arguments about biological plausibility should not be allowed to dismiss observations of potential AEFIs. The excess female mortality was

repeated in subsequent studies and WHO eventually withdrew the HTMV (1992).

4. I found this sentence strange: “Slate investigated of the randomised trials of human papillomavirus (HPV) vaccines and found that potential side effects were collected for only two weeks in the year long study.”

5. Page 13: “PV” has not been defined as the abbreviation for pentavalent vaccine.

6. The comparison of DTP and pentavalent vaccine is frightening. Please indicate whether it is SIDS death or all-cause deaths when it is said for example: “The odds of death after pentavalent vaccine was doubled”. Since it is your study I would have indicated that to the readers: “To examine if deaths following Pentavalent vaccine (PV) were merely coincidental SIDS deaths, we undertook a study of 45 million infants given DPT vaccination and 25 million who received PV”. Given the scary character of this report a bit more information on methods in data collection and analysis would be appropriate. Any hypothesis of why there would be a two-fold difference in SIDS (?) mortality? Did the patterns differ for boys and girls? We have found that DTP and Penta are both associated with much higher female-than-male all-cause mortality rates [7,12].

1. This has not been justified as far as we know. The rationale for revising the Brighton classification has also not been stated explicitly.

Reviewer TJ suggested that WHO must be given an opportunity to defend the changes.

David Legge and I had written to WHO, before we published the short critique in BMJ referenced in the paper (Reference 14). This is copied in the response to TJ. There was no response from WHO.

This present paper was also sent to WHO after it appeared in F1000 to seek their comments. There has not been any response so far.

2. The reviewer is correct that the article has been written in parts and the tense needs to be corrected for consistency. This has now been done.

3. We thank the reviewer for this example that has been included in the text.

4. The Slate story: that was the point of the Slate report – that adverse events were not recorded properly.

5. Abbreviation PV has been removed

6. The DPT Pentavalent story is about deaths within 72 hours of vaccination. As babies taken for vaccination are usually not unwell, these must be considered as SIDS deaths in ‘well children’ and comparisons can only be made with the acceptable death rate for ‘well children’ and it must NOT be compared to the ‘all cause death rate’ which includes in the cohort well and unwell children. This is sometimes referred to as the

'healthy vaccinee effect'

When we report "The odds of death after pentavalent vaccine was doubled" we DO NOT have to make any extra allowance for the 'healthy vaccinee effect' as both DPT and Pentavalent vaccine are given to healthy children. The deaths among children getting pentavalent vaccine was twice as high as those getting DPT

There is no hypothesis for the deaths - except as explained in the Boatman case - that the use of multiple vaccines release more inflammatory cytokines (than when single vaccines given) which can act as neuro-modulators and can cause depression of the serotonergic 5-hydroxytryptophan (5-HT) system in the infant medulla and blunt the normal chemo-sensitive response to excess carbon dioxide and this can result in the death of vulnerable infants during sleep.

The method of data collection is described in great detail in the reference (which would be too long to reproduce in this paper). It may suffice to say that both DPT and Pentavalent deaths were captured in the same 'improved' government surveillance system and the data has been made freely available on-line for rechecking by stake holders, and more studies by future researchers.

The records did not specify sex of child.

Conclusion

1. I do not think the conclusion is really a conclusion to the content of the paper.

   How do we proceed from here? How can we built a better system that finds even the AEFIs we do not want to see and had not expected – and at the same do not create mistrust in the vaccines (BCG, measles vaccines, OPV) which are associated with major reductions in child mortality in low-income countries. What time-frame should be used? AEFI should always be presented by sex. If there are sex-differential patterns of AEFI it might enhance the credibility of this patterns as a true AEFI since we have found sex-differential effects on mortality of most of common vaccines.

   Biological plausibility should not be used to dismiss any new and unexpected pattern. There is now evidence that vaccines may reprogram both the innate and the adaptive immune system epigenetically with effect on general susceptibility to non-targeted infections [2,5]. Hence, the starting point should be that ***unlikely effects are likely*** because we have never examined the possibility.

   It is standard practice in small safety study with deaths to dismiss them because we cannot see a connection. However, deaths following vaccinations should always be classified as potential-even-though-unlikely AEFIs. Otherwise we cannot accumulate the data and detect patterns we had not imagined. For example, when DTaP was tested in an RCT in Sweden there were 4 deaths among 2847 vaccinated children but none among 954 controls [13]. Though the authors recognized that 4 deaths was too high and would have been significant if the whole Swedish population of eligible children had been used as controls, the study could find no link between the vaccine

and the deaths. All properly conducted studies from low-income countries have found DTwP to be associated with increased child mortality [14-16].

1. **The conclusion has been revised as suggested**
2. **We have included a paragraph on "Where do we go from here".**

Competing Interests: None

Reviewer Report 14 March 2018

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?

Tom Jefferson
[1] Centre for Evidence Based Medicine, University of Oxford, Oxford, UK
[2] Centre for Evidence Based Medicine, University of Oxford, Oxford, UK

Thank you for asking my views on this paper.

This is a very long and detailed examination of the philosophical, historical rationale and principles of causality assessment of possible vaccine harms, chiefly death. This is mixed with the narrative of the changes made by WHO to their own assessment rules.

The authors use several important examples to make their points.

I regard this topic as extremely interesting and important and the authors should be congratulated for attempting to pull the main strands together, from David Hume to the Brighton Collaboration.

Despite my interest I found the manuscript extremely heavy going with a difficult-to-follow thread. It soon became apparent that the authors think there has been something akin to an international conspiracy to bury the dead by changing the definitions of probable and likely causality. That may be so, but I could not find any convincing evidence in the paper.

Here and there inaccuracies and typos add to the distractions. For example in box 10, DTP becomes DPT or the suggestions that Rotashield was withdrawn in 1999 as a consequence of the Brighton criteria. As far as I remember in 1999 we were setting up and had not produced the

criteria or any other output yet.

I would also check the data of Rotashield withdrawal from the market.

What follows are a few suggestions to improve the manuscript (ms).

First I would split the ms into 2 parts. One discussing the philosophical-historical basis for causality assessment perhaps as far as Brighton and the second one looking at the more recent changes.

Here I have two further suggestions to offer.

Bradford Hill's criteria should be cited, even though they are not a perfect solution as Hill himself recognised. They should be cited because they have had an enormous influence on modern epidemiology (see Geoffrey Rose's variant for example) and because the formulation of some of them (temporality, strength, gradient) is very apt for vaccine exposure. Take temporality for example. The term AEFI which is so extensively cited concedes temporality when in fact temporality is only as good as the vaccination records. Often "AEFI" is used when we are not sure that exposure has taken place at all or that it preceded the clinical event/possible harm. So a balanced discussion of temporality (one of the absolute conditions for determining causality) must include absolute certainty or high probability that exposure preceded the event and that it had taken place at all.

Second I would offer the connection of probabilism and Fisherian theory with Hume's problem of induction. I see Fisher's work as the patch that allows us to go on with at least a partially clear conscience, as I do not think there is a solution to Hume's problem as nature is not (and never will be) universally uniform.

I would tone down the plot theory rhetoric and would seek a written explanation from WHO for their actions. WHO do not have a good track record of answering researchers but the effort must be made and reported. Ditto for any other point which was unclear to the authors. I am not a great believer in plots, blunders fit the picture and my experience better, but the authors must try and get to the bottom of the rationale for the changes and, while at it, they might just want to ask WHO, CIOMS etc. to check the authors' facts and dates (but not their opinions of course).

Last but not least please ask Brighton whether they were aware of WHO's actions (they must be) and what their views are.

I hope these suggestions are useful to the authors.

Is the topic of the opinion article discussed accurately in the context of the current literature?
Partly

Are all factual statements correct and adequately supported by citations?
Partly

Are arguments sufficiently supported by evidence from the published literature?

Partly

Are the conclusions drawn balanced and justified on the basis of the presented arguments?
Partly

Competing Interests: TJ was a recipient of a UK National Institute for Health Research grant for a Cochrane review of neuraminidase inhibitors for influenza. In addition, TJ receives royalties from his books published by Il Pensiero Scientifico Editore, Rome and Blackwells. TJ is occasionally interviewed by market research companies about phase I or II pharmaceutical products. In 2011-13, TJ acted as an expert witness in litigation related to the antiviral oseltamivir, in two litigation cases on potential vaccine-related damage and in a labour case on influenza vaccines in healthcare workers in Canada. He has acted as a consultant for Roche (1997-99), GSK (2001-2), Sanofi-Synthelabo (2003), and IMS Health (2013).In 2014 he was retained as a scientific adviser to a legal team acting on oseltamivir. TJ has a potential financial conflict of interest in the drug oseltamivir. In 2014-16, TJ was a member of three advisory boards for Boerhinger Ingelheim. TJ was holder of a Cochrane Methods Innovations Fund grant to develop guidance on the use of regulatory data in Cochrane reviews. TJ was a member of an independent data monitoring committee for a Sanofi Pasteur clinical trial on an influenza vaccine. Between 1994 and 2013, TJ was the coordinator of the Cochrane Vaccines Field. TJ was a co-signatory of the Nordic Cochrane Centre Complaint to the European Medicines Agency (EMA) over maladministration at the EMA in relation to the investigation of alleged harms of HPV vaccines and consequent complaints to the European Ombudsman. TJ is co-holder of a John and Laura Arnold Foundation grant for development of a RIAT support centre (2017-2020) and Jean Monnet Network Grant, 2017-2020 for The Jean Monnet Health Law and Policy Network. TJ is an unpaid collaborator to the project Beyond Transparency in Pharmaceutical Research and Regulation led by Dalhousie University and funded by the Canadian Institutes of Health Research (2018-2022).

Reviewer Expertise: Tom Jefferson, Clinical epidemiologist

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 04 May 2018

Jacob Puliyel

Reviewer 1

Referee Prof Tom Jefferson
Reviewer Comment
Authors' response

This is a very long and detailed examination of the philosophical, historical rationale and principles of causality assessment of possible vaccine harms, chiefly death. This is mixed

with the narrative of the changes made by WHO to their own assessment rules.

The authors use several important examples to make their points.

I regard this topic as extremely interesting and important and the authors should be congratulated for attempting to pull the main strands together, from David Hume to the Brighton Collaboration.

Thanks

Despite my interest I found the manuscript extremely heavy going with a difficult-to-follow thread.
It soon became apparent that the authors think there has been something akin to an international conspiracy to bury the dead by changing the definitions of probable and likely causality. That may be so, but I could not find any convincing evidence in the paper.

'Conspiracy theory' according to Barkun is a closed and unfalsifiable system and it is merely a matter of faith with no proof.
We hope we have critiqued various provisions in the revised manual for AEFI and shown how it can lead to harm – how it can result in delays in the acknowledgment of the problems that can result from vaccines. We hope this is a critique of the revised manual 'not unfalsifiable conspiracy theory'.

According to the revised AEFI classification reactions must be 'known to be associated with the vaccine' before it is acknowledged as caused by the vaccine. We have shown how new signals can be (and are being) ignored on account of this proviso.

We merely suggest there is potential for harm inherent in the revised system.

Regarding the observation
"international conspiracy to bury the dead by changing the definitions of probable and likely causality. That may be so, but I could not find any convincing evidence in the paper."

The WHO experts in Sri Lanka removed these categories ('probable' and 'possible') before they reported the deaths were 'unlikely' to be caused by vaccine. This is a verifiable fact. Had the categories not been removed, they would have had to report that 3 death (for with there was no alternate explanation) were 'probably' related to vaccination.

Chronologically at least, the new 'Revised AEFI' categories were developed after the Sri Lanka report was criticized in the BMJ etc.

After the AEFI classification was revised, experts no longer have the mortification of

having to report they have deleted 'Probable' and 'possible'. The revised AEFI have eliminated the categories 'probable/likely' and 'possible'.

In fact the Sri Lanka experts were very keen to absolve the vaccine. They write they felt reluctant to even classify the deaths as 'unlikely' to be related to vaccine. I quote from the Sri Lanka report:
"Unlikely: In defining this category, the panel took note of the fact that the WHO category 'unlikely' is often interpreted to mean that there is (conversely) some likelihood of a causal association between the adverse event and the vaccine(s) administered...." (The full report is uploaded here for easy access http://www.jacob.puliyel.com/download.php?id=213)

I have no doubt that the experts are motivated by a laudable desire to reduce vaccine hesitancy and the attendant risk of vaccine preventable disease.

The reasoning for the revised AEFI categories must be similar to that of the experts of the Sri Lanka report.

We have added a new paragraph explaining that we feel the motivation for the change was a laudable desire to reduce vaccine hesitancy.

Here and there inaccuracies and typos add to the distractions. For example in box 10, DTP becomes DPT or the suggestions that Rotashield was withdrawn in 1999 as a consequence of the Brighton criteria. As far as I remember in 1999 we were setting up and had not produced the criteria or any other output yet.

I would also check the data of Rotashield withdrawal from the market.

The errors have been corrected in the revised manuscript.

The point made by the reviewer about Rotashield is correct. It has been revised. As pointed out by the reviewer, RotaShield was marketed before Brighton was developed. The WHO/UMC system was in place at that time.
Corrections have been made in the revised version.

Bradford Hill's criteria should be cited, even though they are not a perfect solution as Hill himself recognised. They should be cited because they have had an enormous influence on modern epidemiology (see Geoffrey Rose's variant for example) and because the formulation of some of them (temporality, strength, gradient) is very apt for vaccine exposure. Take temporality for example. The term AEFI which is so extensively cited concedes temporality when in fact temporality is only as good as the vaccination records. Often "AEFI" is used when we are not sure that exposure has taken place at all or that it preceded the clinical event/possible harm. So a balanced discussion of temporality (one of the absolute conditions for determining causality) must include absolute certainty or high probability that exposure preceded the event

and that it had taken place at all.

Bradford Hill's criteria have been cited. Thanks.

Second I would offer the connection of probabilism and Fisherian theory with Hume's problem of induction. I see Fisher's work as the patch that allows us to go on with at least a partially clear conscience, as I do not think there is a solution to Hume's problem as nature is not (and never will be) universally uniform.

We did not take the reviewers suggestion to introduce Fisherian theory - to avoid making the write-up even more complicated. As the reviewer stated: the manuscript is already "extremely heavy going"

I would tone down the plot theory rhetoric and would seek a written explanation from WHO for their actions. WHO do not have a good track record of answering researchers but the effort must be made and reported. Ditto for any other point which was unclear to the authors. I am not a great believer in plots, blunders fit the picture and my experience better, but the authors must try and get to the bottom of the rationale for the changes and, while at it, they might just want to ask WHO, CIOMS etc. to check the authors' facts and dates (but not their opinions of course).

The revised manuscript states explicitly that the motivation for the changes is probably to reduce vaccine hesitancy.

The WHO was contacted a year prior to publishing this article in the BMJ but there was no response (*BMJ* 2017;357:j2449, published 19 May 2017). They were again contacted after the first version of this manuscript was published on F1000Research, so they could respond in the comments section. There is no response so far (as of 12/4/18).

Last but not least please ask Brighton whether they were aware of WHO's actions (they must be) and what their views are.

Apparently the present Brighton team approves of these changes. They are now tasked with the responsibility to develop 'case definition' for 'known AEFI' (See CIOMS/WHO report)

Competing Interests: None. I am one of the authors of the article.

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The Best Ever Discussion I Have Heard Promoting the Vaccines: From New FDA Leads

Why Canadians May Soon Look South for Honest Answers on Vaccine Safety and Risk



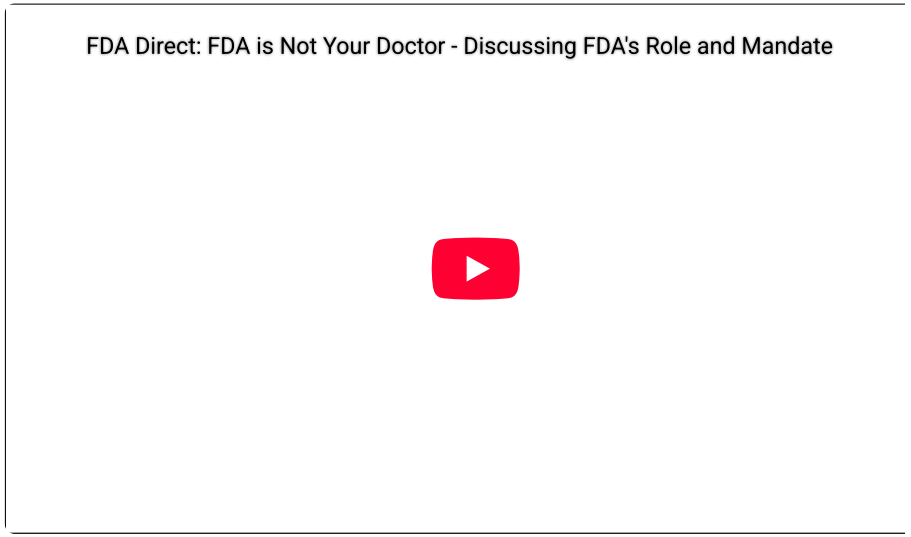
DMITRY GORODNICHY, PH.D.
JUN 05, 2025

5 Share

I have subscribed to the FDA's official YouTube channel and encourage you to do tl same—it has become a source of *some of the most* positive and constructive updates medication and health. Here's the latest discussion featured there. I sincerely hope that all public servants—both those labeled "pro-vaxxers" and those called "anti-vaxxers" (though I dislike both of these terms, as I believe they were purposefully introduced to instigate division, hatred, and intolerance)—will come together to celebrate the restoration of scientific integrity in the development of vaccine produ as demonstrated by our neighbors south of the border.

Key quotes from this discussion are provided below for your easy reference in conversations with your family doctor and government colleagues.

Your Doctor Is Not the Government: The FDA's Bold New Message (YouTube)



Key Themes and Insights

1. Transition to Evidence-Based Approvals

Dr. Makary and Dr. Prasad articulate a shift from the previous "one-size-fits-all" vaccination strategy to a more nuanced, evidence-based approach. They argue that while initial emergency authorizations were necessary, the current landscape dema more robust data to support vaccine approvals, especially for low-risk populations.npr.org+1fiercepharma.com+1

> *"We simply don't know whether a healthy 52-year-old woman with a normal BMI who h had COVID-19 three times and has received six previous doses of a COVID-19 vaccine benefit from the seventh dose."*
> — Dr. Marty Makary

2. Implementation of Placebo-Controlled Trials

A significant policy change discussed is the FDA's requirement for randomized, placebo-controlled trials to evaluate new COVID-19 vaccines for healthy individual under 65. This move aims to ensure that vaccine approvals are grounded in "gold-standard" scientific evidence.reuters.com+10medtechdive.com+10nypost.com+10npr.org

> *"The FDA will approve vaccines for high-risk persons and, at the same time, demand robust, gold-standard data on persons at low risk."*
> — Dr. Vinay Prasad

3. Focus on High-Risk Populations

The FDA's new framework prioritizes vaccine approvals for individuals aged 65 anc older and those with underlying health conditions, such as asthma, diabetes, or obesity. For these groups, immunogenicity data may suffice for approval, while broader populations will require more extensive clinical evidence.fiercepharma.com+2washingtonpost.com+2clinicaladvisor.com+2

> *"Our policy also balances the need for evidence. We want to know more about what thes products are doing, especially as we enter the seventh, eighth, and ninth dose."*
> — Dr. Vinay Prasad

4. Emphasis on Transparency and Public Trust

Both officials underscore the importance of transparency in the vaccine approval process to restore public trust. They advocate for clear communication about the benefits and risks associated with vaccination, moving away from blanket recommendations.washingtonpost.comwashingtonpost.com

> *"The FDA's new COVID-19 philosophy represents a balance of regulatory flexibility an commitment to gold-standard science."*
> — Drs. Makary and Prasad

Conclusion

This discussion by Drs. Makary and Prasad represents a pivotal moment in public health policy, highlighting a deliberate move towards evidence-based vaccine approvals. Their emphasis on scientific rigor and transparency sets a new standard regulatory practices, potentially influencing international approaches to vaccine evaluation.fiercepharma.com+9clinicaladvisor.com+9center4research.org+9

For Canadians and others interested in the intricacies of vaccine approval and safet the FDA's evolving policies offer a model of thoroughness and openness that may inform personal health decisions and public discourse.

Note: For a more in-depth understanding, viewers are encouraged to watch the full discussi on YouTube: FDA is not your doctor: a discussion on a recent COVID-19 vaccine marketir authorization.

PS: US vs. Canada

What makes this discussion from the U.S. FDA so significant is not just the conten it's the **tone and principle** behind it. For the first time since the beginning of the pandemic, the American public is being told plainly that **public health must respec medical nuance, risk-benefit analysis, and individual autonomy.** The FDA's new leadership—Dr. Marty Makary and Dr. Vinay Prasad—have broken the silence on a taboo subject: that a 7th or 8th COVID vaccine dose for a low-risk person with natu immunity may not be supported by evidence. They are demanding placebo-controll trials, age-specific guidelines, and the reintroduction of informed consent into vacc policy.

This stands in **sharp contrast to the Canadian context**, where vaccine policy is still largely dictated by **centralized authority figures like Dr. Theresa Tam**, and where deviation from federal recommendations is often stigmatized—even for doctors. In

Canada, **there is no real equivalent to what the FDA just did**: publicly acknowledg scientific uncertainty, prioritizing individual health status, and openly calling for randomized trials before approving vaccines for healthy individuals.

The FDA's shift sends a powerful signal—not only about **how science should be do** but about **how public trust is rebuilt**. In the U.S., regulatory agencies are reassertin their independence. In Canada, **health policy still feels scripted from the top dowr** with little space for open scientific debate or patient-specific decisions.

For Canadians seeking clarity, transparency, and nuance, the U.S. is now offering a kind of leadership that **Canada's institutions may wish to provide too.**

References

- YouTube – FDA is not your doctor
- Fierce Pharma – FDA limits COVID vaccine approvals
- NPR – FDA draws a line on boosters for healthy adults
- Reuters – FDA sets new COVID booster guidelines

Acknowledgment

Article is written with assistance from ChatGPT using the following prompt: "Summarize ti YouTube discussion between new FDA leads on vaccine approvals, highlighting quotes and implications for Canadians."

Support This Work Across All Channels

If you believe in open dialogue, informed choice, and exploring underreported perspectives, help keep the conversation going—like and share this article on your preferred platform.

I write these articles on my own time as a contribution to my community—especial for those seeking truth and guidance in these increasingly censored times. Your support—through follows, likes, and shares—makes a real difference.

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Where is the Highest Fear of Reprisal and Why?

Data Evidence from PSES 2018-2022 Results

Prepared by Dmitry Gorodnichy, Ph.D.
Email: dmitry.gorodnichy@gmail.com
May 2019. Follow-up: June 2024

Data: Public Service Employee Survey datasets (2018)
Web App: Open Canada PSES App (Mirror: iTrack PSES)
Source Code: GitHub Repository

Question 1: Where in the Public Service is the Fear of Reprisal the Highest?

Answer: The highest fear of reprisal is found in units or divisions that provide scientific evaluation for government policies and industry products.

The images below show the results for "Fear of Reprisal" (Question 36 in PSES 2018) across the government. Divisions or units that have mandates in policy and vendor product evaluations show the highest levels of fear of reprisal (lowest positive ranking) in the public service.

The following units are listed in order of ranking (lowest ranking first). Those marked with an asterisk (*) have improved their ranking since the original analysis in 2019:

- **PHAC - Health Security Infrastructure - Centre for Emergency Preparedness**
- **PHAC - Infectious Disease Prevention**
- **Health Canada - Health Products and Foods - Marketed Health Products**
- **Health Canada - Regulatory Operation - Health Product Compliance**
- **Canada Border Services Agency - ISTB, Several Directorates***
- **ECCC - Industrial, Chemical Waste Directorate**
- **AAFC - Office of Audit and Evaluation**
- **Canadian Institute of Health Research - Research Knowledge Transfer Ethics**

Question 2: Why is the Fear of Reprisal High in These Divisions/Units?

Answer: The fear is NOT related to harassment and discrimination.

Notably, the fear of reprisal in the specified divisions or units is not correlated with harassment and discrimination (Questions 48 - 61). This indicates that the fear arises from other reasons.

It is also noted that for the same agencies, the divisions or units not involved in policy and vendor product evaluations have much lower fear of reprisal (higher positive ranking). This further confirms that the primary source of fear in those units where it is high comes from

the work they do, which—based on observations and firsthand accounts—is conducted under political and industry interference.

In summary, the fear of reprisal highly correlates with the level of political and industry interference in the work performed by professionals in those units where it is high.

How to Read the Images

The iTrack PSES Web App generates two types of images:

Type 1: By Department

For a selected question (e.g., Question 36), this image shows the variation across all departments (units) at the same organizational level.

- **Public Service averages** and **whole organization average** are shown at the bottom (in black and blue boxes, respectively).
- The numbers in the boxes indicate the number of responses for each department (unit).

Type 2: By Question

For a selected unit (the unit with the highest fear of reprisal, i.e., lowest score for Question 36), this image shows the variation across all questions.

- Questions are grouped and colored by theme.
- The numbers in the boxes show the ranking of the selected unit on each question (measured as a percentile of units that show better results).
- The black crosses indicate the Public Service average for all questions.

Note: All images are generated automatically. Viewing them online from the Web App is recommended for better quality.

Data for Later Years

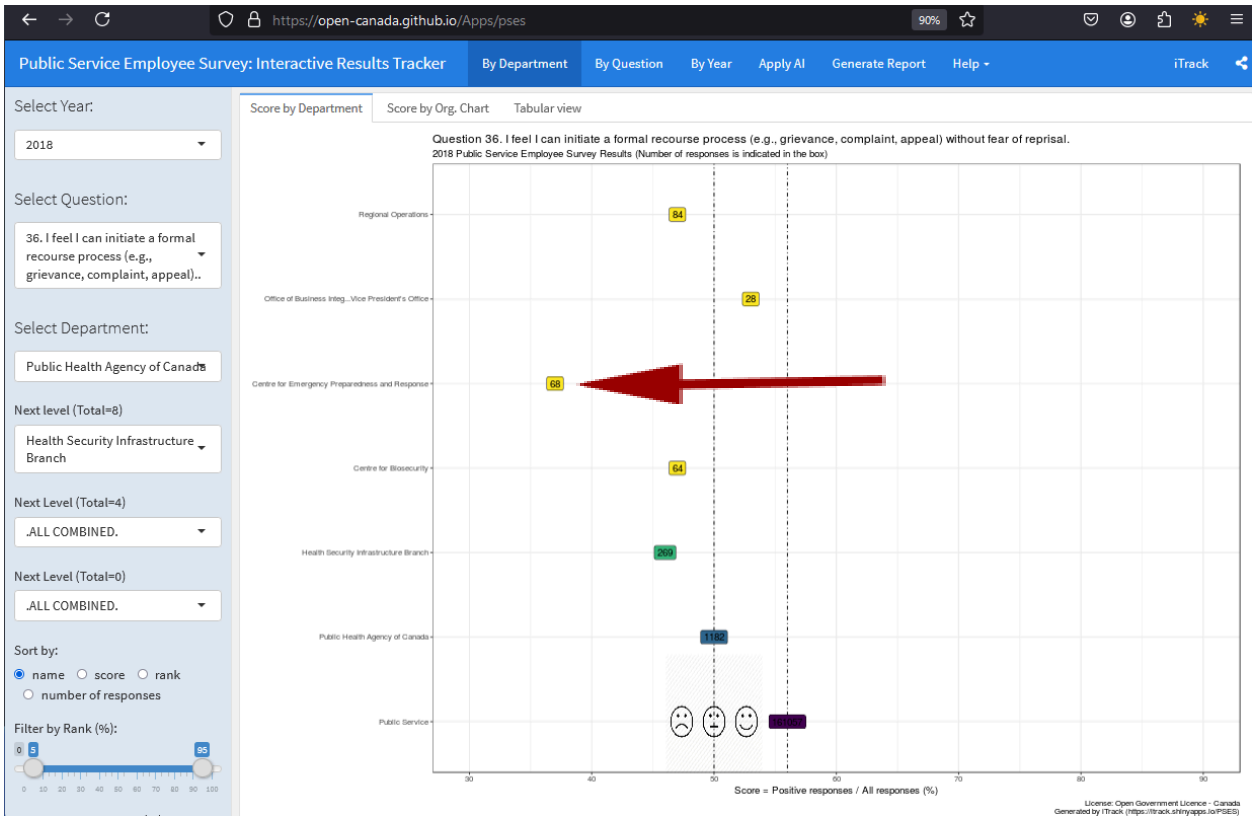
The iTrack PSES Web App generates data only for the PSES 2018 dataset.

Data for other years (2020, 2022) became available after the app was built.

A manual examination of the latest data for the departments (units) in question (i.e., those that showed the highest fear of reprisal in 2018) confirmed that this high level of fear is consistent for all years for which PSES data is published for those units, with a small exception: CBSA, where results have slightly improved since 2018.

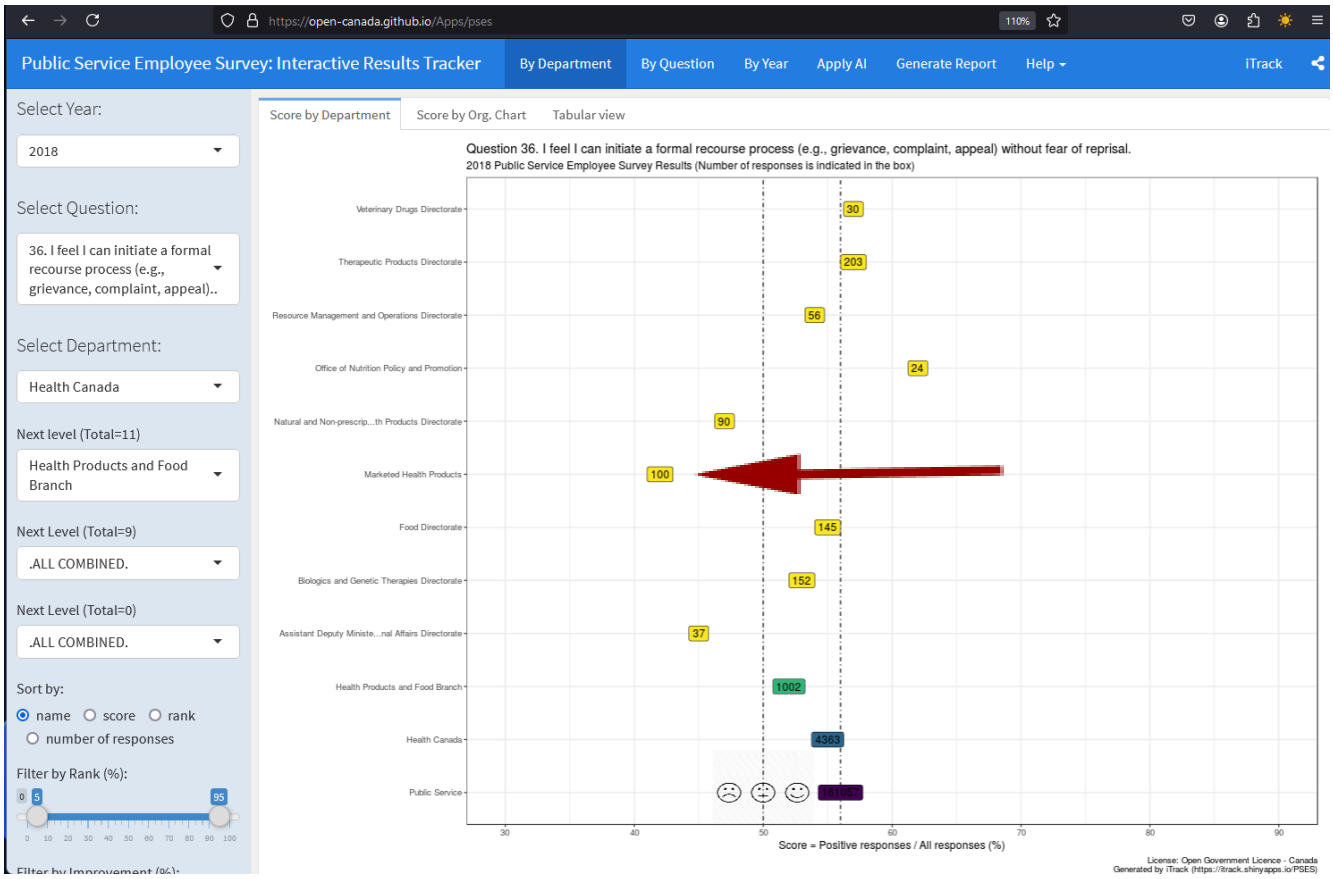
Interested individuals may contact Dmitry Gorodnichy to obtain images for any year or department (unit) of interest.

PHAC - Centre for Emergency Preparedness



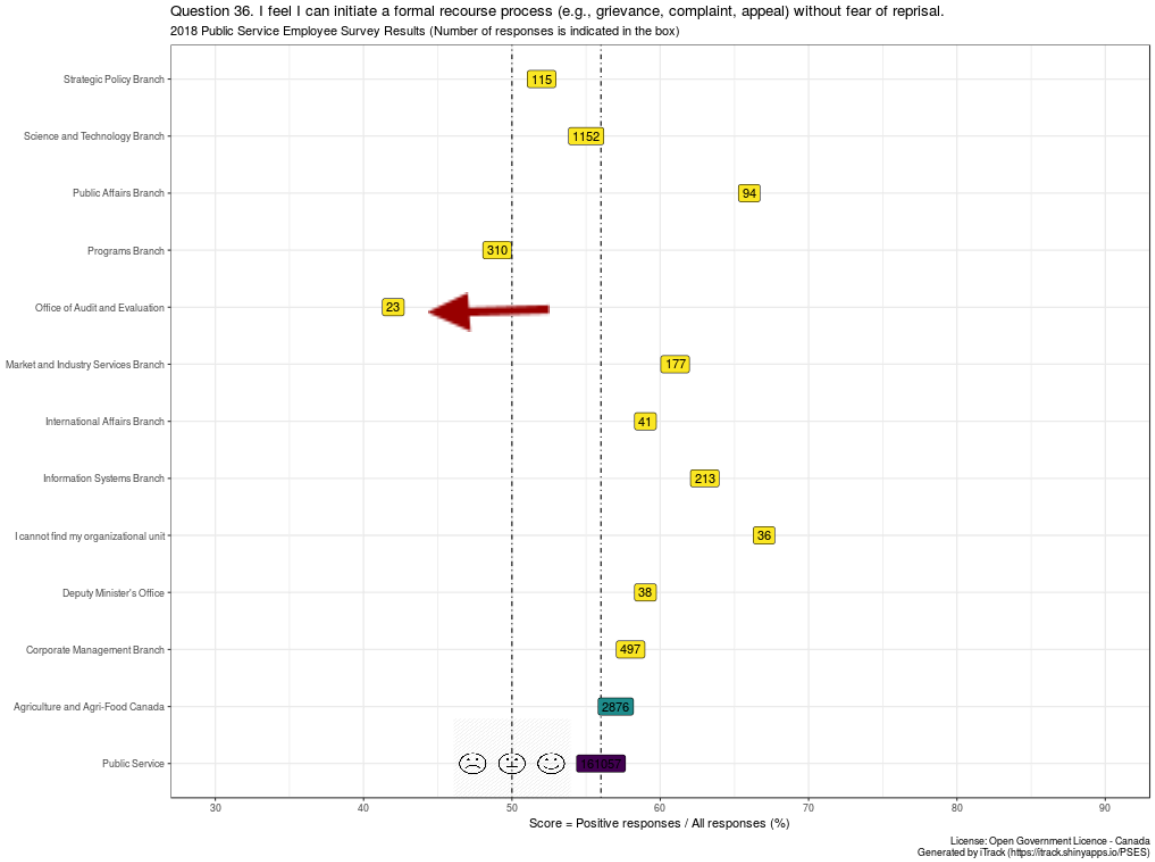


Health Canada - Marketed Health Products



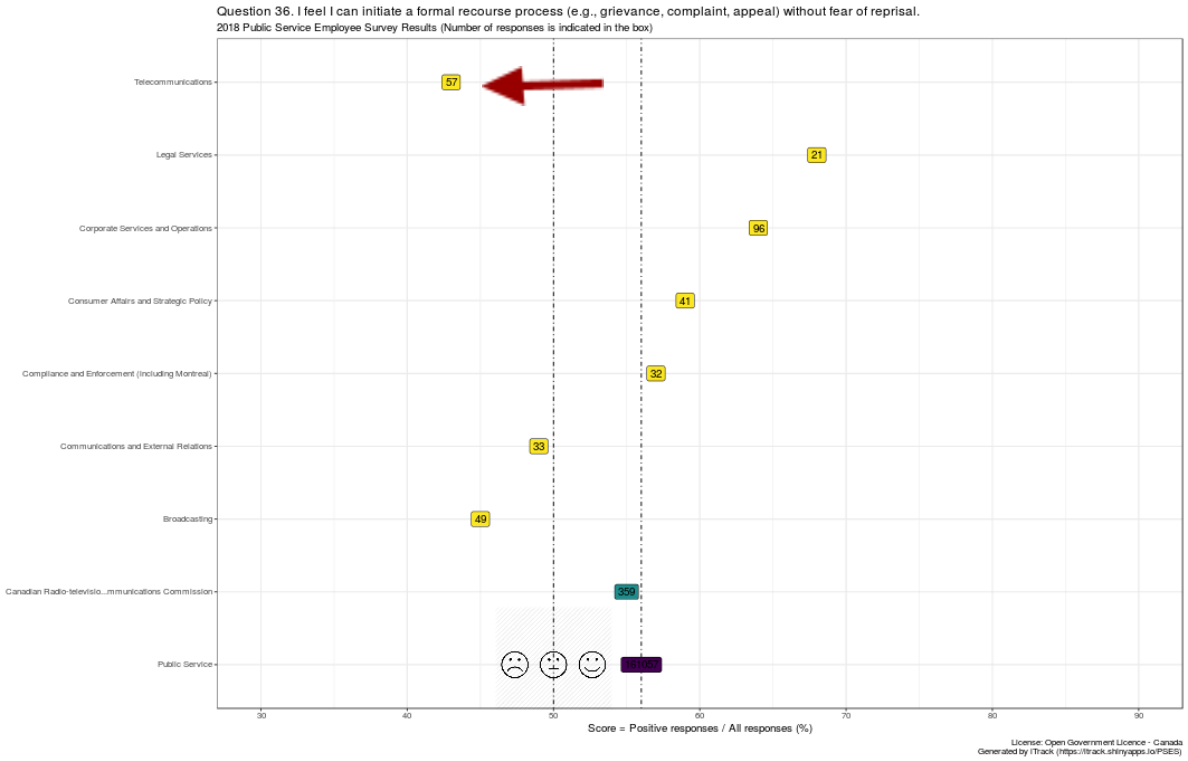


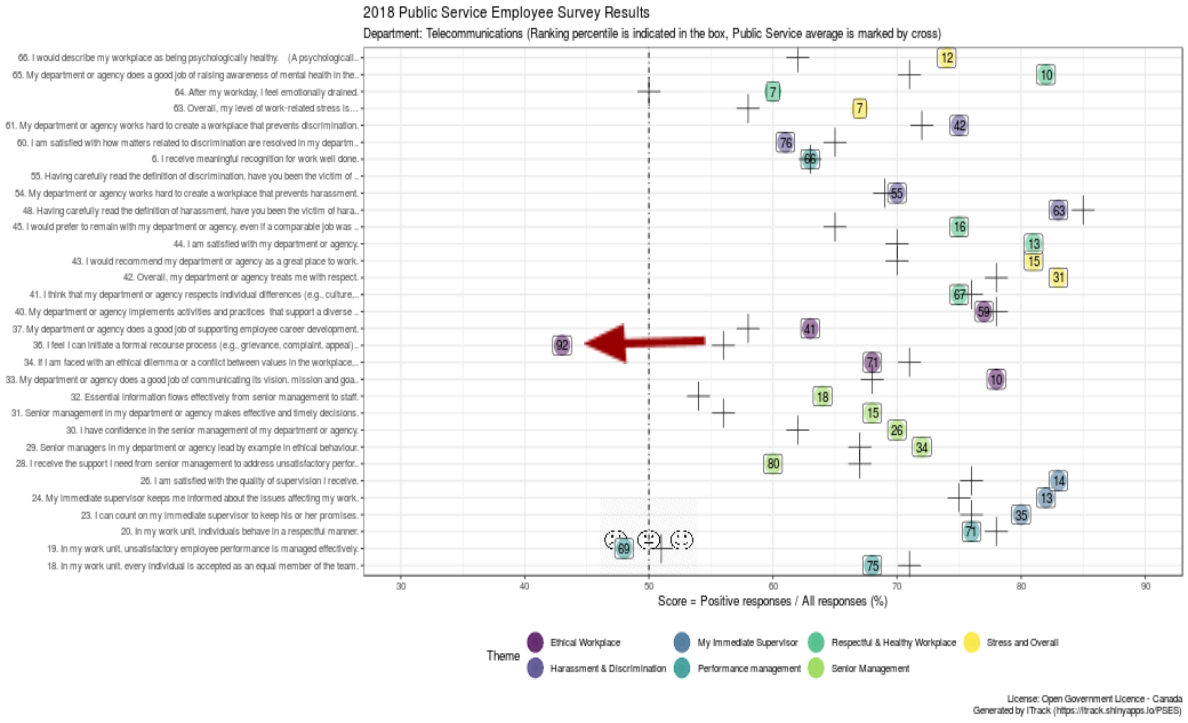
AAFC - Office of Audit and Evaluation



Canadian Radio-Television Communications - Telecommunications

Canadian Radio-Television Communications - Broadcasting

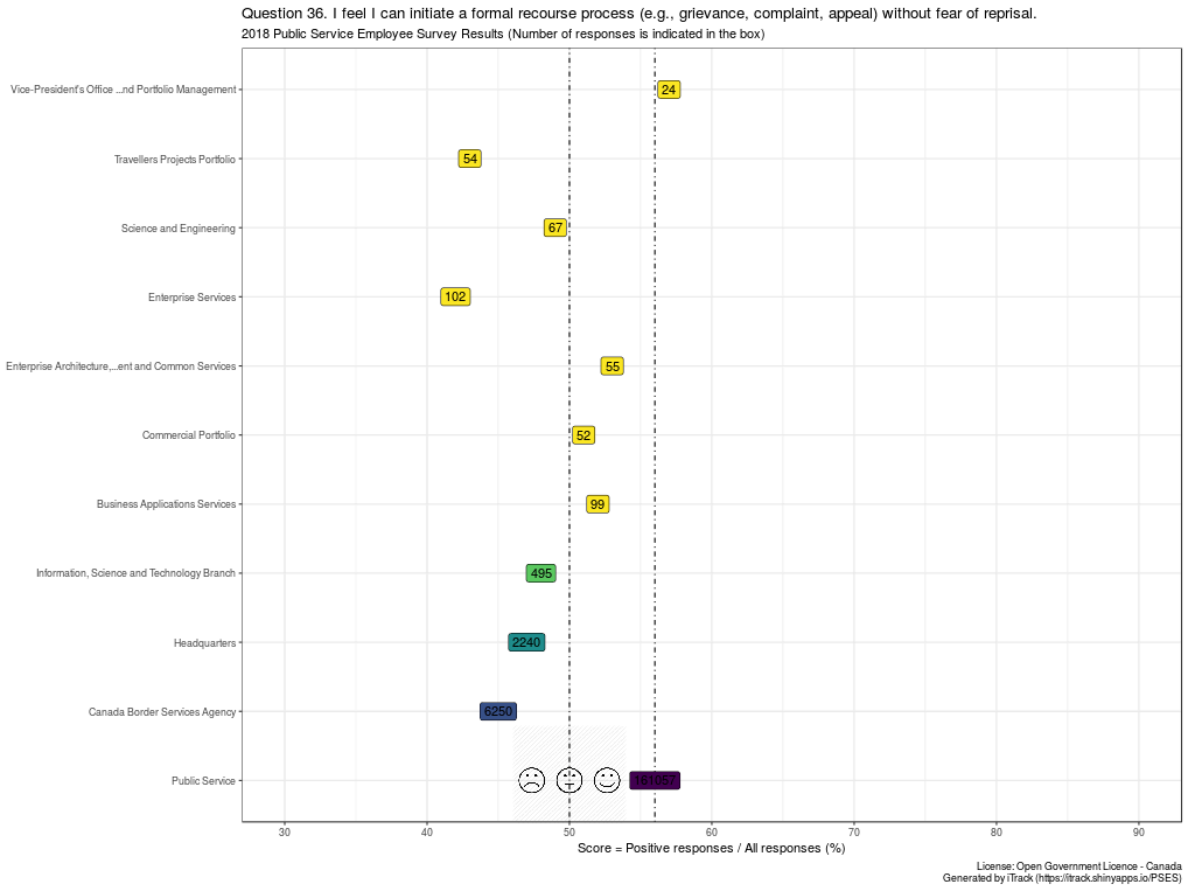


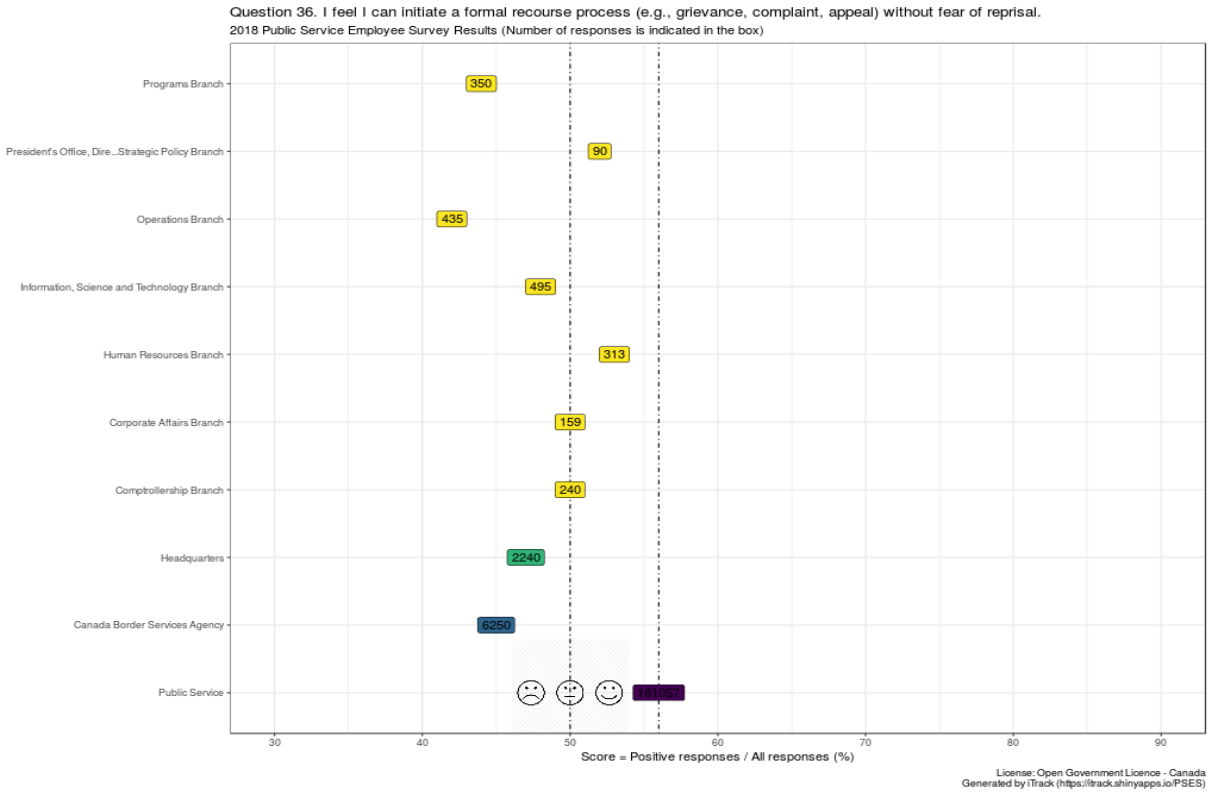


ECCC - Industrial, Chemical Waste Directorate



CBSA:


Question 36. I feel I can initiate a formal recourse process (e.g., grievance, complaint, appeal) without fear of reprisal.
2018 Public Service Employee Survey Results (Number of responses is indicated in the box)
Vice-President's Office ...nd Portfolio Management
Travellers Projects Portfolio
Science and Engineering
Enterprise Services
Enterprise Architecture,...ent and Common Services
Commercial Portfolio
Business Applications Services
Information, Science and Technology Branch
Headquarters
Canada Border Services Agency
Public Service
24
54
67
102
55
52
99
495
2240
6250
161057
30
40
50
60
70
80
90
Score = Positive responses / All responses (%)
License: Open Government Licence - Canada
Generated by iTrack (https://itrack.shinyapps.io/PSES)


Question 36. I feel I can initiate a formal recourse process (e.g., grievance, complaint, appeal) without fear of reprisal.
2018 Public Service Employee Survey Results (Number of responses is indicated in the box)
Programs Branch
President's Office, Dire...Strategic Policy Branch
Operations Branch
Information, Science and Technology Branch
Human Resources Branch
Corporate Affairs Branch
Comptrollership Branch
Headquarters
Canada Border Services Agency
Public Service
350
90
435
495
313
159
240
2240
6250
161057
30
40
50
60
70
80
90
Score = Positive responses / All responses (%)
License: Open Government Licence - Canada
Generated by iTrack (https://itrack.shinyapps.io/PSES)