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The Blind Spot in COVID-19 Vaccination Policies: Under-Reported Adverse Events

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Abstract

Case reports involving two academic researchers suggest that adverse events (AEs) to COVID-19 messenger RNA (mRNA) vaccination are largely underreported due to numerous clinical, systemic, political and media factors. The lack of proper analysis and consideration of the reported AEs also suggests that these injections are not as safe as widely purported. The resulting biased risk-benefit assessment may only produce misinformed public health recommendations and misguided political decisions, thereby exposing the population to an underestimated risk, in possible violation of the precautionary principle and of the right to a free and informed consent. The possible mechanisms underlying AEs to COVID-19 vaccination raise serious concerns regarding the new vaccine application of the mRNA technology that need to be addressed before expanding it to other infectious diseases. The legal considerations of AE underreporting are also discussed, and recommendations are formulated. AEs to mRNA injections are a reality and need to be better assessed than heretofore, diagnosed and reported to public health authorities for follow-up investigation in order to inform policy decisions and updates to physician guidelines in an objective, scientifically based, independent, and transparent manner.

Keywords: *COVID-19 vaccine adverse effects, COVID vaccine safety, public health policy, risk-benefit assessment*

Introduction

The breadth and magnitude of the response to the COVID-19 crisis are unprecedented in human history. A major, worldwide coordination effort was put into place to curb the perceived threat, which initially led to imposing drastic sanitary measures — such as lockdowns, curfews, business closures, mask wearing, hand disinfection, social distancing to segregation between vaccinated and unvaccinated individuals — and a dramatic reduction of human activities and commercial exchanges. This societal shift was made possible, in most countries, by the declaration of a state of emergency by the governments in power, which strengthened their authority, while silencing any opposition, a process that has shaken the democratic foundation of our institutions and society.

In Canada, the authorities decided to combat the COVID-19 crisis by centering their strategy on vaccination. Advised by the National Advisory Committee on Immunization (NACI), the Canadian government opted for a new generation of experimental mRNA injections developed by the pharmaceutical industry (e.g., Pfizer/BioNTech and Moderna), which were presented with the promise that they would lead to a return to normal, which has yet to materialize. These vaccines are based on lipid nanoparticles encapsulating an unnatural, synthetic, modified, and stabilized messenger RNA (mRNA) encoding for the SARS-CoV-2 spike protein (Nance & Meier, 2021; Kim et al., 2022; Santiago, 2022a) and authorized for emergency use (Associated Press, 2022; Moderna TX, Inc., 2020; US Department of Health and Human Services Food and Drug Administration Center for Biologics Evaluation and Research, 2020). Their formulation and mechanisms of action differ markedly from those of traditional vaccines, which consist in the injection of an attenuated or inactivated form of the virus or a derived antigen expressed in a recombinant form that remains at the injected site.

The new synthetic mRNA injections are, nevertheless, considered as "vaccines". Until recently, the CDC's definition of a vaccine was "a product that stimulates a person's immune system to produce immunity to a specific disease, protecting the person from that disease" (CDC, 2018). In September of 2021, this definition was changed to "A preparation that is used to stimulate the body's immune response against diseases" (CDC, 2021). The second part of the definition, "Vaccines are usually administered through needle injections, but can also be administered by mouth or sprayed into the nose", remained unchanged. This widened definition implies that a probiotic yogurt, for instance, would qualify as a "vaccine" according to the new definition, but not the previous one, showing how different a new vaccine might be from traditional ones.

The definition of "vaccination" was also changed from "the act of introducing a vaccine into the body to produce immunity to a specific disease" to "te act of introducing a vaccine into the body to produce protection from a specific disease." (CDC, 2018, 2021). This change, from the concept of "immunity" to that of "protection" (vaguer and more prone to subjectivity), implies that the term "vaccination" may be used for a "vaccine" product that neither confers immunity nor prevents disease transmission, as in the case of the current COVID-19 vaccines.

Defined and considered as a "vaccine", the radically different mRNA injections against COVID-19 may be subjected to the same public health guidelines, regulations, and laws as traditional vaccines — in addition to benefiting from the population's trust and confidence in traditionally developed vaccines — so they may be mandated or legally imposed. The inclusion of the new mRNA injections in the same category as traditional vaccines opens the door to an entirely new class of mRNA-based pharmaceuticals with vaccine purposes that raises moral, ethical and legal issues and considerations to their use. A specific definition and a distinct set of guidelines should have been adopted for these mRNA therapeutics, which, by using the cellular machinery downstream of the DNA code and by instructing our cells to produce a protein gene product that will have a phenotypical impact, are closer to gene therapy than traditional vaccines.

To date, however, these mRNA vaccines have yet to be approved for routine use by regulatory authorities, which may explain why some countries have maintained a state of emergency, so to continue injecting their citizens with these experimental products. As with any new drug marketed for human use, mRNA vaccines, in theory, had to undergo a thorough regulatory review, the adequacy and credibility of which depended (and still depends) on a comprehensive, accessible, and accurate adverse event (AE) recording and reporting system. This is especially critical, considering the new vaccine application of the mRNA technology, the number of doses administered, and the number of people injected with these new products worldwide.

The mechanism by which the mRNA vaccines are purported to confer protection (i.e., through expression and exposure of the viral spike protein antigen to our immune system; see Nance & Meier, 2021) may, by that very fact, be the cause of AEs. For instance, mRNA vaccines have the capacity to force nucleated cells to produce a foreign, stable and bioactive viral protein that may lead to long-term complications. Of particular concern is the changing of the spike-expressing cells from self to non-self, which may raise possible issues of autoimmunity (Lyons-Weiler, 2020; Nunez-Castilla et al., 2022; Vojdani & Kharrazian, 2020; Vojdani et al., 2021) and promote inflammatory reactions (Blaylock, 2021; Baumeier et al., 2022). Furthermore, the empty lipid nanoparticles (eLNP) have been reported to elicit dendritic cell maturation as well as innate immune signaling pathways through TGF-ß induction (Connors et al., 2022), whose activation may have profound consequences yet to be analyzed.

This article examines the rationale to improve post-vaccination AE reporting by highlighting barriers, internal to the system, that produce underreporting. The discussion is based on case reports from two academic scientists involved in advanced research and teaching in the field of medicine. These two examples are used to unveil the weaknesses of the current AE reporting system that could be improved by the authorities. Experience reported by them are analyzed and used to formulate recommendations to health authorities and governments worldwide to achieve more reliable and accurate AE reporting and to guide better informed decisions by policymakers and by the public.

Case Presentation

The two academic scientists in question were otherwise in good health and physical condition before receiving any COVID-19 injection. Both experienced several AEs and are still suffering from AEs consecutive to a COVID-19 injection. Their personal experience with the physicians they consulted has led them to wonder about their lack of professional conscious in their investigation of the cause and origin of the reported AEs during the diagnosis of conditions, treatment, and follow-up. This led to the formulation of the hypothesis that, in the public health system of the Province of Québec, in Canada, at least, the number of AEs attributable to COVID-19 injections may be underreported, and thus underestimated.

Their concerns for their own health, given their background knowledge, training, and investigative mindset, put them in a unique position to testify concerning deficiencies in AE reporting following COVID-19 injections.

TWO CASE REPORTS

Case report #1. One of the two scientists has been dealing successfully with autoimmune type 1 diabetes since 2006. However, subsequent to the first Pfizer/BioNTech injection on July 5, 2021, this individual experienced five different AEs: occasional ophthalmic migraines (starting with two episodes within 8 days of the injection), occasional bilateral (right>left) skin rashes on the forearms, persistent coughing (starting 2.5 months of the injection), two episodes of abnormal internal vibrations (5 months after the injection), and previously unexperienced diabetic imbalance (between 7 to 10 weeks after the injection). The latter seemed to be related to enhanced autoimmunity, which is widely reported as one of the AEs attributed to COVID-19 injections (Baumeier et al., 2022; Chen et al., 2022; Ruggeri et al., 2022). All AEs were self-treated and reported to a specialist treating physician at the CHU de Québec – Université Laval Hospital. The physician, following the instructions of the Collège des médecins du Québec (CMQ) — the professional order of Québec physicians — encouraged an additional COVID-19 mRNA injection, while ignoring, downplaying, and even denying, any possible link between the self-reported AEs and the vaccine.

The physician did not directly address the patient's concerns, never acknowledged that the symptoms could be related to the COVID-19 injections, and continued to insist on another dose of vaccine. Although repeatedly asked in writing over the following three months by the scientist-patient, the endocrinologist never reported any of the experienced AEs to the Institut national de santé publique du Québec (INSPQ) — the governmental agency in charge of recording AEs, following-up, and establishing any possible links between those reported AEs and the injections that preceded them — nor did the treating physician respond to the patient's reasonable concerns. The lack of acknowledgement and consideration of the reported AEs broke the bond of this particular physician-patient relationship that had been built over the years in treating the autoimmune type 1 diabetes conditions. Three months later, a general practitioner — to which the patient finally turned — agreed to report the symptoms to the INSPQ under the guidance and assistance of the scientist-patient.

Case report #2. The other scientist-patient received the first Pfizer/BioNTech injection on October 5, 2021, and, 9 days later, developed warmth and pressure around the neck, difficulty in swallowing and tightness and tingling on sides of the neck. Day 9 also marked the onset of unusual cranial symptoms (lightheadedness, internal pressure within the skull, unusual internal vibrations, numbness and tingling in head extending even to the neck and out to the fingertips). These symptoms escalated the following day. On day 11, the patient experienced the onset of chest pain, which continued to increase through the following day leading to the first visit to the emergency care unit of the Jewish General Hospital (Montreal, QC, Canada) on day 13. The heart/chest symptoms involved heart palpitations, nauseous pain in the sternum, acidic feelings in the thorax, and tachycardia with a resting heart rate at 130+ beats per min. The symptoms continued to escalate further, leading to additional visits to the same emergency care unit on days 15 and 16 post-injection.

The scientist-patient, who is slowly recovering and gradually returning from a six-month medical leave, was admitted to the emergency care unit three times and, after a battery of tests, was diagnosed with a myocarditis and postural orthostatic tachycardia syndrome (POTS; see Patone et al., 2022). None of the medical doctors considered the earlier mRNA injection as a possible cause of the myocarditis or the POTS diagnosis, nor did they report either of these outcomes as AEs to the INSPQ. The medical examiners focused on what the patient had eaten two years prior to the AEs rather than inquiring about the injection received in the preceding week, or even considering it after the scientist-patient suggested it as a plausible cause. When called upon by the patient to consider the suspected link between the symptoms and the injection – ones already being attributed by competent physicians to the COVID-19 injections early after their rollout (e.g., see Das et al., 2021; Patel et al., 2021), as later confirmed by many other researchers (Massari et al., 2022; Østein et al., 2022; McLernon, 2022; Jablonowski & Hooker, 2022; Sun et al., 2022) – the reporting physicians attributed the reported symptoms to "anxiety" in the medical record. On more than one occasion in the following months, physicians would downplay the importance and severity of the symptoms, or even report to the contrary, in the patient's medical record, in the absence of personalized medical care and follow-up of the patient's health condition. Finally, it was a nurse who reported the symptoms as potential AEs subsequent to COVID-19 injection to the INSPQ for further investigation.

Analysis of AE Underreporting

Mechanisms underlying AEs

Myocarditis/pericarditis is essentially the only AE to COVID-19 injection officially recognized by the INSPQ that may entitle patients to an exemption from any of the otherwise mandated shots. Yet, the causes underlying these important medical health sequelae remain undiscussed. How can the COVID-19 injections

in the shoulder cause cardiac inflammation, which may not be symptomatic or diagnosed? Is it related to the injection site, technique and/or anatomy of the patients' shoulders? Are patients who have minor AEs following one injection likely to have more significant AEs following each successive dose? Do the prevalence and severity of post-injection AEs correlate with the integrity of the vaccine mRNA and the level of spike protein expression?

Most concerning is the fact that the mechanisms underlying post-injection inflammation of the heart muscle may also be at play in other organs and tissues, and can be expected, if present, to trigger a diverse array of symptoms or complications in the short, medium and long-term. These sequelae, formerly unknown prior to COVID-19 injections, based on the experiences reported by the two scientist-patients at issue here, are likely not to be regarded according to their actual prevalence and severity, because, as shown in the two case studies, they are hardly likely to be reported at all. The extent to which COVID-19 vaccines induce or exacerbate autoimmune diseases or other comorbid conditions, for instance, is of particular concern and can only be ignored to the peril of millions of recipients (see for discussion Classen, 2021a; Seneff & Nigh, 2021).

It may be hypothesized that post-vaccination AEs are related to the COVID-19 injection nanoparticle formulation, which allows systemic distribution and uptake of the spike-encoding sequence by non-immune cells that are not supposed to be presenting antigens to immune cells. Could this trigger unwanted inflammatory or autoimmune reactions towards spike-expressing cells? Could this explain the great diversity of AEs associated with COVID-19 injections listed in the documents released by Pfizer and in the VAERS database? How can such a diversity in post-vaccination AEs be explained when all of them have in common a supposedly standardized and very controlled (exactly similar fluid) composition of the injected products?

As one might expect, discrepancies in the nature of post-vaccination AEs may reflect, in addition to batch-to-batch variations, a differential tissue/organ distribution of the vaccine formulation upon injection, whereas differences in the intensity of the symptoms may relate to the unknown, but presumably high level of spike protein produced by the cells, which are forced to express, against their nature, a biologically active but synthetic viral protein. Indeed, in a woman with mRNA-1273 COVID-19 vaccine-induced thrombocytopenia, plasma spike (S) protein level 10 days after vaccination was 10 ng/ml (Appelbaum et al., 2022), nearly 100 times higher than those reported by Ogata and colleagues in vaccinated subjects with no apparent adverse effects (Ogata et al., 2022), pointing to excessive vaccine-induced production of spike protein possibly causing AEs (Cosentino & Marino, 2022a, 2022b). The uncertainty surrounding the dose of the active product administered, which may be highly variable, and its biodistribution is deemed to be sufficient to justify a conscientious objection to mRNA technology (Provost et al., 2022).

The actual levels of production of the spike protein would be expected to vary by orders of magnitude depending on a multitude of factors, including the dose versus body mass, genetics, metabolic state of the cells that take up the vaccine mRNA, nutritional and pharmacological status of the recipient, and a host of interactions of unknown consequence between the foregoing factors. In addition, truncated mRNAs may be present in the vaccine (Tinari, 2021; see also Gutschi's, 2022, presentation) and, in turn, may produce a considerable diversity of truncated spike proteins (Santiago, 2022a), leading to shorter antigens and an altered, less specific antibody response with additional autoimmune pathogenic priming potential (Lyons-Weiler, 2020; Vojdani & Kharrazian, 2020; Vojdani et al., 2021).

AE UNDERREPORTING

Several different factors may explain the underreporting of AEs that occur in close temporal proximity to COVID-19 mRNA injections and are classified as either clinical, systemic, political, or media driven.

CLINICAL FACTORS OF AE UNDERREPORTING

Among the clinical factors of AE underreporting that the two scientists observed are:

(i) the lack of openness of the physicians to consider the COVID-19 injection as a possible cause of the reported AEs;

(ii) the existence of an *a priori* belief that any observed AE cannot be attributed to the COVID-19 injections;

(iii) the peer pressure not to consider AEs to the injections as a possible diagnostic explanation;

(iv) the reliance of physicians on the policies and statements of their superseding professional order (CMQ), rather than their own medical knowledge, judgment, and clinical experience;

(v) physicians and other health care professionals blindly following the guidelines of their professional order rather than listening to their patients;

(vi) the lack of knowledge of physicians in immunology and about the COVID-19 injections and their known and documented "side effects" (Borroni et al., 2021; Das et al., 2021; Baumeier et al., 2022; Deutsche Wirtschaftsnachrichten, 2022; Massari et al., 2022; McLernon, 2022; Oster et al., 2022; Patone et al., 2022);

(vii) the lack of a true, authentic and objective investigative mindset of the physicians encountered;

(viii) the lack of knowledge or interest of the patients about human biology or their own health;

(ix) the lack of awareness of the patients for their bodily signs or symptoms of "side effects" (potential AEs), or for noticing changes in their medical condition following COVID-19 injections;

(x) the disengagement of the patients for their own health and their reliance on their physicians for its management (like a car owner bringing a car for repairs to a trusted mechanic);

(xi) not having a doctor, not being able to go to a doctor, or not thinking symptoms are serious enough to see a doctor;

(xii) the voluntary (passive) nature of AE reporting;

(xiii) the time (~45 min) required for already overloaded physicians to fill the required 5-page AE report (hyperlinked here) without monetary compensation; and

(xiv) the lack of hindsight and critical thinking about the new genetic vaccines, which have yet to be fully characterized, and the side effects of which are still in need of documentation with the same thoroughness devoted to their promised expected beneficial effects.

SYSTEMIC FACTORS OF AE UNDERREPORTING

Among the multiple systemic factors that may contribute to underestimating the AEs stemming from COVID-19 injections, concerns are about:

(i) the public being (mis)led to believe that these injections, that have been developed and deployed worldwide in a matter of months (Gutschi, 2022), are as safe and proven as traditional vaccines tried, tested and used over decades, reducing the vigilance for possible AEs;

(ii) the mainstream narrative, held by public health agencies and hammered by the media, purporting that the COVID-19 vaccines are safe and effective, thereby discrediting any person who would raise any doubt or question;

(iii) the power of the professional order of physicians in Quebec (CMQ), which compels its members to follow their specific guidelines in the care and treatment of their patients (including the promotion of vaccination) by threatening them to revoke their license to practice medicine if they do not comply;

(iv) the sometimes blindful obedience of physicians to their professional order over their own professional conscience and critical thinking;

(v) physicians being forced to endorse the dominant narrative without being able to question it or exercise critical scientific thinking, leading them to accept it so as not to jeopardize their careers for which they have made significant sacrifices;

(vi) physicians not being free to speak out against the mainstream narrative, hindering the sharing of potentially important medical information, and preventing increased awareness among their peers and the public;

(vii) the silencing or public slandering of medical doctors questioning the mainstream narrative, thereby discouraging their colleagues from further questioning and investigating;

(viii) the governments bypassing physicians and breaking the doctor-patient relationship through mass vaccination, which makes physicians unable to systematically and clinically follow up their vaccinated patients;

(ix) any delays in reporting and analyzing AE may compromise the timely adjustment of public health policies;

(x) the political influence of the Quebec Government on its public health agency (INSPQ), the investigations and recommendations of which may be subjected to political pressure and influence through which the political authority may constrain or outweigh the science (the INSPQ may be called upon by the government to provide the scientific justification to support a political decision);

(xi) the lack of coherence in the public discourse, whereby governments purport to follow the science, while imposing sanitary measures (e.g., curfews) that are not supported by science or by maintaining others (e.g., vaccine mandates to travel or for health workers) that have become unnecessary in light of the sanitary context, causing more harm than good;

(xii) the delay in reversing health measures for which the emerging data and science are not supportive anymore;

(xiii) the use of science (cherry-picking) by politics, instead of true science-based political decisions, causing a loss of trust in the authorities;

(xiv) the lack of guidance and clear instructions conveyed to laypersons on how to self-monitor and report possible AEs from COVID-19 injections to the appropriate authorities;

(xv) flawed official government data, which considered a person as having been vaccinated only after the 7th or 14th day following the injection, may have led to AE underreporting in the vaccinated group (and corresponding overreporting in the unvaccinated group);

(xvi) the possible pressure and influence of the pharmaceutical industry lobbies and of the consulting firm McKinsey — which coordinated the management of the crisis and had Pfizer as a client during that period — to consider the injections "safe and effective" may have reduced the vigilance of the authorities and health professionals, and downplayed the importance of AE reporting and analysis, or to assimilate them with those from traditional vaccines; and

(xvii) a similar pressure and influence applied to publishing companies and scientific journals leading to a lack of objectivity, independence and openness to reporting COVID-19 vaccination AEs.

It was after one of the two scientist patients was contacted by a registered nurse from the INSPQ that we learned that the public health agency does not consider any AE that appears more than six weeks after a COVID-19 injection. This constraint is based on the standard procedure for traditional vaccines, which COVID-19 injections are not; rather, they are products grounded in the synthetic genetic creation presented to the public as ordinary mRNA — which, again, this new pharmaceutical product is not (see Santiago, 2022). In the presence of a new and unproven technology, which should carry the presumption of being potentially dangerous rather than being presumed safe, it is certainly not good public health practice to dismiss any reported AE at first-hand; AEs should rather be collected and analyzed thoroughly with an open and investigative mind. A recent survey of potential adverse events following COVID-19 vaccination, based on changes in the pharmaceutical records of vaccinated patients, showed that 76.1% of the health-related events occurred beyond the 6-week period prescribed by the health authorities, suggesting that this time period may need to be extended significantly (Banoun & Provost, 2023).

Also, the burden of proof should be to ascertain that the new experimental genetic products are safe. It should not be up to recipients to prove they are not safe. What individual out in the general public or medical profession could possibly demonstrate that the COVID-19 therapies actually cause AEs beyond the proscribed six-week period if the evidence showing this is never recorded or duly considered? Or, if reported, that they are summarily dismissed on the basis of the proscribed six-week limit on AEs?

It is clear that the hierarchical pressure and censorship imposed on physicians and health professionals by their professional orders have a strong influence on the practitioners' mindset that reverberates throughout health-related professions and contribute to a health care system in which AEs are certainly underreported.

Unfortunately, the Quebec government has stopped publicly disclosing the vaccine status of infected, hospitalized and deceased patients, which hampers the continuous monitoring of these new genetic products, downplays the possible associated risks and prevents any correlative analysis that would confirm (or infirm) that these injections are indeed as safe and effective as purported.

POLITICAL FACTORS OF AE UNDERREPORTING

Several of the factors of AE underreporting discussed in the previous two subsections are related to, or conditioned by, political or media driven factors.

The main issue is the unique message conveyed by the pharmaceutical companies, the governments, and the media that "COVID-19 mRNA vaccines are safe and effective". This has proved to be a resonant advertising slogan that has generated confidence and has had a remarkable effect on the compliance of the population to submit to the injections — as did the use of the term "vaccine" —, while, at the same time, the marketing strategy reduced the vigilance of physicians to diagnosing and reporting AEs. In the USA, Jablonowski and Hooker (2022) have documented the fact that such advertising and promotion of a marketing narrative can influence oversight agencies themselves along with all the people they tend to control by their powerful political and regulatory influence.

The government officials, who rule by decree, are rarely, if ever, challenged by the opposition parties in parliament, just as television experts, very often in conflicts of interest, are rarely challenged by independent scientific experts, such as university professors and researchers investigating advanced theories and experimental evidence in the fields of study controlled in large measure by those officials.

The director of the public health agency in Quebec (INSPQ), whose appointment is political, also holds the position of Assistant Deputy Minister of Health and Social Services within the government, making that individual subject to considerable political influence and strict constraints in the performance of his duties. In this respect, Canada is unlike Sweden, for example, where public health is independent of the government. Moreover, the government can remove the Assistant Deputy Minister from his position if it is not satisfied with his work. This lack of political independence of the INSPQ, which is responsible for investigating post-vaccination AEs, may greatly reduce the autonomy of the INSPQ's experts in their investigations and inquiries. It also begs the question of whether the opinions issued by the INSPQ are produced in a truly independent manner or, rather, aligned to support the political decisions or narrative, as the organization allegedly does not encourage expression of dissident views.

It is also notable that the political decisions lag behind the science and reality on the ground. This lag is well documented by the official public health data, the cumulative current scientific knowledge, and the situational experience in other countries. This results in a significant gap between the current ongoing health situation and the measures expected to normalize it. It also prevents timely adjustment of measures that could maximize the impact of the accumulating knowledge on population health.

MEDIA FACTORS OF AE UNDERREPORTING

Among the media factors affecting underreporting of AEs are:

(i) the recurrent messaging of the mainstream media universally claiming safety of the COVID-19 injections;

(ii) the media coverage of the government's daily or weekly press conferences, during which the population is urged to "get vaccinated", a directive that is rarely questioned by the members of the press and leads to the general belief that the injections are indeed "safe and effective";

(iii) the unbalanced media coverage promoting the benefits of COVID-19 vaccination, while downplaying the potential risks, biasing any possible risk-benefit assessment and informed consent by the general public;

(iv) the lack of representative media coverage regarding the victims of complications to the disease, with a focus on the exceptions, thereby distorting the sanitary reality, creating fear and leading to the belief that everybody bears the same risks;

(v) the disregard of naturally acquired immunity and the promotion of vaccine-induced immunity and mass vaccination campaigns;

(vi) the lack of media coverage of AEs reasonably attributable to COVID-19 injections, leading people to believe that there is none, or that they are minor or exceedingly rare;

(vii) the lack of media coverage or publicity inviting declaration of AEs (e.g., how to report them), which should be as important as promoting the injections and informing about the potential risks; and

(viii) the disregard and damage to the reputation of independent scientists expressing dissident views and critical analyses, in order to maintain social cohesion and preserve the single message of safety and effectiveness.

We observed that progress and facts dealing with the same worldwide health crisis in other countries are not covered by our own media, unless the news happens to support the message of the mainstream media, so our country cannot benefit from the valid experience in other countries as they address the COVID-19 issues.

Finally, debates have become impossible, substantive discussions are proscribed, and alternate views are repressed by the media. The latter eventuality is remarkable because journalists are almost never experts in the fields of virology, immunology, medicine, pharmacy, genetics, and so forth. Yet their lack of expertise does not prevent them from adopting a position of authority by repeating the government message to anyone and everyone listening, while they set aside their own critical thinking and ethical boundaries to discredit, disqualify by stigmatization, or censor, without substantial arguments, independent experts who on valid authority express different views or criticisms. The outcome of the media bias is an illusion of scientific consensus and truth where what is being distributed is propaganda. The favorable media coverage of the so-called "fact-checkers", self-proclaimed bearers of the truth, often slandering independent experts, with no possibility of scientific exchange and discussion, contributes to the illusion that all the real experts

are single-mindedly supporting the mainstream message. It does not help that journalists may be fired if they speak out against it.

Consequences of AE underreporting

The number of post-vaccination AEs reported to public health officials would be expected (i) to increase at least proportionally to the number of doses administered, and (ii) to increase by several folds with active surveillance rather than the current subpar passive surveillance system.

The major consequence of AE underreporting is a corresponding underestimation of the risks and a biased evaluation of the risk-benefit ratio, which may be considered to be favorable to vaccination when, in fact, it may not be. This necessarily leads to misinformed public health recommendations (e.g., promoting injections) and misguided political decisions (e.g., imposing mandatory rules) that may be detrimental to public health and expose the population to an underestimated risk of AEs.

Another major consequence is that patients can hardly give a free and informed consent to COVID-19 injections when they are presented with no or incomplete AE data, false positive diagnosis of disease (Basile et al., 2020; Borger et al., 2020; Yeadon, 2020; Lyons-Weiler, 2021), biased recommendations, misguided political decisions, put under pressure by their relatives, friends, peers, employers, or governments, or for reasons unrelated to their health (e.g., to attend a school program or activate a vaccine passport to travel or go to a restaurant). These situations may lead to a form of extorted consent.

Legal considerations of AE underreporting

AE underreporting also merits legal consideration. In particular, it is concerning that the Quebec Public Health Act does not mandate the implementation of an active surveillance and proactive monitoring and reporting of AEs to new vaccines, therapeutics, or technologies, while it allows the government to impose mandatory distribution and acceptance of those experimental products. When redacting and adopting this Act, the legislators certainly bore in mind the safety and effectiveness of "traditional" vaccines and could not expect the definition of the term "vaccine" to be so radically changed as it was in order to include the experimental COVID-19 genetic products. This recent change extends the intent and reach of the Quebec Public Health Act beyond its initial purpose, making its applicability in the mandating of COVID-19 injections highly questionable and disputable.

According to article 83 of the Act:

> The Minister may, by regulation, draw up a list of the contagious diseases or infections for which any person affected is obligated to submit to the medical treatments required to prevent contagion. The list may include only contagious diseases or infections that are medically recognized as capable of constituting a serious threat to the health of a population and for which an effective treatment that would put an end to the contagion is available.

It may be understood that telling someone they are "obligated" to do something is very similar to coercing them to "submit to the [supposedly 'obligatory'] medical treatment". Should it be understood that this article applies to duly authorized medical treatments, and that it may be invalidated if the treatment (e.g., COVID-19 injectables) causes one or many significant AEs — which cannot be accurately assessed if they are underreported? Also, does COVID-19, with an infection fatality rate (IFR) estimated at less than 0.1% for 0-69 year-olds in the pre-vaccine era (Pezzullo et al., 2022), qualify as a "serious threat to the health of a

population", when compared to smallpox — which was supposedly fatal in up to 30% of cases (https://www.who.int/news-room/questions-and-answers/item/smallpox) — used as an example in the following article of the same Act? Is article 83 still applicable if the treatment is being made "available" through emergency use authorization and has not been effective to prevent and put an end to the contagion it is supposed to alleviate?

Article 123 of the Act reads as follows:

> Notwithstanding any provision to the contrary, while the public health emergency is in effect, the Government or the Minister, if he or she has been so empowered, may, without delay and without further formality, to protect the health of the population, (1) order compulsory vaccination of the entire population or any part of it against smallpox or any other contagious disease seriously threatening the health of the population…

Would this article and the preceding one apply to an injectable product that is still experimental? Would "compulsory vaccination of the entire population" be indicated if the contagious disease is known to more particularly affect the very old and sick, "or any part of it" with a pharmaceutical product that does not prevent contagion? Would these articles apply to the SARS-CoV-2 virus (or any other virus), which is ~300 times less deadly than smallpox, used as an example in the article 123?

Recently, in Canada, the Alberta Court of Appeal confirmed that mandatory vaccination for organ transplants does not violate the rights and freedoms of Canadians, which does not apply to medical decisions, thereby rejecting the request of an unvaccinated woman for a life-saving organ transplant.

Currently being debated by our parliamentarians in Quebec are amendments to childcare in which the government could supersede the right of parents to refuse COVID-19 injections for their child. Already, in courts, independent qualified scientists called upon parents opposed to the vaccination of their child see their expert reports being dismissed by the judges, who impose the governments' guidelines and recommendations that may be under the influence of lobbies and pharmaceutical companies. Public health agencies and researchers may want to extend the reach of their work to the legislation in effect and being revised in their jurisdictions, and raise awareness and intervene to defend public health. For instance, is it legitimate for a government to unilaterally decide to extend the state of emergency which it has itself instated, and perpetuate it even when the emergency period is over?

RECOMMENDATIONS

The shortcomings of the system discussed above — from the lack of true compassion and empathy by the health-care professionals to the barriers of AE underreporting — affected the lives of the two scientist patients, as it is likely to affect the lives of millions of people around the world.

Considering all the elements discussed and arguments raised about COVID-19 vaccination AE underreporting, its negative impact on risk-benefit assessment and the importance of correcting every step of AE reporting so that it reflects reality through valid reports, the following recommendations are made to the governments and health authorities worldwide:

1. Improve COVID-19 vaccination AE reporting. In view of all the foregoing, governments all over the world should make reporting of AEs attributable to COVID-19 or any mRNA injections through active rather than passive — in which AEs are underreported by 90 to 95% (Lazarus et al., 2010) — surveillance, i.e.

easily accessible, accurate, and mandatory for those administering the injections, so that the risks are properly taken into account, and so that the estimated risk-benefit ratio is as close to reality as possible. An independent inquiry should be launched to estimate by how many folds are AEs currently underreported, so to allow the use of the corrected prevalence of AEs in risk-benefit assessments of COVID-19 vaccination.

In Quebec, the authorities should also return to the individual assessment of the risk-benefit of COVID-19 injections depending on age and comorbidities, which are, by far, the most important of the known variables in recorded COVID-19 deaths in Quebec (see Table 2.2 reporting "Number of cumulative deaths according to the presence of a pre-existing medical condition by age group" at this INSPQ hyperlinked source.

2. Importance of control groups. It is important to remember that the current COVID-19 injections have been authorized for use under emergency exception and are still considered in phase III clinical evaluation (link to the Pfizer/BioNTech protocol. The anticipated conclusions of that evaluation are limited by a known lack of properly sized control (placebo, vehicle without the active principle) groups and the absence of mandatory reporting of any possible AEs. Moreover, within these phase III clinical trials, the vaccinated and control groups are poorly represented by certain segments of the population, such as children, pregnant women, elderly persons, and those with comorbidities. The control group was even lost when Pfizer offered unvaccinated people to receive mRNA injections.

3. Involve independent experts free of conflict of interests. Public health policies must be formulated by a panel of scientists free of conflict of interests and independent of political influence, lobbies or monetary incentives. Both the promised benefits and the potential harms of COVID-19 injections must be discussed freely and openly, and must involve scientists who have no political or financial conflict of interests. The same for the disclosure and detailed analysis of the exact composition of the vaccines (including ingredients said to be "inactive"), which cannot be concealed under the pretense of industrial secrecy. The population must be provided with enlightening, factual, balanced, unbiased scientific information to enable free (not coerced) and informed consent to medical procedures, rather than being pressured under duress to comply with supposedly "safe and effective" health requirements, such as mandatory vaccination.

Health regulatory agencies must also call upon independent scientists free of conflict of interests to ascertain, in complete scientific objectivity and before giving conditional authorization to an experimental vaccine in a health crisis situation, that there is no other alternative, such as effective early treatments for the disease to be treated by vaccination.

4. Restore the physician-patient relationship. In light of the above, not only the physician-patient relationship should be restored, but several codes of conduct of physicians — whose non-compliance represents serious ethical breaches — have to be reinstated: (i) apply the precautionary principle; (ii) evaluate the necessity and the risk-benefit ratio of any medical intervention offered to their patients; (iii) obtain a free and informed consent from their patients; (iv) for clinicians, apply the ancient rule of "doing no harm"; and (v) the Government of Canada must recognize the right of individuals to refuse treatment irrespective of what the government may claim is for the "greater good".

5. Recognize natural immunity. We also need to recognize and duly consider the natural immunity acquired following a SARS-CoV-2 infection when establishing public health policies (Koch, 1939; Panda & Ding, 2015; Aung et al., 2016; Gazit et al., 2021; Pugh et al., 2022). There is mounting evidence that repeated

COVID-19 injections may actually reduce the effectiveness of natural immunity against SARS-CoV-2 (Goldman et al., 2021; Bardosh et al., 2022; Guetzkow, 2022; Kampf, 2022).

6. Improve transparency of health authorities. Valid science, provided it is not hindered by authoritarian intervention and intimidation, normally progresses rapidly as any health crisis evolves. With that in mind the authorities need to improve their transparency, make their data accessible to independent scientists, and rapidly adapt their public health measures so that they remain scientifically sound and justified. At the same time, it is essential to minimize collateral damage through underreporting of AEs and infringements on the rights of patients in medical contexts. In view of the crucial importance of public trust in science-based policies, in order to maintain social cohesion, news reporting that the CDC made false vaccine safety monitoring statements is far from reassuring. Although the VAERS system is deeply flawed and greatly underestimates signals that should be taken seriously and investigated (Lazarus et al., 2010), the CDC continues to display a lack of seriousness in handling the important warning signals, suggesting that the safeguards and regulations that the public has relied on for years and assumed to be in place for pharmaceutical products have been removed for mRNA-based vaccines (see Latypova, 2022; especially from 10:23 to 15:00 for discussion).

7. Make the pharmaceutical industry accountable. Finally, the pharmaceutical companies should be held liable and accountable, through transparent contracts, for AEs caused by the use of their products — which earn them billions of dollars in annual profits. If the mRNA technology cannot be used to produce reliable vaccines that are independently proven to be safe and effective, then their vaccine use and application should be abandoned, if not prohibited.

Conclusions

AEs associated to COVID-19 injections should not be hidden, denied, or dismissed. They must be reported, documented, analyzed objectively and rigorously, discussed, and pursued all the way to their actual causes. Only by studying them intensively can post-injection AEs be understood and hopefully avoided in the future, while those affected by them are being treated in the best possible ways in the present tense.

The issues and barriers raised in this article about post-vaccination AE reporting, the blind spot of the still ongoing crisis, need to be addressed and resolved to bring the number of AEs much closer to reality, even more so as the mRNA technology is being considered to treat other infectious diseases (e.g., influenza). We must do this if we wish to ensure that mRNA-based remedies are safe and will do much less harm than good in the short, medium, and long-term for every segment of the population — not every injected person will sustain AEs, but anyone who does will be affected and sustain all of it, with potentially life-long consequences. Addressing the chronic blind spots pointed out here is essential if we are to have robust and relevant public health policies enabling measured response to health issues that can improve and hopefully restore public trust in our authorities and in pharmaceuticals in general.

If accurate or concerning AE data show that the COVID-19 injections are actually causing more harm than good (as some have been arguing; see Seneff & Nigh, 2021; Classen, 2021b; Santiago, 2022b), the authorities have the moral obligation to protect the public, take a good look in their "blind spot" and recall these experimental products swiftly and globally, and consider promoting preventive measures and alternate safer medical interventions and treatments against COVID-19.

In a context where a large proportion of the population has already been exposed to one of the highly transmissible Omicron variants and has developed a protective natural immunity against subsequent infections, it may be time to reconsider the role and importance of vaccination in general, and that of the mRNA technology in particular, as the center of strategic public health policy.

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Competing Interests

The author declares no competing interests. The views and opinions expressed here are those of the author and do not necessarily reflect any official policy or any position of Université Laval.

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