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Abstract: Despite the undeniable success of vaccines, we are currently witnessing a crisis of confidence in vaccination programmes. This has contributed to a decline in global vaccination coverage and the return of vaccine-preventable diseases. This paper examines why this state of affairs has emerged by focusing on bio-medical evidence which confirms the success and safety of vaccines yet does not persuade those are hesitant to vaccinate.

Keywords: Vaccine Hesitancy, Bio-medical evidence, Evidence Based Medicine.

1. Introduction

Despite the unprecedented success of vaccines in the 20th century in eradicating smallpox and drastically controlling the spread of diseases like polio, we are presently experiencing a crisis of confidence in vaccination programs. The global decline in vaccination coverage has compromised the effectiveness of vaccines, which function on the basis of a combination of individual protection and the concept of "herd immunity." Herd or group immunity is attained if high vaccine coverage (around 95% of the population for certain vaccines) is reached and maintained. This limits the spread of infectious diseases, ensuring the protection of vaccinated persons as well as those who do not develop immunity after vaccination or remain vulnerable due to certain underlying medical conditions. Falling rates of immunisation compromises herd immunity with drastic consequences as seen in recent measles outbreaks that resulted in 140,000 deaths in 2018 (World Health Organization, 2019a). Since then the situation has worsened: as of mid-November 2019 there are 413,000 cases of measles reported globally, a three-fold increase compared to 2018 (World Health Organization, 2019a). As is evident with present outbreaks of the "novel corona virus", limiting the spread of dangerous vaccine preventable diseases represents a quintessential problem of our times.

A curious aspect of vaccine hesitancy is that the revolutionary effectiveness of mass vaccination programs paradoxically results in an eventual reduction in immunization rates making vaccines "a victim of their own success" (Chen & Hibbs, 1998, 446; Lewis, 2004, 15; Larson et al., 2011, 527). This point is best understood in stages. In the first stage, the prevalence and threat of vaccine-preventable infectious diseases is evident to parents, motivating them to vaccinate their children. The administered vaccines are immensely successful in reducing the spread and prevalence of vaccine-preventable diseases. This leads to the second stage where these diseases lose their importance in the collective imagination and sections of the public turn their attention to: a) the possibility of adverse side effects from vaccinating (Bedford & Elliman, 2000), b) religious objections to vaccinating (Ross, and Timothy J. Aspinwall, 1997), c) opposition to conventional medicine coupled with the perceived need for children to develop their "natural immunity (Browne, 2015)," and d) objections to state mandated vaccinations (Dyer, Blakely, & Johnson, 1998). Despite the moderate success of *dialogue-based interventions* to increase awareness and the partial success of *non-financial incentive* based interventions as well as *reminder/recall* based interventions in certain parts of the world, vaccine hesitancy persists as one of the major threats to global health today (World Health Organization, 2019a, 2019b).

Among the many motives underlying vaccine hesitancy, this paper will focus on parental concerns with the adverse side effects of early-childhood vaccinations in *high-income countries*. The concern with post-vaccination side effects varies vastly with social and cultural contexts. The concern with adverse side effects in high-income countries concerns bio-medical evidence, which is the focus of this paper.

2. Vaccine hesitancy from the parental perspective

To understand the hesitant parents' perspective, I return to the previous discussion of vaccines becoming a "victim of their own success." The application of mass vaccination programs lead to the drastic decline in the threat and prevalence of infectious vaccine-preventable diseases. Parents are therefore not confronted with cases of the disease infecting other children around them. As a result, the prospect of contracting the disease is no longer experienced as a real possibility. Additionally, it is more difficult to convince hesitant parents to vaccinate because of the increased prevalence of misinformation about what vaccines could do to their children. This is exemplified by the controversy surrounding the Mumps-Measles-Rubella (MMR) vaccine, an early-childhood vaccination falsely linked to autism by Andrew Wakefield (1998). Despite the retraction of his now infamous paper, following repeated refutations and evidence of fraudulent research (Chen & Destefano, 1998; Offit, 2010), Wakefield's claim continues to damage the reputation of all early-childhood vaccinations and plays a major role in contemporary vaccine hesitancy and parents' concern with adverse side effects (Largen, 2012). Parental confidence is further jeopardized by the increased commercialization of pharmaceutical research making vaccines a lucrative business, enabling further parental scepticism of the intentions underlying mass vaccination programs.

When bio-medical experts defend the safety and effectiveness of vaccines, they tend to rely on population level analysis. These analyses point to the fact that vaccines are generally safe and that adverse side effects occur on the rarest of rare occasions. The rarity of adverse side effects is contrasted with the increased likelihood and severity of getting the disease if the child is not vaccinated. Given this choice, experts argue that the safest and most reasonable course of action is for parents to vaccinate their children. Consider Health Canada's promotion leaflet (Government of Canada, Health Canada. 2011, cited in Goldenberg, p. 566):

> Misconception: Vaccines are not safe.
>
> The Facts: Vaccines are among the safest medical products available. Prior to approval they are extensively tested and they continue to undergo rigorous ongoing evaluations of their safety when on the market. Serious side effects such as severe allergic reactions are very rare. On the other hand, the diseases that vaccines fight present serious threats. Diseases like polio, diphtheria, measles, and pertussis (whooping cough) can lead to paralysis, pneumonia, choking, brain damage, heart problems, and even death. The dangers of vaccine preventable diseases are many times greater than the risk of a serious adverse reaction to the vaccine.

In other words, bio-medical experts argue that the risks associated with contracting vaccine-preventable diseases is far greater than the rare possibility of an adverse side-effect post vaccination.

However, diseases that experts warn against are no longer prevalent and, therefore, not manifestly threatening to parents. For this reason, bio-medical claims regarding the grave risks of contracting vaccine preventable diseases do not have the desired impact. Additionally, the claim that adverse side effects are extremely rare does not encourage parents to vaccinate. Unlike bio-medical experts, parents do not evaluate the safety of vaccines at the population level, but in

relation to their child. Consequently, hesitant parents are worried rather than reassured by expert claims regarding the rarity of adverse side effects. After all, rarity is hardly reassuring if there is a chance that your own child is the rare case. In other words, hesitant parents are not concerned with the general safety of vaccines but with the safety of vaccines for their particular child. Or, as Maya Goldenberg notes, in the case of the previously discussed controversy surrounding the MMR vaccine, hesitant parents "expressed vaccine fear that would *not be* relieved by reassurances that MMR was safe for the general public. They wanted to know: 'Is MMR safe for *my* child?'" (Goldenberg, 564, emphasis added).

This personal framing of the risk of vaccinating is grounded on parental concern with the *uniqueness of their child*, based on her particular family history in relation to specific side effects, allergies, and autoimmune problems. Some parents also consider the child's birthing time, maturity, sleep patterns, and overall behaviour. Parents deem these factors significant when evaluating whether their particular child is more susceptible to the adverse side effects of vaccination than other children in general. Some parents like David Trowther, as instance of "citizen science," have even explored the possibility of identifying which sub-set of children would respond badly to vaccinations by studying the particular family histories and genetic make-up of children that experienced adverse reactions (Trowther, 2002). However, Trowther's research suffers from sampling and reporting bias.

There have been several official responses to hesitant parents and their personal framing of the risk of vaccinating. Bio-medical scholarship has focused on i) the impact of misinformation campaigns by anti-vax organizations, ii) public misunderstanding of bio-medical research, and iii) distrust of bio-medical institutions, among others. While these factors definitely impact a hesitant parent's reception of the scientific evidence defending vaccine safety, such research only focuses on distorting factors that dissuade parents from vaccinating. It is also important to ask why bio-medical evidence and expert claims regarding the safety and effectiveness of vaccines check the above-mentioned distorting factors. In particular, this paper examines why bio-medical experts continue to use population level analysis when dealing with parents who are not concerned with the general safety of vaccines. Or put differently, this paper analyses *why bio-medical institutions have not been able to marshal scientific evidence in a manner that effectively speaks to parents and their concern with individual cases of adverse side effects post-vaccination*. To understand why this is the case, the next section focuses on the distinguishing features of bio-medical evidence.

3. Evidence-based medicine and the hierarchy of evidence

The dominant operative framework in contemporary medical practice is referred to as Evidence Based Medicine (EBM). According to the standard definition, EBM is "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients" (Sackett, et al., 1996, p. 71). Taken at face value this definition has a ring of obviousness. In principle, we would all like medical professionals and institutions to follow the best evidence when making clinical decisions. However, this obviousness betrays the fact that EBM functions as an epistemological framework that with a very specific conception of evidence (Tonelli, 1998, p. 1235). Additionally, Tonelli notes that EBM extends its epistemological concerns to clinical decision making and the practical concerns underlying bio-medical practice. EBM has been immensely successful in moving beyond many enduring medical controversies, avoiding a number of the pitfalls in medical practice by preventing the misapplication of new technologies and therapies, all the while encouraging critical thinking and scientific scepticism within the bio-medical community. However, with such success the validity of the EBM epistemological framework has been taken for granted, immediately applied to clinical practice and the bio-medical community has been reluctant to acknowledge its limitations (Tonelli, 1998, p. 1235, p. 1237).

What distinguishes EBM as an epistemological framework is its constitution of a hierarchy of evidence. The School of Health and Related Research (p. 541) provides the following hierarchy:

1. Systematic Review and Meta-Analysis
2. Randomized Controlled Trials
3. Cohort Studies
4. Case Controlled Studies
5. Cross Sectional surveys
6. Case Reports
7. Expert Opinion
8. Anecdotal

The hierarchy functions as an evolutionary continuum "moving from simple observational methods at the bottom through to increasingly sophisticated and statistically refined methodologies" (p. 540). This represents a focal point of the EBM epistemological framework: *statistically refined knowledge is privileged over observational insights*. The reasoning being that observational methods tend to be unsystematic and experiential in character. For instance, "case reports" are often based on a single patient and therefore their validity is limited to the particular physiological make up, preferences, and values of that patient. Similarly, "expert opinion" or clinical expertise is gained over years of experience and is therefore unsystematic as it varies with different institutions and the personal make-up of the clinician. Lastly, "anecdotal" at the bottom of the hierarchy designates knowledge derived from personal intuition rather than facts or research.

Despite their unsystematic and varying experiential character, observational methodologies can get things right. EBM places them at the lower end of the hierarchy because, according to its understanding, these methods only get things right incidentally. An often-quoted example is James Lind's famous work on scurvy.[1] During the 18th century, scurvy killed more British sailors than enemy combatants. As a naval surgeon aboard the HMS Salisbury, Lind compared several suggested cures and eventually comes to the conclusion that "oranges and lemons were the most effective remedies for this distemper at sea" (Lind, 1753, p. 493). Lind's findings overlooked that fact that it was vitamin C in oranges and lemons that cured scurvy; an insight Lind was not privy to as vitamins were not isolated and described for another 150 years. While Lind was right and his proposed treatment was highly effective in helping sailors protect themselves against scurvy, he was only incidentally correct, as the particular prognostic factor that achieved the stated therapeutic end was not accurately identified.

What requires emphasis is that EBM's concern with observational methods is not directed at the benefit they provide patients. Lind's treatment was extraordinarily successful and immediately implemented by the British navy, bringing much relief to English sailors. What concerns EBM is that Lind *did not isolate and identify the particular causal factor that protected sailors from scurvy*. In other words, EBM is concerned with the methodology and manner in which Lind's observational insights were attained. *This points to a gap between EBM's conception of good quality clinical research and the goals of medical practice.* As Mark Tonelli notes, the primary goal of medical practice "for its entire history … [has] been defined in terms of benefit to the individual patient" (p. 1236). EBM on the other hand is oriented towards the methodology and process through which bio-medical research comes to its conclusions. This concern with research

[1] Before proceeding it is important to stress that my reference to Lind is for explanatory purposes alone and I do not aim to make a theoretical point about Lind himself in the following paragraph. Especially because Lind's work pre-dates the institutionalization of EBM. Despite this, Lind's research on scurvy has been used in EBM literature to point to the limitations of even successful observational theories. My reference to Lind's work follows in this vein. For more see, School of Health and Related Research, University of Sheffield, *Hierarchy of Evidence*, 540.

process and methodology effectively contributes to beneficial treatment of any and every patient, that is, patients as such. Nevertheless, this orientation is rather abstract and not the same as the immediate pragmatic orientation of medical practice towards a particular individual patient present with specific symptoms in the clinical setting. This gap, although subtle, can lead to a conflict between EBM's focus on methodology and the betterment of the particular individual patient. To better understand when such a gap could arise and lead to a conflict, I shall briefly introduce methodologies on the higher end of the EBM hierarchy.

4. Randomized controlled trials and its limitations

Randomized Controlled Trials (RCTs) are the gold standard among the methodologies in the EBM hierarchy. It occupies the second highest position, with "systematic review and meta-analysis," which occupies the first position, being a synthesis of evidence attained from numerous RCTs. An RCT is undertaken to test a specific drug, treatment, or intervention. It entails randomly assigning participants to a trial into two or more groups. One group, the experimental group, receives the treatment that is being tested. The other group, the comparison or control group, receives a placebo or no intervention at all. The researchers then follow up to see how effective the treatment is by comparing patients in the experimental group with those in the control group. This method is considered to be the benchmark by the bio-medical community because, among other reasons, it attempts to systematically avoid the *post hoc ergo propter fallacy* (Worrall, 2013; p. 546). This fallacy refers to the mistaken claim that if event Y followed event X, then the former must have been caused by the latter. However, the causal link between the two events has not been established. Event Y is merely following Event X. To attain evidence of a causal link, there needs to be an experiment that controls for other associated factors that *could also* be at play in the transition from event X to event Y. This entails putting out of play these associated factors that could be playing a causal role to examine the relationship between event X and Y. Such an examination can go either of two ways: events X and Y are either shown to be causally related or not. In the latter case, it must be either the other associated factors or a combination of said factors and event X that causes Y.

While there is always the possibility of an unknown factor continuing to play a role despite attempts to control the experiment, randomization is taken to be the most effective approach to limit this possibility for two reasons. *First*, if patients in the experimental group were healthier or more likely to react positively to the treatment because of some factor that pertains to their physical makeup, then the trial would be a success since the results would show those in the experimental group doing better than the control group. Randomization checks this tendency by limiting the extent to which such a scenario would take place. Through random allocation, the tendency to group patients of a similar makeup in one group is lessened. However, this claim must not be understood in the strong sense because there always exists the possibility that a random allocation might lead to a highly skewed division between experimental and control groups. Instead, most proponents of randomization argue in a probabilistic fashion. Sheila Gore, for example, claims that randomization is an "insurance, in the long run, against accidental bias" that might inadvertently skew the allocation of patients (Gore, 1998; p. 1958). *Second*, randomization significantly checks selection bias on part of those setting up the trial (Worrall, 2013; p. 548). If clinicians were to decide how patients were to be allocated, the trial would only be single blind, as those setting up the trail would still be influencing proceedings. Randomization avoids selection bias and makes the trial double blind by severely limiting the extent to which those setting up the trial can influence the allocation of patients.

Both reasons are attempts to control the trial for associated factors that could be playing a causal role. This enables RCTs to focus on the relationship between the treatment being tested and the effect it has on the patients. As noted previously, unlike medical practice, EBM is not directly

concerned with a particular individual patient with specific symptoms. Instead, EBM's focus is the bio-medical research process and the methodology it uses to improve/benefit the health of any and every patient, i.e. patients as such. To simplify, there are two gaps, see table below:

Gap 1		Gap 2	
Medical practice's orientation towards an individual patient.	EBM's orientation towards a generalized patient as such.	Medical practice's focus on benefitting the individual patient.	EBM's concern with research process and methodology.

The first gap is between medical practice's orientation towards a particular individual patient and EBM's orientation towards a generalized conception of the patient. The second gap is between medical practice's focus on benefitting the individual patient and EBM's concern for maintain the quality of the research process and methodology; a concern that does not directly co-relate to benefitting the individual patient.

These two gaps present themselves in the case of RCTs. It has been noted that randomization is only able to control for quantifiable differences between patients. Important non-quantifiable aspects like pain tend to be overlooked. While EBM has attempted to rectify this limitation by quantifying pain using "visual analog or ordinal rating scales" (Tonelli, p. 1236), these efforts further emphasize that EBM is only willing the deal with quantifiable differences by converting pain into measurable parameters. In other words, when confronted with non-quantifiable differences between individual patients, the EBM practitioner could either re-affirm RCTs preference for quantifiable parameters or re-orient RCTs by triangulating its findings with other methodologies. In keeping with *Gap 1*, EBM is less concerned with the particularities of the individual patient and more concerned with the generalized patient as such. In keeping with *gap 2*, EBM is more concerned with the research process and methodology than with benefitting the individual patient. For these reasons, and as seen in the case of pain, the EBM practitioner re-affirms EBM's preference for quantifiable parameters at the cost of the non-quantifiable concerns of the individual patient. As a result, EBM's concern with benefitting the generalized patient by focusing on research process and methodology conflicts with a concern for the individual patient.

This point is further evidenced by the fact that non-quantifiable individual differences can be identified with the help of clinical expertise, which EBM places near the bottom of its hierarchy owing to its unsystematic and experiential character. Moreover, as seen with the second reason for RCTs, randomization curbs the involvement of clinicians to avoid selection bias. To put it in terms of the two gaps, EBM's orientation towards the generalized patient (gap 1) and focus on maintaining the quality of the research process and methodology (gap 2) entails that it will not re-orient its research process or methodology to incorporate clinical expertise to better deal with non-quantifiable particularities of the individual patient. The point is not that the problems with selection bias need to be overlooked so that clinicians can identify important non-quantifiable differences between patients. Instead, I argue that the epistemological standpoint that underlies EBM is unable to make a distinction between the right and wrong kind of clinical involvement in patient allocation in RCTs. In other words, when faced with the prospect of tempering its high evaluation of systematic and statistical methodologies to incorporate unsystematic and experiential forms of bio-medical knowledge like expert opinion to more adequately deal with individual patients, EBM maintains its hierarchy of evidence and privileging of systematic and statistical

methodologies over unsystematic and intuition based forms of knowing. This points to the underlying positivist tendencies of EBM's epistemological framework.

Goldenberg notes that EBM holds on to an "antiquated understanding of evidence as 'facts' about the world in the assumption that scientific beliefs stand or fall in light of the evidence" (Goldenberg, p. 2622). This is based on the positivist understanding of the process of scientific inquiry where:

> … any bias that enters scientific inquiry in the context of discovery is eradicated in the purifying process of the context of justification. The evidence left standing after scientific inquiry is assumed to be 'facts' about the world and therefore warrants the title scientific evidence.

It is in this respect that EBM has been attractive to researchers and medical practitioners. It rationalizes the complex social process through which scientific evidence is attained, by effecting a "positivistic elimination of culture, contexts, and the subjects of knowledge production from consideration" thereby portraying the use of evidence as a value free and "neutral technical" measure (p. 2623). This is seen in EBM's re-affirming of the hierarchy of evidence where contextual/subjective knowledge is placed at the lower end while methodologies that eschewed unsystematic intuition and maintained statistical sophistication were placed higher up.

When faced with the prospect of reorienting its research procedures to incorporate non-quantifiable differences between patients, EBM opts to maintain its research procedures for the sake of scientific rigour. Here scientific rigour has a positivist connotation where the subjective aspects of knowledge production are eschewed for research output that is value free and neutral. This is evidenced by EBM's hierarchy of evidence that privileges RCTs, even though this form of experimentation struggles to incorporate a patient's particularity, and downgrades expert opinion that could adequately deal with the particular patient. This rigidity on EBM's part points to a conflict between its concern with maintaining its conception of the quality of the research process and methodology, on the one hand, and adequately dealing with particularities/non-quantifiable differences that characterise the individual patient, on the other. This conflict is explicitly seen in the case of vaccine hesitancy and bio-medical experts' inability to adequately deal with hesitant parents and their personal framing of the risk of vaccinating.

5. Vaccines and the reporting of adverse side effects

To get approval[2] a new vaccine has to go through five phases of rigorous testing that checks for quality and safety.[3] Despite this, vaccines like any other pharmaceutical product, are not risk free.

[2] Before proceeding it is important to note that public health recommendations for vaccines have sometimes been contradicted by EBM findings. In response to scepticism against the MMR vaccine, the Institute for Medicine and the American Academy of Paediatrics has defended the safety of this vaccine. However, some EBM findings that contradicted these claims and concluded that the "design and reporting of safety outcomes in MMR vaccine studies, both pre- and post-marketing, are largely inadequate". For more see, Vittorio G. Demicheli, Alessandro Rivetti, Maria Grazia Debalini, and Carlo Di Pietrantonj, "Vaccines for Measles, Mumps and Rubella in Children." *Cochrane Database of Systematic Reviews (Online)* 2 (2012); also quoted in Robert M Jacobson, Paul V Targonski, and Gregory A Poland, "Why Is Evidence-based Medicine so Harsh on Vaccines? An Exploration of the Method and Its Natural Biases." *Vaccine* 25, no. 16 (2007), p. 3166. However, this issue falls outside the ambit of the present research as this paper is limited to an examination of why the bio-medical evidence cannot convincingly speak to the concerns of hesitant parents.

[3] In phase one, the new vaccine is tested on a limited sample size of healthy people to test for potential adverse side effects occurring post-vaccination. This is followed by phase two where research is done on a larger scale to identify the appropriate dosage and regiments for the proper administering of the vaccine to different target age groups. Phase three sees the use of RCTs that are double blind and placebo controlled in a population with an adequate incidence of

While most side effects are minor, serious adverse effects remain a possibility even after the testing phase. For this reason, on-going passive surveillance programs are maintained to monitor vaccine safety.[4] They function as repositories for voluntarily submitted information regarding instances of adverse side effects. To encourage reporting of adverse side effects, the system accepts any report submitted. This includes reports submitted by doctors, nurses, patients, pharmacists, or parents. VAERS (Vaccine Adverse Event Reporting System) a variant of this system in the United States of America receives approximately 30,000 reports a year (CDC, 2017). About 10-15% of these cases describe a serious adverse effect such as permanent disability, hospitalization, life-threatening illness, or death. The other 85-90% of the reports describe mild side-effects such as fever, arm soreness, and crying or mild irritability. While minor side effects can be proven as caused by the vaccine, it is harder to do so with serious adverse side effects. At this juncture it is important to consider the disclaimer that the CDC providers any user of VAERS:

> While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. *The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable*. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. *Data from VAERS reports should always be interpreted with these limitations in mind*. (CDC, 2020)

In other words, because VAERS accepts any report submitted by anyone, there is no quality check on the submission. Some of these reports could be "incomplete, inaccurate, co-incidental or unverifiable." Additionally, most reports are "subject to biases." For these reasons the CDC asks that any interpretation of the VAERS data must keep these limitations in mind.

The above disclaimer resonates with EBMs concern with the validity of anecdotal claims (last position in the hierarchy of evidence) and other observational methods. In particular, it points to its attempts to systematically avoid the *post hoc ergo propter fallacy*. It is not enough to claim that certain side-effects temporally followed vaccination. To make a causal claim, the process of vaccinating needs to be controlled for other possible causal actors that could be causing the adverse side effect. According to Susan Ellenberg and Robert Chen (1997, p. 15), there are four instances when a serious side effect could be causally attributed to the vaccine:

a) the event conforms to a specific clinical syndrome whose association with vaccination has strong biological plausibility;
b) a laboratory result confirms the association;
c) the event recurs on re-administration of the vaccine;
d) a controlled clinical trial or carefully designed epidemiologic study shows greater risk of adverse events among vaccinated than control groups.

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the target disease. During this phase, statistical considerations determine the ideal sample size to estimate the efficacy of the new vaccine. If the new vaccine passes the RCT phase, it is taken to have met the golden standard of testing and attains a licensure making it ready to be applied in real world conditions with sample sizes between 10,000 to 90,000 subjects in phase four of testing. Lastly, phase five sees local studies conducted to gain licensure in other countries other than the ones in which the previous four phases of testing were conducted. For more see, David R. Nalin, "Evidence Based Vaccinology." *Vaccine* 20, no. 11-12 (2002), p. 1625.

[4] An active surveillance system would follow certain patients to determine what their responses to the vaccine was. As opposed to this a passive surveillance system would not follow patients but wait to receive reports of adverse side effects.

Ellenberg and Chen go on to note that:

> Because few of the adverse events reported to VAERS meet any of the first three criteria and because clinical trials are almost always too small to provide useful information on serious rare events, epidemiologic evidence is the basis for assessing causality for most serious adverse events that are investigated.

Put differently, most reports of adverse side effects do not meet three of the four criteria for attributing a serious adverse effect to the vaccine. A fourth criteria for evaluating a report for adverse side effects through clinical trials still remains. But Ellenberg and Chen claim that the clinical trials would be "too small to provide useful information on serious rare events." For this reason, "epidemiologic evidence" is taken as the basis for "assessing the causality … [of] adverse events."

Conclusion: EBM and vaccine hesitancy

The preference for epidemiological data is limiting when it comes to convincing hesitant parents to vaccinate. As noted previously, experts tend to rely on population level data to argue for the general safety of vaccines. Hesitant parents are however not convinced by epidemiological population level studies because such data only argues for the general safety of vaccines by noting that adverse side effects are extremely rare. Such claims overlook the point that hesitant parents are not reassured by these expert claims but are worried as any possibility of risk could mean that their child could be affected. Despite this, experts continue to marshal population level data to convince hesitant parents. This is evidenced by the bio-medical reaction to the limitations of the VAERS data and reverting to epidemiological evidence as seen in the previous section.

To avoid misunderstanding, it is important to stress that this paper does not criticize bio-medical experts for identifying real problems with the reporting of adverse cases in the VAERS data. These problems remain a serious obstacle to properly identifying the causal factors that contribute towards rare but adverse side effects post-vaccination. Instead, this paper attempts to understand why significant sections of the bio-medical community and most pro-vaccine argumentation continues to use population level epidemiological data to prove the general safety of vaccines, when the target audience of these messages are hesitant parents who are not concerned with general safety but the rare instances of adverse side effects.

I argue that the epistemological framework underlying EBM contributes to the continued reliance of the bio-medical community and pro-vaccine advocates on epidemiological population level data. This framework bases itself on a hierarchy of evidence that is underpinned by a positivist orientation that eschews the culture, contexts, and subjects of knowledge production to attain evidence that is purportedly value free and neutral. As a result, EBM's hierarchy of evidence endorses systematic and statistical methodologies while downgrading subjective and experiential forms of bio-medical knowledge. While the constitution of this hierarchy and its application to medical practice has seen remarkable success, it also important to point to its limitations. With its overarching concern for maintaining the quality of the research process and methodology, the practice of EBM tends to overlook the particularities and non-quantifiable aspects of individual cases or patients. This is particularly the case when EBM practitioners and methodologies are confronted with individual instances and attempt to re-affirm the positivist underpinnings of EBM's epistemological standpoint. As a result, there is a conflict between EBM's aims to affirm its conception of scientific rigour and incorporating the particularities of individual patients/cases.

This conflict extends to vaccines hesitancy. Hesitant parents are not concerned with the general safety of vaccines and so are not persuaded by statistical and population level analysis affirming

the safety of vaccinating. Instead, they are concerned with the rare instances of adverse side effects that might befall their children. The association of these rare adverse side-effects with vaccines is however not provable in terms of EBM research practices and procedures that as previously noted have a difficulty incorporating individual instances and particularities of patients/cases. In such cases the aforementioned conflict between maintaining a certain understanding of scientific rigour and incorporating the particularities and peculiarities of individual patients/cases follows; and EBM reaffirms the former at the cost of the latter. Or as in case of VAERS reporting, bio-medical experts re-affirm epidemiological evidence to assess the causality of the cases of adverse side-effects reported.

While further research is required to show how the bio-medical community can effectively speak to the hesitant parents concerned with rare but adverse side effects from vaccinating, this paper has argued that the present form of the epistemological framework underlying EBM presents an obstacle from doing so.

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