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Value judgments in a COVID-19 vaccination model: A case study in the need for public involvement in health-oriented modelling

Stephanie Harvard^{a,*}, Eric Winsberg^b, John Symons^c, Amin Adibi^a

^a Faculty of Pharmaceutical Sciences, University of British Columbia, 2405, Wesbrook Mall, Vancouver, British Columbia, Canada, V6T 1Z3

^b Department of Philosophy, University of South Florida, 4202 E. Fowler Avenue, FAO 226, Tampa, FL, 33620, USA

^c Department of Philosophy, University of Kansas, 1450 Jayhawk Blvd, Lawrence, KS, 66045, USA

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ABSTRACT

Scientific modelling is a value-laden process: the decisions involved can seldom be made using ‘scientific’ criteria alone, but rather draw on social and ethical values. In this paper, we draw on a body of philosophical literature to analyze a COVID-19 vaccination model, presenting a case study of social and ethical value judgments in health-oriented modelling. This case study urges us to make value judgments in health-oriented models explicit and interpretable by non-experts and to invite public involvement in making them.

1. Introduction

Scientific modelling is a value-laden process: the decisions involved can seldom be made using ‘scientific’ criteria alone, but rather draw on our social and ethical values. This has been shown in health economics (Harvard et al., 2020), climate science (Winsberg, 2012, 2018), and COVID-19 modelling, where critiques of COVID-19 models reflect differences in values around how health policy decisions should be informed (Reddy, 2020; Winsberg et al., 2020). Here, we draw on philosophical literature to analyze a COVID-19 vaccination model (Adibi et al., 2021), presenting a case study of social and ethical value judgments in health-oriented modelling. While this case study provides illustrative examples, our analysis also shows that these types of value judgments are a fundamental, unavoidable component of model building: in other words, the COVID-19 vaccination model that we analyze is not *uniquely* value-laden, but rather a reflection of the value-ladenness of models generally (Harvard and Winsberg, 2021). Given the considerable influence of health-oriented models, as shown by COVID-19 vaccination models, we argue for taking greater care in managing value judgments in health-oriented modelling specifically. We argue in favour of making value judgments health-oriented models explicit and interpretable by non-experts, and inviting public involvement in making those value judgments.

There are many rationales for public involvement in science,

including health research, and many ways of articulating those rationales (Abelson et al., 2016; Douglas, 2005; Wale et al., 2017). According to Douglas (2005), many of the rationales are democratic, and focus on improving instrumental outcomes (e.g., acceptability of policy decisions), substantive outcomes (e.g., amount of information considered in policy-making), or normative outcomes (e.g., democratic legitimacy of policy decisions) in policy-making contexts (p. 153–154). These democratic rationales provide strong reasons to involve members of the public in decision-making, but are sometimes criticized for not adequately justifying public involvement throughout *all* aspects of the scientific process, e.g., in the *development* and *interpretation* of health-oriented models as opposed to just decisions based on model results (Douglas, 2005, p.154). Furthermore, these democratic rationales alone do not give us much to go on when it comes time to get specific about public involvement in research: that is, to define and distinguish between different public stakeholder groups, to determine standards for involving them, to design procedures, and so on. Currently, modelling guidelines developed by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) recommend consulting with an array of “subject experts and stakeholders” (Roberts et al., 2012, p.680) and encourage involving “people with clinical expertise” in assessing model face validity (Eddy et al., 2012, p.846). However, as others have noted, the ISPOR recommendations are highly general (Husbands et al., 2018); as Squires et al. (2016) put it, “The

* Corresponding author. Pharmaceutical Sciences, Room 4103, Building 2405, Wesbrook Mall, Vancouver, British Columbia, V6T 1Z3, Canada.

E-mail address: stephanie.harvard@ubc.ca (S. Harvard).

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ISPOR guidance describes what modelers should do, but it does not describe how they might do it” (p.589). This lack of specific guidance is an ongoing problem: in health economics, for example, initiatives are underway to involve patients in modelling, but this has raised questions around exactly which patients should be involved, what they should do, and with what goals (Harvard and Werker, 2021).

Douglas (2005) has argued that the potential instrumental, substantive, and normative benefits of public involvement in science are linked to an upstream process: the process of managing social and ethical value judgments throughout scientific inquiry. In Douglas’ view, the fact that value judgments are needed throughout the research process makes public involvement in science imperative, and the overarching goal of public involvement should be to bring public values “into the heart of technical judgment” (p. 154). In our view, Douglas’ argument has both conceptual and practical pay-offs when thinking about health-oriented modelling. First, if we understand the goal of public involvement in science in terms of managing value judgments, we see a clear reason for public involvement *throughout* the modelling process, not just in decision-making based on model results. Second, we see a clear reason to involve patients and other members of the general public in modelling, not just clinicians and/or policymakers; that is, at least, if we agree that no one is better equipped to make social and ethical value judgments than anyone else (Douglas, 2009). This is important, as ISPOR guidelines seem to suggest that certain aspects of model development should be left to experts alone—e.g., “For the [model] structure, important questions are whether the model includes all aspects of reality considered important by experts” (Eddy et al., 2012, p.846)—though these aspects have a social and ethical dimension, as we show in Sections 2 and 3. Third, we get a clearer picture of *where* and *how* members of the public can contribute to the modelling process: we have a good idea of where value judgments arise in modelling and what they look like (Harvard and Winsberg, 2021), as we will show in Sections 2 and 3. Finally, if we understand the rationale for public involvement in science in terms of managing value judgments, we link to philosophical resources to help us answer outstanding questions about public involvement in modelling. These include difficult questions like ‘whose values should ultimately be incorporated into health-oriented models?’, which we take up in Section 4.

Public involvement in health-oriented modelling has begun, but early participants have described the process as “*working in the dark*” with researchers (Staniszewska et al., 2021). Our goal is to help illuminate where and how members of the public should be involved in health-oriented modelling, by spotlighting value judgments in a COVID-19 vaccination model we call the ‘AZ’ model (Adibi et al., 2021). To inform policy questions as of mid-April 2021, this model helps do two things: 1) compare expected total numbers of deaths from two different causes (COVID-19 and vaccine-induced prothrombotic immune thrombocytopenia (VITT)) under two different scenarios (immediately vaccinate front-line workers with the AstraZeneca vaccine or delay their vaccination) in British Columbia (BC); 2) compare individual mortality risk under two different scenarios (immediately receive the AZ vaccine or delay COVID-19 vaccination). Here, we analyze the first publicly-available version of the AZ model (Adibi et al., 2021), as this version was the subject of media attention (Wyton, 2021).

2. Value judgments in model development: what to represent and how to represent it?

During model development, value judgments occur when making *representational decisions* (Harvard and Winsberg, 2021). Decisions about ‘*what to represent*’ concern what entities to include in and exclude from a model; decisions about ‘*how to represent*’ concern the entities already chosen for inclusion in it. For example, the decision to include ‘frontline workers’ in the AZ model is a ‘*what to represent*’ decision; the decision to represent ‘frontline workers’ by number of workplace contacts following Mulberry et al. (2021) is a ‘*how to represent*’ decision. In practice,

decisions about ‘what to represent’ and ‘how to represent’ overlap: for example, if modellers want to include something in a model, but find there are no data adequate for them to achieve it, the ‘*how*’ influences the ‘*what*’, as we show below. Representational decisions (value judgments in model development) should be distinguished from *inferential* decisions (value judgments in model interpretation) (Section 3).

2.1. What to represent?

Social and ethical values shape our views about what is necessary or important- or even acceptable-to reason about using scientific models. Consider three people whose views on the AZ vaccine differ: the first believes AZ vaccination should continue (on ethical grounds, given current evidence), the second that it should be halted (on ethical grounds, given current evidence). Only the third believes that more information about the AZ vaccine is required, and supports building a model for the purpose of reasoning about the effects of its continuation. A core value judgment in building the AZ model, then, is that it is an ethically-defensible project, one more worthwhile than (for example) holding a public demonstration to protest the (dis)continuation of the AZ vaccine roll-out. Ascribing this sort of social significance to deciding what to represent in models in fact applies a long-held insight: research questions reflect social values (Weber, 1949; Longino, 1990). One question to ask members of the public outright is whether building the AZ model is a good and worthwhile thing to do, making explicit the model’s intended purpose.

Finer-grained ‘what to represent’ decisions in modelling include what *outcomes* to represent: for example, COVID-19 infections, hospitalizations, and deaths, cases of Long Covid, and VITT. Including these outcomes in the AZ model signifies an ethical judgment that these are the important outcomes to consider when reasoning about the AZ vaccine roll-out in BC— more important, for example, than costs or non-fatal AZ vaccine-induced adverse events, which are not represented in the AZ model. ‘What to represent’ decisions also concern what *variables* to include. When variables are represented (or not) in a model, it means that understanding their influence on outcomes is part (or not) of the research question. One example is the decision to represent British Columbians’ age, sex, and ‘frontline worker’ status in the AZ model, but not their race, income, postal code, occupation, or household size. Consequently, the AZ model is not adequate for exploring research questions like i) the societal-level effects of structuring the AZ vaccine roll-out by race, income, postal code, occupation, or household size; ii) the individual-level effects of race, income, postal code, occupation, or household size on the personal harm-benefit ratio of immediate vaccination with AZ versus delayed vaccination. A question for members of the public is whether it is good or acceptable not to explore these questions with the AZ model, given the model’s intended purpose.

‘What to represent’ decisions are often informed by *how* or *whether* the representation of something can be achieved. For example, if there are no high-quality and/or local data on COVID-19 infections by race, this may be the reason race is not included in a model. However, this does not erase the social and ethical significance of building a model without race, for *at least* the following reasons: 1) modellers *could* use low-quality and/or non-local data or estimates in order to include race; 2) modellers *could* decline to build the model on the grounds that no adequate data or estimates on race exist, and the model results would be problematically incomplete without race. Deciding between these types of alternatives involves not only considering scientific criteria (what philosophers call ‘epistemic values’, values that help in the attainment of truth (Steel, 2010, p.15)), but weighing social and ethical values (cf. Harvard and Winsberg, 2021; Peschard and van Fraassen, 2014; British Columbia’s Office of the Human Rights Commission, 2020).

Because representational decisions determine what information a model will include and exclude, they have the same social significance as the research question. No model can serve every purpose, and choosing which purposes to serve and which to let go has social

implications. This is why to involve members of the public in ‘what to represent’ decisions in health-oriented modelling.

2.2. ... And how to represent it? ‘Representational decisions’ in modelling

‘How to represent’ decisions concern entities already chosen for inclusion in a model (Harvard and Winsberg, 2021). Such decisions often centre around what *inputs* to use: for example, what data sources should be used to model probabilities of events, costs, and outcomes among different populations? These decisions can be challenging for modellers. After all, different data sources (e.g., randomized controlled trials, observational studies) generally have different limitations and higher degrees of adequacy for some purposes (e.g., representing a drug’s efficacy under controlled conditions) than others (e.g., representing a drug’s effectiveness under real-world conditions) (Harvard et al., 2020; Khosrowi, 2019a; Khosrowi and Reiss, 2019). What makes ‘how to represent’ decisions challenging is also what gives them their social and ethical significance: there is always a risk that a representational decision will be *inadequate* for the purpose to which it is put (Harvard and Winsberg, 2021). When this happens, a number of social harms can result, including pernicious gaps in knowledge, damage to public trust, and downstream endorsements of false claims (Harvard, 2020; Harvard and Winsberg, 2021). This ‘representational risk’ alerts us to the need for public involvement in making ‘how to represent’ decisions, like ones in developing the AZ model.

Two related constructs that are represented in the AZ model are excess mortality risk due to receiving the AZ vaccine and due to delaying COVID-19 vaccination, respectively. ‘How to represent’ decisions arise for each of these. Some of them concern which inputs to use to represent excess mortality risk from VITT induced by the AZ vaccine. For example, this risk was estimated by the European Medicines Agency (EMA) at 1 in 153,000 with a 21% chance of death (as of March 2, 2021) and by Canada’s National Advisory Committee on Immunization (NACI) as 1 in 100,000 with a 40% chance of death (as of March 3, 2021) (Adibi et al., 2021). Given the difference in these estimates, the AZ model represents excess mortality risk from VITT in two different ways, using EMA and NACI estimates, respectively (Adibi et al., 2021, Fig. 3). Another decision concerns ‘how to represent’ excess mortality risk due to delaying COVID-19 vaccination. The AZ model does this by representing the chance of both getting infected with COVID-19 over time and dying from the infection, taking into account a person’s age. The initial chance of infection is represented in part through the reproduction number (i.e., the average number of new infections caused by one infected individual), which is represented using three different inputs (1.15, 1.35, 1.5). The chance of dying from COVID-19 taking age into account is represented using COVID-19 case fatality rates by age from two different sources, the BC Centre for Disease Control (for people under 50) and the Public Health Agency of Canada (for people 50 and above). All of the above ‘how to represent’ decisions could be made differently—for example, different base values or probability distributions for VITT could be assumed, a larger space of reproduction number values could be included, a single data source could be used for case fatality rates—in ways that serve some model purposes better than others.

As we noted, ‘how to represent’ decisions often overlap with ‘what to represent’ decisions. To see the overlap, consider more closely the question of ‘how to represent’ excess mortality risk due to delaying COVID-19 vaccination. This risk depends both on the chance of acquiring COVID-19 *and* the chance of dying from it, both of which are influenced by numerous individual-level variables. The question of how to represent this risk ultimately involves deciding *which* of these variables to include in the model. As Adibi et al. (2021) acknowledge in their discussion, their individual-level analysis was based on average rates of COVID-19 infection and related outcomes by age group and “the true risk within age groups is still heterogeneous and is affected by many factors including but not limited to exposure, medical history, work environment, and socioeconomic status” (p.10). Since the AZ model

does not include these variables, the model is not adequate for the purpose of reasoning about their effect on individual-level excess mortality risk. If an individual’s goal is to know about the effect of these variables in order to inform her individual decision around taking the AZ vaccine, the AZ model is not adequate for her purpose.

There is a tendency to view representational decisions as “scientific judgments”, a term that has been used to describe modelling decisions that are a source of uncertainty (Bojke et al., 2009, p.739). This tendency masks the social and ethical significance of these decisions. For one, representational decisions determine what information is included in and excluded from the model. For example, readers of Adibi et al. (2021) who wish to know the effect on excess mortality risk if the reproduction number drops below 1.15 or the VITT risk is as high as 1 in 50,000 will not find that information. Furthermore, representational decisions *are* a source of uncertainty, at least in the sense that they directly influence model results—sometimes, the effect of representational decisions, like choice of parameter values, is predictable (Harvard et al., 2020). Consequently, representational decisions embody risk preferences. If individuals take the risk of VITT particularly seriously, and thus think the consequences of under-estimating the VITT rate particularly severe, that rate could be increased tenfold or more in sensitivity analyses, beyond those performed by Adibi et al. (2021). Alternatively, a “threshold analysis” could be done to identify critical values for VITT rate, beyond which individuals with specific risk preferences would be better off delaying vaccination (Drummond et al., 2005, 43). To be sure, there is no ‘scientific’ reason not to perform sensitivity analyses beyond a certain range, or not to conduct threshold analyses, in any context. Rather, decisions around whether and how to deploy these modelling techniques are moored to social and ethical purposes, including honouring conventional and institutional methodological standards.

The view we present here reflects a well-established point in the philosophy of modelling: the primary virtue of scientific models is not truth or some univocal measure of accuracy. Rather, the primary virtue of models is *adequacy-for-purpose* and accuracy viz that purpose (Parker, 2020). A clear consequence is that the goal of *representational decisions* is not necessarily to land on what is ‘true’, but rather on what is adequate for the purpose at hand (Harvard and Winsberg, 2021). Unless a model’s purpose is to help only modellers themselves reason about a problem, taking into account only the factors *they* deem important and considering only *their* risk preferences, then other stakeholders should be involved in making representational decisions. Excluding them will increase ‘representational risk’, the risk that representational decisions will be inadequate for purpose and result in social harm (Harvard and Winsberg, 2021).

3. Value judgments in model interpretation: what is true or likely?

At the stage of model interpretation, the goal is generally to make inferential decisions as to truth-apt claims—claims of the sort that appear in the conclusions of scientific papers and media headlines. An example of a truth-apt claim is “The benefits of continuing immunization of front-line workers with the AstraZeneca vaccine far outweigh the risk both at a societal level and at a personal risk level for those over 40, and those over 30 in high-risk areas” (Adibi et al., 2021, p.1). Truth-apt claims can also incorporate probabilities: the above claim would still be ‘truth-apt’ if it said ‘probably outweigh’ instead of ‘far outweigh’.

It is useful to appreciate two well-understood philosophical points about truth-apt claims. First, there is no ‘scientific’ way to determine the standard of evidence beyond which a claim is true. Rather, choosing the standard of evidence requires an ethical judgment, a comparative assessment of the ethical consequences of possible courses of action under uncertainty (i.e., of endorsing a claim as true when it is actually false, of remaining silent, etc.). This is no small ethical problem, since a common goal is to extrapolate claims across human populations and

time periods, and the latter often differ in ways that limit our ability to do this (Khosrowi, 2019b). Second, many ‘true’ claims are “mixed claims”, claims that embed normative, i.e., value-laden, presuppositions (Alexandrova, 2018). Importantly, any claim that incorporates the term ‘benefits’ is a mixed claim, since ‘benefits’ is a normative concept—for example, benefits do not need to be defined in terms of deaths averted, but could be defined in terms of quality of life achieved. Unsurprisingly, a recent analysis of claims in a health technology assessment found that the majority were ‘mixed’ (Bloemen et al., 2021).

At the core of the ‘value-free ideal’ for science is the desire to avoid the problem of “wishful thinking”, to prevent us from endorsing claims as true just because we want them to be (Anderson, 2004). For this reason, the idea of involving members of the public in determining what is a ‘true’ claim can cause discomfort. However, this does not change the fact that *someone* has to make an ethical judgment as to the right standard of evidence for a given context, and that *someone* has to decide which mixed claims will be endorsed as ‘true’ based on model results. As Douglas (2005) notes “Regardless of which theoretical ideal of democracy one might hold, it is not acceptable for a minority elite to impose their values on the general populace” (p.156). To uphold any ideal of democracy, we must facilitate public involvement in model interpretation, with ‘public’ broadly construed.

4. Discussion

COVID-19 vaccination puts a particular ethical problem front and centre: not all health interventions that are net-beneficial at a societal level are net-beneficial for each member of society (Adibi et al., 2021, p. 9). Even if it is true that the benefits of vaccinating front-line workers with AZ far outweigh the risk both at a societal level and at a personal risk level *on average* for British Columbians over 40, this does not mean that the expected benefits of the AZ vaccine outweigh the expected harms *for every individual*. Adibi et al. (2021) acknowledge this in their discussion, and confirm that the ‘true’ risk within age groups of delaying vaccination depends on numerous factors, which influence both the initial risk of acquiring COVID-19 and the subsequent risk of dying from it. Based on the current evidence, it is reasonable for certain individuals over 40 to conclude that their excess mortality risk from receiving the AZ vaccine immediately is higher than that from waiting for a different one. For example, individuals who work from home in regions with very low COVID-19 incidence (e.g., Northern British Columbia, where the reproduction number was estimated at between 0.93 and 1.02 in April 2021 (British Columbia Centre for Disease Control, 2021)), and who consistently have few or no close contacts may come to this conclusion—and find it supported by the National Advisory Committee on Immunization’s statement of May 3, 2021 (National Advisory Committee on Immunization, 2021). Furthermore, it can be expected that some individuals will take factors other than excess mortality risk into account when deciding whether to receive the AZ vaccine, such as the higher rates of certain non-fatal adverse events (e.g., menorrhagia) that appear to be associated with it specifically (Merchant, 2021). In short, some people have good reasons to decline the AZ vaccine.

This raises a moral problem, if we take it for granted, as the current evidence suggests we should, that more lives will be saved *overall* if fewer people decline the AZ vaccine. This problem will elicit different views from people with different values. Some will judge that all people are obliged to help protect each other from COVID-19 through vaccination specifically, even if, for some individuals, it means taking on some increased risk of mortality—especially if the increase is small and similar to other risks that one faces regularly. Others will argue that no such obligation exists and, like most medical treatments, vaccination involves a personal choice. We have reason to expect that people with different views will make different value judgments when building policy-oriented models (Intemann, 2015). For example, it is reasonable to hypothesize that modellers with ‘utilitarian’ views would be less likely to include predictor variables whose influence on results might

contribute to vaccine hesitancy among the consumers of their results. This hypothesis would be consistent with qualitative evidence that modellers’ values influence their choice of predictor variables: for example, health economics modellers have reported not including age and sex as predictor variables in cost-effectiveness analyses in order to prevent discrimination based on age and sex (Harvard et al., 2020, p.7).

Although the AZ model has many unique attributes, and reflects dilemmas specific to COVID-19 vaccination, it is not ultimately a special case. Not only does all scientific modelling require making value-laden representational decisions (Harvard and Winsberg, 2021), but most health-oriented models will evoke the tension between the concept of ‘benefit’ at the societal and individual levels, respectively. At least, all models “whose purpose is to inform medical decisions and health-related resource allocation questions” (Roberts et al., 2012, p. 679) will evoke this tension: this includes health economic models that quantify both clinical and economic outcomes, but also infectious disease transmission models which exclude costs but nonetheless inform decision-making during epidemics (Roberts et al., 2012, p. 679). Representational decisions about what to include in these models, which Roberts et al. (2012) call “normative decision-making aids” (p. 697), are social and ethical decisions.

The fact that modelling teams have control over what information is included in health-oriented models, and that modelling decisions are influenced by values, raises the tough questions of *who* should be involved in modelling and *whose values* should ultimately inform modelling decisions. So far, we have argued very generally in favour of public involvement in modelling, but we have not helped to answer the difficult questions concerning the *specifics* of public involvement in practice. In health oriented-modelling, these include questions such as which public stakeholder groups to involve and whether to prioritize or privilege input from any particular group; clinicians, policy-makers, or patients, or members of the general public are just some examples of ways of conceptualizing relevant public stakeholder groups (Roberts et al., 2012). It also includes questions about how to define ‘good practice’: for example, when involving clinicians in developing model structures (Husbands et al., 2018) or involving patients throughout the modelling process (Harvard and Werker, 2021). Initiatives to involve patients in modelling, in particular, have raised many questions, including which patients should be involved, what roles they should play, how to manage power dynamics in modelling teams, what variables should be considered when establishing procedures, and so on (Harvard and Werker, 2021). We cannot answer all of these questions here. However, by focusing on the ways in which public involvement in modelling supports the cooperative management of value judgments, we aim to fruitfully link health modellers to resources from philosophy of science that can help answer these questions over time.

Among philosophers, there is good agreement that the best strategies to ensure science is as ‘objective’ and socially responsible as possible are to involve people with a diversity of values and in a diversity of socially-situated positions (Longino, 1990, 2005; Rolin, 2017; Intemann, 2017; Kourany, 2003). Right away, this suggests that two or three people in similar social situations is probably not adequate for a health-oriented modelling team—even before we know exactly what number of people or manifestation of diversity is ideal or acceptable in a modelling team, we can spot where improvement is necessary. Currently, ISPOR recommends involving clinicians, policymakers, and patients during model development (Roberts et al., 2012), but these recommendations have not resulted in consistent change to modelling practice; the model presented as a case study here, for example, was not developed in a formal collaboration with stakeholders. To whatever degree we strengthen and diversify modelling teams in practice, the question of whose values to incorporate into a model will become more difficult. Resources in social epistemology can point us to research questions and inform our priorities. For example, -whose values and knowledge have been systematically excluded from health-oriented modelling in a way that constitutes an *epistemic injustice* (Kidd et al., 2017)? It may not be possible to

incorporate everyone's values and knowledge into models right away, but we could start by incorporating those that have been persistently excluded due to racism, sexism, colonialism, and other unjust social structures.

Addressing shortcomings in health-oriented modelling by structuring and facilitating public involvement requires institutional-level initiatives. For example, Horner and Symons (2020) have argued that health-oriented simulations should be engineered and evaluated according to a set of public norms—among which norms for public involvement are just one part—and establishing public norms cannot be done well by individuals. In engineering, institutions have developed processes for deliberating with respect to values and standards in safety-critical contexts (Horner and Symons, 2020). In health-oriented modelling, a similar process should be undertaken by institutions to establish analogous norms and implement the structural supports that will be necessary to promote real changes to modelling practice. We think this institutional process requires the involvement of diverse constituencies, with different values and different social positions, to advance the greater pursuit of epistemic justice (Anderson, 2012).

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