

A friendly critical analysis of Kass's ethics framework for public health

Anne-Marie Turcotte-Tremblay, MSc,^{1,2} Valéry Ridde, PhD^{1,2}

ABSTRACT

Kass's framework has played a seminal role in stimulating reflections on the ethics analyses of public health programs. This framework stipulates that public health programs should not be implemented if there are not at least some existing data to demonstrate the validity of their "assumptions". The purpose of this commentary is to provide a constructive critical analysis of this framework. We argue that it is difficult to adopt Kass's framework in the public health field, in part because of the labile definition of what constitutes "data" or "evidence". Moreover, we argue that public health actors have the responsibility to base their interventions on the best available evidence, but that when data do not exist they may still be required to intervene with prudence to protect the health of the population. In such cases, policy-makers should first implement pilot interventions coupled with rigorous monitoring mechanisms, independent evaluations and ongoing dialogue with stakeholders so that public health measures can be modified or adapted quickly to avoid unintended harm to the population. Populations can also participate in the assessment of the interventions' risks and acceptability to avoid paternalistic approaches. We conclude that more flexible frameworks may be more useful in the field of public health.

KEY WORDS: Ethics framework; public health; individual liberties; evidence-based public health

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Can J Public Health 2016;107(2):e209–e211
doi: 10.17269/CJPH.107.5160

Public health (PH) aims to prevent diseases, protect the population, promote and monitor population health, and reduce health inequities. To these ends, interventions are implemented in complex environments characterized by variations in resources, stakeholders and practices. Faced with this complexity, PH experts must determine which interventions should be prioritized, implemented with caution or avoided. Kass developed an ethics framework proposing a series of filters for selecting interventions.¹ Kass argued that the greater the burdens posed by a PH program (e.g., constraints on individual liberties) the stronger the evidence must be to demonstrate that it will achieve its goals. Kass stated that *"if at least some data* do not exist that demonstrate the validity of a program's assumptions† the analysis can stop right here, and, ethically, the program should not be implemented"*. The issues that the framework tackled, such as the paternalistic nature of PH and the need for evidence-based interventions, still trigger debates today.^{2,3} The purpose of this commentary is to provide a constructive critical analysis of some of the framework's propositions and to further the discussion regarding the adoption of an ethics framework adapted to the complexities of PH.

We agree with Kass's statement that greater burdens posed by a PH program call for stronger evidence of potential effectiveness. PH actors have a responsibility to actively seek and analyze existing evidence before implementing an intervention so that they can select the most effective interventions while minimizing undesirable consequences, including wasting resources or

unnecessarily breaching individual liberties. Research has shown that governments' ideologies, political agendas and values can influence policies, sometimes resulting in negative consequences on population health.⁴ For example, there is growing recognition that the introduction of user fees for health care was based on ideologies rather than evidence.⁵ Studies have demonstrated that user fees create major financial barriers that limit access to care.⁶ Similarly, many researchers are concerned that the rapid introduction of performance-based financing (PBF) in low-income countries has not been based on rigorous empirical evidence.⁷ Pilot interventions conducted in Burkina Faso, Mali and Senegal did not have sufficiently rigorous designs, and decisions to rapidly expand the intervention were sometimes taken before the results of the evaluations were known. Growing data suggest that PBF may lead to unintended consequences.⁸ The implementation of interventions with high burdens for the health system, workers or populations should be based, as much as possible, on rigorous evidence.

We would like to add some nuance, however, to Kass's statement that PH programs should not be implemented if there are not at least "some data" demonstrating the validity of a program's assumptions.¹ In an article on evidence-based PH,

Author Affiliations

1. University of Montreal Public Health Research Institute, Montréal, QC

2. School of Public Health, University of Montreal, Montréal, QC

Correspondence: Anne-Marie Turcotte-Tremblay, University of Montreal Public Health Research Institute, 7101 Avenue du Parc, 3rd floor, Montréal (Québec) H3N 1X9, E-mail: anne-marie.turcotte-tremblay@umontreal.ca

Acknowledgements: AMTT received a training bursary from the Canadian Institutes of Health Research (CIHR). VR holds a CIHR-funded Research Chair in Applied Public Health.

Conflict of Interest: None to declare.

* The author does not make a clear distinction between the terms "evidence" and "data".

† The author does not define program "assumptions", but we understand them to be the mechanisms by which it is believed the programs will reach their objectives.

Brownson and colleagues⁹ argue that PH actors should use the best evidence available and not the best evidence possible. This evidence is based on a complex cycle of observation, theory and experimentation. When population health is at stake, PH actors may need to rely on theory or observation to fulfill their mandate. They may be called on to react either to old threats that have become important public problems or to new emerging threats,¹⁰ even when experimentation data are not readily available. Rapidly evolving threats can include new technologies (e.g., electronic cigarettes) or viruses. However, it is essential to carefully evaluate and monitor stakeholders' motives, the implementation process, the long-term impacts and the unintended consequences of such interventions. When insufficient evidence exists, pilot interventions could first be implemented, coupled with rigorous monitoring, independent evaluations and ongoing dialogue with stakeholders, so that policy-makers can quickly adapt PH measures to avoid unintended harm.

Moreover, there are debates within the scientific community concerning what constitutes data or evidence. No consensus exists on the definition of these labile concepts. Some researchers posit a hierarchy of evidence, with randomized controlled trials at the highest level, followed by cohort studies, case-controlled studies/case reports and expert opinions.¹¹ Others suggest experimental approaches are not necessarily required to analyze the effectiveness of PH interventions.¹² Randomly assigning participants to an exposure group may, in some cases, actually be unethical or irrelevant or to informing decision-makers. Moreover, Massé¹³ warns us against the "fetishism of methods and indicators" which presupposes that prevention programs' performance is as easily captured as the treatment of diseases. Not all variables can be quantified. Furthermore, inferring causality between a complex intervention implemented in an open environment and a given health outcome can be difficult.

It is important to recognize that scientific knowledge is constructed through accumulation of evidence over time and that the evaluation of risks is partly a social construct.¹³ Seemingly conflicting results and interpretations must be integrated and reconciled. PH actors may have a responsibility to promote population health even when the data appear to be contradictory. In those cases, the PH community should attempt to reach a consensus regarding the validity of different results. PH actors should also inform populations regarding the risks to which they are exposed and the uncertainties related to the evidence.¹³ Populations can be involved in assessing risks and their acceptability, to ensure that population values and cultural norms are respected.

Ethics frameworks in PH should recognize the pertinence of the precautionary principle, which states that where there are threats of serious or irreversible damage the lack of full scientific certainty should not be used as a reason for postponing measures to protect the population or the environment. This approach requires that PH actors evaluate the risks and benefits of an intervention compared with those resulting from a failure to intervene. Although it is true that the precautionary principle is usually adopted when experts have good reasons to believe that there are risks, it is not clear whether these reasons would meet Kass's standards of sound data, because the concept of data has not been clearly defined.

Nevertheless, the precautionary principle has been useful to protect populations from the unknown risks related, for example, to genetically modified organisms (GMO).¹⁴ European countries have passed laws requiring that food products with GMOs be labelled. In contrast to Kass's concerns about the paternalistic nature of PH, interventions such as labelling can actually promote individual liberties and empower populations by providing them with information relevant to questioning powerful organizations and protecting their own health.¹³

We would also recommend adopting a broader definition of health for the ethics framework. Kass argued that the goals of PH programs "ought to be expressed in terms of reduction of morbidity or mortality". Later, she asserts that a program "ultimately cannot claim success if behavior is unaffected and morbidity and mortality rates remain unchanged... This is not to suggest that each program must reduce morbidity by itself. Individual health education or screening programs, for example, might be pieces of larger initiatives to reduce cardiac morbidity and mortality". This approach is not sufficiently aligned with the World Health Organization's (WHO) definition of health, that is, a state of complete mental, social and physical well-being, and not merely the absence of disease.¹⁵ Some PH programs specifically aim to foster social well-being. While they may be unable to infer causality between their interventions and morbidity or mortality rates, this does not mean they are not effective in improving health, as defined by WHO.

For the reasons above, Kass's ethics framework appears too restrictive for the complex nature of PH interventions. We believe a more useful framework would offer broader and more flexible principles that stimulate reflexivity and dialogue regarding the practice of PH without imposing rigid conditions for selecting interventions. For example, Massé¹³ proposes an analytical framework based on the arbitration of core values that can justify or limit PH interventions (e.g., respect for healthy lives, common good, beneficence, utility, individual liberty). In contrast to Kass's framework, which prioritizes individual liberty and effectiveness, Massé argues that the core values are non-absolute guides and that none are hegemonies. Massé's framework invites PH actors to identify 1) the explicit and implicit values underlying an intervention, 2) the values that present a potential conflict with the target population and 3) the values that are in conflict or inconsistent with the intervention's components. Its arbitration process calls for transparency and open discussion with all stakeholders to try to reach consensus. This framework is not mechanistic or linear and does not enclose stakeholders in a normative cage.

Health and liberty are two core values. PH actors must try to ensure that both are respected as much as possible. An ethics framework geared towards PH should be adapted to the complexity of the field, recognize the pertinence of the precautionary principle, use a comprehensive definition of health and stimulate reflexivity on public health practices, rather than imposing rigid guidelines. Ultimately, public health interventions should minimize unnecessary burdens on the population while fulfilling the mandate to improve population health and reduce social health inequalities.

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Received: June 9, 2015

Accepted: February 6, 2016

RÉSUMÉ

Le cadre de Kass a joué un rôle primordial pour stimuler les réflexions sur les analyses éthiques des programmes de santé publique (SP). Ce cadre stipule que les programmes de santé publique ne devraient pas être implantés s'il n'y a pas au moins certaines données existantes pour démontrer la validité de leurs « hypothèses ». L'objectif de ce commentaire est de fournir une analyse critique constructive de ce cadre. Nous soutenons qu'il est difficile d'adopter le cadre de Kass dans le domaine de la PH en raison, notamment, de la définition labile de ce qui constitue des « données » ou des « preuves ». De plus, nous soutenons que les acteurs de la santé publique ont la responsabilité de fonder leurs interventions sur les meilleures données disponibles, mais que, lorsque les données n'existent pas, ils peuvent avoir l'obligation d'intervenir avec prudence pour protéger la santé de la population. Dans ces cas, les décideurs politiques devraient d'abord mettre en œuvre des interventions pilotes couplées à des mécanismes de suivi rigoureux, des évaluations indépendantes, et un dialogue continu avec les parties prenantes afin que les mesures de santé publique puissent être modifiées ou adaptées rapidement pour éviter des préjudices involontaires à la population. Les populations peuvent également participer à l'évaluation des risques et de l'acceptabilité des interventions pour éviter l'adoption d'approches paternalistes. Nous concluons que des cadres plus souples peuvent être plus utiles dans le domaine de la santé publique.

MOTS CLÉS : cadre éthique; santé publique; libertés individuelles; données probantes