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## Original Research

# An ethical framework for evaluation of public health plans: a systematic process for legitimate and fair decision-making



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## ABSTRACT

**Objectives:** Given the increasing threats of communicable and non-communicable diseases, it is necessary for policy-makers and public health (PH) professionals to address ethical issues in health policies and plans. This study aimed to develop a practical framework for the ethical evaluation of PH programs.

**Study design:** A multidisciplinary team developed an ethical framework to evaluate PH plans from 2015 to 2017.

**Methods:** In this study, the multi-method approach was used. First, a list of moral norms in PH policy and practice was drafted and completed in two interactive sessions. Then, the Delphi method was used for consensus about the structural components to be adopted in the framework. After developing the framework, its efficiency was assessed by evaluating Iran's Fourth Strategic Plan for HIV/AIDS Prevention and Control.

**Results:** The framework was developed in the following three sections: (i) determination of the general moral norms in PH practice and policy; (ii) five steps of evaluation; and (iii) a procedural evaluation step to ensure fair decision-making. The ratio of the ethical points of the PH plan increased by 46% after implementation of the framework, and the frequency of ethical points increased significantly after applying the framework ( $P = 0.001$ ).

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*Conclusion:* The application of the framework for the ethical evaluation of various PH programs ensures a comprehensive and scientific-deliberative decision-making process, while also contributing to the development of the framework.

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## Introduction

Public health (PH) efforts should aim to improve the social, economic, and environmental conditions in which people can live a healthy life. All activities concerning the health of populations are within the PH domain. Given the consequentialist nature of PH, its main goals are to preserve and promote the health of populations and reduce inequalities in health outcomes.<sup>1</sup> The characteristics of the multidisciplinary field of PH, lead to ethical issues being at the heart of the subject: it is a common good, with a preventative approach that is provided by the government.<sup>2</sup> PH is a collective effort, as its goals cannot be achieved by individual efforts; thus, it requires government action in addition to community participation.<sup>2,3</sup>

Public health ethics is a sub-branch of bioethics, which help PH professionals and health-related organizations to make some necessary trade-offs so that public health goals can be realized. The objectives and activities of PH make this area unique in terms of applying and overcoming ethical principles and moral norms.<sup>4</sup> The objectives of PH are related to moral norms, in particular, prevention of harm and beneficence, producing utility (optimization of benefits over harms) and justice.<sup>5</sup>

Some PH interventions are still a threat to other moral norms, such as individual freedom and autonomy, privacy, and confidentiality.<sup>5,6</sup> With the increasing threats of communicable and non-communicable diseases (NCDs), and populations with chronic health problems, such as diabetes and obesity, it is necessary for PH professionals and other health-related institutions to address ethical conflicts in their policies and practices.<sup>5</sup> Given the objectives of PH, providing universal health coverage requires informed and correct decision-making, based on empirical evidence and moral judgment. For example, the goal of ending the AIDS epidemic by 2020 is only possible if people are being informed about their illness through voluntary testing and access to health-care services. In addition, the elimination of stigma and discrimination is one of the key topics that should be addressed when planning for the prevention and control of the disease worldwide.<sup>7</sup> Moreover, the socio-economic burdens of NCDs are particularly severe in developing countries, accounting for 75% of all NCD-related deaths. Thus, in order to achieve sustainable development goals, the WHO has established global governance to address complex issues that could not be managed alone. These interactions have raised a range of ethical challenges, including conflicts of interests and governance issues. Transparency, accountability, and management of conflicts of interests are ethical issues requiring

attention to prevent NCDs and chronic diseases. Therefore, policy-makers and governments have been working closely with food and drink industry partners to address a number of determinants and processes, which today are tackled by a set of institutions globally. These new challenges call for tools and methods for overcoming ethical conflicts and maximizing benefits.<sup>8</sup>

The American Public Health Association identified 10 essential functions for the effective implementation of PH programs,<sup>9</sup> which resulted in the development of a variety of ethical frameworks. Initially, the following two concerns led to the formation of practical frameworks for ethical evaluation of PH: (i) public involvement rather than individual autonomy; and (ii) prioritization and allocation of scarce resources, especially in developing countries, which has raised the debate on justice.<sup>10</sup> So far, several practical frameworks have been proposed for the ethical evaluation of PH programs, but none are universally approved.<sup>11–13</sup> Most of these frameworks were based on common underpinning assumptions, but they were formed to address ethical issues either theoretically or practically. Kass<sup>11</sup> was the first pioneer who proposed a primary practical framework for ethical evaluation of PH, including six steps, based on two key values of social rights and social justice. Childress et al.<sup>14</sup> conceptualized general moral considerations in PH practice and introduced six justificatory conditions to solve conflicts in the context of PH. In the stewardship model proposed by the Nuffield Council on Bioethics 2007,<sup>15</sup> only practical recommendations for ethical decision-making were mentioned. On the other hand, given the debates raised about priority setting, especially in developing countries, ethical frameworks based on fundamental values of fairness and accountability have been proposed, which combine normative and empirical methods, and the involvement of all stakeholders and partners in policy decisions.<sup>16–18</sup> Thus, to enable legitimate and fair decision-making when considering priority setting in PH policy, the 'accountability for reasonableness'<sup>19</sup> framework was created, which was then developed by health system stakeholders in developing countries specifically for their requirements.<sup>20–22</sup> Given the evolution and specialization of these frameworks, Ten Have et al.,<sup>12</sup> proposed a practical framework to evaluate overweight and obesity interventions, after providing an inventory of relevant moral norms. At the heart of the framework is a list of eight questions on the morally relevant features of a program, which is then followed by procedural recommendations for applying the ethical framework. Marckmann et al.,<sup>13</sup> proposed an ethical framework to guide professionals in planning, conducting, and evaluating PH interventions. Their

proposed framework contains an explicit normative foundation with five substantive criteria, five questions on the morally relevant features of a PH program, and seven procedural conditions to guarantee a fair decision-making process. However, the authors did not assess its practical application to determine the efficiency of the framework.

These ethical frameworks require further development to enable in-depth evaluations of PH plans or interventions and to be able to efficiently address new ethical challenges in the continuously evolving area of PH.

Being mindful of the evolving nature of PH and in order to find a systematic approach to address ethical issues in PH policy and practice, this study aimed to develop a comprehensive practical framework for the ethical evaluation of PH programs and interventions. Utilizing a systematic approach, in addition to performing a qualitative process of ethical analysis of PH plans, reduces the risk of underestimating related ethical considerations and ensures the achievement of PH objectives practically.<sup>13</sup>

## Methods

In this study, a multi-method approach was used.<sup>23</sup> The framework for the ethical evaluation of PH plans was developed in the following order:

- (A) A list of general moral norms in PH policy and practice was created, which was based on broad and narrow moral norms presented in a systematic review of the literature.<sup>24</sup> The primary draft was then completed in two interactive sessions (expert panels) with six Iranian biomedical ethics and PH community professionals who had at least 10 years of experience in their respective fields. The group included three men and three women who were recommended by the Vice Chancellor of Iran's National Institute for Health Policy Research.
- (B) The Delphi method was used to validate the content and determine the components to be used in the framework structure. In the first round, we emailed the list of general moral norms to 20 Iranian experts with expertise in biomedical ethics or PH policy and asked them to determine the relevance and importance of each of the norms by scoring with a 5-point Likert scale (1: very low; 2: low; 3: moderate; 4: high; and 5: very high). Overall, 14 of the 20 experts responded. Based on received comments and scores, the norms that scored  $\leq 3$  were merged with other norms, and then the median was calculated using a frequency distribution table for each norm. In the second round, the list of revised general moral norms, with median scores resulting from the first round, were emailed to the previous 14 respondents who were then asked to re-score each norm. Analysis of scores on the revised list of moral norms showed that all respondents were in agreement in terms of which components should be used in the structure of a practical framework.
- (C) After determining and validating the moral norms to be applied as structural components in creating the practical framework, it was further developed in six detailed steps (see the Results section).
- (D) To assess the efficiency of the framework, Iran's Fourth Strategic Plan for HIV/AIDS Prevention and Control was evaluated by the final users (program experts) of the framework. After obtaining permission from the head of the Center for Communicable Diseases and Iran's Ministry of Health and Medical Education (who had previous involvement in the project), two group discussion sessions were held with nine experts from the Ministry of Health and its affiliated universities. These experts were specifically chosen by the Director of the HIV/AIDS Control Office. In the first session, which lasted 2 h, after expressing the goals of the meeting and obtaining the oral agreement of participants, they were asked to identify ethical considerations in the form of potential strengths and weaknesses (ethical points) associated with the Fourth Strategic Plan of HIV/AIDS Prevention and Control without using the framework. Then, to determine the content validity of the framework, participants were asked to rate the relevance, simplicity, and clarity of the resulting questions using the 5-point Likert scale. After summarizing the responses, the framework was refined and finalized at a meeting with attendance of those experts (content validity index [CVI] = 96.2%). Then, an evaluation session of the program, which lasted 3 h, was conducted using the developed framework and its application guide with nine previous participants, as follows:
  1. Form an evaluation team, consisting of three ministry experts, three university experts, and three experts working in other relevant PH institutions;
  2. Specify and balance the list of moral norms in PH policy and practice, in each domain;
  3. Answer questions in the form of 'yes' or 'no' by mentioning the potential strengths or weaknesses (ethical points);<sup>12</sup>
  4. Make recommendations regarding ethical pitfalls based on weaknesses (negative points);
  5. Evaluate the program by integrating the results from the evaluation of each domain and decision-making as: (i) the program is acceptable; (ii) the program is acceptable with some revisions; or (iii) the program is not acceptable.
- (E) In order to determine the total number of weaknesses and strengths (sum of the positive and negative ethical points) that may be obtained by evaluating Iran's Fourth Strategic Plan for HIV/AIDS Prevention and Control through applying the framework, the program was previously evaluated by three members of the research team. A total number of 50 negative and positive ethical points were elicited, and this was considered the reference point. Finally, to calculate whether there is significant difference between the frequency of provided answers as strengths (the number of positive points) and weaknesses (the number of negative points) before and after applying the framework, the number of ethical points compared with the reference was analyzed using the Mac-Nemar non-parametric test due to the abnormal distribution (confidence interval [CIN] = 99%).

## Results

The framework for the ethical evaluation of the PH programs was developed by the following three sections: (i) determination of the general moral norms in PH practice and policy; (ii) five steps of evaluation; and (iii) a procedural evaluation process for fair decision-making.

Table 1 shows the list of general moral norms that should guide ethical analysis. The starting point for any ethical analysis is the use of these criteria. In evaluating a PH policy or plan, all or some of these criteria may be applied, and some additional criteria may be required for specialist areas.

### Evaluation steps

The second part of the framework development consisted of the evaluation steps (Table 2).

**Step 1:** What are the expected health benefits of the program to the target population(s)?

**Table 1 – General moral norms in public health policy and practice.**

#### Providing health benefits

Prevention of harm, minimization of the burdens (including externalities in both personal and community levels)  
Producing utility (optimization of benefits over harms), effectiveness, and promotion of the health benefits and values (including cost-effectiveness and cost value)

#### Respect

Self-respect, respect for human beings and other species of life, future generations, and cultural and social values  
Respect for individual autonomy and rights (right to health, education, etc.)  
Observing privacy and confidentiality of information  
Prevention of stigma and discrimination

#### Community empowerment and participation

Increasing public awareness (e.g. health literacy, legal literacy)  
Empowerment for making informed decisions and right choices  
Fostering individual capabilities, personal and social responsibility and commitment, moral virtues and healthy behaviors  
Creating and developing healthy structures (e.g. law, policy and environment)  
Community participation, including collaboration and partnership of the involved institutions and stakeholders

#### Justice and fairness

Fair distribution of the resources, opportunities, benefits, and burdens regarding vulnerable and disadvantaged groups  
Equal access to primary healthcare services  
Reducing avoidable social inequalities through prevention or reparation of them (action on social determinants of health)  
Reciprocity and compensation (e.g. legal regulations to support public and healthcare givers against potential harms)

#### Accountability for reasonableness

Transparency (honesty, trustfulness, disclosure and public justification)  
Assurance of public participation, including all people, groups, partners and stakeholders in decision-making and implementation (procedural justice), and minimizing conflicts of interests  
Commitment and keeping promise, comprehensiveness and sustainability of the services, and trust building

The necessity of the program should be determined on the basis of the burden of disease or epidemiological evidence. Evaluation of the benefits requires a precise definition of the objectives and the expected effects based on sound data and evidence; for example, reducing the mortality rate of breast cancer from six to four per 1000 population, over the next 5 years by mammography screening of women over 30 years of age. The other ethical consideration is the development or revision of the national guidelines in line with the program objectives.

**Step 2:** What are the potential burdens (risks and costs) of the program?

The second step is to identify potential burdens of the program, including risks and autonomy constraints, and other financial and non-financial costs of the program for groups that are directly or indirectly affected. Occasionally, PH interventions are associated with some risks (for example, the existence of a false-positive result in sequential or unnecessary screening tests); therefore, it is necessary to estimate the risks of the program. The more frequent the burdens of a program, the greater the evidence should be for the benefits. An autonomous choice is a decision that is not influenced by the interference of others or restrictions, such as inadequate understanding and awareness.<sup>25</sup> But in order to increase the effectiveness, they may be morally accompanied by harmful impacts, such as stigma and discrimination.<sup>11</sup> For example, the stigma associated with obesity can cause feelings of worthlessness and loss of will, in addition to lost opportunities, such as employment and access to healthcare services, and ultimately discrimination and inequality, deprivation and undesirable health outcomes.<sup>12</sup> ‘Stigmatization’, ‘violation of confidentiality’, and ‘disclosure of information’ are more sensitive to data collection activities. In cases where an infection or disease is on the list of diseases to be reported, the necessary measures for information security should be considered in the program evaluation. For example, ‘contact tracking’ (e.g. for follow-up purposes) poses additional privacy risks because not only the name and condition of the infected person are reported but also their contact details.

**Step 3:** Is the program effective (balancing of benefits and burdens to maximize the benefits of the program)?

The principle of utility in PH is defined as optimization of the benefits of the program over its burdens, including risks, harms, and other financial and non-financial costs.<sup>26</sup> In the third step, which completes the previous two steps, the determination of effectiveness of the program takes place through balancing the expected benefits and potential burdens of the program. For example, evidence suggests that the risk of developing measles-induced encephalitis is one per 1000 children, which is reduced to one per 1,000,000 children following vaccination. If there is a risk of an epidemic in a region, vaccination is effective because of the increasing risk of infection.

If the third step shows that a program imposes a potential or actual burden, then morally, it is essential to determine

**Table 2 – Steps of ethical evaluation of the PH program.**

Options	Yes	No	Strengths and/or weaknesses
<b>Step 1: What are the expected health benefits of the program in the target populations?</b>			
Have the priority and necessity of the program been determined on epidemiological evidence?			
Have the program objectives been determined on valid evidence?			
Have the exact rates of expected benefits been determined?			
Are the strategies in line with the objectives of the program (or is there another strategy required?)			
Have the evidence-based national guidelines been considered in-line with the objectives?			
<b>Step 2: What are the potential burdens (risks and costs) of the program?</b>			
Are the financial burdens of the program calculated based on evidence?			
What are the probable non-financial burdens and potential risks of the program?			
Does the program threaten autonomy and freedom of choice?			
Does the program cause stigma and discrimination?			
Does the program threaten privacy through breaching of confidentiality? (data collection activities)			
<b>Step 3: Is the program effective (balancing of the benefits and burdens to maximize the benefits of the program)?</b>			
Do the benefits justify the restriction of autonomy?			
Do the benefits justify stigma?			
Do the benefits justify the breach of the confidentiality of information?			
Are the cost-effectiveness or cost value of the program determined or approved by experts?			
Have the ways to reduce the probable risks of the program been determined? (e.g. giving incentives instead of mandatory interventions, or selecting another strategy)			
<b>Step 4: Is the distribution of expected benefits and possible burdens fair and equitable?</b>			
Has equal geographical access (rural, urban and marginalized populations) to basic services, including information and education been considered?			
Have the needs of special or vulnerable groups, such as children, pregnant women, the elderly and immigrants, been considered?			
Have the social determinants affecting health, such as gender, low income and low-literacy, been considered to reduce disease and death?			
If there are any possible risks, have compensation mechanisms been considered for the community?			
If there are any possible risks, have compensation mechanisms been considered for health workers?			
<b>Step 5: Does the program raise awareness, empowerment and community participation?</b>			
Does the program increase awareness in the community?			
Does the program increase the ability to make informed decisions?			
Have cooperation and participation of all affected governmental and non-governmental organizations and groups been considered?			
Have healthy social structures (including policies, law and regulations, and environmental facilities) been considered?			

ways in which these harmful effects can be minimized. Thus, an analysis must take place to investigate whether the program can be adapted to minimize burdens, while maintaining the benefits, or whether there is an alternative intervention or strategy. Therefore, alternative interventions or strategies need to be reviewed. If there are two interventions or strategies to solve a PH problem, assuming that the benefits are not significantly different, it becomes a moral obligation to opt for the strategy with fewer risks of moral issues, such as autonomy and privacy. In general, less enforcement of compulsory measures and consideration of incentives results in less infringement of individual autonomy. For example, if evidence suggests that a voluntary screening program essentially tests the same number of people as a compulsory program, it is not morally necessary to enforce a mandatory program; or, if a disease surveillance system has the same effect using unique identification codes as it does with the national identification codes, it is morally preferable to use identification codes.

Cost-effectiveness analysis and calculating the quality-adjusted life year (QALY) index is recommended for managing the financial burdens of the program. Cost-value

analysis is another formal analysis that considers many factors, including the severity of the disease as a social value. In cost-value analysis, in contrast to cost-effectiveness analysis, the severity of the disease after the intervention has greater weight than that of healing time, resulting in reduced discrimination for those who are less likely to heal quickly. Thus, the evaluation of lifelong improvement programs for both healthy and less healthy/able people is the same. In addition, this type of evaluation is more ethical to use because it takes into account the views of the community about the value/worthiness of the evaluation.<sup>27</sup>

**Step 4: Is the distribution of expected benefits and potential burdens fair?**

The fourth step of the framework involves the distribution of benefits, opportunities and burdens, and fair access and action on social determinants of health of the program. Sometimes, the benefits of a program are limited to a specific group, and the other group(s) will bear the burden. For example, implementing HIV prevention and control interventions only in minority or poor communities or

implementing heart disease risk-reduction programs only in men is unethical without strong justification.

When a program with a probable harm is implemented for a given group in order to achieve significant benefits for another group, a strategy should be considered to compensate for these risks (compensatory justice). For example, in a pandemic such as severe acute respiratory syndrome (SARS), psychological support should be provided to patients in the event of quarantine. Also, employees who are infected need to receive the necessary medical and social supports.

**Step 5:** Does the program raise awareness, empowerment, and community participation?

The program should increase the knowledge and awareness of the community, in such a way as to enable them to make the right decision, regardless of external pressure and insufficient understanding. Recent theories promote the cultivation of moral virtues and strengthening of the autonomy of individuals in order to make the right choices and exhibit healthy behaviors. For example, in a program to prevent obesity, instead of limiting the autonomy of individuals through restricting access to fast foods or soft drinks, the individuals should be aware, mindful, and able to choose the right and healthy behaviors. On the other hand, healthy lifestyle, in addition to the development of healthy behaviors, requires improving environmental conditions and social structures.<sup>28</sup>

**Procedural evaluation:** Following evaluation of the program by these five steps, fair procedures were evaluated to ensure accountability (see Table 3).

### Application

Finally, assessing the efficiency of the framework through examination of the HIV/AIDS Prevention and Control program showed a 46% increase in the ratio of positive and negative

**Table 3 – Procedural evaluation of the PH program.**

Options	Yes	Somewhat	No
Have the affected partners, organizations and groups participated in decision-making?			
Have efforts been made to minimize the conflict of interests among different groups and organizations (financially and non-financially) in decisions?			
Is public justification considered for community engagement (transparency of evidence and reasons, description of the implementation process and how to announce results to bring people together with the goals of the program)?			
Are monitoring and evaluation seen in planning?			
Are infrastructures and resources needed to ensure the program's sustainability?			
Is there the possibility to revise the program?			
Has the fulfillment of the procedural conditions been approved?			

**Table 4 – Frequency of ethical points before and after applying framework by users.**

Step	Reference [N]	Before [n/N (%)]	After [n/N (%)]	Difference [n/N (%)]
1	8	2/8 (25)	6/8 (75)	4/8 (50)
2	8	2/8 (25)	6/8 (75)	4/8 (50)
3	8	0/8 (0)	4/8 (50)	4/8 (50)
4	8	1/8 (12.5)	5/8 (62.5)	4/8 (50)
5	8	3/8 (37.5)	6/8 (75)	3/8 (37.5)
6	10	4/10 (40)	8/10 (80)	4/10 (40)
Total	50	12/50 (24)	35/50 (70)	23/50 (46)

Step 1: What are the expected health benefits of the program in the target population/populations?

Step 2: What are the potential burdens (risks and costs) of the program?

Step 3: Is the program effective (balancing of benefits and burdens to maximize the benefits of the program)?

Step 4: Is the distribution of expected benefits and potential burdens fair?

Step 5: Does the program raise awareness, empowerment, and community participation?

Step 6: Fair procedures are evaluated to ensure accountability.

ethical points before and after applying the framework (see Table 4). The frequency of ethical points (nominal answers in the shape of negative and positive points codified to numeral codes) had a significant difference before and after applying the framework ( $P = 0.001$ ).

### Discussion

We developed and implemented a comprehensive practical framework for ethical evaluation of PH programs, which included the following three sections: (i) determination of the general moral norms; (ii) five steps of evaluation; and (iii) a step for procedural evaluation. In our proposed framework, providing health benefits, respect for all, equity, community empowerment and participation, fairness and accountability, and their derivatives were considered as general moral norms in PH policy and practice. Childress et al.<sup>14</sup> mapped out general moral considerations in PH by identifying the three moral goals of producing benefit, avoiding harm, and maximizing utility; meanwhile, they focused on distributive and procedural justice and respecting autonomous choices. Respect is one of the fundamental dimensions of well-being that is essential to achieving social justice.<sup>29</sup> Achieving PH goals requires strengthening of the autonomy of the public to enhance creativity and vitality as members of the community.<sup>30</sup> Therefore, we considered respect for all human beings, other species of life, the environment and subsequent generations, instead of relying solely on respect for individual autonomy; and, while emphasizing the protection of privacy and the confidentiality of information, focused on developing the capabilities, responsibility, and empowerment of individuals to choose healthy behaviors and participate in the community.

At the heart of our framework, there are five steps to evaluate a PH plan in depth. Considering the consequentialist nature of PH,<sup>2</sup> in the first step of evaluation, focus is on the

expected benefits based on evidence; in the second step, probable burdens of the program were addressed; and in step three, focus is on the effectiveness of the program through balancing and maximizing the benefits over the harms and other costs. Marckmann et al.,<sup>13</sup> believe that the first criterion is the expected benefits of the program; in the event of uncertainty about the expected benefits, the implementation of the program should be discontinued, and there is no need to evaluate other criteria. Reducing possible burdens and risks, and increasing effectiveness of the program is one of the main goals of ethical evaluation<sup>11</sup> that hasn't been appropriately addressed by Marckmann et al. Priority setting of healthcare services and allocation of resources is one of the important ethical issues in PH policy and requires the use of cost-value analysis,<sup>27,31</sup> in addition to cost-effectiveness analysis. These formal analyses provide the systematic, quantitative, and comparative inputs of health interventions, which help us with ethical decision-making (with some limitations).<sup>26</sup>

In the fourth step, fairness and equitable distribution was addressed by providing equal access to various population groups and paying special attention to vulnerable and disadvantaged groups. Fairness is a broad concept which includes 'equitable resource allocation, access to all types of care and financing, equity in health outcomes and accountability'.<sup>19</sup> Unlike other frameworks, the specific focus of this step is on the social determinants of health. Kass<sup>11</sup> has also noted the importance of social determinants of health, in addition to access and fair distribution of benefits and harms. In a stewardship model proposed by the Nuffield Council on Bioethics 2007,<sup>15</sup> reducing health inequalities has been mentioned as one of the ethical aims. Unlike the present study, Ten Have et al.<sup>12</sup> focused on avoiding stigma and discrimination. Marckmann et al.<sup>13</sup> mentioned the elimination of financial and non-financial barriers to access programs and emphasized the need for compensation, as we did in the present study.

Preda and Voigt<sup>32</sup> noted that reduction of health inequalities is required as a matter of social justice. Healthy lifestyle is influenced by both individuals and social determinants, including structural factors and living conditions.<sup>33</sup> Therefore, in the fifth step, community empowerment and participation were focused on separately, while other frameworks suggested this issue only as the health-related empowerment<sup>13</sup> and informed choice<sup>34</sup> under the principle of respect for autonomy. While social justice, in addition to distributive and procedural justice, requires capacity building, fostering individual capabilities, and improving well-being dimensions at the level of adequacy, including reasoning and autonomy, to make the right decisions and informed choices.<sup>29</sup>

The five steps of our framework consisted of five questions and sub-questions, which makes it very user-friendly. However, the frameworks proposed by Ten Have et al. and Marckmann et al. include eight and five general questions, respectively, on the morally relevant features of a program, without any sub-questions to help users apply it in practice.<sup>12,13</sup>

Regarding the establishment of global governance to address complex issues and the requirement of responding to a range of new ethical challenges, including conflicts of

interest and governance issues,<sup>8</sup> the final step of our proposed framework includes evaluation of the fair procedures to ensure accountability, solidarity and public trust. In this step, we have examined the accountability items in detail, as well as the monitoring and evaluation items to ensure implementation of the ethical criteria in practice. The accountability framework was firstly proposed by Daniels and Sabin<sup>17</sup> in 1998, including the four conditions of 'publicity, relevancy, openness to appeals, and enforcement condition'; Marckmann et al.<sup>13</sup> subsequently added the three conditions of 'consistency, participation, and management of conflict of interests'.

In assessing the feasibility and efficiency of the framework, the frequency of ethical points increased significantly after applying the framework to final users, which shows the overall effectiveness of the proposed framework. However, more discussion sessions are recommended in each domain. Marckman et al.<sup>13</sup> emphasized the need to evaluate the effectiveness of their proposed framework, but did not perform an analysis. Ten Have et al.<sup>12</sup> did assess the feasibility of their framework and concluded that their framework, in addition to providing ethical pitfalls, has the potential for ethical decision-making because of the possibility of discussing and presenting arguments; however, they emphasized the fact that evaluation of its usefulness is necessary through further application.

Kapri and Razavi<sup>35</sup> observed that budget analysis and cost-effectiveness analysis have been used for policy making and prioritizing in developing countries, while in high-income countries, multi-criteria analysis and accountability for reasonableness have been used more frequently. Our proposed framework can evaluate and cover all the criteria mentioned, while providing a scientific-deliberative decision-making process through a systematic approach. Recommendations indicate the use of a scientific and deliberative evidence-based approach for ethical decision-making in PH policies and interventions.<sup>11,18,36–39</sup> Kapri and Razavi<sup>35</sup> also emphasized the need for knowledge sharing between researchers and policy-makers and the formulation of practical guidelines to ensure informed policy making.

The strengths of this study are that it is based on a systematic review of literature, in addition to consensus with other frameworks. The framework consists of a complete schedule of general moral norms (including mid-level principles), five steps of evaluation (providing the possibility of a multi-criteria analysis), and also a step for evaluation of fair procedures to ensure accountability. A limitation of this study is that the efficiency of the framework was evaluated by testing its performance on only one PH program.

## Conclusion

We developed and implemented a comprehensive and user-friendly framework for ethical evaluation of PH programs, which consisted of the following three sections: (i) general moral norms; (ii) five steps of evaluation; and (iii) a step for procedural evaluation, so that it can be utilized to evaluate a PH plan in practice, at global level.

The practical nature of PH requires the application of moral norms through a practical guideline. It implies a systematic



approach as well as procedural conditions. The application of this comprehensive framework for ethical evaluation of various PH programs is recommended not only for a deliberative ethical decision-making process but also for contributing the evolution of the framework.

## Author statements

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### Competing interests

The authors have no competing interests to declare.

## REFERENCES

- Dawson A. *Public health ethics: key concepts and issues in policy and practice*. Cambridge University Press; 2011.
- Faden R, Shebaya S. The stanford encyclopedia of philosophy: public health ethics. In: Zalta EN, editor. *Metaphysics research lab*. Stanford University; 2016.
- Dawson A. Public health ethics and the justification of HIV screening. *Am J Bioeth* 2011;11:48–9.
- Akrami F, Abbasi M. Exploring the prominence of ethical principles and moral norms in the areas of clinical practice and public health. *Ann Med Health Sci Res* 2018;8:11–5.
- Childress JF, Bernheim RG. Introduction: a framework for public health ethics. In: Bernheim RG, Childress JF, Melnick AL, Bonnie RJ, editors. *Essentials of public health ethics*. USA: Jones & Bartlett Publishers; 2015. p. 1–20.
- Institute of Medicine. *The future of public health*. Committee for the Study of the Future of Public Health, National Academy Press; 1988.
- UNAIDS. *Paris declaration: fast-track cities: ending the AIDS epidemic: cities achieving 90-90-90 targets by 2020*. 2014.
- UK Health Forum. *Public health and the food and drinks industry: The governance and ethics of interaction. Lessons from research, policy and practice*. London: UKHF; 2018.
- APHA. *10 essential public health services*. 2014.
- Jayasinghe K, De Silva D, Mendis N, Lie R. Ethics of resource allocation in developing countries: the case of Sri Lanka. *Soc Sci Med* 1998;47:1619–25.
- Kass NE. An ethics framework for public health. *Am J Publ Health* 2001;91:1776–82.
- Ten Have M, Van Der Heide A, Mackenbach JP, De Beaufort ID. An ethical framework for the prevention of overweight and obesity: a tool for thinking through a programme's ethical aspects. *Eur J Publ Health* 2013;23:299–305.
- Marckmann G, Schmidt H, Sofaer N, Strech D. Putting public health ethics into practice: a systematic framework. *Frontiers in public health* 2015;3:23.
- Childress JF, Faden RR, Gaare RD, Gostin LO, Kahn J, Bonnie RJ, Kass NE, Mastroianni AC, Moreno JD, Nieburg P. Public health ethics: mapping the terrain. *J Law Med Ethics* 2002;30:170–8.
- Nuffield Council On Bioethics. *Public Health: ethical issues*. London, England: Nuffield Council; 2007.
- Daniels N, Sabin JE. Accountability for reasonableness: an update. *BMJ: Br Med J* 2008;337.
- Daniels N, Sabin J. The ethics of accountability in managed care reform. *Health Aff (Millwood)* 1998;17:50–64.
- Martin D, Singer P. A strategy to improve priority setting in health care institutions. *Health Care Anal* 2003;11:59–68.
- Daniels N, Bryant J, Castano R, Dantes O, Khan K, Pannarunothai S. Benchmarks of fairness for health care reform: a policy tool for developing countries. *Bull World Health Organ* 2000;78:740–50.
- Kapiriri L, Norheim OF, Martin DK. Fairness and accountability for reasonableness. Do the views of priority setting decision makers differ across health systems and levels of decision making? *Soc Sci Med* 2009;68:766–73.
- Kapiriri L, Norheim OF, Martin DK. Priority setting at the micro-, meso- and macro-levels in Canada, Norway and Uganda. *Health Pol* 2007;82:78–94.
- Petricca K, Bekele A. Conceptualizations of fairness and legitimacy in the context of Ethiopian health priority setting: reflections on the applicability of accountability for reasonableness. *Develop World Bioeth* 2017:1–8.
- Hall R. *Mixed methods: in search of a paradigm*. 2012. [https://www.researchgate.net/profile/David\\_Geelan/publication/273520118\\_While\\_Heisenberg\\_is\\_not\\_looking\\_the\\_strength\\_of\\_'weak\\_measurements'\\_in\\_educational\\_research/links/55e5260408aeb1a7ccb962b.pdf](https://www.researchgate.net/profile/David_Geelan/publication/273520118_While_Heisenberg_is_not_looking_the_strength_of_'weak_measurements'_in_educational_research/links/55e5260408aeb1a7ccb962b.pdf).
- Abbasi M, Majdzadeh R, Zali A, Karimi A, Akrami F. The evolution of public health ethics frameworks: systematic review of moral values and norms in public health policy. *Med Health Care Philos* 2017;21:387–402.
- Beauchamp T, Childress J. *Principles of biomedical ethics*. USA: Oxford University Press; 2013.
- Childress JF. Moral considerations: bases and limits for public health interventions. In: Bernheim RG, Childress JF, Melnick AL, Bonnie RJ, editors. *Essentials of public health ethics*. USA: Jones & Bartlett Learning, LLC, an Ascend Learning Company; 2015. p. 21–43.
- Nord E. *Cost-value analysis in health care: making sense out of QALYs*. Cambridge University Press; 1999.
- Buchanan DR. Promoting justice and autonomy in public policies to reduce the health consequences of obesity. *Kennedy Inst Ethics J* 2015;25:395–417.
- Powers M, Faden RR. *Social justice: the moral foundations of public health and health policy*. USA: Oxford University Press; 2006.
- Shickle D. The ethics of public health practice: balancing private and public interest within tobacco policy. *Br Med Bull* 2009;91:7–22. ldp.022.
- Nord E. Beyond QALYs: multi-criteria based estimation of maximum willingness to pay for health technologies. *Eur J Health Econ* 2018;19:267–75.
- Preda A, Voigt K. The social determinants of health: why should we care? *AJOB* 2015;15:25–36.
- Cockerham WC. Health lifestyle theory and the convergence of agency and structure. *J Health Soc Behav* 2005;46:51–67.
- Riiser K, Løndal K, Ommundsen Y, Misvær N, Helseth S. Targeting and tailoring an intervention for adolescents who

- are overweight Some ethical concerns. *Nurs Ethics* 2015;22:237–47.
35. Kafiriri L, Razavi S. How have systematic Priority Setting Approaches influenced Policy making? A synthesis of the current literature. *Health Pol* 2017;121:937–46.
  36. Ruger JP. Ethics in american health 2: an ethical framework for health system reform. *Am J Publ Health* 2008;98:1756–63.
  37. Petrini C. Theoretical models and operational frameworks in public health ethics. *Int J Environ Res Publ Health* 2010;7:189–202.
  38. Thompson AK, Faith K, Gibson JL, Upshur RE. Pandemic influenza preparedness: an ethical framework to guide decision-making. *BMC Med Ethics* 2006;7:1.
  39. Carter SM, Rychetnik L, Lloyd B, Kerridge IH, Baur L, Bauman A, Hooker C, Zask A. Evidence, ethics, and values: a framework for health promotion. *Am J Publ Health* 2011;101:465–72.