**Original article**

**Title: Framework for ethical review of public health programs, functions and research.**

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**ABSTRACT:**

**Background**: Much emphasis of bioethics is on individual rights, however, majority of public health functions, such as surveillance, disease notifications, contact tracing, isolation, quarantine may infringe the core ethical principles to being benefit to the larger community. The ethical dilemma in public health is to balance respect for individual freedom with the responsibility of governments to provide their citizens with some degree of protection in relation to health. Therefore, ethical justification for public health program or intervention needed before intervention goes live.

**Objective**: This paper aims to review the existing frameworks and guidelines and propose a framework that may be used for scrutinizing the public health programs/functions/intervention from the ethics perspective particularly in India and low-income countries.

**Methodology:** A systematic review of literature was carried out to comprehend the existing frameworks, guidelines and mechanism for the ethical review of public health programs and research. Subsequently in-depth interviews of public health professionals were conducted to get their viewpoint. Finally, a framework for ethical review of public health programs, functions, intervention is developed through triangulation of data and collaborative process.

**Results**: For systematic review various documents like frameworks for ethical review, UN declaration (1942), World Medical Association- Declaration of Helsinki**,** American Public Health Association (APHA) declaration (2002) on principles of the Ethical Practice of Public Health, Universal Declaration on Bioethics and Human Rights (October 2005)**,** Universal declaration of human rights (1948), Public Health Accreditation Board- Standards and Measures (version 1.5) , review articles, case studies,..etc were included.

During in-depth interview, public health professionals opined about overall limited knowledge regarding ethical issues in public health practices and suggested the need for updating curriculum and in-service training of public health staff on ethics and public health. Participants stated multiple issues that pose ethical dilemma while delivering the core public heath functions and highlighted most likely reason for the same. The most common issues shared by participants was individual choices versus community goods while implementing public health functions like disease notification, isolation and quarantine.

**Conclusion**: The public health ethics need attention similar to ethics in biomedical research, research ethics or good clinical practices . As public health sector deals with masses, every public health action/intervention/program/function/policy should to be comprehensively reviewed from ethics standpoint. The proposed framework and mechanism may assist to foster an environment and culture that supports, develops & inculcate ethical practices.

**KEY WORDS:** Public health, Ethical dilemma, Review, Framework

**INTRODUCTION:**

Public health is the art and science of preventing disease, prolonging life and promoting health through the organized efforts of society (1). Its primary aim is to promote and protect people’s well-being through various interventions aimed at individual, society, environment and policy levels. This would make a positive impact upon health, promotion of greater health equity and protection of citizens from threats to health (2). Health is primarily a matter of individual choice; however, ‘*Public health’* is mostly the government’s responsibility at various levels viz. local, state and national (3, 4).

In bioethics, much emphasis is on individual rights, however, the majority of public health functions, such as *surveillance, disease notification, contact tracing, isolation, quarantine* may infringe the core ethical principles to benefit the larger community. Principles of bioethics in public health practice are challenging to follow, often due to conflict between individual autonomy and government’s responsibility to ensure promotion and protection of health of population. Therefore, an ethical justification for a public health program, function or intervention is needed before it goes live or implemented. Several frameworks for ethical review of the biomedical research are available, however, they provide limited practical directions to address ethical dilemma of public health program or intervention (3-7).

This research paper aims to fill this gap by reviewing the existing frameworks, guidelines and recommendations and proposing a framework that may act as a handy tool or a roadmap for scrutinizing the public health programs from the ethics perspective particularly in the context of India and low-income countries.

**METHODOLOGY:**

We started with a systematic review of literature related to ethical review of public health programs and research. In-depth interviews of public health professionals were conducted to get their viewpoint. Finally, a framework is developed through a collaborative process.

**Systematic literature review -**

This was carried out to comprehend the existing frameworks and mechanism for the ethical review of public health programs. The databases like Pubmed, Medline, Scopus, EMBASE, Google scholar were searched. A systematic search strategy was developed, which consisted of following search terms and phrases - Public Health, Ethics, Ethical declaration, Ethical Framework, Public Health Research, Public Health Institutions, Ethics in Public Health education. We reviewed key documents such as UN declaration(1942)8, Helsinki declaration (1964, amended 2013)9, APHA 2002 Declaration10, Universal Declaration on Bioethics and Human Rights (October 2005)11, Universal declaration of human rights (1948)12in addition to other literature to understand various provisions for ethical standards and guidelines for the biomedical and public health interventions.

**In-depth interviews -**

Interviews were conducted with public healthcare authorities, academicians, researchers, community stakeholders, NGO representatives, members of Institutional Ethics Committee etc. The objective of the in-depth-interviews was primarily to get familiar with the issues and situations in public health practice that pose the ethical dilemma and are not addressed under the current guidelines. Secondly to assess perception of public health professionals regarding the need for a standard framework which can resolve the ethical dilemma and facilitate decision making while practicing public health. Total ten interviews were conducted in English language. An ‘In-depth interview guide’ included points such as:

1. What are the situations or circumstances within public health practice that leads to an ethical dilemma and why do you think they pose such challenge?
2. Where do you think, we could find for resources that may offer possible solutions for ethical challenges in public health programs or interventions?
3. Do the public health programs need to be ethically reviewed? If yes, what should guide the review process?
4. Who or what agency you think is appropriate to review such proposals? What could be the responsibility of civil society and community members in such process?
5. Does ethical review of public health intervention/function/program may have any implications on program implementation and health outcome? If so, what could be the possible implications?
6. What are your views regarding the incorporation of ethics in public health education?

**Framework for ethical review of public health programs**

From literature review data was extracted and entered in a matrix prepared for the study. It was later reviewed and the quotes/points relevant to specific search items was placed under the corresponding tab like ethics/public health, ethics/declarations, ethics/research, ethics/public health institutions, ethics/framework. Overview of strategic frameworks, declarations and documents was undertaken and presented in the result section.

Recordings of in-depth-interviews were first transcribed. Two independent observers read the interview transcripts. Transcripts were analyzed and key themes related to ethics in public health practice and research were identified.

Finally, findings from systematic literature review and in-depth-interviews were triangulated to propose a framework for ethical review of the public health program and interventions. The framework was aligned with the core public health functions and it provided the opportunity to ponder over the individual rights versus community goods while planning and implementation of a public health program or intervention.

**RESULT:**

**Systematic Review of literature:**

Total 86 documents were assessed, out of which 22 were found relevant and included in the study. It included Journal articles, frameworks for ethical review, reports, book chapters, declarations. All these documents were reviewed thoroughly. Most of these documents serves as broad guidelines for ethical review and not as a code of conduct or guiding principle for ethics in public health practice. All frameworks/guidelines highlighted the importance of aim & objectives of the public health interventions and its relationship with the overall goal of public health is to reduce morbidity and mortality, promote health and improve the health outcome of community. We presented below some key framework / guideline with their salient features that aligns with the objective of this paper.

**Framework of Public Health in US proposed by Nancy Kass** (**2001**)proposed an analytic tool with a set of six questions for decisions regarding balancing the risk and benefits of public health programs. The author provides a description of relevant ethical considerations around those six issues. The framework addressed values of public health, including responsibility of government to promote positive health of community and minimizing social inequalities. Paper also deals with issues of ethical burden on individual or community, like challenges for privacy and confidentiality, autonomy, and justice (3).

**Framework on Public Health ethics in USA by Childress *et al* (2002)**, attempted to balance conflicts between promoting of public health and other moral values. The paper provided a conceptual framework for public health ethics and addresses nine general moral considerations in public health ethics. Initial three moral values reflect the goal of public health and remaining are in line with the principles of maintaining the confidentiality and trust versus mistrust. The framework defined the degree of protectiveness of public health interventions and coercive intervention in behavior (8).

**European framework on public policies, law and bioethics** **(2006)** provides guidance for developing public health policy, public health programs and their implementation across the European Union. It provides an approach to analyze the conflict between individualistic approach and community interests. The paper provides analysis of attitudes of a community on topics like parental rights, incentives & enforcement, solidarity, rights and responsibilities. The framework proposes three primary goals - promotion of population health, promotion of health-related autonomy and promotion of health-related equality (9).

**Nuffield Council on Bioethics framework (2007)** addressed public health ethics issues for policymakers in government, industry, other organisations and individuals. It proposes two analytic tools, the first one is *'stewardship model'* that describes acceptable goals and restrictions for public health policy. It emphasizes on achieving desired health outcomes while keeping limitations on people's freedom to a minimum, special focus on consent and care of the vulnerable. The second tool, an *'Intervention ladder'* lists levels of invasiveness of public health policies on individual choices, indicating ‘stronger justification’ for a intervention / program with “higher” the position on ladder (6, 10)**.**

**Framework by Tannahill (2008)** provides guidelines for decision making whether or not to implement an intervention by describing the position of evidence and ethics. The framework consists of a 'decision-making triangle' with ten ethical principles on top, and evidence and theory as the base. The paper mentioned that the use of proposed framework will contribute to the values around accountability, transparency and openness (11).

**Principles of the ethical practice of public health (2002) by public health leadership society**, provides a ‘code of ethics’ for public health institutions. This was adopted by ‘American Public Health Association’. The framework consists of a set of ethical principles which include – ‘fundamental causes of disease and prevention of adverse health outcomes; achieving community health while respecting the rights of individuals; public health policies, programs, and priorities developed and evaluated with community participation; advocacy for and empowerment of vulnerable community; evidence to implement effective policies and programs to protect and promote health; public health institutions should protect the confidentiality of information and ensure the professional competence of their employees; public health professional to engage in collaborations in ways that build the public's trust and the institution's effectiveness; to provide communities the information needed and obtain consent for them for implementation; public health programs and policies should incorporate approaches that anticipate and respect diverse values, beliefs, and cultures in the community; should be implemented in a manner to enhance the physical and social environment’ (12, 13).

**World Medical Association’s Declaration of Helsinki** (1964, amended 2013), emphasized privacy and autonomy of individual, informed consent, providing rationale research and scientific benefits, adopted scientific approaches, benefits of intervention outweigh harms, protecting control group, balancing the individual well-being versus those of science and society (14).

**Universal Declaration on Bioethics and Human Rights dated 19th October 2005** (Article 27) highlights on limitations for the application of these principles only by law. It includes laws in the interest of public safety, protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law (15).

**Universal declaration of human rights (1948),** article 25mentioned that ‘each person has right to a standard of living which is necessary for the health and well-being of himself and of his family, including food, clothing, housing, medical care and necessary social services etc’. As per article 30, ‘for any state, group or a person, nothing in this declaration may be interpreted as implying any right to engage in any activity or to perform any act aimed at the destruction of the rights and freedom set forth herein’ (15) (16).

**Public Health Accreditation Board, Standards and Measures (version 1.5; Measure 11.1.2 A)** talks about identifying ethical issues and making ethical decisions. These measures are useful to assess health policies and its implementation to identify and address ethical issues around public health programs / interventions (17).

**Barrette D H *et al*** (2016)presented case studies from ethical viewpoint for public health practitioners at all levels and across all public health functions. These case studies demonstrate and provides learning to incorporate critical analysis from ethical perspective in public health practice. Case studies also highlighted that clinical and research ethics do play a role but are not sufficient for ethically review the public health programs or interventions and therefore suggested the need for framework for ethical review of public health program with careful consideration of individual autonomy and public interests (18).

**In-depth interview:**

Public health professionals opined that overall they have limited knowledge regarding ethical issues in public health practices and suggested the need for updating curriculum and in-service training of public health staff on ethics and public health. Participants stated multiple issues that pose ethical dilemma while delivering the core public heath functions and highlighted most likely reason for the same. The most common issues shared by participants was individual choices versus community goods while implementing public health functions like disease notification, isolation and quarantine. This issue is important for diseases that have stigma, discrimination in community like Tuberculosis, HIV / STI, Leprosy.

Interview revealed that public health professionals lacks necessary knowledge and skills to make appropriate decision by balancing risk *versus* benefit of public health program. They often depend on a variety of moral values, societal values, individual perceptions or discussion with their colleagues/peer/guide or law & policy document for their decision-making.

Many other public health functions and decisions, such as equitable distribution of resources, reaching to the most vulnerable and ensuring equity, negotiating political interference in resource allocation, multiple and conflicting responsibilities, engaging with community in making decision, and cost versus benefit analysis…etc, pose challenges while planning and implementing public health program. Participants mentioned that the policies and implementation guidelines addressing these functions needs to undergo critical appraisal from ethical viewpoint, before passing it off to the district or peripheral level for implementation.

The most common reasons for lack of rigorous scientific scrutiny of public health interventions or programs for ethical issues as highlighted by respondents were lack of awareness & inadequate training in bioethics and public health ethics; Non-availability of framework for ethical review of public health programs/functions or interventions especially in developing countries; Absence of a standing mechanism and/or committee to review public health programs and top to down approach for policy/program designing, decision making and implementation.

**Proposed framework for ethics review of public health program:**

We proposed following critical issues that needs deliberation while reviewing the public health program, functions, intervention or public health research from the ethical viewpoint.

Table 1: Framework for ethics review of public health program in Indian & LMIC context

|  |  |  |  |
| --- | --- | --- | --- |
| **SN** | **Parameter** | **Key questions to consider?** | **Description** |
| 1 | Relevance | What are the goals of the proposed public health program / intervention / research? | Public health program or functions may not be implemented in silo and needs to align with the overall goal of proportionately improving core health indicators and promoting the wellbeing of the population. There needs to be enough justification and significance for a proposed public health program / research. |
| 2 | Effectiveness | Are goal and targets of the proposed public health program achievable?  How effective is public health program in achieving its stated goals? | Does the program / intervention is backed by evidence for problem in question? These evidences need to be appropriate for the specific context. Are laws and regulations otherwise relevant? |
| 3 | Benefits and potential harm to population | What are the expected benefits of program / intervention to the target population?  What are the possible burden or harm of public health program?  Are the potential benefits of the action justified? | Public health interventions, especially targeted interventions may segregate community groups and pose the risk for stigma and discrimination, such as sex workers, IDUs, patients of Leprosy, HIV infections etc. Targeted intervention may be cost effective strategy; however, the risk of stigmatization and discrimination need to be assessed and compared to benefit prior to launching such interventions. |
| 4 | Alternative approaches | Can burden be minimized?  Are there alternative approaches?  Are there enough justification or evidence for proposing the specific public health action? | Careful consideration and analysis of alternative approach or actions for public health problem may lead to an acceptable option that can be justified ethically  Interventions should be advocated based on facts and not just belief. |
| 7 | Autonomy | How does the intervention affect the autonomy of the individuals in target population?  Does the public health action respect professional and civic roles and values? | The critical question that public health program needs to address is how to make the particular public health function less restrictive and minimal intrusive?  Many public health functions, such as Notification, Isolation and Quarantine may pose challenge to individual rights, however for the larger public good, they need to be supported by the appropriate law.  For making a decision to implement these programs, public health professionals need to balance the benefit of these program with the risk they lead to individual autonomy. |
| 8 | Impartiality, Equity and Equality | Is it possible to fairly implement the public health program?  Are benefits and risks of a program balanced? | Potential benefits and harms to be distributed fairly, with legitimate representation of vulnerable community  Equitable distribution of resources irrespective of social, ethnic, regional variations is critical for public health system to function optimally. Resource allocation needs to be backed up by evidence and scientific data, incentives and disincentives policies such as conditional cash transfer.  Interventions may get adapted to extend the benefits to vulnerable and needful population, avoid unnecessary wastage of resources that ensure equity in access and distribution of resources. |
| 9 | Ethics and data | Are public health data collected ethically?  Was informed consent was taken?  How the data security and confidentiality issues are addressed? | Ethical principles have great importance in confidentiality, security, and access to patient records. The public health program or interventions needs to specify the methods and approaches of data collection, data handing, data storage and data security.  Other key issues that needs clear mention in the public health program proposal/ operational guidelines are methods or approaches for ensuring confidentiality of information collected from community, developing guidelines for data sharing, ownership of date, data quality and maintaining transparency in data handling |
| 10 | Cost invested and opportunity cost | What is the cost and opportunity cost of intervention? | All public health functions / interventions incur cost and pose burden on existing scare resources. The review needs to address the critical question if the cost of intervention is justified in terms of the short- and long-term benefit for society and individual. |

**DISCUSSION:**

Many public health programs pose challenge to the core principles of bioethics and therefore require a different approach (2, 3, 19, 20). An ethics analysis may bring out fairness, respect and relevance of public health program and improve validity to public health interventions / programs.

The study highlights critical concerns for lack of systematic ethical review of public health interventions or programs. These includes lack of awareness and training of public health practitioners regarding the core ethical principles, lack of structured framework or guidelines for ethical review of public health programs/functions/interventions, and lack of institutional mechanism for the same.

Creating awareness and capacity building of public health professional in ethical reasoning of public health programs / functions is critical. This may be done through in-service training of public health professionals. Such programs should focus on creating awareness and enhancing ethical quotient in addressing the range of ethical conflicts they come across in their practice (21, 22). Adoption of case-based approach for brainstorming & thought-provoking discussions on various case scenarios depicting the routine ethical challenges faced by public health professional may contribute to significant capacity building.

At present, ethics incorporation in curriculum of public health academic program is variable across courses and institutions, and grossly inadequate (21, 22). Ethics education in the form of structured module and credits needs to be an integral part of curriculum of educational programs in public health.

Considering key themes that emerged out of in-depth interview of the public health professionals and review of guidelines / frameworks by other authors, we proposed an outline for ethics review of public health program for Indian context. The proposed framework need not be considered as a code of ethics in public health (Table 1). This may be viewed as an analytical framework, guiding the public health professional to consider the ethical implication of public health program, policies, interventions or public health functions. The level of ethics review of public health programs needs to be proportionate to the degree of risk or harm to individuals and communities.

Institutionalizing the entire process of review is critical for effective and fair implementation of ethical review process of public health program. These mechanisms may be in the form of government accredited review board. It can be standalone or independent review board, or the existing review board may create a subcommittee for the review of the public health program from ethical viewpoint.

Ethical review of the public health programs or functions may serve as a tool to enhance credibility of public health functions and therefore increase its chances of uptake and coverage. The other potential benefits may include:

1. Program may get molded as per actual situational context and therefore more likely to be accepted by the community.
2. Public health program will be all inclusive and may get adapted to extend the benefits to vulnerable and needful population, avoid unnecessary wastage of resources that ensure equity in access and distribution of resources. The process shall minimize the risk of marginalization or stigmatization of the vulnerable population.
3. Public health programs / interventions align well with countries overall goal of reducing the morbidity and mortality and thereby improving the lives of people / community.
4. Risk analysis, cost analysis may help to allocate the scare resource to best possible use for public good.
5. The issues of restriction of individual autonomy may be minimized.
6. Role of civil society and community members in the process of planning and delivery will further enhance the trust of community in public health system.

**Conclusion**: The public health ethics needs attention similar to ethics in biomedical research, research ethics or good clinical practices. As public health sector deals with masses, every public health program or policy may influence significantly to population and therefore should be comprehensively reviewed from ethics standpoint. The proposed framework and mechanism may assist to foster an environment and culture that supports, develops and inculcate ethical practices. Raising awareness and capacity building of public health professionals around public health practice and ethical issues

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