

such general guidance has served well in the determination of potential risks and benefits (which to this day have not been converted to an exact measurement of a net risk-benefit ratio), it would serve to determine a just compensation for a life lost or disabled. It has the potential to make ECs more meticulous in their engagement with research protocols. In the long run, one hopes that it would serve us to make death or disability due to clinical trial very rare for a participant.

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## Good epidemiology, good ethics: empirical and ethical dimensions of global public health

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#### Abstract

*This paper examines the following ethically and epidemiologically relevant challenges, as yet neglected in public health ethics: how to distribute resources and health risks and benefits, how to define evidentiary criteria that justify public health interventions, and how to define terms in which programme goals, successes, and failures will be assessed and monitored. We illuminate critical intersections of empirical and ethical dimensions of public health work, drawing upon three global public health interventions— inclusion of the Hepatitis B vaccine in the Universal Immunisation Programme, Universal Salt Iodisation, and the Global Polio Eradication Initiative—and suggest strategies for addressing and responding to them.*

#### Introduction

We draw upon three national public health programmes in India—the inclusion of the Hepatitis B vaccine in the Universal Immunisation Programme, Universal Salt Iodisation (USI), and the Global Polio Eradication Initiative (GPEI)—to explore critical intersections of epidemiology and public health ethics that can be applied to new public health initiatives and ongoing projects throughout the Asian subcontinent and the world.

The first of these programmes, the inclusion of Hepatitis B vaccine in the Universal Immunisation Programme, has been introduced in several phases in India. It is too early to see the influence of this programme on health outcomes in India, but

one success is worth mentioning. The high cost of the vaccine was a major criticism of universal Hepatitis B immunisation in India; government support and increased production by local manufacturers have resulted in dramatic cost reductions of the vaccine (1). In public health, critical debates continue about whether Hepatitis B inclusion in the Universal Immunisation Programme is justified; in what follows, we focus particularly on questions about the role of epidemiology in ethics and policy decision-making that Hepatitis B vaccine inclusion raises.

The second programme, USI, is implemented worldwide and has sought to correct iodine deficiency in pockets of populations with goitre. India has seen a steady decline of neonatal hypothyroidism (2), but the rise of thyroid pathologies continues to raise important epidemiological and ethical questions we will explore here.

Finally, the GPEI has been one of the most visible public health programmes. Its success in India is marked by India's removal from the list of countries in which polio is endemic. We analyse a few of the most prominent ethical questions raised by the GPEI and suggest possible applications to other elimination or eradication programmes. Measles elimination, for example, is being pursued by the World Health Organisation (WHO) and member-countries on a regional basis. Four regions have attained the goal of elimination, including countries of the Western Pacific by 2012. Africa has a pre-elimination plan, and in the South East Asian region, including India, measles elimination is becoming a priority (3). We suggest several ways that new public health initiatives and ongoing public health projects can benefit from the inquiry we launch here.

### **Background: epidemiology in public health ethics**

Epidemiological approaches to gathering data, monitoring incidence and prevalence of disease, and assessing outcomes of population-based interventions have traditionally been acknowledged as central to public health. The need for integrating epidemiology into population-based perspectives of health and public health practice cannot be overemphasised (4). Some interventionist approaches tend to ignore the broad-based understanding of health determinants and can, thus, be ill-equipped to motivate rigorous responses to important questions about health justice and community well-being (5).

The contemporary dominant paradigm of clinical epidemiology, which seems to be most influential in informing current public health policy, is defined as "the science of making predictions about individual patients by counting clinical events in groups of similar patients" (6). This paradigm tends to focus narrowly on individuals and interventions. In contrast, "traditional" epidemiology and population-based perspectives of health and well-being tend to more fully acknowledge broader questions of ethical and epidemiological relevance. For example, important tensions within epidemiological research include whether and when to adopt biomedical/clinical or social approaches to studying health, when to adopt broadly integrated or specialised intervention strategies, and how to determine when and how investigators should initiate research.

Another important tension relates to reconciling community members' and epidemiologists' perceptions of what constitute the most important needs in a community (7). These tensions illuminate significant ethical questions about the goals and methods of empirical work in epidemiology. Consideration of those questions informs our analyses of whether, when, and in what manner studying the social, cultural, geopolitical, environmental, economic, and other population-based dimensions of illness and loss of life become and persist as global public health priorities.

Major ideas, concepts, and principles from ethics have been widely applied to clinical practice and biomedical human subject research for several decades. Interestingly, despite the fact that public health interventions and programmes involve sizeable populations, ethics in public health is a relatively new area of academic and policy interest. Generally, most current public health ethics literature tends to incorporate communitarian approaches to concepts such as "common good", which require critiques of autonomy-oriented ethics paradigms more prevalent in clinical, individualist approaches to health. Autonomy-oriented approaches tend to have grown from liberalist traditions of justice theory firmly ideologically committed to individualism (8-10) and are, thus, well-suited to clinical frameworks of thinking about health. Because of the recent and present dominance of individualist rather than population-based approaches to health in wealthy, acute-care-driven healthcare systems, the relationship between epidemiology and ethics has not yet been considered in the bioethics literature with the prominence it deserves. Greater consideration of this relationship enables scholars and practitioners of public health to think more powerfully about health justice and to more effectively relate health justice goals to improvements in public health policy, research, and both population-based and clinical outcomes for under-served and marginalised populations.

Bioethics graduate programme curricula often include the useful publication *Ethics and Epidemiology* (11), but even this text shies from interrogating epidemiological evidence of racial/ethnic inequalities, lack of parity between health services for physical versus mental illnesses, and other kinds of health justice questions. The Public Health Leadership Society has published *Principles of the ethical practice of public health*, which acknowledges several important values at the core of public health ethics. This document suggests that the critical role of epidemiology in public health practice includes collecting, responding to, and offering health information, promoting health, and addressing sources of health risks as key features of ethical practice (12). Like other current public health ethics literature, however, it stops short of formally acknowledging epidemiology as critical for responsible public health practice or publicising the importance of good epidemiology in just and ethical public health policy formulation.

Population-focused epidemiology emphasises social determinants to understand health trends more than biological frameworks and is now more frequently embraced

in clinical epidemiology (13). A historical transition in the use of the term “primary care” is also worth considering as a possible explanation. The concept of “primary care”, sometimes also called “primary level care” has become a clinicalised distortion of the Primary Health Care (PHC) doctrine, which was adopted in 1978 by WHO member states to establish inter-sectoral, community-based, and collaborative health services in response to health injustices of inequalities in health status and access to health services. Because the PHC doctrine was criticised by some as too ambitious, too idealistic, and unresponsive to specific causes of death, particularly of children (14), about a year after its adoption, it was replaced by a revised doctrine called Selective Primary Health Care (SPHC). PHC was re-christened “Comprehensive Primary Health Care” and SPHC emerged as a narrower, technology-centred approach to health (15), implicitly diverting attention from the development of broad-based, comprehensive, and integrated health services that seek to respond to the social determinants of health (16). The currently dominant doctrine prioritises acute-care-driven medicine and its focus on biomedical and pharmaceutical technological innovation over public health-driven, population-based perspectives of health and well-being.

### **Ethically relevant current trends in epidemiology and public health**

One consequence of this current paradigm is a tendency among clinicians and contemporary public health programmes to disproportionately value interventions such as vaccines, micro-nutrients, insecticide-treated bed nets, and contraceptives that are easily packaged discrete entities. These specific interventions have their uses, but over-reliance on them can lead to oversimplification of multi-causal health problems, which might be more fully assessed from population-based epidemiological, rather than clinical interventionist perspectives.

A related issue is the emergence of a trend to fund global health programmes with specific interventionist initiatives, such as the Global Alliance for Vaccines and Immunisation (GAVI), rather than programmes seeking to influence the social determinants of health or those focusing more broadly on systemic, multi-factorial problems such as water sanitation and hunger. An increase in the number and variety of players in global healthcare seems to have also prompted a shift in power, particularly in the role of technical leadership from WHO and other organisations (17). This shift suggests the emergence of opportunities for collaborative leadership among those organisations, public health practitioners, and scholars in public health ethics. For example, values presupposed by different public health strategies can be explicitly acknowledged, scrutinised, and compared to help canvass the merits and drawbacks of several possible responses to public health crises. Public health practitioners and ethics scholars can also consider how changes in financing might track changes in values presupposed by public health programme goals and outcomes.

Another important trend is that public health programmes are now more frequently international and have administrative and funding structures that are centralised; one example is

the “Three Ones” in the HIV/AIDS programme: “one action framework, one national coordinating authority, one monitoring and evaluation system” (18). Centralised funding is due, in part, to the infusion of significant capital (via philanthropist organisations such as the Gates Foundation, for example). These programmes often place a sharp emphasis on standard operating procedures for intervention implementation and less emphasis upon contextual factors, such as social determinants (19). The growth of international/global health as an academic discipline, with its strong bias in favour of narrower, technology-centred approaches to health, complements this trend. The growth of health informatics also tracks the growth of international/global health as an academic discipline, and enhances monitoring and surveillance of public health projects across the globe.

From an ethics and justice point of view, there are reasons to be cautious about centralisation that is motivated by corporations. Corporate influence in public health and corporatisation of government structures can lead to the weakening and isolation of critical local public health leadership (20). Additionally, the financial weakness of developing countries relative to the financial strength of philanthropists (typically from western, developed countries) is also ethically significant. When developing countries lacking wealth are unable to fund public health programmes, support for such programmes becomes more centralised and perhaps too dependent upon philanthropy. From a post-colonialist bioethics view of justice (21), an empirical question for public health organisations and practitioners is whether, when, and how philanthropic financing disproportionately influences the goals of public health projects or reifies western, white hegemony in developing countries.

### **Intersections of epidemiology and ethics in three public health projects**

Because epidemiological approaches to health are always context-specific, they are frameworks well-suited to aid ethical analysis, in both developed and developing societies, of public health problems and programmatic responses. Three global public health interventions—the inclusion of the Hepatitis B vaccine in the Universal Immunisation Programme, Universal Salt Iodisation, and the Global Polio Eradication Initiative—illuminate key challenges of ethical and epidemiological relevance that have not yet been studied in the public health ethics literature: decision-making about distributions of health risks and benefits, developing evidentiary criteria for when public health interventions are justifiable, and defining the terms that will be used to assess and monitor programme goals, successes, and failures.

### **Decision-making about resource allocation and distribution of health risks and benefits**

#### ***The case of universal immunisation with the Hepatitis B vaccine***

The case of universal immunisation with the Hepatitis B Vaccine raises some important empirical and ethical

questions related to setting public health priorities and publicising project goals, risks, and benefits. The WHO recommended that, by 1997, the Hepatitis B vaccine should be included in national immunisation schedules (22). In a later document, the WHO emphasised that the vaccine should be an “integral part of the national immunization schedule [and] should be the highest priority in all countries” (23). Because of low endemicity of Hepatitis B, several countries chose not to include the vaccine in their national schedules (1), however. The traditional marker for the Hepatitis B virus (HBV), the Hepatitis B surface antigen, can vary throughout populations of states or regions within a country.

European countries, in particular, were divided in their opinions about universalising the vaccine. The United Kingdom, for example, decided only to screen all pregnant women and vaccinate at birth only babies of women who tested positive for the virus (24). A concern about this approach is that some communities in a country with low endemicity can actually be at higher risk than national endemicity rates suggest. If a country with low endemicity chooses not to follow the WHO recommendation, populations at higher risk could be denied a necessary vaccine. Alternatively, some states or regions within a country might have high endemicity, which can skew the national average to suggest that a policy of universal immunisation is necessary for an entire country when it might not be.

Variability among endemicity rates within countries suggests a need to categorise endemicity rates by state or region, rather than by country, while avoiding the stigmatisation of particular communities. If immunisation schedules are based upon measurements that inaccurately represent actual specific needs, and if resources are committed to communities with less need and not committed to those with significant need on the basis of those schedules, then the lack of acuity in how endemicity rates are labelled (25) can be a source of moral hazard.

But the ethical questions in this case are not just simply questions of access; they are also about the distribution of health risks and benefits within a society. Good health policy and ethics decisions about the distribution of risks and benefits of a particular project depend upon ongoing collection of good data and reliable, accurate representation, and perhaps, wide circulation of that data. In the absence of reliable epidemiological data, an epidemic may be labelled as “silent” and therefore assumed to be large. In India, for example, it has been generally claimed that 25% of chronic HBV carriers die of hepatocellular carcinoma, but actual data suggest this figure is actually 3.1% (26). Similarly, reliable interpretations of death rates due to chronic liver disease are limited by lack of epidemiological data about alcohol-related causes of hepatic pathologies (27). The smaller data figure, or a lack of data altogether, makes it harder to justify public health interventions for hepatocellular carcinoma.

A need for balancing effective vaccine administration strategies with optimal vaccination outcomes also suggests important empirical and ethical questions related to risks and benefits.

For example: What are effective public health leadership strategies for identifying short-term and long-term risks posed by “silent” epidemics exacerbated by social or cultural taboos, stigma, or lack of reliable epidemiological data? In the absence of good epidemiological data or in the presence of data suggesting a small incidence, which other criteria, if any, can be used to justify interventions? Which anthropological factors need to be accounted for while considering whether a programme is easily integrated into the social and cultural life of a community? Which strengths and weaknesses of a community’s infrastructure and local health service system can be identified?

The Indian immunisation schedule introduced the Hepatitis B vaccine more than a decade ago and synchronised it, to aid public access to it, with the diphtheria, pertussis, and tetanus (DPT) schedule. But, a birth dose of Hepatitis B vaccine was not part of this schedule, despite the fact that peak transmission of Hepatitis B is during the intra-natal period, and despite the fact that the costly Hepatitis B vaccination programme is far more effective when administered at or within 24 hours of birth (27-29). Considering the increased risk to newborns not immunised at birth, ethical questions can certainly be raised about the birth dose not being included in the Indian immunisation schedule until after the schedule was introduced. Vulnerability of the specific population at risk might be one criterion that could be useful, in future public health practice, for weighing ease of administration of a vaccine against optimal timing of administration.

Ethical questions that can be used to guide collaborative deliberation about the kinds of issues raised by this case have to do with which features of a programme’s administration and leadership influence whether it will be sustainable and effective. For example: According to which criteria ought the severity of an illness, urgency of a health risk, or variations in rates of infection in different communities be assessed? Additionally, how ought it be determined whether, when, and which resources should be devoted to population-based health programmes? Who ought to participate in making such determinations? It can also be worthwhile to consider: Which criteria (programmatic ease, risk to vulnerable populations, or other factors) should be used to prioritise interventions? Finally, what are socially and culturally appropriate ways for building consensus to implement health change in a community, particularly when using new interventions related to illnesses with social stigma? In this and other cases, the practice of inviting and integrating a plurality of perspectives lends credibility to programme designs and maximises opportunities for transparency and trust among public health workers and community members.

## **Development of evidentiary criteria that justify public health interventions**

### ***The case of universal salt iodisation***

In 2005, the WHO reported an increase in prevalence (30) in developing countries of goitre —enlargement of the

thyroid gland—and recommended continuation of universal iodisation (a global programme involving about 130 countries) to combat hypothyroidism due to iodine insufficiency. In other countries, however, USI has led to increases in hyperthyroidism. In response, some countries (including the US) (31) decreased recommended iodine intake amounts.

Consumption of processed foods, widely available in the developed world, in addition to consumption of iodine in common table salt creates a danger of iatrogenic hyperthyroidism. A policy of universal iodisation promotes “forced inclusion” (32) of euthyroid (normal) individuals, who are subject to excessive iodisation and, thus, at higher risk for thyroid disorders due to excessive iodine intake, including hyperthyroidism and iatrogenic thyroid autoimmunity (33, 34). So, one important ethical and epidemiological challenge for USI is balancing the benefits of sufficient iodisation against the risks and harms of excessive iodisation. Such a balance might not be achievable through universalisation, but it may be possible through efforts targeted to respond to the needs of particular populations.

Interestingly, the prevalence of goitre has not changed remarkably even after universal iodisation. One reason for this is that goitre, as a clinical indicator, suggests a range of hypothyroid disorders not necessarily due to iodine deficiency. In India, for example, the prevalence of goitre varies in different states and ranges from mild to moderate in severity from both clinical and epidemiological perspectives. One review suggests the incidence of goitre is inflated because goitres that are palpable but not visible can be euthyroid (31). Though there are pockets of nutritional iodine deficiency in India and Bangladesh, goitre alone is not a reliable enough indicator of hypothyroidism (35). Another puzzling finding from a recent Indian study is the high prevalence of goitre, despite iodine sufficiency (36). This study documents cases in which iron deficiency coexists with the presence of goitre. If iron deficiency is confounding, the entire USI intervention programme might be based on insufficient epidemiological understanding of thyroid disorders.

Empirical questions to ask in this and similar cases have to do with which scientific findings merit revising key concepts used to articulate programme goals. For example: Are criteria for what constitutes a case of a disease clinically-based (on symptoms) or biologically-based (on virology, cytology, or pathogen behaviour, for example)? Which methods of surveillance validate or certify goal achievement? Other areas of ethical and empirical consideration in this case relate to defining key terms and criteria that define benchmarks in long-term global public health initiatives, particularly those related to the conceptual and practical relationships between programme policies and guidelines, and health workers’ capacities to accurately assess and respond to individual needs. For example: What are conceptual and practical relationships between programme goals and scientific findings? When is it appropriate to characterise epidemiological data as hypothetical (in estimated numbers of cases, for example)

versus actual (as in real, reported cases)? When and how ought community oversight, monitoring, and auditing be formally built into programme performance criteria? Finally, for this case and cases like it, pertinent public health ethics inquiry would consider what threshold of epidemiological evidence should be required to justify the allocation of scarce resources to global public health initiatives.

## **Defining and monitoring programme successes and failures**

### ***The case of the Global Polio Eradication Initiative***

In 1993, the International Task Force for Disease Eradication met to evaluate infectious diseases as potential candidates for eradication and elimination. Later in 1997, the Dahlem Workshop on the Eradication of Infectious Diseases was convened to strategise and define the terms “eradication”, “elimination”, and other related epidemiological concepts. Though these two terms are often used interchangeably in both scientific and popular discourse, the Dahlem assembly clearly defined each. Eradication was defined as “permanent reduction to zero of the worldwide incidence of infection caused by a specific agent as a result of deliberate efforts; intervention measures are no longer needed” (37). In other words, eradication entails the cessation of all infection and of all public health programmatic activity devoted to cessation; for example, smallpox is eradicable. By contrast, elimination was defined as “reduction to zero of the worldwide incidence of infection caused by a specific agent in a defined geographical area as a result of deliberate efforts; continued measurements to prevent re-establishment of transmission are required” (37). Measles and poliomyelitis were considered candidates for elimination (37). Despite this classification, GPEI collaborators—led by the WHO, the United States Centers for Disease Control and Prevention, the United Nations Children’s Fund, and others—seem committed to polio eradication.

The most important feature of the GPEI strategy is administration, during national immunisation days, of supplemental doses of Oral Polio Vaccine (OPV) to all children under five years of age; the goal is to rapidly interrupt polio transmission (38). A critical challenge with an OPV-based campaign, however, is that OPV has important iatrogenic risks; it can cause Vaccine Associated Paralytic Polio and Vaccine Derived Paralytic Polio. So, the narrow focus on “wild” virus, instead of the paralytic disease of poliomyelitis, is ethically troubling. With iatrogenic and mutant viruses causing the same symptoms as those caused by wild poliovirus, it seems reasonable to assume it makes no difference (from the point of view of a child paralysed by polio or parents of that child) whether the virus causing the symptoms is wild, vaccine associated, or vaccine derived.

The WHO’s 2005 publication of *Cessation of Routine Oral Polio Vaccine (OPV) use after global polio eradication* lists the term ‘post eradication’—a contradiction according to the Dahlem definition—as a header on the GPEI website (<http://www.polioeradication.org/>). This seems to acknowledge that OPV-

based approaches can achieve elimination, but not eradication (39), even when detection of paralytic cases due to wild poliovirus is zero.

In response to what might appear to be refinement of Dahlem's concept of eradication, Dr Jacob John, a key figure in the GPEI, has proposed use of the term "true eradication," "zero incidence of infection with wild and vaccine viruses" (40). One might wonder why the GPEI doesn't just use the term elimination. The Pan American Health Organisation and Rotary International, key players in a coalition against polio in the Americas, for example, use the term "elimination" to define their achievements. A 2009 article in the *American Journal of Public Health* suggests that Dr John Sever, Rotarian, infectious diseases chief at the National Institutes of Health, and colleague of Albert Sabin (developer of the OPV), "proposed going further and aiming for the eradication of polio by 2005" (41), the year of Rotary International's centennial. It is not clear whether the adoption of the goal of eradication was motivated by an impulse by leaders in polio research to commemorate the presence and accomplishments of a large non-state player. But it is clear that eradication was endorsed at the highest level of state engagement in public health, the World Health Assembly. It is well worthwhile to question, from an ethics point of view, whether emphasis on the term "wild" and use of the term "eradication" is appropriate in an OPV-based strategy, given the nature of polio and the risks of iatrogenic harm from OPV.

A few key empirical questions related to this case have to do with: What makes the definition of a key concept (such as control, elimination, or eradication) complete? Also, what are significant differences among clinical, epidemiological, and political perspectives of health research? Which procedures are in place for managing the conflict that can arise from these differences when defining programme goals? What are best practices for collaborative, inter-sectoral, and cross-disciplinary work in public health? Ethical questions in play prompt us to wonder who ought to be regarded as authoritative definers of key concepts and criteria in public health. And how ought programme successes and failures be represented to community members who do not have clinical, epidemiological, or political expertise? Additionally, how ought clinical, epidemiological, or political experts interact with members of the public or the media to represent and publicise an intervention's risks and positive and negative programme outcomes? The cross-disciplinary nature of public health work also prompts us to consider the nature and scope of the roles of clinicians in defining epidemiological and political goals, of epidemiologists in defining clinical and political goals, and of policy experts in defining clinical and epidemiological goals. What ought to be the roles of community members? How ought consensus to be achieved across hierarchies and power differentials?

The interplay of empirical factors and ethical questions regarding research and interpretation of epidemiologic data is complex in such interventions. Programme administration should be formally acknowledged and assessed at the

beginning of collaborations, through the duration of the programme on ongoing and as needed bases, and during the evaluation of programme operations and outcomes. The practical question of who is granted authority to design and implement programmes, survey progress, and assess outcomes is further complicated by questions about whether and when it is appropriate to change the criteria for determining programme success.

## Conclusion

We have suggested several important empirical and ethical questions in three major public health projects, and have argued why addressing these in public health research, scholarship, and teaching equips public health professionals to facilitate discussion about the cross-disciplinary, inter-sectoral, and collaborative nature of leadership in public health policy-making, research, and intervention design. We have also suggested that such questions can assist in the development of guidelines for assessing the planning, implementation, and ongoing surveillance of public health projects from a variety of perspectives. Responding to these questions can facilitate transparency and trust by motivating discussions among different stakeholders about the goals and outcomes of public health projects and aid members of the public and the media in articulating the ethical and epidemiological importance of public health interventions and the broader goals of public health.

The questions and issues discussed here suggest that good work in public health requires formal acknowledgment of the merits and drawbacks of purposes of several parties, clarification of different groups' intentions, and responsiveness to cross-disciplinary colleagues' contrasting definitions of rigour. Such work requires patience and steady, persistent shared leadership among stakeholders, including experts in several fields and community members. We recommend that policy-makers and public health practitioners, including epidemiologists, biostatisticians, social scientists and clinicians, respond to the questions we have identified in the planning, implementation, and surveillance of all public health projects. The questions and issues illuminated here can be used to launch discussions (in public health research, scholarship, and teaching, for example) about the nature of leadership in public health. Policy-makers and public health practitioners can also draw upon these concepts and questions to evaluate and strengthen their collaborations in communities.

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