Integrating ethics, health policy and health systems in low- and middle-income countries: case studies from Malaysia and Pakistan

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Abstract Scientific progress is a significant basis for change in public-health policy and practice, but the field also invests in value-laden concepts and responds daily to sociopolitical, cultural and evaluative concerns. The concepts that drive much of public-health practice are shaped by the collective and individual mores that define social systems. This paper seeks to describe the ethics processes in play when public-health mechanisms are established in low- and middle-income countries, by focusing on two cases where ethics played a crucial role in producing positive institutional change in public-health policy.

First, we introduce an overview of the relationship between ethics and public health; second, we provide a conceptual framework for the ethical analysis of health system events, noting how this approach might enhance the power of existing frameworks; and third, we demonstrate the interplay of these frameworks through the analysis of a programme to enhance road safety in Malaysia and an initiative to establish a national ethics committee in Pakistan. We conclude that, while ethics are gradually being integrated into public-health policy decisions in many developing health systems, ethical analysis is often implicit and undervalued. This paper highlights the need to analyse public-health decision-making from an ethical perspective.

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Introduction

High-income countries can learn vital lessons from low- and middle-income countries (LMICs) which, through persistence, manage to form much-needed public-health structures that harmonize with pre-existing local public-health systems.[1] Crucial to this developmental process is the extent to which concepts of ethics are incorporated, in meaningful ways, into determinations of *which* public-health structures are to be formed, *how* they are to be created, *why* they need to be prioritized over others, and *who* should be their beneficiaries and trustees. Scientific progress is a significant basis for public-health change, but the field also invests in value-laden concepts and responds daily to sociopolitical, cultural, and evaluative concerns. The concepts that drive much of public-health practice are shaped by the collective and individual mores that define social systems.

This paper seeks to describe the ethics processes in play when public-health mechanisms are established in LMICs by focusing on two cases where ethics enjoyed a crucial role in producing positive institutional change in public-health policy. Our specific aims are threefold: first, we introduce a view of the relationship between ethics and public health; second, we provide a conceptual framework for ethical analysis of health system events, noting how this approach might enhance the power of existing frameworks; and third, we demonstrate the interplay of these frameworks through the analysis of a programme to enhance road safety in Malaysia and an initiative to establish a national ethics committee in Pakistan. We conclude that while ethics is gradually being integrated into public-health policy decisions in many developing health systems, it is often implicit and undervalued. We hope that this paper will highlight the need for both analysing public-health decision-making from an ethical perspective.[2]

Ethics and health systems

Health systems are defined by WHO as "all the activities whose primary purpose is to promote, restore or maintain health".[1] This definition focuses on those initiatives taken with the main intent of health production (e.g. a vaccination programme), as opposed to external initiatives that have a positive effect on health (e.g. education). In LMICs, these systems face several challenges including under-investment, lack of human capacity, lack of public satisfaction, inadequate utilization and poor health outcomes.[3–5] Health policy-making and public-health practice in such a context involves complex processes where a mix of experiences, politics, evidence, finance, values and ethics all interweave; the failure of any one component can be fatal to any policy.

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The search for value-based and ethical policies has recently gained momentum and the global literature has called for further exploration of the role of ethics in public health.[6] In particular, consideration of the situation in LMICs and analysis of case studies has been advocated.[2,7] While there have been extensive explorations of public-health policy in LMICs (such as by WHO), they have tended to focus on the attributes of specific health policies and systems rather than the role of ethics in the policy process.

Several prominent ethicists have provided useful frameworks for analysing public-health programmes,[8] research activities,[9] health policy reforms[10] and public-health practices.[11–13] Drawing from this previous work, we propose that ethics can also be viewed and studied more broadly as an integral component of health systems development. In this form, ethics is an organizational, development-oriented force that provides both methodological and motivational support to public-health practitioners and policy-makers. Crucial to this conceptualization of ethics through the lens of public-health and health systems is knowledge of society and social institutions, which differs from knowledge of diseases or nature-society interactions.[8] As bioethics increasingly straddles both medical care and public health on the global terrain[6] we see greater necessity for revisiting core public-health values and concerns, particularly those that arise most commonly in LMICs.

Conceptual framework for ethical analysis

Three core concerns frequently arise at the formative stages of public-health policy development: prevention, accountability and social justice. We will briefly characterize each and indicate how a systems approach to ethics and public health might enhance the power of existing frameworks to deal with these concerns, a point to be illustrated in our case studies.

The core mission of public health as a profession is to promote the health of populations by identifying risk factors for disease, disability, injury and death and by implementing measures to reduce people's exposure to these risk factors.[14] The term "prevention" captures the essential concern to intervene systematically in the causal processes by which risk factors threaten health and survival in human populations. A classic example is the provision of sanitation and clean water to protect a population from waterborne diseases. "Accountability" refers to the notion that people and organizations should be held responsible for the plans, behaviours and foreseeable results of commitments that they willingly pursue. A promising approach to promoting accountability in health sector reform proposals comes from the work on benchmarks of fairness tested in several LMICs.[10,15] The role of monitoring accountability with respect to policy proposals and implementation warrants careful health systems analysis. Information from LMICs is particularly scant; difficulty in accessing relevant information (i.e. lack of transparency) often hinders accountability.[16]

Notions of "social justice" often play an important role in public-health policy and are usually applied out of a concern for equity.[17] Social justice may also be understood as fairness in the distribution of the benefits and burdens of social cooperation.[18,19] Benefits of social cooperation include improved health and survival resulting from effective public-health interventions. The concern for equity is to ensure that such benefits are fairly distributed within the population, reducing as much as possible the extent to which people's health status and lifespan are determined by morally arbitrary attributes such as race, ethnicity or socioeconomic status. Burdens of social cooperation include the imposition of constraints on behaviour that might adversely affect members of the population. For example, when public-health interventions are implemented at the population level through law enforcement, as in the case of seatbelt or helmet laws, the effect is to limit the freely chosen actions of some individuals who might otherwise willingly accept their own exposure to the risks in question. Issues of social justice may arise in this context when burdensome public-health measures are not adequately counterbalanced by benefit or when they target some segments of the population but not others.[8] Policy processes can also be deficient in social justice when they include some perspectives at the expense of others; research suggests that perspectives of the poor and marginalized are often excluded.[20,21]

By emphasizing these three core domains in public-health ethics, we seek to extend, not to replace, leading conceptual frameworks to better reflect the experiences of public-health professionals working in LMICs. Insofar as existing frameworks of public-health ethics were constructed with high-income countries in mind, they tacitly take for granted an advanced health system and functioning services, supported by relatively stable economic, political and social conditions. Accordingly, the main professional role assigned to public-health policy-makers and practitioners is to decide how to use and direct the suite of available public-health institutions. Ethics is typically viewed as a tool to inform and constrain such decisions. By contrast, public-health professionals in LMICs often need to make decisions about which public-health institutions ought to be constructed or reformed, and in what form, while at the same time attempting to use those institutions. As a result, the function of public-health ethics in LMICs involves a far more delicate and dynamic balancing act requiring the identification of local values and public-health policies through valid research, and the provision of complementary support and guidance to promote social justice, accountability and preventive practices in an inherently unstable environment (Box 1). The application of this approach is illustrated using two case studies based on recent work done by the authors in low- (Pakistan) and middle-income (Malaysia) countries.

Case studies

Malaysia: research for policy change

Malaysia, like many of its neighbours in the region, is completing its transition from non-motorized to motorized modes of transport. With the high prevalence of motorcycles, it is not surprising that they constitute the majority of road traffic fatalities and injuries in Malaysia. Of 6268 fatalities resulting from road traffic crashes in 2003, almost 60% (3635) were motorcyclists,[22] a dramatic increase from the 981 motorcyclists killed in 1980. In addition, 46 455 motorcyclists suffered injuries from a crash the same year.[22] While the alarming data and strong public interest in road traffic injuries was motivation

for policy-makers to take action, their primary interest was in implementing programmes and campaigns, research was secondary.

The Department of Road Safety within Malaysia's Ministry of Transport is responsible for carrying out road safety initiatives. As a newly established department, it was highly motivated to carry out activities that would demonstrate its effectiveness; however, senior staff had limited resources and held reservations about investing in research. They were concerned about the time required to carry out what they viewed to be a long research process. Further, as is the case for all research endeavours involving intervention testing, there was the possibility of the intervention having no impact.

Researchers and policy-makers negotiated a mutually beneficial research direction. As motorcyclist fatalities constitute more than half of all traffic-related deaths in Malaysia, the chosen goal for the initiative was to reduce motorcycle crashes, injuries and fatalities. The specific objectives included testing an intervention using visibility enhancement materials (reflectors); since other interventions had been explored by local researchers.[23,24] The focus on a field trial was appealing to policy-makers because it was more practical and, as part of the trial, an intervention would be implemented in one district. From a policy perspective, launching an intervention represented a tangible outcome that was evidence of work towards the prevention of motorcycle injuries and fatalities and it addressed the "how to" questions that policy-makers are often confronted with every day.

Initially the Department of Road Safety wanted to develop a national campaign focusing on motorcycle reflectors; therefore it was beneficial for it to know the effectiveness of the reflectors in preventing motorcycle crashes. If the reflectors were effective, the Department could move forward knowing that its campaign would result in reductions in motorcycle injuries. If the field trial turned up negative findings, it would save money since the cost of the field trial would be far less than the cost to launch a nationwide campaign. Highlighting the benefits of potential negative findings was critical in convincing policy-makers to invest in research.

Box 1. **Key messages from analysis of ethics in public-health policy**

- Complexity of process in health policy-making and public-health practice: a mix of experiences, politics, evidence, finance, values and ethics all interweave. These are co-dependent components.
- Ethics can be viewed and studied more broadly as an integral component of health systems development. In this form, ethics is an organizational, development-oriented force that provides both methodological and motivational support to public-health practitioners and policy-makers.
- This approach requires knowledge of society and social institutions, as distinct from knowledge of diseases or nature–society interactions.
- The function of public-health ethics in low- and middle-income countries should involve:
  - a far more delicate and dynamic balancing act requiring the identification of local values and public-health policies through valid research; and
  - the provision of complementary support and guidance to promote social justice, accountability, and preventive practices in an inherently unstable environment.

Following the planning of the field trial, a public launch of the intervention sponsored by the Department of Road Safety and the Ministry of Transport was held in the Klang District. Ongoing discussions regarding the implications of this work are taking place between researchers from Universiti Putra Malaysia and Johns Hopkins University and local policy-makers. Results are being disseminated with the aim of informing all stakeholders and community representatives as well as policy-makers in other ministries within the Malaysian government. This process has strengthened the relationship and opened the channels of communication between academic researchers and policy-makers and will serve as the basis for future collective research and practice in the country.

Pakistan: institutionalizing research ethics

Pakistan Medical Research Council (PMRC) was formed in 1962 to spearhead the promotion and development of health research in the country, linking it to national development. To facilitate its work, the Council was given an autonomous status through an executive order and has endeavoured to achieve its objectives by forming collaborations within country and abroad. PMRC has established a network of 18 research centres throughout Pakistan and works with international agencies such as WHO. It fully participated in the events of the 1990s which focused on boosting health research in LMICs and bringing to world attention the gross "10/90" disequilibrium.[25] The "10/90 gap" is a term given to the disparity that approximately only 10% of the world's expenditure on health research and development seems to be devoted to problems relevant to the poorest 90% of the world's population.

The global effort to help LMICs reduce the 10/90 gap also brought into clearer focus many ethical issues in the conduct of health research and the need for establishing oversight mechanisms nationally and globally to address these issues. PMRC recognized the need for such a mechanism in Pakistan and, in collaboration with national and international partners, organized a series of lectures and seminars to create awareness for bioethics. One such seminar in July 2002 recommended the development of a National Bioethics Committee (NBC) in Pakistan.

The recommendation for the constitution of a NBC was successfully pursued by PMRC with the Ministry of Health. A small group of experts and policy-makers gathered in September 2002 under the chairmanship of the Director-General of Health to discuss the terms of reference and scope of work. Nominations for a broad-based NBC were invited from all relevant medical, health, media, legal, human rights, industrial and social institutions in Pakistan. These nominations were reviewed by a special committee and the ministry's approval was received in January 2004. The NBC was thereafter officially inaugurated.

Analysis of case studies

Malaysia

A cardinal achievement of the Malaysia road safety initiative was to engage the joint efforts of policy-makers and researchers around a shared public health goal: reducing motorcycle crashes, injuries and fatalities through

preventive practices. In particular, policy-makers and researchers negotiated a shared approach to collecting and interpreting relevant evidence. This approach supported accountability in: (i) the allocation of limited public resources, and (ii) the formation and use of an evidence base. This case also illustrates how existing analytic tools for public-health ethics may be extended for application to the policy-research interface in LMICs.

Under Kass's framework, policy-makers ought to examine existing data to determine the likely effectiveness of a proposed programme in achieving public-health goals of reduced morbidity and mortality.[8] Kass's rationale for this requirement emphasizes the ethical obligation to limit unwarranted burdens on the public. The Nuffield Council in England echoes the same rationale.[13] More to the point for LMICs, accountability in the allocation of limited resources requires that the opportunity-cost of a public-health programme be justifiable by reasons that include evidence of its effectiveness.[26]

When existing data are uninformative, research is needed. But this raises a further question of accountability. Given that a public-health problem might be seen by the public as urgent, how does one justify the expenditure of limited time and resources on research that may produce negative results? Rather than dismiss or ignore this entirely reasonable concern on the part of policy-makers, researchers in the Malaysia case engaged it directly by: (i) designing a field trial to include the implementation of an intervention in a district, and (ii) clearly communicating the ways in which either positive or negative results would contribute to the desired public-health outcome.

While Emanuel et al.'s ethical benchmarks are designed primarily for use in clinical research, the principle of "collaborative partnership" is also relevant to public-health intervention research in LMICs.[9] Under the complex economic, political, and social circumstances that characterize LMICs, research results have little chance of influencing policy or resource allocation unless policy-makers are sufficiently engaged with research programmes.[9] At the same time, in order for public-health policy to be truly evidence-based, the conduct of research must be protected from entanglement in the politics of policy-making. Assuming that political interests will naturally produce pressure to affirm existing or planned policy choices, the Nuffield Council notes the dangers posed by inadequate standards of evidence. For example, appeals to "evidence" collected and interpreted by means not subject to independent peer review; the inappropriately selective use of peer-reviewed evidence; and the risk that scientific experts may be urged to endorse conclusions more definite or precise than the evidence base can support.[13]

In the Malaysia case, several procedural elements might mitigate such risks and promote accountability. First, the design and conduct of research in a manner sensitive to policy-makers' reasonable concerns is, in principle, fully consistent with the highest standards of scientific peer review to which the field trial was subjected. Second, convincing policy-makers that the field trial results would have tangible value, whether or not the tested intervention proved effective, may have weakened any tendency to identify their political self-interest exclusively with positive results; consequently, the risk of bias in subsequent use of the evidence may have been reduced. Third, plans for disseminating trial results to local community representatives and to policy-makers in other Malaysian government ministries can include measures to reinforce the understanding that the results have value for public health regardless of efficacy.

Pakistan

The two salient concerns of public-health ethics in our Pakistan case are social justice as a background motivation and accountability as the primary operational objective. The formation of Pakistan's NBC resulted from PMRC's active involvement in documenting the under-distribution of global health research benefits to populations in LMICs. While this disparity might be seen as a failure of social justice on a global scale, redressing the 10/90 gap is in part a matter of domestic social justice, i.e. of how the benefits and burdens of social cooperation are distributed within each sovereign state. Closing the gap would require governments of LMICs, such as Pakistan, to participate in dramatically increasing the amount of health research undertaken for the benefit of their own populations. Ensuring accountability for the conduct of this research with human subjects requires that protocols undergo independent ethical review.[9,27] In the absence of existing national institutions for independent ethical review, the PMRC and the Director-General of Health established the NBC.

The NBC's terms of reference include preparing national ethics guidelines for health research in Pakistan, reviewing research proposals for studies to be undertaken at the national level, and accrediting, monitoring and coordinating other research ethics committees. This complex combination of responsibilities raises the question of whether accountability would be improved by a greater division of labour. Hindering such division is a typical challenge to institutional design common to LMICs experiencing a net out-migration of highly trained professionals.[28] The same labour-market dynamics that make human resource capacity-building a pervasive concern in some national health systems also carry over to the formation of research ethics institutions.[7] As a result, capacity building in research ethics has become very important in countries like Pakistan, and several organizations, including the Fogarty International Center of the National Institutes of Health in the United States of America, have responded.[29]

At present, awareness of the need for some metric to assess ethics accountabilities, or the ethical quality of research ethics review, is only beginning to enter the field of research ethics.[30] Taylor demonstrates the need for such a metric and outlines a process for developing one. Notably, she recommends starting with an exploration of how quality is defined and measured "in fields closely related to human subjects' research such as health care delivery".[30] Applying a systems approach to institutionalizing research ethics in LMICs amounts to doing exactly that. Thus, the challenges faced by national bodies like Pakistan's NBC represent promising opportunities for emerging experiences in LMICs to inform practice at the leading edge of research ethics.

Conclusion

We have not mentioned one aspect of ethics that might be considered relevant to public-health policy – human rights.[31] Frameworks for the analysis of public-health policies in terms of human rights ramifications are available;[32] however, the cases used in this paper did not call for a detailed application of human rights frameworks and space did not permit a conceptual analysis. The rapidly evolving nature of public-health systems in LMICs necessitates substantial use of novel approaches to study and improve existing processes. Such analysis might be performed using a combination of conceptual frameworks for public-health ethics. This paper provides one such method and two illustrations, analysing health systems events in LMICs. It has highlighted three core public-health values – prevention, accountability, and social justice – that frequently arise at the ethics/public-health policy interface. Additional methodological techniques and creative partnerships are required to further analyse this interface. Ethical innovation in public-health policy-making will come from multiple sources including international organizations and leaders, as well as local partnerships and practitioners responding to local challenges. We welcome further dialogue from all parties involved. ■

Competing interests: None declared.

Résumé

Intégration entre éthique, politique sanitaire et systèmes de santé dans les pays à revenu faible et moyen : études de cas en Malaisie et au Pakistan

Les progrès scientifiques sont un préalable important à l'évolution des politiques et des pratiques dans le domaine de la santé publique, mais sur le terrain, les individus investissent aussi dans des concepts chargés de valeur et répondent quotidiennement à des préoccupations sociopolitiques, culturelles et évaluatives. Les concepts qui influent le plus sur les pratiques de santé publique sont ceux façonnés par les mœurs collectives et individuelles définissant les systèmes sociaux. Le présent article s'efforce de décrire les processus éthiques en jeu lors de la mise en place de mécanismes de santé publique dans les pays à revenu faible et moyen, en se concentrant sur deux cas dans lesquels l'éthique a influé de manière cruciale sur l'apparition d'une évolution institutionnelle positive de la politique sanitaire.

Nous commençons par donner une présentation générale de la relation entre éthique et santé publique ; en second lieu, nous apportons un cadre conceptuel pour l'analyse éthique des événements touchant les systèmes de santé, en notant dans quelle mesure cette approche peut renforcer le pouvoir des cadres existants, et enfin, nous démontrons les interactions entre ces cadres à travers l'analyse d'un programme d'amélioration de la sécurité routière en Malaisie et d'une initiative pour établir un comité national d'éthique au Pakistan. Nous parvenons à la conclusion que si l'éthique est intégrée progressivement aux décisions de santé publique dans nombre de systèmes de santé en développement, l'analyse éthique est souvent implicite et sous-évaluée Cet article attire l'attention sur la nécessité d'analyser les décisions de santé publique sous un angle éthique.

Resumen

Integración de la ética, la política sanitaria y los sistemas de salud en los países de ingresos bajos y medios: estudios de casos de Malasia y el Pakistán

El progreso científico es un motor importante de la evolución de las políticas y prácticas de salud pública, pero en ese terreno se aplican también diversos valores y hay que responder diariamente a problemas sociopolíticos, culturales y evaluativos. Las ideas que orientan gran parte de las prácticas de salud pública se ven conformadas por costumbres colectivas e individuales que definen los sistemas sociales. La finalidad de este artículo es describir los procedimientos éticos que entran en juego cuando se establecen mecanismos de salud pública en los países de ingresos bajos y medios, centrando la atención en dos casos en los que la ética contribuyó de forma decisiva a propiciar cambios institucionales positivos en las políticas de salud pública.

En primer lugar presentamos una panorámica de las relaciones entre ética y salud pública; a continuación, ofrecemos un marco conceptual para el análisis ético de eventos en los sistemas sanitarios, indicando cómo podría este enfoque reforzar las posibilidades de los marcos existentes; y, en tercer lugar, demostramos la interrelación entre esos marcos analizando un programa de mejora de la seguridad vial en Malasia y una iniciativa de creación de un comité nacional de ética en el Pakistán. Llegamos a la conclusión de que, si bien las decisiones de política en materia de salud pública están incorporando gradualmente principios éticos en muchos sistemas de salud en desarrollo, con frecuencia los análisis éticos se realizan de forma implícita y están infravalorados. En este trabajo se subraya la necesidad de analizar la adopción de decisiones de salud pública desde una perspectiva ética.

ملخص

إدخال الأخلاقيات والسياسات الصحية والنُظُم الصحية في البلدان المنخفضة الدخل والمتوسطة الدخل: دراسات حالة من ماليزيا وباكستان

إن التقدُّم العلمي أساس مهم للتغيير في السياسات والممارسات الصحية العمومية، ولكن هذا المجال يستثمر أيضاً في المفاهيم الغنية بالقيم، ويستجيب بشكل يومي للشواغل الاجتماعية السياسية، والثقافية، والتقييمية. وتتشكل المفاهيم، التي تحرك الكثير من الممارسات الصحية العمومية، بتأثير الأعراف الجماعية والفردية التي تحدد النُظُم الاجتماعية. وتستهدف هذه الورقة وصف العمليات الجارية المتعلقة بالأخلاقيات عند إدخال آليات الصحة العمومية في البلدان المنخفضة الدخل والمتوسطة الدخل، وذلك بالتركيز على حالتين أدَّت فيهما الأخلاقيات دوراً محورياً في إحداث تغيير مؤسسي إيجابي في سياسات الصحة العمومية.

فالخطوة الأولى التي قام بها الباحثون هي عرض العلاقة بين الأخلاقيات وبين الصحة العمومية؛ والخطوة الثانية هي تقديم إطار نظري للتحليل الأخلاقي لأداء النظام الصحي، مع الإشارة إلى الطريقة التي يمكن لهذا الأسلوب من خلالها أن يحسن قدرة أُطُر العمل الموجودة؛ والخطوة الثالثة هي بيان التفاعل بين أُطُر العمل هذه، عن طريق تحليل برنامج استهدف السلامة على الطرق في ماليزيا، وتحليل مبادرة لإنشاء لجنة وطنية للأخلاقيات في باكستان. واستنتج الباحثون أنه برغم إدماج الأخلاقيات تدريجياً في قرارات السياسات الصحية العمومية في العديد من النُظُم الصحية النامية، إلا أن التحليل الأخلاقي غالبا ما يكون ضمنيا ولا يقدَّر حق قدره. وتلقي هذه الورقة الضوء على الحاجة إلى تحليل عملية اتخاذ القرار الصحي من منظور أخلاقي.

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