Bioethics in Health Policy Development: A Primer for Decision-Makers
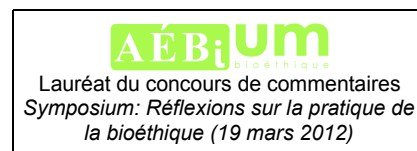
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Résumé

Le plus souvent reconnu comme un associé de la médecine et des organismes de règlementation de la recherche biomédicale, le domaine de la bioéthique a récemment élargi sa compétence académique pour inclure un rôle croissant dans les processus de décision dans des contextes de politiques de santé. Grâce à cette expansion, les professionnels de la santé et les administrateurs sont de plus en plus informés de l'utilité et de la nécessité d'intégrer les considérations éthiques dans l'élaboration des politiques. Cependant, beaucoup de ces professionnels ont du mal à définir le lien entre l'éthique et les processus décisionnels ainsi que le rôle (s'ils en ont un) des bioéthiciens dans la structuration des politiques de santé. Écrit pour un public multidisciplinaire, cet article vise à aider et à clarifier ces concepts en fournissant un aperçu aisément tangible de l'analyse éthique dans les politiques de santé. La discussion va d'abord définir les questions éthiques communes en matière de politiques de santé. Elle va ensuite clarifier la manière dont les cadres, structurés à partir de principes éthiques, peuvent guider l'élaboration de politiques et aider les professionnels de la santé à développer des compétences de prise de décision. La discussion se conclut en décrivant le rôle du bioéthicien dans ce processus comme étant un professionnel permettant la traduction des connaissances entre l'éthique appliquée et les contextes de prise de décisions en matière de santé. À la suite de la lecture de cet article, on espère que les professionnels de la santé, indépendamment de leur origine professionnelle, acquerront une meilleure compréhension des questions éthiques dans l'élaboration des politiques de santé et, ainsi, les bioéthiciens cesseront d'être considérés comme d'étranges associés parmi les décideurs.

Abstract

Most commonly recognised as a close bedfellow of medicine and regulators of biomedical research, the field of bioethics has recently expanded its academic jurisdiction to include a growing role in decision-making processes within health policy contexts. From this expansion, health professionals and administrators are increasingly knowledgeable of the utility and necessity to incorporate ethical considerations in policy development. However, many of these professionals have difficulty defining the link between ethics and decision-making processes, and what role – if any – bioethicists play in the structuring of health policies. Written for a multidisciplinary audience, this article aims to help clarify these concepts by providing a readily tangible overview of ethical analysis in health policy. The discussion will define common ethical issues in health policy and how frameworks structured upon principles of ethics can guide policy development and aid the decision-making capacities of health professionals. The discussion concludes by describing the role of the bioethicist in this process as a professional that serves to translate knowledge between applied ethics and decision-making contexts in health. Upon reading this article, it is expected that health professionals, regardless of occupational background, will gain a better understanding of ethical issues in health policy development, and as such, the bioethicist will hopefully cease to be viewed as an odd bedfellow amongst policy-makers.

Mots clés
la bioéthique, les politiques de santé, l'application des connaissances, la prise de décision, le cadre

Keywords
bioethics, health policy, knowledge translation, decision-making, framework

Introduction

It's not hard to make decisions when you know what your values are
▪ Roy Disney

The development of effective health polices requires a challenging, multi-tiered analysis that must consider a wide variety of issues ranging from economic, social, cultural, and legal factors, as well as the opinions of diverse stakeholders. In addition to these essential factors, health policy development inherently faces several value-based judgements that are of equal importance for detailed analysis. What are the ultimate goals of health research? And how ought these goals define how resulting medical innovation is implemented and distributed amongst the population? Which forms of pathology are most significant for our society? Under inevitable conditions of limited resources, which populations merit priority in targeted health interventions? What constitutes an effective treatment of a given pathology? And what proportion of treatment strategies ought to comprise disease prevention efforts? The above are but a brief list of important ethical questions – each with no simple answer – that must be subject to ethical reflection and analysis in order to achieve a measure of consensus and legitimacy, as well as to enable political action. While the importance of attending to ethical issues in health policy and decision-making processes seems readily understandable, encouraging ethical analyses amongst health professionals that are unfamiliar with ethics is like placing a proverbial 'cart before the horse'.

This article aims to contribute to raising awareness and basic knowledge of ethics-based assessments in policy development amongst health professionals. This awareness building will begin with a brief overview of the field of bioethics and why ethical analysis is of significance in health policy decisions. Methods on how to incorporate ethics-based analysis in decision-making contexts will centre on defining core principles of ethics required to establish assessment frameworks used in policy development. Integral to this process is the bioethicist, a professional who serves as a bridge between ethics and health research, two domains of scholarship that initially may seem to be disparate domains of knowledge. But first, the discussion must begin by understanding that applied ethics in health policy is a relatively new and thus largely unfamiliar domain of scholarship.

Unfamiliar territory? Principles of ethics, decision-frameworks, and health policy development

Genius of any kind is the ability and willingness to leave the known world behind and explore new territory

▪ Karla Mclaren

It seems reasonable to assume that many health professionals have modest experience with the field of bioethics, and moreover, the application of ethics in policy development may be for many an unfamiliar methodology [1, 2]. This possibility should come as no surprise since bioethics is a relatively young field of scholarship (originating between the post-war era of the 1950's [3, 4] to the 'technological era in healthcare' of the 1970's [5]), and the specific sub-field or specialty of *health policy ethics* is at a very early stage of development. In 2005, Nuala Kenny and Mita Giacomini, two leaders in health policy studies, described scholarship in health policy ethics to be in its infancy [6]. This expert opinion echoes the views of another ethicist and health policy expert, L. R. Churchill [7]. A 'primordial stage of development' is likewise an apt description of the specialty of *public health ethics*, the origins of which can be traced back to the 1990's [8]. Though at the early stage of academic inquiry, the following section will note that the need to include ethical assessments in health policy decisions has long been recognised.

Why is ethics relevant to health policy decisions?

At the outset, the most basic question to ask is why health interventions necessitate an analysis of their ethical implications. The simplest response is that society now demands careful attention to ethics in health contexts [9]. This demand arises from the uncovering of well-known abuses of power in what were blatantly unethical biomedical and epidemiological studies involving human subjects. The Tuskegee [10] and the recently exposed Guatemalan [11] syphilis studies are apt examples, where vulnerable populations (numbering in the thousands of people) were denied treatment for this disease in order to study its transmission and devastating individual and population health effects. Technological innovation in biomedicine is an additional issue of ethical significance because along with the benefits of new technology arise novel risks. Assisted reproductive technologies are a notable example, where along with curing many forms of infertility, science has concomitantly enabled novel means to produce 'designer babies' and the commodification of human reproduction [12]. Further ethical tensions surface from the advent of new challenges to health, as seen with the advent of the epidemics of AIDS or allergy; thus, questions abound as to what these emerging problems entail for society as a whole and how we should best address these threats to individual and population health.

In addition to the above societal demands for ethical reflection in health, ethics deliberations and analyses also serve a *practical* function in decision-making and health policy contexts. At the most basic level, an 'ethics perspective' offers a different way of assessing problems that have long plagued health policy [13, 14, 15 p.4], thus enriching policy discourse by expanding policy development beyond solely monetary, political or evidence-based factors [16]. Recall that health policy development is a complex endeavour that must consider a wide variety of issues ranging from economic, social, cultural, to legal factors [17 p.384]. Equally important are the ethical implications of health policy, and so in order to have all the 'tools' necessary to achieve the highest standards in health policy, one tool should arguably be an analysis of ethical implications [18].

Trevor-Deutsch and colleagues offer an excellent summary of this practical aspect of applying principles of ethics as tools to guide health policy:

> Thoughtful bioethical analysis gives rise to well-reasoned, ethically justifiable solutions based on widely held ethically justifiable moral beliefs that are likely to resonate positively with a society that supports them. It does so by offering solutions that optimize as many ethical considerations as possible, while recognizing that others may be compromised, and explaining why. [19 p.293]

Simply put, by incorporating ethical reflections in health policy assessments, decision-makers are better positioned to determine whether the outcomes of policy are indeed desirable, and if not, are able to identify possible courses of action that could lead to better outcomes [7]. Furthermore, incorporating an ethics analysis into policy development can help decision-makers to be meticulous in their reasoning by requiring decisions to uphold facts and arguments and not merely personal beliefs or self-interests [20]. Using widely held principles of ethics as guides helps define goals and core values that should be met by health professionals and the policies put in place. In turn, these guides aid decision-makers to have greater consistency and transparency with their decisions, and as such, they gain additional means to explain how and why they arrived at their decisions [16].

Indeed, the outcomes determined by health policy decisions, such as the structuring of health care systems, undoubtedly have profound ramifications for society. This fact alone highlights the importance that policy decisions be based on important societal values and attend to a range of ethical considerations. How exactly is this done and what strategies can be employed in order to structure ethically sound health policies that complement core social values?

Implementing ethics in health policy development

One common method to plan ethically sound policies is to ensure that policy development is structured according to a *framework* composed of well defined and widely accepted ethical principles and theories. These principles and core theories of ethics represent general values that uphold fundamental 'rules' (e.g., ensure fairness, avoid harming others, the need to protect the vulnerable) that orient ethical analysis of specific cases or within specific contexts [21 p.12-18, 22]. Determining which principles should comprise an analytical framework is influenced by many factors (e.g., current knowledge of risks and benefits inherent to a situation, preconceived goals or common social values, general intuitions on how best to handle a dilemma stemming from previous experience). What is most important to note is that each ethical principle focuses consideration towards relevant moral issues, which in turn "establish and define important concepts and can be used to describe important aspects of the positions we hold" [23 p.397]. Thus, consider the example of determining whether a health care system should subsidize the implementation of a novel technology [24]. In addition to issues of financial feasibility and medical efficacy, the merits of this technology can also be assessed with regards to its foreseen distribution of benefits and risks across a population. Guidance on this front can surface from a framework structured on the ethical principle of utility maximisation (maximise benefits while minimizing harms) along with the need to ensure a fair distribution of utility within society (will certain groups inherently benefit from the technology while others will not?) [19]. Following this assessment, if the technology is expected to produce greater harms than benefits for society, ethical reasoning guided by this framework would suggest that this technology does not merit government subsidies. Another problematic situation would be if the technology could provide a net benefit but these benefits will be unequally distributed in society (e.g., the technology can only be implemented in urban areas). Once again, ethical reasoning might question whether this unequal distribution of benefits is fair and acceptable, and thus provide valuable insights when debating the merits of this technology.

While exercises in normative ethics are typically 'prescriptive' in nature [6], such that normative conclusions aim to determine (or proclaim) what ought to be done in specific circumstances, decision-frameworks should not be perceived as prescriptive tools for health professionals. To expand, decision-making frameworks do not aim to be authoritarian in structure or implementation. That is,

these guiding frameworks do not 'order' health professionals to radically change their practice parameters or to conform to the values and ethical principles inherent to each framework. Indeed, ethics frameworks are not the 'rule of law'. The function of these frameworks is instead to help identify and articulate the issues and values at stake in decisions-making processes, which in turn can empower health professionals so that they may better-evaluate various options and make better-informed choices. Ethics-based frameworks "should therefore be understood less as norms that are applied, in the model of "applied ethics", and more as guidelines that are *interpreted and made specific* for policy and clinical decision making" (original emphasis) [25 p.182]. Overall, employing ethics frameworks as guides does not imply dictating the content and conclusions drawn from an analysis. Rather, employing frameworks in health policy discourses "encourages broader and more robust moral discussion, requiring personal sensitivity as well as a trained appreciation of the many issues that can be relevant" [23 p.397]. To conclude, ethics frameworks in health policy development serve to improve a professional's decision-making capacities but do not stipulate what these decisions must be.

The development of frameworks to guide decision-making processes in health is now a nearly ubiquitous research activity in bioethics scholarship, and ethics frameworks constitute a primary instrument for ethical analysis in health contexts [19]. A diverse range of frameworks are now available to health professionals as guiding instruments in a breadth of decision-making processes. Notable examples include: frameworks for public health practice [20, 26] and policy [17], frameworks to guide decision processes for nurses [27] and clinicians [28], and principles that guide professional duties in pandemic flu crises [29, 30] and following acts of bioterrorism [31].

Implementing ethics analyses in health policy: Easier said than done

Though bioethics scholarship is continually developing ethics frameworks as tools to guide policy development, the current implementation of ethics analyses by decision-makers in health faces notable challenges. For instance, though an analysis of ethical issues can provide valuable tools in decision-making processes, Gibson and colleagues [32] question whether such tools are actually available to most decision-makers. This does not appear to be the case since understanding in how to implement ethics analysis appears to be limited amongst most health decision-makers. For example, Gibson et al. note that "[a]lthough healthcare decision-makers are increasingly successful in using clinical evidence and applying economic analyses to set priorities, they are less confident that their priorities are *ethically* sound" [32 p.51] (emphasis added). This current lack of familiarity and confidence in executing ethically sound decisions in healthcare contexts occurs at a period where experts observe a significant and growing demand for practical approaches to incorporate ethics assessments in health service organizations [32].

The above observations are indicative of a broader problem amongst decision-makers in health [16]. Though policy specialists increasingly recognize the utility of ethics analysis in policy development, these specialists remain unfamiliar with ethics as a field of study and lack experience in employing sometimes abstract theories of ethics in day-to-day practice. Therefore, while the targeted end-user for ethics-based frameworks are decision-makers in health – i.e., the professionals and administrators who will determine what policy decisions are put forth and implemented in actual, real-world settings – lack of knowledge about the scope and use of ethics frameworks means that these professionals may be incapable of developing these tools on their own. This division between developers of ethics frameworks and actual decision-makers is due to what has been described as a 'two communities' divide between health professionals [33, 34]; the expertise of health professionals has become so specialised that transferring knowledge from one area of expertise to another is often difficult [35]. It is here where the interdisciplinary field of bioethics demonstrates its ability to 'bridge' disparate communities and domains of knowledge.

The role of bioethics: Ethics frameworks in health policy necessitate a knowledge transfer activity

As noted by Jocelyne Saint-Arnaud [36 p.19], the nature of the field of bioethics is one that situates itself not exclusively at a theoretical level, nor at a strictly practical level, but rather at a dialectic space between the two. This 'theoretical level' is in reference to the theory-heavy discipline of Philosophy, where abstract principles and theories of ethics are typically conceived and serve to advance debates centring on questions of 'what ought one do in a hypothetical situation'. The 'practical level' is in reference to real-world health contexts where health professionals face immediate dilemmas and ask questions such as 'what must we do in this pressing situation'. Occupying the space in between, Bioethics provides a 'Rosetta Stone' function,[1] and can serve to implement theoretical tools to aid in the resolution of actual dilemmas in health [20]. Being familiar with both philosophical theory and practical challenges in health care, the bioethicist can be a key actor in the translation of knowledge between these two disparate contexts. In turn, this role of 'knowledge translator' enables the systematic incorporation of ethical principles in decision-making processes by uncovering methods to make this process readily tangible to decision-makers in health through the development of ethical frameworks as guides in policy assessment strategies.

Conclusion

People are lonely because they build walls instead of bridges
▪ Author unknown

In order for decision-makers to capture the full benefit of ethical analyses in health policy development, the links between the seemingly disparate fields of ethics and health research need to become readily apparent amongst health professionals and administrators. Without such familiarity, further incorporation of ethical analyses in policy development will undoubtedly face difficulties, or will not be implemented at optimal levels. This scenario represents nothing more than a lost opportunity, one that can be avoided by raising awareness of ethics amongst health professionals and by encouraging collaborative efforts between policy developers and members of the bioethics community.

Without question, a merging of 'ethics' and 'health policy' is a straightforward indication that advancing scholarship at the intersection of these two domains will necessitate interdisciplinary research, and thus collaborative initiatives are therefore inevitable. Undeniably, it would be an overly demanding claim that diverse specialists in health become equally specialized in another, unrelated domain of scholarship, that is applied ethics. The need for expertise beyond a level of general awareness and interest concerning ethical issues, however, is not essential. This expertise is already available through specialists in fields such as bioethics, where these health professionals are specifically trained to execute the knowledge transfer activities required in policy development. Indeed, establishing greater ties between the health policy and applied ethics communities sounds simple enough, though it will require a sustained initiative to bridge divides and build capacities that enable real collaboration.

Despite academic divides that create 'two community' barriers to interdisciplinary research in health policy, health professionals should not hesitate to initiate interactions with specialists in applied ethics. For one, most health professionals will likely have had some association and familiarity with ethicists in their place of work through evaluations of research protocols by institutional review boards, or ethics consultations in the clinical context. This established professional network should not be underestimated, but rather seen as an opportunity. Merely engaging in conversations with these

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[1] The mere term, *Bio-ethics*, is representative of a field of study aimed at knowledge transfer between theoretical and practical domains of inquiry. As described by Hubert Doucet: "It is clear when looking at the origins of the term [bioethics] that it is was coined with a view to bringing two worlds that normally ignore one another into dialogue" [37 p.14].

colleagues – outside contexts of evaluating research proposals or participating in ethical consults for particular dilemmas – would be a simple means to exchange ideas, and initiate future collaborations and shared learning opportunities. Indeed, these opportunities would be endless.

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