

Issues in Bioethics

Ethics in Health Policy and Guidelines in Healthcare

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ABSTRACT

The development of policies in health and healthcare should incorporate ethical premises as well as thoughtful consideration of the values pertinent to the particular society and the goals to be achieved by specific policies. Social inequalities, changing values, and emergent challenges to traditional beliefs, add complexities that require a thorough analysis to compile policies that are fair and equitable. This article provides some recommendations for clinicians, health administrators, policy makers and technocrats who often grapple with complex health issues.

Problemas de Bioética

la Ética en la Política de Salud y en las Orientaciones de la Atención a la Salud

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RESUMEN

El desarrollo de las políticas de salud y atención a la salud deben incorporar premisas éticas, así como consideraciones sopesadas en relación con los valores pertinentes a la sociedad en cuestión y a las metas a alcanzar mediante tales políticas específicas. Las desigualdades sociales, los valores cambiantes, y los desafíos emergentes frente a las creencias tradicionales, añaden complejidades que exigen un análisis exhaustivo a fin de adoptar políticas que sean a la par justas e equitativas. Este artículo ofrece algunas recomendaciones para los médicos clínicos, los administradores, los responsables de trazar políticas, y los tecnócratas, quienes a menudo tienen que vérselas con complejos problemas en el área de la salud.

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INTRODUCTION

Moral direction for health professionals and scientists in their work is sometimes provided through the public policy process, including specific regulations and guidelines by government agencies. Many countries and jurisdictions regularly use ethical premises in their development of health policies, rules, decisions, and analyses. Such considerations help in the development of standards for science, medicine, and healthcare. Yet clinicians, administrators, bureaucrats and technocrats who have to make decisions in regard to policies, guidelines, or procedures, often grapple with the complexities underlying the process of effecting them, as such policies or guidelines should be fair and should be perceived as

being equitable. Further, good decisions depend on a thoughtful consideration of the values, desires, and goals of all parties pertinent to the issue.

In both industrialized and less industrialized countries, ethical concerns have been shifting away from issues related to the individual patient, and more towards matters concerning healthcare rationing. Yet the problems in medicine and healthcare cannot be reduced to the issue of economics alone, as the organizational aspects of healthcare as well as the philosophical goals of medicine and healthcare may also be significant determinants of the nature of care. Nevertheless, a guide for the best method of rationing would see the poorest sector (20%) of populations being provided with free healthcare (whether in health centres or in hospitals) paid for by governments, the middle category (60%) receiving a mixture of public and private care (utilizing health insurance and the possible use of private wards in public hospitals), while the richest category (20%) would have the option of joining in the healthcare services provided for the middle category,

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or alternately – assuming full responsibility for their health-care. The provision of healthcare should not only be affordable and economically sustainable, but also should be just and equitable. Further, attention should be paid to alleviating those background social conditions that have medical and health consequences (1).

While limitation of space will not allow for a detailed discussion of many of the areas for which health policy can be set, this article will mention some of these areas – priority-setting, issues surrounding the welfare of children, reproductive health, substance abuse, recalcitrant behaviour, HIV testing, issues in pharmacy, rationing scarce life-saving resources, and end-of-life care – in which ethical considerations are very important. It will also make some specific recommendations in a couple of these areas after some analysis.

Ethics in Health Policy-Making in the Caribbean

Countries in the English-speaking Caribbean, like most countries of the South, have limited healthcare resources and so ethical issues such as priority-setting, rationing scarce life-saving resources, and end-of-life care should assume even greater importance. However, the extent to which health policy for Caribbean island states have been written utilizing ethical premises will vary from country to country, as some countries may have written well-deliberated policies that provide clear moral directions on specific issues relating to health and healthcare, while others are yet to address such concerns.

Some policies are best developed at a national level while others are more appropriately designed at an institutional level. For instance, healthcare policies that reflect the ethical issues surrounding end-of-life care may be better determined at the institutional level (the meso-level of resource management), while the determination of where to install scarce, expensive life-saving equipment such as renal dialysis machines (and policies surrounding their use) may best be made at a national level (the macro-level of resource allocation). Ethical matters such as priority-setting, however, would be relevant at both the national and institutional levels.

Some English-speaking Caribbean countries have also shown an interest in crafting specific guidelines in relation to research with human subjects within their borders. An increasing plethora of multi-centre and transnational research endeavours across the Caribbean have been fuelling the need for each island-state to develop its own regulatory framework for the oversight of research to ensure the protection of its inhabitants who are the subjects of research. Again, some of the larger countries (*eg* Jamaica, Trinidad and Tobago) are further along the road of providing guidelines specifically written for their own needs, while smaller island states are currently discussing how best to pool their resources to provide an appropriate ethical oversight of research within their borders.

Other ethical matters such as the welfare of children, issues surrounding reproductive health, and HIV testing at

the workplace, have also received attention in the health policies of some English-speaking Caribbean island states. However, some specific ethical considerations in some of these matters will be proffered in this article.

Priority-Setting

Setting priorities is a challenge for every healthcare system worldwide as demand for healthcare outweighs the supply of resources allocated to finance it. Hence many questions may arise. Which programmes should a health authority fund? Which drugs should be placed on a drug benefit formulary? Which patients should be admitted to a hospital's intensive care unit? The field of health economics provide tools for addressing some of these issues (*eg* cost-effectiveness analysis, programme budgeting and marginal analysis), but empiric studies indicate that these tools have had limited influence on decision-making and that such analyses are often unavailable when needed (2). The information which these tools provide, however, should be weighed within the context of other values, such as equity, the health of individuals as against that of communities, and democratic decision-making. In addition, persons with diverse moral views may differ about what constitutes a fair allocation of resources to meet competing healthcare needs. Hence, the problem of priority-setting may become one of procedural justice, that is, legitimate institutions using fair processes (3).

Priority-setting is also important in the area of public health, which includes other considerations such as the cost of healthcare, the mal-distribution of community health services for rural populations, and the just allocation of scarce resources between primary healthcare, secondary care and tertiary care. Policies should utilize outcome studies as guides for the use of resources, and the general statistical data of epidemiological studies can be translated to address the needs of particular patients. Here, policies should also seek to protect the public from communicable diseases (while safeguarding individual confidentiality), and immunizing children to minimize the risk of harm.

Member states of the Caribbean community all need reliable and up-to-date data from their individual societies to plan for their public's health, and so governments in general, and Ministries of Health in particular, should place greater emphasis on gathering the required data. On-going collection, management, and analysis of pertinent health statistics are necessary in order to effect improvements in healthcare. Hence, national health policies should prioritize those research that seek to collect such data and establish disease registries. The Council for International Associations of Medical Sciences (CIOMS), in its International Ethical Guidelines for Biomedical Research involving Human Subjects, recommends that the health authorities in host countries ensure that all externally sponsored research ought to respond to the health needs and priorities of the host countries (4). Caribbean island states should extend this recommendation to internally sponsored research as well. This could be done in conjunction with the effort to upgrade their capacities

for the oversight of research using research ethics committees.

Priority-setting should also include certain procedural safeguards such as transparency, disclosure of conflicts of interest, fair access to decision-makers, and fair chairing and leadership of the group that is setting the priorities (5). Consequently, setting priorities in medicine, health, and health policy should not only be ethically made, but also empirically based.

The Welfare of Children

Each newborn infant is born perfect (as yet untainted by society) yet helpless, and so may be unable to survive without the help of parental caregivers and social support from the wider community (including immunization, healthcare services, *etc*). Healthcare policies that address issues surrounding children should seek to create the best environment, promote adequate shelter and nutrition, and provide fair opportunity for growth and development to help the child to mature and assume the full responsibilities of adulthood and citizenship.

Where birth defects exist, health is compromised, or where behaviour correction becomes necessary, care should be provided with the greatest of respect and without mental or physical abuse. Policies regarding children should be crafted with the cognizance that the level of civilization attained by any society will be determined by the attention it has paid to the welfare of its infants and children.

Reproductive Health

The term reproductive health embraces a concept for both men and women that includes the rights of an individual to prevent pregnancies, space the birth of children, and access relevant services and information. This health includes a state of physical, mental, and social well-being in all matters related to the reproductive system and its processes. Policies in this regard should seek to increase the ability of persons to produce healthy children without the risk of dying in child-birth, and to have information and services that can help them to make informed decisions at the right time and with the safest contraceptive methods.

Consequently, one may argue that denying persons access to means for safe abortions (that is, without the attending risk of infection and other health hazards) is *de facto* denying them their right to reproductive health. The United Nations Population Fund (UNFPA) states that adolescents report a general lack of access to adequate information about reproduction, sexuality, family planning, and health (6). The UNFPA insists that the belief that education regarding sex leads to promiscuity is a myth, and rather – sex education encourages responsible behaviour. Hence, information should be easily accessible and health services should exist to test, refer, treat, and conduct preventive programmes that can help persons to make the safest and healthiest choices.

Substance Abuse and the Public's Health

Is substance abuse a private or public problem? Whereas we should respect the right of individuals to determine their actions and the course of their lives, when a person's actions may negatively impact on the welfare of the society, then the person's actions become a matter of public concern. Some substances, even when used in relatively small quantities, may lead to anti-social behaviour, or physical or psychological dependence. The effect may be due to the direct effects of the drug on the body or to a particular predisposition that the individual may have. Use of some of these substances therefore may result in a deeply engrained habit or addiction.

Persons who abuse substances invariably deny being dependent on these substances, and may claim to be in full control of their actions. However, where their actions may have a significantly negative effect on others, some coercion of the person to seek appropriate treatment may be necessary in order to positively benefit the person and the society. Policies written to effect this, however, should be fair, transparent, and subject to review.

The Control of Recalcitrant Behaviour

People who know, for instance, that they are infected with HIV but who continue to expose others to the infection pose a problem for the general society. The issue creates tension between the traditional public health laws and civil liberties, and no consensus exist on how to deal with such recalcitrant behaviour by HIV-infected individuals. However, even if the overall impact of this recalcitrant behaviour on HIV spread is small, public health officials remain legally and ethically bound to protect others from the risk of infection.

Policies that address this issue can also establish precedents for the control of other infectious diseases, and may include a mixture of public health, mental health, and criminal law concepts, with responses ranging from official indifference to quarantine. Procedures involved, however, should be accountable, transparent and fair.

Ethical Issues Surrounding HIV Testing at the Workplace

In the past, some corporate companies have required HIV screening as a pre-condition for employment, with positive testing precluding employment. However, policies of screening for HIV sometimes infringe people's rights of privacy and confidentiality. Screening that identifies the individual screened necessarily involves some loss of privacy because some people gain access to this private information. For people who test positive, major risks ensue that may be both psychological and social. Psychological risks include anxiety and depression, and social risks include stigmatization, discrimination and breaches of confidentiality.

These risks, however, may be substantially reduced by social decisions to establish firm rules and regulations against breaches of confidentiality and against discrimination in employment, housing, and insurance. Mandatory HIV

testing in the workplace would be an unwarranted invasion of personal privacy, carries significant risk for the violation of confidentiality, voids the doctrine of informed consent (as such testing would be conducted through coercion) and would be unfair and unjust since the notion of justice involves the forbidding of discrimination against people on the basis of a handicap. Human rights values cannot be overridden by business expediency alone. Hence, regulatory intervention may often be necessary to correct an imbalance in power between employers and employees.

Some Ethical Issues in Pharmacy

A complex relationship exists between healthcare as delivered by professionals, the pharmaceutical industry, and patients who may be suffering. The pharmaceutical industry makes drugs, and hopes for financial gain. Patients often need to have appropriately prescribed drugs, in order to improve their well-being. Providing the link between the industry and patients, pharmacists make a living by selling prescribed drugs, but they also have the responsibility to make sure that patients use the right combinations of drugs appropriately. Some persons may also argue that pharmacists have a further duty to ensure that patients have access to particularly beneficial drugs, such as opiates for cancer pain. Collectively, pharmacists (perhaps through their association) would thus lobby their local Ministries of Health or relevant arms of government to ensure that, for instance, enough opiates are imported, and, as a corollary, governments (through their Ministries of Health) would have the responsibility to ensure access to such medications by those in need.

Three systems of justice may be applicable in healthcare and pharmacy: 1) The Libertarian system – in which the principle of market forces apply, where the greatest good is thought to be derived from competition among the various parties 2) The Egalitarian system – in which goods are distributed according to the basic needs amongst all those entitled to receive them, and 3) The Utilitarian system – which professes the greatest good for the greatest number, with limitations (due to financial constraints) occurring in areas not considered essential.

In this milieu, good ethical policies in pharmacy seek to change the focus of practice from the product to the patient, with pharmacists bridging the difference between a profession and a business (50% of a pharmacist's time may be spent in the distributive business activity, with the rest of time being spent on more patient-oriented functions such as counselling patients about their medications, reviewing drug use, and conferring with healthcare providers). Consequently, specific ethical obligations arise, including truthful disclosure to patients (to ensure that patients are adequately informed about medication that is being supplied), confidentiality of patient information, autonomy (pharmacists should honour the patient's right to self-determination, and so, after fully explaining, they should not inveigle patients to take medication that they may not want to), and ethical

interactions with healthcare providers (pharmacists should be vigilant in matters of competence and impairment). Other ethical obligations also arise, such as in product selection, product pricing and fairness to patients, ethical dispensing of prescription and non-prescription products (taking care not to sell ineffective or harmful products, or dispense potentially harmful doses), and proper industry relations with pharmaceutical manufacturers and third party payers.

In adhering to ethical policies, the pharmacist should provide appropriate advice to patients concerning the best available drugs to obtain the optimum treatment benefit, without overburdening the patient financially. However, pharmacists may reserve the right to refuse to fill prescriptions based on moral and religious grounds, for example, prescription items which they think are to be used as abortifacients.

Rationing Scarce Life-Saving Medical Resources

Many issues in healthcare pose a conflict between patient autonomy (with the duty of respect for the patient's right to self-determination that is based on Immanuel Kant's theory of deontology, *ie* duty-based ethics), and utilitarianism (outcomes-based or consequentialist theory), which is based on the ethical objective of maximizing the greatest good for the greatest number (which draws heavily on probabilities applied to groups of individuals) (7). However, in creating public policy, the outcomes-based utilitarian approach is the dominant ethical principle. In fact, this theory underlies most of healthcare economics. Hence, policies that address the issue of rationing scarce life-saving medical resources should balance the best interests of the patient against the matter of social justice. In this consideration, more persons needing these resources usually exist than do the required medical resources (*eg* dialysis, organ transplantation). Consequently, while some life-saving resources such as dialysis or organ transplantation are as yet unavailable in some English-speaking Caribbean countries, in those countries where these resources exist, policies regarding these resources (whether at the national level or institutional level) should be written to facilitate patient access that is not based solely on socio-economic considerations.

In many countries of the North, organ transplantation is now established as medical treatment for heart, liver, and kidney failure, and so those patients who are selected for transplantation waiting lists have established an entitlement to be provided with the organ they need (7). This patient entitlement to established medical treatment places a moral obligation on healthcare professionals and administrators to provide as many organs as is possible (although this obligation has not yet found its way into codes of professional ethics). Hence, the increasing shortage of organs for transplant in many countries and the death rate on the list of persons waiting for these organs have required transplant professionals to look for organs in extended donor pools (8). However, in the Caribbean, we should be reminded that high

moral and ethical decision-making underlie the process of organ transplantation, and so the process ought not to be embarked upon unless the organ recipient has the chance for a good quality of life. Further, organs for transplantation should be procured only through the altruism of the organ donor and no one should conceive a child simply to procure organs from the child for another child.

While organ transplant teams are aware of their deontological obligations to each individual patient, due to the severe limitation of available organs, they are invariably forced to make decisions based on utilitarian considerations. Similar considerations may exist for access to dialysis machines, but the matter may be more complicated when considered within the two-tiered healthcare system that exists in Caribbean countries such as Jamaica. There, renal dialysis offered in the private sector is expensive (albeit, discounted by the providers), yet insufficient machines exist within the public sector to help all the patients who need dialysis. Therefore, written policies ought to be developed at the national level for the two public sector hospitals that provide dialysis service. Further, there should be an ethical imperative to increase the amount of dialysis delivered to patients by seeking to obtain better equipment, accompanied by better overall care to the patient through better trained staff, with efforts to reduce the latter's turnover (and loss from the dialysis service) (9). The private sector institutions that provide dialysis services should also have written policies that follow ethical premises, since, where more patients exist than they can care for each week, they may also need to ration access to their machines.

Consequently, in determining which patients should benefit, in addition to the medical criteria for suitability for the procedure (including age and generally sound physical condition), background personality traits of individuals become relevant, including strong personal motivation, psychological suitability, capability of adhering to a strict diet, and the likelihood of turning up for scheduled sessions, for instance, in the matter of renal dialysis.

Next, five social factors should be considered and weighed in further deciding upon recipients – the relative likelihood of successful treatment, life expectancy, the person's family role, the potential for making future contributions, and the person's record of service or contributions. These features, however, should only serve to narrow the group of contending individuals, with the chance factor (for example, the lottery) being used to choose the final recipients.

It should be noted that the utilitarian approach reduces a person to his or her social role, relations and functions, but does not recognize the person's transcendence and dignity as a person. Thus, since any criteria for deciding the question of life and death are alien to the meaning of human existence, the decision to which they lead would be tantamount to the casting of lots. Hence, selection by chance would come closest to embodying both the moral (*ie* a sense of man's

dignity) and non-moral values that we are trying to maintain.

Consequently, we should have the natural randomness – first come, first served – or the artificial randomness in the form of the lottery as the final arbiter in the policy. This method serves an objective and impersonal function, and avoids subjective bias in determining who shall live, *ie* it provides equality of opportunity.

Quality End-of-Life Care

Each year 56 million people die worldwide, with 85% of the deaths occurring in less industrialized countries (10, 11). Yet very little has been documented regarding the quality of end-of-life care in these less industrialized countries. Advances in technology and the impact of technology on medicine have obscured the need for human compassion for the dying and their loved ones. However, poor quality end-of-life care ought to be viewed both as a public health as well as health systems problem, with the need for a strengthening of the capacity and the transfer of information necessary to improve the quality of end-of-life care.

Poor quality end-of-life care is a global public health problem as each death affects the lives of at least five other persons in terms of informal care-giving and grieving relatives and friends (12). Hence, the total number of persons affected each year worldwide by the 56 million deaths per year is at least 300 million people, or about 5% of the world's population each year. So, improving end-of-life care will require improvements in healthcare systems (the majority of deaths occur in hospitals in many countries), large-scale educational programmes, and more research involving end-of-life care in less industrialized countries. Medical research is particularly disproportionate (the so-called 90/10 gap), where 90% of the research is undertaken on those diseases that cause only 10% of the global burden of disease (12). Ethically, the lives of people in less industrialized countries should have as much significance as those in industrialized countries – despite the injustices and inequalities of global health distribution – and it may be doubly unjust for persons in less industrialized societies to suffer in the dying phase of life when this suffering is preventable by simply utilizing current medical knowledge and appropriate medication. Therefore, where none exist, Caribbean island states should also develop written policies detailing high quality care for their elderly and persons near the end of life.

Aid-in-Dying

Technological advances often times accelerate social change, but modern medical technology may also provide social and legal challenges. For example, without providing a cure or any reasonable hope of a cure (and often without providing a tolerable death), technology can sustain biological life – sometimes for many years. This ability has made the process of dying a focus of increasing concern, as the dilemma has been when to extend life and when to end it. Whilst many of the smaller island states of the Caribbean have yet to contem-

plate such dilemmas, those with life-sustaining technologies ought to have written policies in regard to aid-in-dying.

The terms physician-assisted suicide and aid-in-dying have sometimes been used interchangeably as they both imply the patient choosing the particular course of action, however they differ in that the former specifies the actor and does not imply that the patient is dying, while the latter denotes a benevolent act in the dying phase of life. Some jurisdictions (for example, some states in the United States of America) have permitted the administration of a life-terminating drug and the withholding or withdrawal of life support as legitimate means to provide aid-in-dying under specified circumstances (13). Some of these conditions include the notions of imminency, and pain and suffering in the terminally ill, and hence when present in technologically dependent persons, these conditions allow for such persons to receive aid-in-dying. Thus, in most industrialized countries, extraordinary, heroic, or aggressive treatments may be withdrawn under such circumstances, while, on the other hand, it would be considered obligatory to maintain ordinary treatments (14). Such withholding or withdrawal of life support is not considered assisted suicide or aid-in-dying where it is clear that starting or continuing the particular treatment offers no benefit to the patient.

Consequently, under special conditions, persons who can live relatively long periods of time but only with the assistance of mechanical devices could elect to receive aid-in-dying. However, policies that address aid-in-dying should ensure that the aid is available only if specific criteria are met (including that an independent review body would have to agree).

Transhumanism

Humanity may be radically changed by technology in the future. The feasibility of redesigning the human condition, including changing such parameters as the current inevitability of ageing, limitations on human and artificial intellects, unchosen suffering, and our confinement to the planet Earth, are all foreseeable. Transhumanism includes philosophies of life that seek the evolution of intelligent life beyond its currently human form and human limitations by means of science and technology, especially genetic engineering, nano-technology, artificial intelligence, and uploading (15). With this possibility, therefore, some argue that systematic research should be conducted to better understand these coming developments and their long-term consequences.

Many moral issues may arise, as persons may wish to use technology to extend their own mental and physical capacities, to improve children while in utero, to improve their control over their own lives, as well as their own personal growth beyond current biological limitations. Whilst assisted reproduction is currently available in Jamaica and Trinidad and Tobago, Caribbean island states should be contemplating whether they ought not to be developing policies that anti-

cipitate the technological ability, for example, to select for gender and genes that regulate height and specific behaviours. Growing concern about genetically modified foods add to the plethora of issues that ought to be considered. Planning for the future therefore mandates taking into account the prospect of this dramatic technological process, and the development of fora where people can rationally debate what ought to be done, with the creation of a social order where responsible decisions can be implemented.

Challenges for the Future

Many challenges in health policy for the future are derived from acute social inequalities across societies, and often involve persistent or day-to-day situations. Others arise from the emergent frontiers, *eg* biotechnology (stem cell research for cell differentiation to effect repair, reconstitution of blood, or organ transplantation, *etc*), and *eHealth* – a revolution in information technology that is affecting medical practice, not only by raising many ethical issues, but also in changing the way doctors learn and access medical literature (16). Further, many patients are increasingly using online internet resources to educate themselves about their illnesses and medications, and pharmaceutical companies not only seek to influence the prescribing habits of doctors, but are increasingly using direct advertisements to market their products to patients (who in turn are likely to pressure doctors to prescribe these for them). Addressing these challenges will require a thorough analysis of people's individual rights and liberty, religious beliefs and moral convictions, as well as the particular culture, and the possible consequences for society. Invariably, however, policies that are ethical will reflect a collective intellect that incorporates ethical principles, charity, sensitivity, and responsible decision-making.

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