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Ethical aspects of innovation in health in Portugal

Fábio Miguel Nogueira

Abstract

Effective management of resources is a current concern of health institutions in Portugal, requiring rationalization and prioritization according to ethical principles to ensure fairness. Access to innovation has proved fundamental in promoting health care and consequently improving quality of life, albeit with associated costs. Given the rapid development of science and the growing prevalence of innovation in the form of technology and treatments, a clear, conscious and reasoned discussion about the adoption and establishment of priorities with regard to innovation in health is imperative. Centered on a definition of innovation in health, the study of priorities, the perception of the same and their political aspects, the present article proposes a critical reflection in the light of ethical aspects that evidence the main questions related to the introduction of innovation in health in Portugal.

Keywords: Health policy. Health sciences, technology and innovation management. Health priorities. Principle-based ethics.

Resumo

Aspectos éticos da inovação em saúde em Portugal

A gestão eficaz de recursos é preocupação atual das instituições de saúde em Portugal, havendo necessidade de racionalização e estabelecimento de prioridades de acordo com princípios éticos que garantam a equidade. O acesso à inovação tem-se revelado fundamental na promoção dos cuidados de saúde e na consequente melhoria da qualidade de vida dos cidadãos, ainda que com custos associados. Tendo em conta o rápido desenvolvimento da ciência e a crescente disponibilização de inovação, na forma de tecnologia ou terapêuticas, tem-se mostrado imperativa uma discussão clara, consciente e fundamentada sobre a adoção e o estabelecimento de prioridades no que respeita à inovação em saúde. Centrado na definição de inovação em saúde, no levantamento das prioridades, na percepção dessas prioridades e nas suas dimensões políticas, o presente artigo propõe uma reflexão crítica à luz de aspectos éticos que evidenciem as principais indagações relacionadas com a introdução da inovação em saúde em Portugal.

Palavras-chave: Política de saúde. Gestão de ciência, tecnologia e inovação em Saúde. Prioridades em saúde. Ética baseada em princípios.

Resumen

Aspectos éticos de la innovación en salud en Portugal

La gestión eficaz de recursos es una preocupación actual de las instituciones de salud en Portugal, existiendo una necesidad de racionalización y establecimiento de prioridades de acuerdo con los principios éticos para garantizar la equidad. El acceso a la innovación ha demostrado ser fundamental en la promoción de la atención de salud y la consecuente mejora en la calidad de vida, aunque traiga ciertos costos asociados. Dado el rápido desarrollo de la ciencia y la creciente disponibilidad de innovación, en forma de tecnologías y tratamientos, ha resultado imprescindible una discusión clara, conciente y fundamentada acerca de la adopción y el establecimiento de prioridades en materia de innovación en Salud. Haciendo foco en la definición de innovación en salud, en la definición de prioridades, en la percepción de las mismas y en sus aspectos políticos, este artículo propone una reflexión crítica a la luz de los aspectos éticos que evidencian los principales interrogantes relacionados con la introducción de la innovación en salud en Portugal.

Palabras-clave: Política de salud. Gestión de ciencia, tecnología e innovación en Salud. Prioridades en salud. Ética basada en principios.

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The daily routine of health institutions is characterized by economic restraint, which imposes restrictions, notably on management and on health professionals, as well as on the introduction and dissemination of new technologies and innovative therapies. The search for cost-effectiveness associated with the quality of health care, should guide health work; however, this assumption may be incompatible with the availability of the latest advances, leading to the re-definition of priorities. The proper management of these technologies involves ethical aspects that will allow the various stakeholders to make conscious and acceptable decisions. Although influenced by these technologies, the ethical aspects associated with health priorities will be addressed according to the perspective of management, users and decision makers.

All decisions should be based on the Code of Ethical Conduct, adopted by the various institutions of the Serviço Nacional de Saúde (Portuguese National Health Service – SNS) as a guide to relationships, external and internal, arising from compliance with the professional and the public service mission, with a view to promoting greater efficiency and equity¹.

Ethics and bioethics in health

Resource management is increasingly present in health institutions, leading to rationalization of those resources and establishment of priorities. The need for an ethical basis to define the acceptable limits to ensure fairness in the provision of care, in the selection of innovative therapeutic and in health management then become clear². But what is ethics? What is it for? What ethical principles should govern decision-making? How does it apply to health?

Ethics means character, and should be understood as a set of moral principles governing the rights and duties of each individual and which are established and accepted at a particular time. This is the “science of morals or philosophy of morals”³. Focusing on human beings, ethics aims to encourage perfection, mediating the relationship between good and evil. For the ethical theories, what is desired is the being: who is free and independent, who acts in a beneficent and benevolent manner, who exercise justice and virtuous of character. Any ethical discussion is guided by the principle of responsibility, either individually, as part of society or globally, and aims at adopting a conscious attitude, that is supportive, responsible and virtuous with all human beings³.

The term “bioethics” is relatively new, and came about with the technological advances associated with biology and the ethical problems derived from the discoveries and applications of biological sciences. Bioethics is the multidisciplinary and systematic study of human conduct in the area of life and health sciences, conducted and interpreted in the light of moral values and principles. The reflections of bioethics are not limited to large current ethical dilemmas such as abortion, euthanasia, or the human genome; but also include the fields of experimentations with animals and humans, the rights and duties of health professionals and users, psychiatric and pediatric practices, and those practices involving unconscious individuals, as well as human interventions in the environment that can influence the balance of living species³: *Bioethics was initiated by scientists concerned with the direction of their research, doctors seeking to guide their relationship with patients, hospital administrators seeking criteria for the management of resources, moralists trying to develop an ethic of responsibility, and theologians presenting the religious experience to construct the meaning of existence*⁴.

With the unusual achievements of biotechnology, bioethics has asserted itself as a discipline formed in the debate between the different areas of human knowledge. Although having emerged associated with health, bioethics is not limited to it. In its clinically related aspect, this discipline rests on four principles that should guide its actions with regard to health care: beneficence, non-maleficence, autonomy, and justice or fairness³⁻⁵.

Concerns regarding ethical issues in health care cannot be reduced to simple rules contained in the professional ethics laws or codes, rather ethical issues must encompass respect for the individual as a social being, admitting that their essence is their freedom, but with commitment and responsibility³. Caring is much more than an act, it is an attitude, an occupation and a concern; it is accountability and involvement with others. But how does health professionals’ ethical training happen? Schuh and Albuquerque⁴, citing Merton and Becker, show that it is an educational process with two great moments: direct learning through dialectical education; and indirect learning, in which the attitudes, values and behaviours are acquired during the experience with the monitors, patients and team members (a teaching methodology called “hidden curriculum”).

Health innovation

The desire for access to innovation is a priority of current society. Innovative technologies have been instrumental in promoting health care and improving citizens' quality of life; however, there are costs associated with these technologies and with the evolution and growth of science. Health innovation can refer to the process or the product⁶. According to Barros, quoted by Nunes⁶, the process of innovation is focused on reducing costs, in order to promote the achievement of the same results without waste, emphasizing that the changes in the organisation are the key to sustainability.

Product innovation happens in the field of technology and medicine, and has associated costs. It must be considered, though, that innovation and sustainability are a possible combination. For Rosen⁷, health innovation can be grouped into: screening technologies; new drugs; gene therapies; minimally invasive and laparoscopic surgical techniques; transplants; telemedicine; medical devices for diagnosis and intervention; nanotechnology and professional development.

According to the International Network of Agencies for Health Technology Assessment (IN-AHTA), health technology (HT) can be defined as *an intervention that may be used to promote health, to prevent, diagnose or treat acute or chronic disease, or for rehabilitation. Health technologies include pharmaceuticals, devices, procedures and organizational systems used in health care*⁸.

HT has a significant impact on the budgets of the various health systems, which requires a prior assessment of their actual need⁷⁻⁹. The evaluation of health technologies (EHT) studies the medical, social, ethical and economic implications of the development, dissemination and use of HT. For the adoption of a particular technology, it is necessary that its effectiveness is proven and its budget expenditure is justifiable, in order to promote its ranking in terms of cost-effectiveness. The EHT should be carried out in a variety of contexts: the current scenario using the HT; description of the technological characteristics; safety; diagnostic accuracy; effectiveness; cost analysis and economic evaluation; in addition to the ethical, organizational, social and legal aspects¹⁰.

In recent times, there has been greater reliance on the incorporation of HT in the provision of care. The constant changes in technologies have materialized in the longevity and quality of life of

the population, but also brought new challenges and problems. Decentralization promoted by the new public management of health units has added decision-making levels to multiple stakeholders involved in the incorporation of new HT. In brief, public and private managers are interested in the effectiveness and efficiency of provided services; academics aim at the advancement of knowledge and the acquisition of prestige; technology companies want to develop products and markets to ensure profits; health professionals strive for excellence in their activities, which focus on prevention, diagnosis and treatment of diseases; users are interested in solutions to health problems; and citizens in general, who finance the health systems, it is essential to use resource properly with a view to bigger and better benefits⁹.

The increasing incorporation of technology, the ideology of perfect health and the cultural tendency to associate health benefits with consumer products have been responsible for the increase in costs that health systems cannot support, which is why a wider debate of the problem is urgent. How will this situation impact the right to health, enshrined in the Basic Law of Health. According to this law, *it is a fundamental objective for citizens to obtain equal access to health care, whatever their economic status and wherever they live, and to ensure an equitable distribution of resources and use of services*¹¹.

Given the scarcity of resources, it is imperative to create policies that favour the access of vulnerable groups to these resources and to focus the discussion on equitable access. It is noteworthy that the growing biopower of biotechnology companies is partly responsible for the current discussions on the right to health, in so far as the marketing of products with "*branded marketing*" induces consumers to view access as a legally claimed right⁹. It is necessary to look at this new paradigm in the light of ethics and bioethics, seeking understanding between all involved.

Ethical issues in health innovation – priorities

Human rights in relation to health, have long been established in various international conferences and transposed into Portuguese law. In general, health appears as an essential right, comprising elements such as justice and autonomy, which are essential to fulfil other rights¹².

Currently, the right to health includes the active participation of the citizens themselves, which

are major contributors to the maintenance of their health. From the right to health, comes the need to improve the management of finite resources, creating priorities and planning costs. This optimization of resources always has to be made according to the capacity of the health system, which is not limited to the public sphere, including the social and private sectors, for which the state assumes a regulatory role¹³.

Several factors have contributed to the scarcity of resources in health. If the experienced economic difficulties are a huge constraint, it is certain that the increase in expenditure is also due to the aging population and the growing complexity of technology and treatments. It is necessary to demystify the concept that “health is priceless”, educating the public about what the welfare state is and about the impact of ungoverned health management. It is essential to align the proposal with the established priorities, in order to ensure care that meet the needs of people. It is therefore important to evaluate the main health problems, their impact on families and the economy, and the associated expenses and gains¹³.

It is imperative to innovate in management, making the best with what is available, eliminating waste and focusing on valuing professionals. However, it is necessary to involve all health stakeholders in setting priorities, reducing debt, improving quality and reducing waste. In what way? Ethics will be the unifying element for all involved, in that its principles should govern politicians’, managers’ and health professionals’ decisions. Ethics will allow the search for values, virtues and principles in order to ensure user protection in unexpected illness situations, whatever their socioeconomic status¹⁴.

It is for the political authorities to invest in economic development, social cohesion, competitiveness and productivity, as well as in the health system. One aspect to consider in politics would be true *professionalization*, which implies the preparation of elected representatives for the exercise of activities related to politics because, currently, politicians may be graduates from different curriculum areas¹⁴. Politics is not seen as a profession, despite the remuneration assigned to it, in addition politicians do not have specific training and, in most situations, keep other occupations, from which they move away momentarily to accomplish the task for which they were elected. Ethically, this professionalization is essential *for a proper balance between limited resources, according to the needs of the community or the hospital population and individual rights, and equitable access to care*¹⁵. Note

*that the issue is not regarding cost containment in itself, which is always inevitable however great the resources, but the rational responsibility of choosing priorities and the effectiveness of the fight against inefficiency and waste in health*¹⁶.

It is up to the health institutions to respect each person and individual autonomy, much more than the overall health of populations. However, it is necessary to provide equitable care, without unfair differences that are likely to alter the health status of populations of different social, geographical or demographic contexts¹⁴. It is the responsibility of health professionals to do their best for patients, always promoting the principle of non-maleficence, and to enlighten them to become capable and autonomous in decisions about their own health.

Similarly, the autonomy of each professional should never be the subject of questioning, and professionals should be allowed access the techniques and technology that best enable the fulfilment of their mission². Professionals should defend their patients, based on the consideration that the individual’s right to choice exceeds the collective right. In the medical field, for example, the rationalization of the supply of expensive medicines is understood as a form of non-dispensing care, which is unacceptable from an ethical point of view, and that translates into the option of considering the need for cost reduction or denying services on the part of decision makers.

Admittedly, after all, restricting the supply of expensive medicines can have legitimacy if it is based on a transparent rationale, which includes evidence regarding their benefit and the principles and values involved in this measure. Decisions should involve priority criteria based on the severity of the clinical situation and the lost years of potential life, favouring younger, but respecting fairness. Health professionals should defend their patients, but also need to think of other patients, current and future, of their own institution or others, and this moral and ethical imperative should guide the allocation of resources¹⁴.

The decision of professionals should always be based on the best evidence, and in this respect, the industry has a fundamental role. In the context of medication, it is essential to establish independent, accessible, transparent and effective mechanisms for monitoring medication, which are increasingly sensitive to the ethical issues raised in the introduction of innovative treatments; as seen in the case of oncology, in which the use of think tanks has been

spreading specialised knowledge in society in general and among decision makers.

In the 2nd Edition of Think Tank – Innovation in Health, in 2014, it was shown that access to innovative treatments in oncology can be obtained with various measures: the involvement of patients and civil society, by defining priorities in resource allocation; adoption of innovative financing models and defining strategies for negotiating new HT; organizational innovation; regulation and evaluation; and strengthening information systems¹⁷.

In HT, it is essential to create an EHT system that allows the acquisition of different technologies with respect for their justification. The creation of the Sistema Nacional de Avaliação de Tecnologias de Saúde1 – SiNATS (National Health Technology Assessment System) in Portugal by the Autoridade Nacional do Medicamento e Produtos de Saúde I.P. – INFARMED (National Authority of Medicines and Health Products IP) is to allow the maximization of health gains, promote the sustainability of the Serviço Nacional de Saúde – SNS (National Health Service), ensure the efficient use of public resources, monitor the implementation and effectiveness of HT, reduce waste and inefficiencies, promote equitable access and ensure better quality of life to citizens¹⁸.

It is up to managers to ensure the sustainability of health institutions. Although the prospect of simply reducing immediate expenses without applying any ethical principle may seem easier, managers must lead in an ethically conscious manner, thus contributing to the consolidation of the health organization's commitment towards its values. Equating health managers to care providers in the deontological plan can bring together these professional categories and enhance the human and economic quality of management in health facilities².

Last but not least, citizens must respect ethical principles, so that their empowerment for decision making enhances the proper use of resources and access to treatment, ensuring a greater return on their application.

Public perception of health priorities

Health policies are usually targeted to ensure populations receive high quality, advanced and fully accessible service. In a context of rising health costs, this has been difficult to achieve so the ethical task, in this scenario, is to define a social contract to protect these values. The policy instruments available

to ensure the control of expenses are not fully adequate in ethical terms, so there is a need for “ethical juggling”¹³.

In health priorities, it is essential, from an ethical point of view, to define what is an acceptable social health contract. If, in health care, it was possible to guarantee ethical value for money, setting priorities would be much easier; but the various ways of doing so have associated ethical problems, demonstrating that, in fact, there is no alternative to “ethical judgment.”¹³

Currently, the general public are increasingly called upon to participate in health decision-making processes, so that their empowerment is important. More information and transparency gives citizens decision-making power and sufficient capacity to utilize resources adequately and adopt treatments, with greater returns¹⁴.

But what importance do people give to health? According to the National Council of Ethics for the Life Sciences¹³, citing Malheiros, there are two occasions when public perceptions are important in setting priorities: the moment of discussion and the time of communicating the choices made to the public. Health occupies a top place in the concerns of people, but the fact that they assume that access to health services is a guaranteed right leads them to undervalue it as a subject of discussion. In general, health seems more important when it is not guaranteed, since it depends essentially on the perception of risk that is incurred and how far we are able to live under such risks. The media have a key role here, by creating expectations and questions in society they can influence this perception. An example of this are the current discussions regarding: public-private partnerships, access to new drugs for hepatitis C, and pandemics, among many others¹³. Building individual or collective (cultural) perceptions as “all that is new is better”, leads many people to seek services (for example, abroad), ignoring scientific evidence and national laws and questioning the lack of and the availability of health services in their country⁹.

Today the problem of priorities is a constant in a country of limited resources; but citizens have a say, insofar as they are responsible for their actions and respective consequences. However, this association comes through knowledge: knowing to act or refrain from knowingly, responsibly, initiating a cause that produces an effect. Then there is the need to equip citizens with knowledge of health and the causes of disease, so that they can participate in health and health system decisions¹³. It is expected,

therefore, to provide the public with autonomy, that is, a capacity to decide on the imposed limitations, upon which they must guide their actions. The right to autonomy includes the duty of respecting others³.

Health therefore has complex and multiple dimensions, multiple viewpoints and multiple knowledge, and it is important to think of it holistically, indicating paths and ethical possibilities, in which the citizen must be a valued party¹⁹.

Political priorities regarding health – ethical aspects

The SNS has presented successive deficits and accumulated debts that generate delays in payments to suppliers. Faced with this situation it raises the question regarding the ethics of transgenerational debt. Does it make sense to leave to future generations the responsibility for balancing the SNS due to the current political inertia in decision making regarding its sustainability?

On the political scene, the debate is now focused on the adjustments necessary for the provision of quality care and the improvement of health indicators. It is essential that the health system is centred on the citizen and that the Ministry of Health has a plan focused in four strategic vectors: 1) economic and financial sustainability of the SNS; 2) quality and access improvement; 3) empowerment of citizens for greater intervention in the use and active management of the system; and 4) promotion of health (and healthy lifestyle habits) and prevention of the disease¹³.

With regard to the SNS, it is with the centralization of purchasing and of shared services of the Ministry of Health, and with changes in management models, which are very focused on the commodification of health institutions, especially hospitals, that the government aims to promote the sustainability of the system. In primary care, cost reduction can be achieved by better management of professionals and the creation of performance standards, as well as with prescription *meios complementares de diagnóstico e terapêutica* – MCDT (medicines and complementary diagnostics and therapeutic means). Improving the quality of access ensures that the services provided match the demand, as the hierarchization of services prioritizes equal access. The main objective is the access of all citizens to the family doctor and the transfer of care provided in hospitals to community-based structures. In the hospital environment, it is intended

to promote good clinical governance practices, strengthen outpatient surgeries and encourage the accreditation of units.

The development of a national network of integrated continuous care might also help to reduce costs, since this system will cost less than spending on hospital networks. The empowerment of citizens, promotion of health and disease prevention will be achieved through the adoption of healthy lifestyles, the focus on public health, the social determinants of health, the control of behavioural risk factors and the promotion of health research. Citizens will actively participate in the process of enhancing their health and in the achievement of better management of the system and better health outcomes, in addition the current model should be adapted to the demographic, epidemiological and behavioural changes that are currently underway¹³.

Taking into account health efficiency, without ever forgetting the humanization of care, several actions become necessary: consolidating a medication policy capable of promoting the use of generics and the generalization of prescriptions by their international non-proprietary name; enhancing the improvement of clinical practice through mentoring standards, in order to reduce bad practices (therapeutic obstinacy, unnecessary MCDT prescriptions, etcetera); informing citizens on the proper use of resources; keeping the focus on organizational systems, such as the primary health care network and the continuous care network; creating a network of palliative care; reassessing the hospital network; introducing into discussion issues of high-impact for families, including dementia, cancer, rare diseases and chronic diseases¹³.

Despite all of this, in the name of sustainability, it is not intended to reduce SNS funding, which would mean the degradation of care capacity. More than choose, ethically, what the SNS should cease to do or what will be excluded from it, the focus of government should turn to the investment in health policies and system development, modernization and humanization, eliminating waste caused by confused mixing between the public and private interests (which undermine the SNS) and the appreciation of human resources, which are the source of efficiency gains and the main asset value that health services have.

In summary, the main ethical concern of governments should be to not fall into the trap of sustainability and to promote the changes necessary to build an SNS that is efficient, equitable, fair, and citizen-centered¹³.

Final considerations

The budget constraints we have been experiencing have raised the issue regarding the sustainability of the National Health System. The social justice of the choices made is increasingly debated, especially as regards the introduction of innovation in health, based on the individual rights achieved and materialized in international conventions and in the Portuguese Constitution.

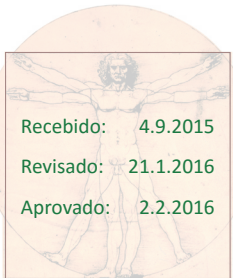
Today, the efficient management of scarce resources is imperative, as an appropriate and convergent response to the growing demand for health care following the best scientific evidence. In this difficult

mission, ethics and bioethics can be a support tool, guiding decision making. They are the one that will facilitate the mediation of everyone involved in health – from decision makers to users, through managers, health institutions, biotechnology companies, health professionals and citizens in general – in an attempt to promote a commitment from all of them to ensure the provision of safe, timely, efficient and equitable care.

In the name of sustainability, the interests of society cannot be forgotten, so that the management of resources must be carried out wisely, focusing on the accountability of all those involved in promoting health and in promoting its efficiency

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