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# From production to evaluation of health systems technologies: challenges for the 21st century

## ABSTRACT

The study analyzes factors and processes identified in the literature that determine the patterns of production, use and assessment of the health care technologies, which are part of the "medicalization" of contemporary societies. We also evaluate the scientific and technological public and health care policies proposed during the 1990s in developed and developing countries to enhance the impact of scientific and technological development on population health. Problems facing these policies were identified, as were the challenges to be overcome in the twenty-first century.

**KEYWORDS: Science. Technology. Policy making. Delivery of health care. Technology assessment, biomedical.**

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## INTRODUCTION

The production, circulation and consumption of products and services are essential to the sustainability of capitalist societies, even when they occur under varying political and social contexts. Products and services for health systems today constitute an important economic activity at both the national and international levels. Following the Second World War, industrial development became increasingly dependent on scientific and technological advances. This was particularly true of sectors supplying the health systems: medicines, equipment and various types of materials.[46]

Five factors are considered decisive elements in the expansion of these production sectors in developed countries: 1) proposal and implementation of scientific and technological policies by the State, and the availability of public resources for scientific research and technological development (the latter at a smaller scale); 2) consolidation of health policies that increased access to health care as part of the social and political recognition of the right to health as an essential right of the population; 3) strengthening the idea that medical doctors possessed proper knowledge, competence and autonomy, and the development of new types of services, health professions, care models and diagnostic and therapeutical procedures; 4) acceptance of health as having a social value and of its "medicalization", that is, health problems are recognized as medical problems to be addressed by the health services; 5) changes in the demographic and epidemiological profiles of populations (in the context of economic and social developments that began in the 19th century) such as reduced mortality by infectious diseases, increase and diversification of chronic-degenerative diseases and increase in life expectancy, which lead to new health requirements and demands on the health services.[11,23,36,51,55]

Identifying the "medicalization" of health, the expansion of health systems, and the increasing demand on health services and spending as important phenomena does not imply health care is a more important determining factor for population health. The literature produced on the relationships between health and health care is large and multifaceted.[17,26,41,58] One of these aspects is that, throughout time, all societies have determined who should be responsible for the care of human, physical, psychic and moral suffering. As in modern societies, science came to assume qualities previously attributed to gods and doctors became their priests; indeed "*sanare dolorem opus divinum est*".[42]

Even in developed countries, studies on the determinant factors of health/disease from a populational perspective clearly show the continued and decisive importance of economical and social living standards on health conditions. However, conceptual and methodological difficulties arise when dealing with the identification of causal factors and of the specific effects that comprise the life of social groups with worse living conditions. This, in light of the complex relationships between the biological, psychological, cultural, social and economical dimensions.[1,12,28,34]

An additional difficulty in these analyses is defining the components of health systems: i.e. all sectors and activities with socially defined responsibilities relating to population health (basic sanitary conditions; environmental, sanitary and epidemiological vigilance; health education and professional training; public safety; non-governmental organizations; and others), or simply health services.[16] Life in a society continually produces states of health/non-health in the population. When individuals or the society consider the "non-health" state as a disease and threat, health services have, in contemporary societies, a central responsibility in confronting this.[39] In all capitalist countries, the complex historical economic and social processes led to the "medicalization" of societies and to the development of systems of health services with common characteristics. Recognizing this fact does not preclude studies on specific circumstances and contexts, in light of the various characteristics of health services systems. Likewise, this recognition does not invalidate the development of political and technical propositions with the objective of making these systems contribute in the best way possible to the well-being and health of the population.

In a global perspective, the 1990s were characterized by recurring economic crises. Despite indisputable scientific and technological advances, living conditions, for many, seemed worse than in previous decades. It is inappropriate to discuss the above statement here in the framework of economic and political science. It suffices to note that in the field of health, the global context was also characterized by persistent poverty and an increase in social inequality and exclusion, unemployment and the rise of the informal economy, population growth and aging, extensive urbanization, economic and political instability, weakening of the general governance of health systems, low performance of the health systems, scientific and technological development marked by the creation of new demands and costs, and a complex profile of populational epidemiology with the persistence of old problems and the emergence of new diseases. During this time, it was believed that if health systems and services underwent important

transformations in their characteristics and performance, they could contribute to the reversal or decrease of these problems.[4,32,33,54]

These changes could have been attained through general political and economic actions and through the development of specific sectorial policies able to integrate political and economic objectives within processes of production, incorporation, utilization and evaluation of technologies. Such policies were proposed throughout the 1990s, most frequently by the governments of developed countries; but also by those in development, such as Brazil; and various Brazilian and international organizations.

This article had as its objective the identification and discussion of some of these proposals, their implementation and the difficulties encountered since the beginning of the century. A framework inspired by that proposed in the 1970s by the Office of Technology Assessment (OTA) of the United Sates Congress for the stages of development and dissemination of health care technologies was adopted as the organizational strategy for this discussion. Despite its dependence on a much criticized linear model of scientific and technological development, this approach was useful considering that its categories are still used in the literature and in political proposals.[6,43] Two main stages comprising the path for health care technologies from knowledge to the socially incorporated technologies: the first represent processes developed with successive intentions, relatively integrated and outside the health services and systems; the second the processes involving their evaluation and utilization as technologies, of either product or process, in health systems and services.

## TECHNOLOGICAL PRODUCTION

### Basic and applied research, development and innovation in health

The literature on scientific and technology policy underscores the importance of the document presented by Vanevar Bush to President Roosevelt following the Second World War in 1945, in which he defended public investment in basic research (until then primarily financed privately) and the creation of a national institute responsible for it, leading to the creation of the National Science Foundation (NSF) in 1950.[24] The document was based on central concepts that were maintained as dogma during decades, and were present in the majority of national scientific and technology policy proposals (including in Brazil): 1) (true) science affirms itself through its own merits, and its primary motivation should be the production of knowledge; 2) quality "pure" or basic research creates conditions for the development of "applied" research and leads to technological development and innovation, in a linear and sequential process; 3) only countries possessing a strong foundation in research will be able to develop the technological processes necessary for economic development.[38]

In the official NSF report of 2000, there is an introductory chapter called "Science and Technology in Times of Transition: the 1940s and 1990s" that points to the similarities and differences between these two periods. Notable as a characteristic of the 1990s is the importance of public support for policies that incorporate the need for the identification of the complex relations (networks and interactions) between research, technological development and innovation (Nelson,[37] 2003). In addition to financial resources, decisive and contemporary questions for the social impact of research in the national and international perspective are: information technologies, training for scientists, engineers, and science instructors, partnerships between the public and private sectors and social responsibility.

One of the main issues hampering the increased impact of research is the extreme concentration of human and financial resources and scientific and technical competence within a very small group of countries. For example, 85% of the most cited articles between 1993 and 2001 were produced in only eight countries, and 98% in 31 countries, including Brazil.[27] Even if patterns could be identified that differentiate performance for areas of knowledge and economic indicators, and some mobility was seen as possible, it would be necessary to change the general dynamic of global research and development (R&D) in order to make possible the contribution of science and technology (S&T) in decreasing poverty.[27] Examples of the difficulties relating to this are the constant conflicts between pharmaceutical corporations, governments and international organizations relating to research, development, patenting, production, financing and distribution of medications.[5,29]

**Table** - Stages of production, evaluation and utilization of health care technologies.

| Stages | Description |
|---|---|
| Production | Basic research/ Applied research/ Development/ Innovation |
| Evaluation and utilization | Pre-market: clinical trials, registration, regulation<br>Incorporation and utilization: initial diffusion, dissemination, obsolescence |

In Brazil, the Ministry of Science and Technology incorporated the questions about the impact of S&T in its policy proposals. Its "Livro Verde" *(*Green Book)[35] (2001) emphasizes the expansion of research in Brazil throughout the 1990s, mensurable by the number of graduated Ph.D.s, articles published in reviewed journals and public resources allocated to research. On the other hand, recognition was also given to the urgency needed in the development of mechanisms that increase its potential for economic impact and contribution for the population's quality of life.[52] A document drafted by the *Sociedade Brasileira para o Progresso da Ciência* (SBPC - Brazilian Society for the Progress of Science)* in 2005, affirms as a priority the formulation of a State policy that creates norms, institutions and structures that transcend the transitory nature of government administrations and would be anchored in social and political consensus concerning the relevance of S&T for the country. In this document, topics emphasized included: the importance of public universities, university-corporate relationships, interdisciplinary dynamics, basic education and training of teachers, training in the engineering sciences, financial and material resources, and policies and processes that promote the impact of scientific and technological development in Brazilian society.

In the annals of the 2nd National Conference on Science, Technology and Innovation in Health in 2004,[3] persistent problems were identified in the regional decentralization and determination of human resources, in the ability to manage innovation processes and in the dissemination of scientific and technology information. In relation to the productive health sector in Brazil, difficulties included weakened production and increased importation during the 1990s. As regards the promotion of research there were significant increases in public investment, new financing protocols to stimulate the transfer of technological knowledge and development were created, an increase in the participation of state (regional) funding agencies and a continuing difficulty in estimating private investment. To address these problems and the ethical commitment for improving, in a short, medium and long term perspective, the health conditions of the Brazilian population, it was decided that the National Policy for Science, Technology and Innovation in Health should adopt as central principles: extensivity; inclusiveness; selectivity; complementarity; competitivity; scientific, technological and ethical merit; social relevance; management responsibility; and social control. For this, it will be necessary to increase and diversify the sources of funding and implement new financing mechanisms and definitions of priorities, in addition to those traditionally used to support research.[21]

In the field of health, the demarcation between basic and applied research, development and innovation of technologies in health are particularly challenging. In technologies of "traditional" products (equipment, medication, materials), it is possible to identify intermediate steps, with processes and actors relatively differentiated but, also, each time more integrated. The common characteristic is the participation of an entity outside of the health services, an industry, and the non-participation, or at least reduced participation, of "research subjects" in the development processes. For these technologies, important questions for S&T policy include: the implementation of strategies to approach researchers and corporations (such as technology "incubators"), the identification of the impacts of more immediate financial interests on the traditional processes of research (formulation of scientific questions and methodologies and dissemination of results),[30] and the differentiation between innovation and technological improvements.

Therefore, these product technologies only realize their potential as diagnostic or therapeutic health care procedures when they are part of process technologies that, in principle, should also be based on scientific knowledge. However, in health care, not all knowledge linked to an action is constructed by means of processes recognized as "scientific research", which does not diminish its value. The process technologies present in health care have varied characteristics. They include everything from procedures with more structured technical components, such as those related to surgery, to programs of care, education and management whose legitimacy is supported by other indicators.

Generally, surgical procedures are established by means of production processes that are similar to product technologies, having as a difference the fact that they are under the control of medical doctors, and thus without the direct participation of industry. Many of the process technologies presently incorporated into health care have become the object of "research and evaluation in health services and systems". Thus, through the strengthening of the scientific basis for health care and for the production of "evidence", an attempt is made to transform health care. However, the challenge for this research is to overcome the conceptual and methodological level and contribute to the solution of problems, promoting quality of care and the imple-

*Sociedade Brasileira para o Progresso da Ciência - SBPC. Propostas de Diretrizes e Programas do GT de Desenvolvimento Científico e Tecnológico. Available from http://www.sbpc.org.br [access in 2006 Apr 20]

mentation of more effective health care policies and producing positive impacts on care and population health.[7,13,41] Without immediaterelations with health services, the lines of research that propose to integrate explicitly knowledge of various areas with the objective of producing results useful for the resolution of health problems, called "translational research" and "foresight policies", are also part of this scenario of "research for action" (although with a greatly different meaning from that of the 1970s).[22,25]

Recently, another important question is the growth of bioethics as a social issue. This is particularly true of clinical and research ethics with humans, given its impact on research procedures. This theme is too large to be adequately addressed here, particularly in the analysis of its impact on services and health, and of the effective incorporation of ethics as a transforming dimension for practices. However, it has undoubtedly become part of the new policies and financing procedures and in the approval of research projects, particularly those involving risk to human research subjects, in the majority of countries.[10,15,50]

## EVALUATION AND UTILIZATION OF TECHNOLOGIES

### Health policies or hurdles in a race to the market?

Beginning in the 1970s in more advanced countries, progressively more powerful public structures became responsible for the initial analysis of medication, materials and equipment that industries planned to introduce onto the market to be used by the population and the health services as part of sanitary vigilance. One of the emblematic institutions during this phase is the American Food and Drug Administration (FDA), a pioneer in the identification of the essential attributes of technologies for the protection of population health (efficacy, security and quality) and of the procedures used during trials as conditions for commercialization.[6]

In the initial phase, analyses and trials were both the responsibility of the FDA or third parties recommended by it. With time, however, this framework became considered excessively bureaucratic and time-consuming. In the 1990s, such evaluative studies became the responsibility of corporations, with results analyzed, verified and approved (or not) by the public authorities. This tendency is mirrored in the sanitary vigilance of nearly all developed countries. In Brazil, the *Agência Nacional de Vigilância Sanitária* (Anvisa - National Agency for Sanitary Vigilance), created in 1999, initiated its activities according this model. The public regulatory mechanisms responsible for registering technologies and their approval for commercial use should, by definition, administer conflicts of interest – national economic interests, corporations, managers and professionals, the population – and there are frequent complaints relating to their decisions, both in developed and underdeveloped countries.[5]

It is difficult to estimate the impact of progressively more complex parameters for demonstrating the efficacy and safety of technologies on population health. Information on the volume of technologies considered potentially interesting to corporations, but discarded along the way, are not public knowledge. At the same time, scientific and technological developments have led to the proposal of technologies, particularly medicines, with ever growing scope to affect biological processes, making it difficult to establish what is acceptable from the clinical practice and ethics standpoints. The particularly critical stage is phase III of clinical research, during which the product is near commercialization. Despite growing methodological sophistication, the determination of clinical efficacy and of the risk from adverse effects observed during a limited period in thousands of patients acting as proxies the population as a whole is always susceptible to unexpected findings. Because of this, legislation now seeks to append phase IV to clinical research (of effectiveness and population safety) which will also be the responsibility of corporations. The early identification of unexpected risks and the design of corrective actions have not been a simple undertaking since, during the process of launching a product onto the market, the economic interests involved are significant.[15,18]

Technological evaluation in the area of health, as an institutionalized activity, began in the 1970s and was pioneered by the Office of Technology Assessment (OTA) of the American Congress, created to produce independent studies on new technologies for which new legislation would need to be proposed. With time, this agency lost importance and authority and was closed down at the start of the 1990s. Technological evaluation as part of the health system was developed in Western Europe at the end of the 1970s, notably those countries with public health systems and universal coverage (Sweden, the Netherlands, and the United Kingdom). In the beginning, they were dedicated to producing data on the effectiveness and safety of new technologies, primarily those of high cost. Notable among these technologies were equipment, since clinical research procedures were not as well-defined as they were for medications (a problem that persists today). In time, the scope of information nec-

essary for new technologies increased, adding a dimension of (economic) efficiency to the analyses. This constituted a complementary vigilance mechanism of the public sector in the introduction of new health care technologies. Recently, some countries have begun to require cost-effectiveness studies for the approval of medication, which thus constitutes a fourth hurdle for industry to reach the market.[53] The principal challenge of sanitary vigilance, in all countries, has been to carry out its technical and legal activities with rigor and autonomy, without transforming them into excessively expensive and heavily bureaucratic rituals, and to occupy a clearly defined role in economic, industrial, legal and health policies. This is not an easy endeavor.[8]

**Incorporation and utilization: initial strategic diffusion; much dissemination, little obsolescence**

Once authorized, the technological use of products and procedures in the health systems spread in a relatively slow and restricted manner to the most, technically and financially, relevant professionals. Frequently, these are specialists who were already involved or followed the initially phases of this technology. Generally, they have links with academia and are important instructors and legitimators of opinions and practices for health professionals and for the general population.[9,31] This phase of more restricted use of technology, both with respect to the type of patient and to professional competence, has been decisive for its large-scale dissemination in the health systems, which occurs when adequate financial conditions are created.[45,48] In countries that develop public sector mechanisms for this activity, it is during this stage that technological evaluations of interest to managers responsible for the regulation of its routine use in services are developed. This is done through the definition of criteria for access and financing.[57]

These technological evaluations should produce knowledge based, scientifically and methodologically, on effectiveness, utility, benefit and efficiency, such that they assist managers in choosing between existing alternatives. Hopefully, in this way, the technical, ethical, political and economic dimensions relating to the decision to incorporate and use technologies in health systems can become better integrated. In the majority of developed countries, mechanisms exist that are responsible for the development of these evaluations, although the way they are inserted into the health services system varies greatly (central or regional, associated directly or indirectly with managers responsible for decisions of incorporation and financing, type of evaluation, and others). Their conclusions nearly always have an air of recommendation, rather than approval or disapproval, and thus they maintain close relations with research in health services.[40,43,49]

Nearly all technologies approved for use in the systems are disseminated, with varying levels of speed, intensity and increase of use. The factors that influence the speed of dissemination include: the type of technology (association with diseases of higher or lower risk and social impact), medical specialty to which it is linked, characteristics of the health systems and policies, and the country's "culture". Thus, mechanisms adopted by public authorities to guarantee the controlled use of technologies have had an almost negligible impact. This is reflected, beginning at the end of the 1990s in nearly all countries, in the increase in health spending associated with the persistence of inequality to access, use and results of technologies.[2,20,47] It is evident in the literature that the authors that study technological evaluation in health come to defend the need for policies based on "evidence", and concede the need to integrate the "technical" and "political" dimensions of health care, and the participation of managers, health professionals and the population (at all levels) in the decisions to incorporate and use technologies.[14,19,44,56]

The discussion developed until now, by pointing to the complexity of the processes relating to the introduction of new health care technologies, contributes to the understanding of the low impact of policies to inhibit, control or redirect its use. These policies, however, seem to have had an impact that is less defined and more difficult to measure for the professional practices, of management and demands from the population, leading to increased valuing of issues related to the routine use of technologies. This leads to a scenario where extreme situations are avoided. However, new challenges are continually appearing. The development of biotechnology alters the models that have been the basis until now of diagnostic and therapeutic procedures and can lead "medicalization" societies to become societies of "biomedicalization". This process foregoes the standardization of technologies and instead adopts a strategy of individualized customization and will have repercussions that are difficult to predict.[11]

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