

Development of health technology assessment in France

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Objectives: The aim of this study was to describe the history of health technology assessment (HTA) in France.

Methods: The approach was a descriptive review done by people who have been very much involved in this history.

Results: The interest in HTA and evaluation as a tool for health decision making goes back to the 1970s in France. During the 1980s, there were several attempts to develop a national HTA agency, which finally came to fruition with the development of the Agence Nationale de l'Évaluation Médicale (ANDEM) in 1989. ANDEM's main success, perhaps, was in making HTA known in France by developing its own assessments, writing and validating appropriate methodologies for assessing medical technology and medical practices, and by organizing in France the development of programs of consensus development conferences, which the ANDEM either organized itself or supported and validated. In the mid-1990s, the mandate of ANDEM was extended to hospital accreditation and the agency's name was changed to Agence Nationale d'Accreditation et d'Évaluation en Santé (ANAES). Finally, in 2005, the National Authority for Health (HAS) was formed to consolidate efforts to centralize the programs of HTA, aiming at helping decision making regarding reimbursement and pricing, in one agency and to define the optimal use of health technology in France.

Conclusions: HTA has become a strong influence in the healthcare system in France. These developments may be considered rather typical of the approach to public policy questions in France, where regulation is more in use than in other countries (at least in the healthcare field). At the same time, this approach has made lobbying and other attempts to influence decisions common as well, so one might say that HTA is more politicized than in some other countries in Europe.

Keywords: France, Health technology assessment, History, Health policy

The healthcare system of France is characterized by solidarity and universal coverage and responsibility. A range of public and private institutions provide care for the population in a planned and highly regulated system that is compulsory for all legal residents (2).

Controls over health technology include: (i) regulation of drugs for efficacy and safety and regulation of drug prices; (ii) scrutiny of medical devices for efficacy and safety; (iii) regulation of placement of high technology, under the *schéma régional d'organisation des soins* (SROS); (iv) a regionalized hospital system, that helps ensure appropriate location of health technology; (v) global hospital budgeting, replaced

by activity-based financing in 2008; and (vi) a gatekeeper role for general physicians.

Development of Assessment Activities in France

France followed a course of development and diffusion of health technologies similar to other countries during the post-World War II period. However, during the 1960s, concerns began to be apparent concerning such issues as discrepancies between available technology (mainly hospital beds) and the needs for such technology. These concerns led to the development of the *carte sanitaire* in 1970.

The *carte sanitaire*, a system for controlling health facilities and services by direct regulation, has been an important tool for health planning in France, at a time when excessive equipment, related to scarce resources, became apparent. It was replaced by the SROS in 2003. The basic philosophy has been to stimulate reorganization and equalization of the distribution of services and facilities. The *carte sanitaire* has regulated the availability of resources for geographic areas and population groups. Naturally, such regulation, based on *indices de besoins* (need indexes defined at the national level as a ratio between a certain amount of population at the regional level and several pieces of equipment of some kind) was enormously complex. The basis for the norms and standards has been some sort of analysis of needs and benefits, but these processes were not transparent nor obviously based on good analysis. The indices were frequently accused of being manipulated to fit with budgetary limits instead of reflecting medical needs. In part, it was this situation that stimulated the development of more “rational” approaches to health planning.

There were also early attempts to develop the use of evidence in health policy. Use of cost-effectiveness in perinatology and other fields began as early as the 1970s (1) as part of the wider national project of modernizing the process of choices within the public budget by introducing such methods as statistics, computer models, and econometrics (Rationalisation des choix budgétaires [RCB]). The National Perinatal Care Program included a large study examining seven possible strategies for preventing deaths and handicap in the perinatal population. In the final analysis, the results of the program were uncertain, because perinatal mortality began to fall steeply before the program was fully implemented and the program was never implemented on the scale initially envisioned. Likewise, the utility of the cost-effectiveness study to influence events was uncertain. There was a certain amount of disillusion with this approach that resulted.

However, this experiment of the RCB in the field of health care did make the need clear for a more rational approach to governmental budgetary choices, based on the consequences of those choices. At that time, the medical profession was not ready for a negotiation process based on efficacy regarding their choices for new technologies; they would express their wishes, while the public budgets were supposed to buy the equipment and pay for the running costs, with the only limit of quantitative restrictions (the *indices de besoin*) (8). As a matter of fact, economists and computer specialists had found themselves in great difficulty to fill up the “effectiveness column” in the cost-effectiveness approach; for this, the cooperation of some part of the medical profession was necessary.

In 1984, under a special assignment from the Minister of Health, a plan for the development of health technology assessment (HTA) was developed by Dr. Papiernik (a physician and professor of obstetrics, commissioned by

the Minister of Health of the time, Edmond Hervé), supported by Moatti (a health economist from the INSERM), and Weill (a social scientist nominated by the Minister) (Papiernik and Herve, 1985 unpublished). The approach proposed (i) put more emphasis on efficacy and less on utility, (ii) created a special foundation, run by physicians and independent from the Ministry of Health, with a scientific orientation but clearly distinct from the INSERM (the national agency funding most health-related research) to be able to develop applied research (9). The team of Papiernik, Moatti, and Weill wished to establish close links with the International Society for Technology Assessment in Health Care (ISTAHC), because the new field of research (HTA), intermediate between the fundamental sciences and the decision-making processes of the Ministry of Health, the insurance authorities, and others, was not considered respectable in France. The team believed that legitimacy of the new field could be demonstrated by becoming part of this prominent international movement for HTA. The decision was taken to create the foundation, but an election occurred in which the political power changed, and the foundation was not funded.

THE DEVELOPMENT OF ANDEM

Then, approximately 5 years later, the Government made a second try. Dr. Armogathe, a general practitioner and a representative of the medical profession, was commissioned to develop a national program, with the support of Weill. The result was the creation of the Agence Nationale de l’Evaluation Medicale (ANDEM) in 1989 (9). ANDEM was established by law as a nonprofit, independent association in charge of leading all technology and healthcare assessment with an impact on the public health, with the exception of pharmaceuticals, which were assessed by another government agency. (Weill was on the scientific advisory committee to ANDEM for some years.) The tasks of ANDEM were (i) to develop an internal project in HTA; (ii) to validate the methods and means of external projects; (iii) to disseminate the results of assessments; and (iv) to build a resource center of documentation on French and foreign assessments. HTA was firmly established in ANDEM, but became a key place for attention from lobbies, mainly physicians from leading health organizations and high ranking civil servants. All aspects of ANDEM’s work were somewhat politicized.

During its 7 years of life, ANDEM carried out several assessments based on a systematic review of existing literature. By 2000, ANDEM had carried out twenty-eight assessments (2). In addition, ANDEM organized and supported a larger number of consensus conferences (8).

Perhaps the greatest accomplishment of ANDEM was to make HTA visible in France. Many people had been interested in assessment as a tool to improve health care in France. ANDEM gave them a focus and encouragement (6).

Development of HTA in Other Institutions

In fact, ANDEM was not the first public HTA program in France. In 1982, the hospitals of Paris developed a Committee for the Evaluation and Diffusion of Medical Technology (CEDIT) to advise the General Director of the hospitals on investment in new and costly health technologies (2). CEDIT mainly worked, and continues to work, through synthesis of existing literature, but has also done several prospective assessments and economic studies, with a highly pragmatic approach, designed as a practical help to decision makers. Its work goes on today.

After the formation of ANDEM, other hospitals began to develop activities related to HTA. INSERM, the national health research institute, began to fund assessments, especially of prevention; physicians acted mainly through consensus conferences and efforts to disseminate HTA results; and the National School of Public Health began to pay more attention to assessment of technology and quality. In addition, the national health insurance became increasingly interested in coverage policy as it could be influenced by HTA. Private consulting grew with the new monies available, so that gradually a cadre of physicians trained in economic, statistics, and informatics became more prominent (2).

The Development of ANAES

The main reason for the change in the agency was the addition of accreditation of healthcare organizations to its responsibilities. Accreditation was mandated by the government in 1996. One of the reasons for change seems to have been that the government became dissatisfied with the development of HTA. ANDEM had made HTA somewhat prominent and respectable, but many physicians and hospitals continued to practice without change, ignoring evidence of efficacy, safety, and cost-effectiveness. The government apparently decided to take a more regulatory approach.

In the mid-1990s, the government proposed a new agency to replace ANDEM, the National Agency for Health Evaluation and Accreditation (ANAES). ANAES would also be an independent, nonprofit organization. HTA activities were to continue and grow. However, in addition, ANAES was given the responsibility to develop a program for the accreditation of hospitals that would incorporate HTA as one of its methods. ANAES had two major divisions, one for HTA and clinical practice guidelines and the other for accreditation.

The HTA activities and the center for documentation continued, more or less as before. Assessment reports were published and consensus conferences were supported. The ANAES developed guidelines for accreditation in a decentralized program.

The Development of the National Authority for Health (HAS)

In 2004, the government decided to establish an independent scientific authority with expanded powers and mandate (actually established in 2005) (4). One reason for this change was that HTA activities and activities related to HTA had spread to several government programs. The main purpose of the change was to bring all these activities under one roof. The HAS presently has a budget of 69 million EUROS and approximately 400 permanent staff, and can call on an additional 3000 experts (3).

The HAS has the responsibility for carrying out assessment of drugs, devices and medical equipment, medical and surgical procedures, and biological tests; HAS administers the accreditation program with its 775 surveyors that perform accreditation visits; HAS certifies physicians as qualified to practice; and HAS provides information to the national health insurance related to coverage of services and reimbursement (3). However, the decisions on pricing and coverage are made by other agencies. For example, a list of reimbursable medical devices and drugs is developed by the Ministry of Health (4).

In 2006, HAS carried out an impressive number of assessments. Almost 1,200 opinions on different aspects of health care were issued (3).

HAS has expanded outside participation in its activities, to include gaining advice on its work program (5). According to HAS, three principles are of highest importance in its work: scientific rigor, anticipation, and arbitration (5).

An interesting new approach to HTA in France began under the HAS is to certify information sources, such as specific Internet sites (3).

HAS has involved itself actively in international activities. In addition to participation in the well-established societies and networks like HTAi, INAHTA, and Euroscan, HAS leads a work package about evidence development in the European Network for Health Technology Assessment (EUNETHTA) project and is the leader of the European Union Network for Patient Safety (EUNETPaS) project, both funded by the European Commission.

DISCUSSION

During the past 25 years, HTA has become increasingly and continually prominent in the French healthcare system. HTA is now one of the major health policy tools for the government. Twenty-five years ago, only a handful of experts were involved in the field of technology assessment. They were neither fundamental researchers nor classic administrators, but were mostly social scientists (economists) and (at that time) not physicians. Mainly, because they were not physicians, they found themselves in a quite marginal position, and no precise place in the system or carrier existed for them. Today, a whole body of specialized experts, highly competent

and well considered, working in a high level, highly respected and prominent kind of organization has emerged from the medical profession.

France may have developed HTA in a somewhat different way than other countries. Typically, the French government relies more on regulation than many other countries.

This is certainly true in the field of health policy. Considering the weight of public health care in France, compared to private delivery, most of the costly medical technology is paid by the public budget. Therefore, the need for the government to make informed choices has become even more crucial as public budget deficits are not only maintained but continue to grow. Moreover, the government is now clearly taking on the role of protector of safety and quality of care, in a system where advocacy from users is becoming more intense. Such user involvement was supported by law since 2002. Doctors and hospitals are now expected to practice in an evidence-based manner.

At the same time, regulation invites political involvement. HTA in France is not merely a method of scientific analysis and systematic review. HTA is a tool to support regulation. However, because of its prominence in decision making, HTA is also the focus for lobbying by physicians and hospitals. The resulting system perhaps depends more on negotiation than is seen in some other countries.

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