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Perspective

PERSPECTIVE: SOME CONCLUSIONS FROM MY LIFE IN HEALTH TECHNOLOGY ASSESSMENT

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I have worked in health technology assessment (HTA) since 1975, beginning in the United States Congress Office of Technology Assessment (OTA), where we were charged with defining "medical technology assessment". My main concern in HTA has always been efficacy of healthcare interventions. After years in OTA, I was invited to the Netherlands in 1985, where the Dutch government invited me to head a special commission concerning future healthcare technology and HTA. From there, I became involved in over forty countries, beginning in Europe and then throughout the world. My most intense involvements, outside the United States and Europe, have been in Brazil, China, and Malaysia. During these 40-plus years, I have seen HTA grow from its earliest beginnings to a worldwide force for better health care for everyone. I have also had some growing concerns, outlined in this Perspective article. Within HTA, I am most disappointed by a narrow perspective of cost-effective analysis, which tends to ignore considerations of culture, society, ethics, and organizational and legal issues. In the general environment affecting HTA and health care, I am most concerned about the need to protect the independence of HTA activities from influences of the healthcare industries.

Keywords: HTA, History of HTA

My education and training experiences led me to the field of HTA—medical school, internship, and residency in internal medicine, 2 years at the Center for Disease Control (CDC), a Master in Public Health (tropical public health), another master's degree in health services administration and sociology, several years in academic community medicine, a fellowship in international health systems, and a health policy fellowship. My father always wanted to study abroad, but for financial reasons could not. He stimulated me to spread my wings beyond the borders of our own country.

I began to develop my life-long concern about efficacy and safety while an intern in 1963, when I realized that we were using unproven clinical procedures on patients without supervision. I had not been introduced to the notion of efficacy in my medical education and training. Notably, someone had read about gastric freezing as a treatment for peptic ulcer, so we tried it on patients. Shortly afterward, in 1969, a clinical trial showed that this procedure was both useless and harmful (1).

When I went to CDC, I discovered that there was a great institutional concern about efficacy of preventive procedures. I wondered at that time why the same was not true for clinical medicine.

During my health policy fellowship in Washington DC in 1974–75, I heard Archie Cochrane speak on effectiveness and efficiency (2). Dr. Cochrane pointed at the extensive problems of lack of efficacy of health interventions and anticipated the spread of randomized clinical trials (RCTs) to address this problem. He said that this would lead to a "probable decrease in clinical and administrative freedom". I was enthralled by his presentation and surprised at how soon I was able to follow-up on it.

At the end of my health policy fellowship in 1975, I was offered a job with the new Congressional Office of Technology Assessment (OTA), which had just decided to develop a health program. Our first task was to define medical technology assessment (3). Over the next 7 years, along with the team that I recruited, we wrote a series of reports that served to outline this new field (4;5). The report closest to my heart was "Assessing the efficacy and safety of medical technologies" (6). The main basis for this work was a 1975 letter from Senators Jacob Javits and Edward Kennedy, who had been briefed on Cochrane's lecture, that asked OTA to "examine current Federal policies and existing medical practices to determine whether a reasonable amount of justification should be provided before costly new medical technologies and procedures were put into general use".

These reports became well known in the United States and, increasingly, internationally. The report on computed tomography (CT) scanners was a world-wide "best seller" (7), and led me to be in contact with people from other countries. An early important experience was being invited to a WHO Latin American meeting on medical technology and its assessment in Brazil in 1981.

During my first period at OTA, the basis was laid for the 7 years of work. A specific assessment was suggested by the advisory committee for the health program, which expressed doubts if electronic fetal monitoring (EFM) was worthwhile. By then I had left OTA to join the National Center for Health Services Research and Steve Thacker and I decided to do a complete review of the literature and a synthesis of studies related to EFM. We collected 600 English language references and found four randomized studies of EFM that showed no

benefit, and many poor studies concluding there was benefit. We concluded that there was no evidence of benefit from EFM in obstetric practice (8). This publication led to a storm of criticism, which we later described in an article in this journal (9). We were accused of being ignorant, naive, seeking mainly to contain medical costs, as well as having no integrity. Ultimately, our conclusions have been vindicated, for example, when around 1985, the American College of Obstetrics and Gynecology changed its position toward EFM, although EFM is probably used more now than it was in the 1970s.

I returned to OTA in 1978, as head of the health program, and had a successful experience, particularly in developing reports cited above on the theme of evidence in health care. I left OTA in 1983.

The OTA experience was fantastic in many ways. The staff of OTA was superb, bright, hardworking, and committed. We could call on anyone for advice, and every OTA study included an advisory committee of the best experts we could identify. We could also hire consultants to help on reports. This was a wonderful learning experience. However, I was increasingly frustrated with the generally limited perspectives in the U.S. Congress: United States oriented, only interested in the next 2–3 years, essentially no interest in developing countries.

I learned many important lessons at OTA. I learned a great deal about listening to different points of view, including political views. I learned to listen and not to spend much effort telling others my views. I learned not to lecture others. I learned to seek the "truth", however welcome or unwelcome it might be. I learned the importance of working with others with different training and expertise. I learned to share, not dictate the conclusions, but reaching them together (OTA was closed by the Congress in 1995 when the funding was not approved after a close vote).

My next position was as Deputy Director of PAHO, WHO for the Americas. This experience introduced me to many people in public health from Latin America. The Director was Brazilian, and I was able to go to Brazil for the Organization. However, I found the administrative job frustrating and I missed the work on HTA. I was approached by an official of the Dutch government, who invited me in 1985 to head a 2-year study of future healthcare technology, based in the Hague. I eagerly accepted.

I used all these lessons I had at OTA and more, as I moved to Europe to head the study on future scenarios for health care and HTA for the Dutch Government (10). After the study was completed, I decided to stay to see how my recommendations were carried out. At the same time, other countries were interested in having my advice. Other European countries were establishing HTA programs, beginning with development of the Swedish Council on Health Technology Assessment (SBU) in 1987. At approximately the same time, the World Bank invited me to be involved in a study of the Chinese health sector, including health technology, which led to relationships with Chinese institutions and experts. And the World Bank also invited me to be involved in other countries, including Russia, Poland, and Serbia. A public health agency invited me to Brazil many times to teach and consult, beginning approximately 1990.

I stayed in the Netherlands, I took Dutch citizenship, I married, and I combined a 50 percent job with TNO, a Dutch research institution, with international work in China, Brazil, Malaysia, Poland, Romania, and Serbia, among others. I was involved in establishing an Asian regional network in Asian countries, including China, India, Korea, Malaysia, Philippines, Singapore, and Thailand. The network tried to raise awareness of HTA, among other activities, and carried out a multi-country study on CT scanning.

In the earliest years, I was often asked to lecture on the methods and results of HTA. A central theme of the questions I was increasingly asked to address was what to do with HTA results, how to change medical practice and health policy.

My final important HTA activity was in Europe. A group of experts from different European Union (EU) countries applied to the European Commission for funding to explore coordinated work on HTA. From 1993 to 2002 through the EUR-ASSESS project and the follow-up projects HTA-Europe and the European Collaboration for Assessment of Health Interventions (ECHTA), we developed the basis for a European program in HTA (11).

During these developments in HTA around the world, and my involvement in them, the profession of HTA has remarkably changed. There was no career structure in HTA until after 1990. About that time, people began to get advanced degrees in HTA rather than public health or health economics and health services. HTA has gradually become a visible and important field in public health and health policy.

With HTA developing in North America, Europe, and Australia, it seemed natural to consider how to improve coordination and communication. The *International Journal of Technology Assessment in Health Care* was the result in 1985, with an editorial board made up of the leaders in HTA, mostly in Europe and the United States. Also in 1985, to further international exchange, the International Society for Technology Assessment in Health Care (ISTAHC) was established (later HTAi).

The *Journal* has also been instrumental in promoting the ideas of HTA, publishing the results of HTA, and supporting and developing international standards and methods of HTA.

A key aspect of both the *International Journal* and the societies (ISTAHC and HTAi) has been their role in spreading HTA and their inclusiveness. HTA is not a group of elite people from developed countries, but includes interested individuals and groups from all over the world.

ISTAHC had an interest group on developing countries, which has continued within HTAi. I chaired this group for a time, but always believed it should be chaired by someone from

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a developing country. I am happy that HTA now has an interest group on developing countries led by experts from different countries, including Turkey, Argentina, Brazil, India, Kazakhstan, and South Africa.

Today in HTA, economic analysis has become very prominent, and efficacy seems to be somewhat de-emphasized. There is now a growing argument that "big data" can perhaps replace the difficult and expensive RCT. I fear that the fundamental importance of answering the questions about efficacy definitely may move to the background. The perspective of HTA as a broad socially oriented form of policy analysis encompassing social, cultural, legal, and ethical implications is still described in projects concerning the nature of HTA (12;13), but cost-effectiveness seems to be the dominant paradigm, also in methodology development. I regret this trend.

I have been much praised and rewarded in my work, and the contributions of others often are not equally recognized. My main reflection on these 40+ years in HTA is how much I owe to colleagues and friends. Without the friendships, support (and criticisms) of many others, my professional life could not have developed as it has.

My greatest concern today is the role of industry in HTA. Industry can be an important source of information and help. But how can we refer to industry as partners when our first concern is the public health? The commercial health care industry is mostly concerned with creating returns for their shareholders.

There are many concerns one can raise about industry. High medicines prices today are a key concern for many countries. The development of the World Trade Organization and its requirement that all countries have pharmaceutical patents for at least 20 years have made these monopoly prices possible (14). In many documented cases, prices exceed the cost of research and development (R&D) by many times; cancer drugs and treatment for hepatitis C are the most visible issues now (14). The industry claims that high prices are necessary to cover the costs of R&D, without revealing the amounts it spends on R&D.

An important challenge for today's HTA is independence; it is difficult to find experts who do not have financial relations with the industry. HTA is not free of these influences. In 2014, several senior HTA experts from seven countries wrote to HTAi to protest industry influence in activities of our international society (15). The response to the concerns expressed in the letter is still being developed.

National HTA programs usually work on their own, and they resist consolidation and coordination, despite various attempts to harmonize HTA, especially in Europe. A recent edition of the newsletter *Politico*, published in Brussels, says that the European Commission is about to release a plan to harmonize HTA results to arrive at a common method of measuring the efficacy of drugs and reduce duplication of efforts (16). The article quotes a spokesman for the Institute for Quality and Efficiency in Health Care (IQWIG), the Germany HTA agency, that the agency takes no money from drug makers, and that IQWIG is keen to protect its independence. In short, Germany and probably other larger countries resist harmonization because they do not trust the industry-influenced results of other HTA programs.

HTA has become an important force in the health care world. I am proud of my part in making this happen. I think it is very important that we indulge in self-criticism and seek continually to broaden and improve the role of HTA (and other evidence based activities) in the health field.

CONFLICTS OF INTEREST

Dr. Banta has nothing to disclose.

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