INTRODUCTION

Today, because of scarce resources for healthcare, the explosion of new health and medical technology, and the cost of that new health and medical technology, the need to ensure cost-effective use of health technologies has become a critical public issue in all healthcare systems around the world. As a result, Health Technology Assessment (HTA) is, or is becoming, a critical function in any healthcare system. The main approach used across most healthcare systems consists of conducting cost-effectiveness analysis, a standard tool used in health economics, whereby the costs and benefits of one health intervention are compared with costs and benefits of another by calculating the incremental cost-effectiveness ratio, which expresses the cost per additional unit of health benefit conferred for one intervention compared to another [Gold et al. 1996]. The field of HTA lends itself to a number of opportunities for the field of operations research (OR) and systems sciences, both in terms of applications and research, and hence is one focus of this report.

This chapter examines HTA work conducted in the public health arena in five countries, with a focus on operations research used in the context of health technology assessments. Applications of HTA, active research areas in the field of HTA as well as state-of-the-art OR work being done in related aspects of public health are described. The five countries are:

- United Kingdom
- Germany
- Austria
- The Netherlands
- France

UNITED KINGDOM

Significant funding is available in the United Kingdom for research studies related to HTA.* Most funding is being directed toward randomized clinical (or control) trials (RCTs), which generate data that is useful for subsequent HTA studies. Therefore, it is not surprising that there are many researchers who are interested in applying their models and techniques within that field.

Several government health agencies are involved in HTA-type research. For example, HTA represents the largest single research area for the Department of Health (DH), which is responsible for developing health and social care policy and guidance in the U.K. The National Institute for Clinical Excellence (NICE), part of the National Health Service (NHS), provides national guidance related to treatments and care for NHS patients in England and Wales. It was organized specifically to evaluate new treatments and drugs and to conduct HTA. Furthermore, one of the three primary research streams at NHS specifically focuses on HTA. Finally, the

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* For more information on funding and sources in the U.K., see Chapter 2, “Trends in Information Technology and Chronic Disease Management,” by John Blake.
Medical Research Council—similar to the National Institutes of Health (NIH) in the United States—also funds clinical trials and HTA.

Current projects in the U.K. include research into the cost-effectiveness of screening programs, such as those for Down Syndrome and cervical cancers, as well as those in the developing world where funding is limited. Other current HTA projects include end-stage renal disease, diabetes, coronary heart disease, and HIV/AIDS.

Studies are being planned that will look at ways to develop new OR methods to address a wide range of issues in the U.K. For example, researchers are very interested in developing new health impact assessment methods in conjunction with environmental impact assessments and in developing new methods for risk assessments in order to improve HTA studies. Future research within the OR field will be directed towards designing new evaluation methods and techniques in the absence of RCT data, in part to reduce costs because RCTs are typically very expensive. Another future project will be screening for asymptomatic left ventricular failure. From a more methodological standpoint, researchers will look at how co-morbidities can be accounted for and how they can influence the effectiveness of different screening programs.

Another group plans to develop methods for identifying where a given diagnostic test needs to be placed on the Receiver Operating Characteristic (ROC) curve for that test to be cost-effective. The ROC curve is a way to represent the diagnostic accuracy of a diagnostic test. In the U.S. this approach is often referred to as “the challenge region.”

**GERMANY**

The focus on explicit control and regulation of health technologies was not a major issue in the past. While regulations for licensing pharmaceutical and medical devices was important, other types of technologies did not receive much attention. As noted by the International Society of Technology Assessment in Healthcare (ISTAHC, 2002, p.9), “keys to the rapid change of that situation were both the stimulating efforts of networking on a European and an international level as well as an increasing reliance on HTA in regard to the support of decision making on different levels of healthcare.” The German Scientific Working Group Technology Assessment for Healthcare was established in 1997, as a direct result of the German HTA project, funded by the Federal Ministry of Health starting in 1995.

As in the U.K., significant funding is available in Germany to support HTA. The most significant funding source by far is the German Ministry for Health and Social Affairs. Other potential sources of project funding include three Directorates-General within the European Commission (Research, Health & Consumer Protection, and Employment & Social Affairs), the German Research Council, and several philanthropic foundations.

A number of HTA activities exist and include several institutions, including the Office of Technology Assessment at the German Parliament. The major activity can be observed in the use of HTA results by the Federal Standing Committee of Physicians and Sickness Funds for the purpose of decision making on the coverage of technologies in the benefits catalogue (ISTAHC 2002). Current HTA projects in Germany include cystic fibrosis, drug therapy in terminal illness, and coronary heart disease. Furthermore, German researchers have expressed great interest in conducting comparative studies among EU countries.

While a more systematic approach to HTA and its use has started, there are still considerable inconsistencies in the different healthcare sectors (especially between ambulatory and in-patient settings) with regard to coverage decisions and the management of diffusion and usage of health technologies (Ibid). The Reform Act of Statutory Health Insurance 2000 was implemented with the aim of improving this situation and strengthening the use of HTA in the system. Interestingly, in the future, information technology hardware and software will be evaluated to determine whether and where investments are justified, just as, in the past, health and medical technologies were similarly evaluated. An Institute for Quality and Efficiency in Healthcare is currently being formed; hopefully its HTA studies will provide some opportunities for operations researchers to test, develop, and implement new techniques. A joint committee between the sickness funds and healthcare providers in Germany is being formed to make decisions about benefit catalogs. This work will require HTA studies to define those benefits that should be placed in the catalogues.

Longitudinal studies of disease, utilization, and evaluation of health technologies are currently being pursued in Germany with the goals of creating guidelines and establishing contracts. A brand new program in Berlin with
an educational perspective is being implemented whereby comprehensive evaluations of health technologies will be conducted from their inception through to their implementation and utilization within the healthcare system.

AUSTRIA

Only recently have strategies for steering the cost-effective use of health technologies become an important public health issue. Although not yet institutionalized as an instrument to support and/or control the dissemination and use of health technologies, a substantial amount of HTA is now being performed in Austria. One academic institution in particular has been performing HTA over the last decade: the Institute of Technology Assessment at the Austrian Academy of Sciences (Ibid).

The research funding sources are very similar to those available in Germany. Funding is available from the European Union as well as two funds—the Healthy Austria Fund and the Austrian Research Fund—several Austrian government ministries, and the Austrian National Bank. All of these organizations currently fund HTA research in Austria and have expressed interest in continuing to do so in the future.

Operations researchers in Austria are involved in a number of projects, including the evaluation of government policies related to vaccination and AIDS/HIV. Other topics of research include HIV and hepatitis C transmission and prevention, coronary heart disease, drug use and prevention strategies, and diabetes. The research in Austria has raised a number of research questions; for example, in diabetes research the goal is to develop good models of how the disease evolves over time and how different treatment strategies will slow down the progression of the disease and prevent complications.

THE NETHERLANDS

Like many small European countries, the Netherlands has a long history of interest in HTA and medical technology assessment. For example, transplant programs are evaluated before any treatment decisions or screening programs. It appears that this trend is due to the fact that health research in Europe, especially in those countries without a domestic pharmaceutical industry, is performed with an emphasis on cost containment, thus supporting HTA-type research that can be used to justify the costs of drugs within the healthcare system.

The Netherlands has a very active HTA program today. The Institute for Health Technology Assessment, in Rotterdam, is the largest of its kind in Europe. It employs about 35 high-level researchers, a mix of operations researchers, public health people, and economists. More than 60 percent of the funding for the institute comes from the pharmaceutical industry, and the rest comes from the government and other sources. Cost-effectiveness analysis (CEA) has been part of medical studies for quite a while in the Netherlands, which also has a large and talented group developing improved utility- and question-based methods for health-related quality-of-life assessments. Current HTA projects in the Netherlands include:

- Alzheimer’s
- Hypopituitarism
- Erectile dysfunction
- Fecal incontinence
- Leukemia
- Migraines
- Spinal cord injuries

There is a strong interest in forming a national institute modeled after NICE in the U.K., and this will most likely happen. HTA will soon be introduced as a requirement for any drug before it can be sold and for medical technology producers before they can distribute medical technology in the Netherlands. Furthermore, extensive research is being conducted into new methods for quality-adjusted life years (QALY) assessments and for determining how to use the information obtained from these assessments in the context of HTA and cost-effectiveness models. Such research is described further in a subsequent section.
FRANCE

Interest in HTA in France does not appear to run as deeply as in the Netherlands and other European countries. This is due, in large part, to a limited number of funding sources. Funding is available from the EU, the French government, and the private sector. In addition, French researchers have been able to obtain some funding directly from Federal agencies in the United States such as NIH, the Centers for Disease Control and Prevention (CDC), and the Environmental Protection Agency (EPA) to conduct operations research in related public health fields.

Much of the HTA work being done in France is performed directly by government agencies, in particular INSERM, the National Institute for Health and Medical Research, and ANAES, the National Agency for Accreditation and Evaluation of Health and Healthcare. Unlike health research organizations in many other countries, INSERM conducts OR that is directly applicable to epidemiology and public health. Areas of research interest include AIDS vaccine trials and methadone programs.

Current HTA projects at ANAES include research in age-related macular degeneration, hip replacement, cardiovascular disease, the use of robotics for surgery, and the evaluation of imaging studies and technologies. ANAES has a small extramural research program that permits a limited number of outside researchers to participate.

An estimated 45 to 65 percent of medical technologies that are now being used have no research-based evidence of effectiveness. To address this problem, future HTA research should, for example, focus on better identification and resolution of issues related to health technology deployment and implementation.

Under the leadership of Professor Chick at INSEAD, a strong OR group is pursuing state-of-the-art research in public health by developing sophisticated stochastic infection models for AIDS and other STDs; modeling infection/transmission rates in novel and powerful ways, and developing new associated risk assessment methods. In the future, the objective is to eventually consolidate the various techniques and models into tools that will assist decision-making processes in various fields, such as secondary transmission risks and water treatment decisions (the latter in cooperation with the U.S. EPA). Chick and his colleagues are leading modern risk assessment research along a hierarchy of modeling techniques involving increasing levels of complexity: from systems dynamics models, to stochastic models, to microsimulation models, and finally to dynamic social network models (e.g., Riolo, Koopman and Chick 2001). These techniques, and especially their integration into usable decision support tools, hold great promise for the analysis, control and surveillance of infectious diseases as well as in the analysis of the effectiveness of health interventions and technologies.

RESEARCH ISSUES

Research issues in the field of HTA (addressed primarily in the Netherlands) include the development and implementation of appropriate methods for measuring and estimating costs and effectiveness; the development and implementation of a variety of mathematical and statistical models to examine, represent, and analyse the impact of diseases and conditions on individuals and populations over time; and the development and implementation of economic models to predict and analyse the costs related to health technologies at individual and population levels over time.

As noted by Kongnakorn and Sainfort (2004), the measurement of health outcomes is a critical matter in medical decision making and health technology assessment. Clearly, when clinicians and patients make clinical decisions such as choosing among alternative medical treatments, they base at least part of their judgment on their perceptions of expected relative gains or losses in future health. The existence of a good metric for measuring future health resulting from alternative treatments would greatly facilitate the process of making such decisions. Indeed, the ultimate goal of medical treatment, and of health technologies, is not to improve a particular clinical parameter or eliminate particular symptoms, but to improve the health of patients. There is little dispute that improving health in medicine involves two main components: increasing life expectancy or “length of life” and increasing “quality of life” of patients [Fryback 1998]. Clinical outcomes defined in terms of mortality or physiological measures such as blood pressure or intermediary diagnostic test results are often necessary, but insufficient for making a final treatment decision. Patients’ preferences for health outcomes need to be captured and explicitly included when contrasting and evaluating alternative treatments for making medical decisions. Thus, any health outcome measure would need to account, in some way, for both length and quality of life.
Similarly, at the population level, capturing and aggregating individual preferences is also often deemed necessary for evaluating new treatments, health services or health technologies. Failure to include such information may result in suboptimal decisions that do not conform to individual or societal preferences. In HTA, an important goal is to permit comparisons across diseases or conditions. Therefore, health benefits need to be expressed in generic terms such as “health-adjusted life years” (HALYs), as opposed to disease- or condition-specific terms (such as number of disease-specific cases averted).

HALYs are viewed as a large field of research encompassing a number of measurement systems, which differ in at least three overall dimensions: (a) disease-specific versus generic measures; (b) non-preference versus preference-based measures; and (c) use for individual versus societal decision making. A generic measure permits comparisons of health benefits across diseases or conditions and is not naturally tied to a certain disease or condition (as would be the case with physical measures such as blood pressure or total cholesterol level or a condition-specific rating scale such as a scale measuring back pain). As noted by Fryback [Ibid], another fundamental difference between measurement systems is whether the numbers generated reflect individual preferences for different health states—and thus are derived from human judgment about the relative desirability of being in one health state versus another—or are derived in a manner not directly related to preferences. For example, the eight scales of the short-form health survey SF-36™ [Ware and Sherbourne 1992] produce numbers that do not reflect individual preferences. Utility-based models such as the Health Utility Index [Torrance et al. 1982], on the other hand, are specifically designed to reflect preferences.

Finally, it is important to note that measures designed to support individual decision making may or may not lend themselves to aggregation across individuals in a population to assist in societal decisions. Thus, in terms of the applicability and validity of measurement systems, it is important to consider the viewpoint being adopted. In the U.K., Nord et al. [Nord et al., 1999], for example, have identified a number of limitations in aggregating individual measurements of health-related quality of life for assessing the societal value of healthcare investments and have proposed adjustments for dealing with such problems.

A number of measurement systems have been developed by researchers from many different disciplines. The most widely used model, developed with contributions from operations researchers, economists and psychologists, consists of the QALYs model, a generic, preference-based measurement system designed to assist in individual decision making. It is widely used for societal decision making and health technology assessment, provided that its limitations are properly dealt with [Nord 1999]. In Europe, health is described in the EQ-5D system, a system developed by the EuroQol Group (1990), an international research network established in 1987 for self-health assessment by researchers from Finland, the Netherlands, Sweden, and the United Kingdom. The EQ-5D presents health in terms of five dimensions: mobility, self-care, usual activities (work, study, housework, family, or leisure), pain or discomfort, and anxiety or depression. The model is a generic measurement system designed primarily for studying population health and performing cost-effectiveness analyses. Research continues to be extremely active in this area throughout the world but especially in Europe and in the United States.

**SUMMARY**

In terms of research funding, HTA predominates in European countries. As a result, more OR people are involved in HTA than in other research areas covered in this report. Much of the work is being done by government agencies, which provides opportunities for OR groups to participate, thereby testing new methods and contributing to the field.

Very few government healthcare agencies, with the exception of NHS in the U.K., actually have an OR group working with them. Agencies in France, for example, are dominated primarily by clinicians, public health professionals, and economists. The focus areas of HTA studies vary from country to country depending on their perceived needs and available resources, though several comparative studies are currently being performed among EU countries.

From the standpoint of OR, most of the HTA work being performed in the countries discussed here is of an applied nature. That is to say, most studies use existing tools and focus on a single medical technology or disease of interest. Much less research is being done on the methodology behind the conduct of HTA studies themselves. Two notable exceptions are the Netherlands and France. Research in the Netherlands has a heavy
methodological research focus on outcome measurements and health-related quality-of-life assessments. Research in France has a heavy methodological focus on research into epidemiologic and public health issues.

REFERENCES


