PHARMACEUTICAL COVERAGE POLICY IN EUROPE

Focusing on the Experience of the Netherlands and Switzerland

H. David Banta, M.D., M.P.H.
Health Technology Consultant
World Health Organization (EURO)

67 rue de la Roquette
75011 Paris, France

Introduction

During the past several decades, health policy debates around the world have been dominated by the costs of health care, "value for money in health care", and related issues. Health technology assessment (HTA) developed in part because of the problems identified with efficacy, safety, and cost-effectiveness of health technologies (broadly defined) and partly because of the needs of health policy and practice for such information. The United States was the innovator in this area, forming the Health Program of the Office of Technology Assessment in 1975. While HTA covers a broad area of concerns, its core is to evaluate efficacy, safety, and cost-effectiveness of health care. In HTA, "health technology" is a broad concept, including pharmaceuticals and equipment, but also medical and surgical procedures and also organized systems of care.

Since 1975, HTA has gradually spread around the world. European countries active in HTA include the United Kingdom, the Netherlands, Spain, and France. Essentially all countries in the European Union now have national publicly-funded programs in HTA, usually associated with the ministry of health or its equivalent. Many countries around the world have such programs or are developing them. One indication is that the International Network of Agencies for Health Technology Assessment (INAHTA), an organization of public agencies, has about 35 members and receives 2-3 applications for new membership every year. Furthermore, health policy papers from the European Commission (EU) have stressed the importance of improving quality and cost-effectiveness of health care and have pointed to HTA as a key tool for the future in Europe.

Health technology assessment, as carried out by most countries, follows a process such as this:

- Identification and priority-setting
- Literature search and synthesis
- Original data collection
- Final synthesis and conclusions (recommendations?)
- Dissemination and implementation of HTA findings
- Evaluation and feedback

The growth in the field of HTA, and related developments, means that a great deal of information is now available to support such activities as defining a benefit package based on careful assessment of (especially) benefits, risks, and costs

HTA is a form of policy analysis. One of its key strategies is to identify policies and work with policy-makers to assure that assessment information is used. Some of the most important policies in this regard are those toward research and development (R&D), national drug policy, national equipment policy, regulation and placement of expensive technologies, payment (including coverage), information dissemination, and education and training.

Relationship Between Health Insurance Coverage and Health Technology Assessment

Coverage of health care interventions – called "benefits" from the perspective of those receiving services from a health care plan and in the language of health insurance –

means that the cost of these interventions is partly or fully paid for or reimbursed by a health care plan (Eddy, 1991) This may be a national health care system or any social or private insurance system. In practice, benefits coverage is largely implicit in national health systems. It can be an explicit issue in health systems based on social insurance, such as most of those in Europe, because the insurer (or Sickness Fund) must decide what to cover and what not to cover.

The issue of coverage and how to make such decisions has only been an issue for less than 20 years. During that time, a number of countries have made great progress in defining an explicit benefit package based on principles such as health benefits (efficacy and effectiveness) and cost-effectiveness. However, much remains to be done, even in the most advanced countries.

Beginnings of Policies Toward Coverage

Until the early 1970s, it was generally assumed that more medical services – more medical and health technology – was by definition a good thing. Health care providers, especially physicians, provided services that were good for the health of the population and the costs of these services were covered by health systems. The attitude of insurance companies and sickness funds was that their job was to pay for services provided in a timely manner, efficiently with a minimum of bureaucracy and administrative interference, and without corruption. It was assumed that physicians were providing the appropriate services.

However, the assumption that the provided services were appropriate began to be questioned by a number of individuals and groups, stimulated by rises in the expenditures for health care that began as early as 1965. The search for the "culprit" for such rising expenditures pointed directly to health technology, broadly defined, or what economists refer to as "inputs" to health systems. Policy-makers began to ask themselves whether such expenditures were justified by the "outputs" in terms of health benefits.

This new questioning of the value of health services led directly to the field of health technology assessment (HTA), It also stimulated the development of the Cochrane Collaboration, a world-wide network of centers and people to identify evidence of efficacy and synthesize it to provide the evidence for better practice, evidence-based medicine and evidence-based health care, and related developments, including changes in coverage determination.

In the United States, such questioning led to Blue Cross Blue Shield (BC/BS) Association, then the largest health insurer in the United States, to begin to develop standards for coverage. BC/BS developed the Medical Necessity Program (MNP) in 1977. In early reports, BC/BS identified, without any difficulty, a number of procedures, especially in the diagnostic area, that did not seem to provide any important benefits. BC/BS then began to remove payment for these benefits by explicit statement, sometimes referred to today as "a negative list". BC/BS was encouraged by this experience, and later established a "Technology Evaluation Center" to systematically evaluate benefits, especially new technologies seeking entrance to the insurance benefit package. The Technology Evaluation Center (TEC) was established about 1983, and assisted by the Medical Advisory Panel (MAP)

which includes world-renowned experts in evaluation and health technology assessment; it has evaluated the safety and efficacy of a large number of technologies. Unfortunately for other such organizations, the evaluations carried out by TEC are considered proprietary and confidential by BC/BS, carried out to guide its own coverage decisions.

Following the early BC/BS experience, the US Medicare program, a national program aimed mostly at paying for medical care for the elderly, became concerned about coverage. Following the introduction of the computed tomography (CT) scanner in the United States in 1973, questions were raised about the benefits of such an expensive technology (typically about US$1 million at that time). Investigation by the US Office of Technology Assessment (OTA, 1978) found that an explicit coverage decision had been made based on a telephone call to one or two radiologists. The US Congress passed legislation in 1978 to establish a National Center for Health Care Technology (NCHCT), one of whose tasks was to give advice to the Medicare program on coverage decisions, based on good science. The program for this purpose was named the Office of Health Technology Assessment (OHTA) and has continued, under different names, to give coverage advice to the program since that time, although NCHCT disappeared as part of Reagan Administration government cut-backs. The Medicare program considered making formal studies of efficacy and cost-effectiveness the basis of coverage decisions. However, the Medicare Act states that services shall be provided as "usual and customary". Legal advisers felt that this wording was not strong enough to allow a very aggressive policy toward coverage.

A number of other US organizations, mostly Health Maintenance Organizations (HMOs) or insurance companies, also do HTA for coverage purposes. These include Aetna and Prudential, two private health insurance companies, and Group Health Cooperative of Puget Sound, TEMINEX, United HealthCare, and the University Health System Consortium, all HMOs or managed care organizations (Rettig, 1997)

The experiences in the United States have been followed by similar activities in Europe, although with a lag period of more than 10 years. This paper will focus on two of the most advanced countries, the Netherlands and Switzerland. However, almost all countries in Western Europe with social insurance have developed such coverage systems or are intending to do so. Leaders include France and Germany. A more implicit process is carried out in the United Kingdom and Sweden, which have national health systems, but also have strong HTA programs.

The Netherlands Experience

The **Dutch** health care system is a mix of a reimbursement model (health insurance) and public contracts. Most individual health care providers are private entrepreneurs. Hospitals are private/non-profit. General practitioners are paid by a mixture of capitation and fee-for-service. Specialists are usually paid fee-for-service. However, an increasing percentage of specialists work for hospitals on salary. All inhabitants of the Netherlands are obligatorily insured for long-term medical care, and about 60% of the population are members of the 20 or so sickness funds. Almost all of the rest have private health insurance. Referral to secondary care by a general practitioner is required in the case of all sickness fund patients.

The issue of efficacy/effectiveness of health technology became an issue in the Netherlands in the early to mid-1980s. In 1982, the Sickness Funds Council was confronted with patients who demanded that the costs of heart and liver transplantation that had been performed abroad would be reimbursement by the sickness funds. The debate stimulated by this case led to a 1983 government paper, "Limits to the Expansion of the Benefit Package" (Grenzen aan de groei van her verstrekkingenpakket). The paper stated that in the future all major new medical technologies were to be assessed for their efficacy and cost-effectiveness and would be admitted to the benefit package according to their priorities. A serious problem was the lack of expertise in assessing efficacy and cost-effectiveness in the Netherlands.

In 1985, three major evaluations were begun on liver and heart transplantion, plus in vitro fertilization, funded by the Sickness Funds Council and the Ministry of Health. The actual evaluations were carried out in three university hospitals. The final reports in 1988 and 1989 led to coverage decisions with defined conditions of use. All three technologies were eventually covered.

The lack of expertise and experience in evaluation in the Netherlands led the Director General of Health to ask the Steering Committee for Future Health Care Scenarios (Stuurgroep Toekomstscenario's Gezondheidzorg) for advice on a long-term policy on health technology assessment (HTA). A project on future health care technology under the direction of a specially-appointed committee met from 1985 to 1987 and developed a comprehensive overview of future health care technology, including recommendations for the development of HTA and its use in policy decisions.

In 1988, the government responded to this report with a report "Limits to Care" (Grenzen van de Zorg) that was presented to the Parliament. The government requested advice on limits to health care from three important councils, all of which pointed to HTA as an important tool for establishing the border between effective and ineffective care, as well as establishing the border between affordable care and non-affordable care. The Sickness Funds Council emphasized that HTA could help break the automatic addition of new technology to the health care benefit package.

In 1988 the Sickness Funds Council and the Ministry of Health, in cooperation with the Ministry for Education and Science, established the "National Fund for Investigational Medicine" (Fonds Ontwikkelingsgeneeskunde) with a budget of 36 million guilders (about US$20 million) a year. Projects under this fund may evaluate new or established technologies, examining efficacy, cost-effectiveness, social, ethical, and legal implications, depending on the policy decisions that may be taken. In practice, projects have mainly dealt with new technologies proposed for the benefit package. Proposals were initially solicited from the medical faculties ("bottom-up approach"), but evaluations showed that these proposals were often not high priority, so the program has gradually changed to emphasize commissioned research on important topics ("top-down approach"). In addition, the government has from time to time requested for support for a study of a technology of policy importance, such as lung transplantation. Recently, a large part of the Fund has been moved to the National Organization for Science (NWO), but its principles remain similar. Results of the evaluations have generally had great influence on health policy, especially coverage decisions.

Another important report was published by the Sickness Funds Council in 1991: "Limits to the Growth of the Benefit package: Third Advice" (Grenzen aan de groei van het verstrekkingspakket: derde advies). The report stated that efficiency was an important criterion for inclusion of a new technology in the benefit package and that technology assessment could evaluate this aspect of a technology. The central point in this report concerned inclusion of essential services in the benefit package. The Council concluded that the legal basis for controlling development of the benefit package was insufficient, since the law defines help by medical specialists and general practitioners as "insofar as this help is considered usual by the medical community". The report also acknowledged that legal policies were not enough to assure the appropriate definition of limits to care. Consensus forming and clinical protocols were seen as two possibilities for going beyond formal policies.

By the 1990s, then, HTA and coverage had become an important health policy issue in the Netherlands. In 1989, a special commission was appointed with the task of analysing choices in health care. One of the key sections of its 1992 report dealt with how to define the basic benefit package (Dunning, 1992). In its report, the committee acknowledged serious problems of ineffective and cost-ineffective technologies and overuse of effective technologies in the Dutch health care system. It proposed the use of four screens or "sieves" or "funnels" to define a basic benefit package. First, is the care **necessary**, meaning (for example) is it necessary to assure normal function or to protect life? Second, is the interventions proven to be **effective** by controlled clinical trials? Third, is the care **efficient**, meaning is it shown to be cost-effective by a formal analysis? Is the cost reasonable when compared to the benefits? Fourth, is it possible to leave the care to **individual responsibility**? For example, the committee concluded that in vitro fertilization and homeopathic medicines could be left to individual responsibility (although, in fact, in vitro fertilization is fully covered as a benefit). The committee concluded that applying these four screens in selecting technology to be included would result in a rather extensive benefit package without excessive costs.

However, this model has in fact not been fully applied because of practical problems. As the report itself acknowledged, information on effectiveness and cost-effectiveness is often lacking, requiring prospective studies. Such studies may take years. Another problem is that coverage policy is a **macro** policy, which has limited effects at the bedside of the patient. Other policies must be developed to influence medical practice, such as clinical guidelines and protocols. Another problem is that there are thousands of health technologies. No comprehensive list of technologies has ever been made for all of health care, much less an assessment. As one insurance executive noted, "We must take as a basic assumption that those things that doctors do now are effective. Otherwise, we have to assess everything in health care in a short period of time, which is impossible" (Cranovsky et al, 1997). Such areas of health care as mental health care, home health care, chronic disease care, and nursing home care are examples of huge areas of activity that are essentially not affected by coverage policy.

Faced with these problems, the Sickness Fund Council and the Ministry of Health have followed a pragmatic policy, based on assessing new technologies before they enter the benefits package.

Technologies following into the general category of "advanced medical care" are treated in a special way. Prohibition, temporary prohibition (while an HTA is done),

and not very strong regulation by favouring certain specific interventions are all possible. The Investigational Medicine Fund prospectively evaluates these technologies, usually by a randomised controlled trial with a simultaneous cost or cost-effectiveness analysis. During the assessment process, placement of the technologies is regulated by a "certificate of need" program, the so-called "Article 18" program, after its Article in the Hospital Provisions Law.

Pharmaceuticals are more comprehensively assessed. For pharmaceuticals, there is a positive list of pharmaceuticals and a price reference system; co-payment is applied when a drug is higher priced than other drugs with the same therapeutic goal. Extensive information on cost-effectiveness of specific pharmaceutical products is presented by the Sickness Funds Council to all physicians. Within two years, all drugs are expected to be assessed for cost-effectiveness, with coverage decisions made on the basis of such information. There are also institutionalised deliberations between physicians and pharmacists on the local level concerning the appropriate uses of pharmaceuticals. It is worth noting that the expenditure for pharmaceuticals in the Netherlands is the lowest per capita in the European Union.

Another important point is that the European regulation of drugs through the European Medicines Evaluation Agency (EMEA) means that regulation cannot be used to prevent a drug from entering the market in any particular country. Once a drug is accepted in one country, it is almost automatic that is be allowed on the market in all members of the European Union. Therefore, controls over pharmaceuticals at the national level have tended to shift to the payment (or coverage) decision. This change has greatly stimulated the area of pharmaceutical coverage policy in Europe.

Preventive procedures are also systematically assessed (Banta and Oortwijn). Dutch prevention policy is based on a report of the government to the Parliament which emphasizes that programs should be based on evaluation of effectiveness and cost-effectiveness (Ministerie, 1995). Dutch prevention policy follows this principle. Several organizations are charged with identifying and assessing preventive procedures of a possibly high priority. Special funds for this purpose are available. Health problems are chosen as priorities for policy on the basis of criteria such as the burden of disease and the availability of effective and acceptable preventive interventions. When an assessment of a procedure is positive, special efforts are made to implement it into practice (Ministerie, 1997). However, all preventive interventions have not been assessed in the Netherlands because of the high number of possible interventions and the relatively short period of time that this policy has been in effect. A more systematic process applies to screening, which is subject to a special law on population screening (Wet Bevolkingsonderzoek) from 1996. The purpose of the law is to protect the population against screening that may be harmful to physical or mental health (Ministerie, 1996). The law states that all proposals for population screening must seek approval from the Minister of Health before they are launched. Any proposal for a national screening program must be referred to a special committee of the Dutch Health Council, an organization set up to give the government advice on scientific issues in health and health care. The committee is required by law to carry out an assessment of the safety, effectiveness, appropriateness, ethical aspects, etc., and make a recommendation to the Minister of Health. The Minister of Health makes the decision concerning implementation of a screening activity after

receipt of this report. The law also includes a provision requiring an assessment by the Health Council Committee of any research on screening. Recently, for example, the Committee approved a large randomised clinical trial (RCT) of prostate cancer screening on the basis of lack of evidence of benefits from such screening.

At the same time, old technologies have been assessed. The approach to old technology has been quite interesting. A quasi-Delphi study was carried out, in which hundreds of physicians, most working for or with Sickness Funds as employees and advisors, were asked to suggest health technologies that might be ineffective or outmoded. The resulting list had more than 1000 candidates for assessment. In the Delphi study, they were asked to prioritise this list, eventually coming to 125 candidates. Those 125 technologies are presently being assessed by a process in which the scientific literature is reviewed to determine if evidence for efficacy and/or cost-effectiveness is sufficient to answer the question as to whether coverage should be continued. If the evidence is sufficient to continue coverage, that is the recommendation. If the evidence is sufficient to lead to a presumption of limited efficacy and/or cost-effectiveness, the recommendation is to remove the technology from the benefit package (by a "negative list"). If the evidence is not sufficient, a prospective study is generally mounted to determine whether access to the technology should be continued or discontinued.

In time, then, more and more of health care will be assessed. But the full definition of a basic benefit package will take many years.

The Netherlands experience illustrates some important points. First, it shows the difficulty of developing a benefit package based on efficacy and cost-effectiveness, particularly in the short-run, although pharmaceutical coverage policy is more advanced and comprehensive. Second, it shows that coverage decisions can be based on such considerations. This is an important finding, because it means that services can be dropped or forbidden entry to the benefit package in such a way as to both enhance health benefits and save money simultaneously. Dutch policy makers have no doubts about the value of this approach to defining the benefit package.

The Swiss Experience

Switzerland has a mixed social and private system of health care. Each canton (state) has its own health law, and the health care administration is highly decentralized. Since 1996 the entire population has a choice between different health plans, including health maintenance organizations, which compete with each other, especially on the basis of additional packages of benefits. An estimated 35% of the population is covered by semi-private or private insurance schemes supplementing the compulsory insurance, but this number is falling. Hospitals are generally private/non-profit, but receive part of their budgets from government. The cantonal governments plan their own health services.

Switzerland has carried out more and more HTA for coverage decision making since the mid-1980s. This experience convinced Swiss policy-makers of the necessity for a formal process to define a basic benefit package (see Cranovsky et al, 1997). At a meeting on 30 August 1990, the Federal Commission for Health Insurance Benefits asked the Swiss Federal Social Insurance Office to establish a list of criteria to be met

when applying for recognition of medical services as reimbursable. The proposed procedure was approved by the Commission in 1992 and subsequently implemented. Beginning in 1992, a manual was developed to guide applicants in gathering the required documentation in accordance with recognized principles of medical and economic evaluation of medical services. The draft manual has been through several revisions and is still a draft, but is available in German, French and English (Swiss Office).

On 1 January, 1996, a new law introduced compulsory basic health insurance with specially regulated cantonal subsidies for basic sickness insurance coverage. The 1996 law provides for a list of approved medical procedures for basic health insurance. However, that does not mean that all medical and health care procedures are listed. In the case of physician and hospital care, all diagnostic and therapeutic procedures are reimbursed unless it has been expressly established that their effectiveness, appropriateness, and cost-effectiveness are not (or not yet) proven ("negative list"). There are approved lists for other health services, such as drugs, laboratory procedures, and preventive procedures.

All requests for the inclusion of new procedures in the positive lists are submitted directly to the Federal authorities by interested parties. The health insurers and the organizations of physicians are asked if the procedure is established or controversial. If both state that the procedure is established, it is generally covered. If either or both states that the procedures (the technology) is controversial, there is an organized process of assessment and gathering opinions before a coverage decision is made. An information synthesis on known efficacy, effectiveness, and safety is carried out, as well as collection of information on economic, legal, ethical aspects, drawn from the scientific literature and Swiss and foreign reports. If such information is available from Swiss registries, data on utilization, outcome, side effects, cost, manpower considerations, and technical aspects, are also part of the process. While experts may be contracted to do all or part of this work, the Federal Office of Social Insurance has the responsibility for producing a report detailing its conclusion. Then a specially appointed Federal Coverage Committee makes the final decision.

The Committee has a number of options. It can say "no" to coverage, it can say "no" but ask for a further assessment, or it can say "yes" to coverage. It can also say "yes" conditionally. One option frequently used, particularly in the case of expensive or complex medical procedures, is to say "yes", but only if the procedure is carried out by specially qualified professionals in determined settings. Another option is to say "yes", but only for certain medical or health indications. A final option used fairly frequently is to require further data collection, particularly by setting up a registry to collect information on technical, medical and economic aspects of the technology. The aim of this conditional coverage is to carry out a thorough HTA and make the revision of coverage after a stated period of time.

Pharmaceutical coverage is subject to a separate process under a sub-committee of the Federal Coverage Committee, made up of experts in pharmacology, clinical use of drugs, and policy-makers dealing with drugs. Here, too, there is a strong movement to require cost-effectiveness information as part of the process.

An interesting incident in Switzerland focused on routine ultrasound screening in pregnancy. After an assessment showing no evidence of benefit, the Federal authorities proposed to withdraw reimbursement for the procedure. Swiss obstetricians and patients, assisted by industry, lobbied actively against the proposal. The media made it a prominent issue, implying that the Federal authorities did not care about the health of foetuses and babies. The final outcome was that the Swiss authorities withdrew the proposal, but required that a special data collection effort be carried out involving a registry to determine the implications and possible benefits of the screening. This proposal was acceptable to doctors and patients, and the study is underway.

The Swiss authorities have been able, in a relatively short period of time, to change the health insurance law to make the powers of the Federal government explicit and to strengthen the basis of coverage decision-making. In time, as in the case of the Netherlands, an entire defined benefits package may be possible, but that time is sometime in the relatively far future. In the meantime, Swiss policy-makers also have no doubt that this approach has improved the quality of health care while making it simultaneously more cost-effective. In short, the Swiss experience indicates that basing coverage decisions on HTA is an essential part of making the health care system more cost-effective, especially in a system based on social health insurance.

Lessons from the International Experience

A series of lessons can be drawn from these and other country cases:

- Assume that most present services are efficacious and should be paid for
- Examine new technologies entering the health care system and pay for those effective and/or cost-effective ("positive list")
- Pharmaceutical products are relatively easy to deal with. They can be defined and information on their value is also available. Many countries now have positive lists of drugs to be paid for and/or lists of drugs that will not be paid for ("negative list"). There is a general movement toward cost-effectiveness. Other policies toward pharmaceuticals supplement the coverage decision, including promotion of generic products and controlling prices of pharmaceuticals on the market.
- Some areas of health care have been relatively well evaluated, and should be included, e.g., disease prevention
- Questionable technologies can be identified, examined, and removed from coverage if that is appropriate ("negative list"). This process will take many years

A final and very important lesson is that HTA and coverage decisions must be separated, at least to an extent. HTA is fundamentally a scientific process. It is based on the scientific literature, although it sometimes supports prospective research, including clinical trials. Coverage decisions, however, are political. Those making such decisions are subject to many forces, such as patient and clinical preferences, demands from policy makers (including the Minister of Health), industry lobbying, and media promotion. HTA should be seen as an input, although an important one, to this process.

It is certainly appropriate that insurance programs make explicit coverage decisions based on clear and transparent criteria. The fundamental issue here is the basis for these decisions. It seems obvious that the main issue is efficacy: does the technology actually offer a health benefit to the patient or population? It also is worth noting that The United States and Europe generally do not have a sufficiently strong basis in law to make coverage decisions based mainly on cost-effectiveness considerations. As noted, in Switzerland, the insurance law was actually changed to address this problem. The usual criteria, such as "customary practice", "experimental", and "cosmetic" are vague and difficult to define, and easily become targets for legal challenges. Wording such as "effective" and "cost-effective" can be defined with some precision and are preferable.

Limitations of Formal Policies

Physicians have a substantial degree of autonomy and considerable prestige in all health care systems. Therefore, an important issue is how to integrate HTA into clinical decision-making. The most important level of decision-making in health care is the clinic, where the clinicians and the patients decide what shall be done, within the limits of the policy framework. However, if physicians do not accept this policy framework, they have many ways to sabotage it. In addition, it must be recognized that coverage policy is insufficient in itself. Such a policy must be supplemented by others intended to more directly influence physician decisions, such as clinical guidelines and other informational strategies.

The country cases have already illustrated some ways that clinicians can be involved in HTA and coverage. Ideally, the coverage process would involve clinicians at all stages, from defining the problem through the research and to the final coverage decision. In fact, HTA rarely gives enough detailed information to define indications. Furthermore, evidence includes both published scientific information based on good studies and information taken from experience.

Summary

Coverage policy and its involvement with HTA have developed rapidly in Europe during the last 15 years. This has been made possible by development of the field of HTA, whose results can now largely be found in databanks available through the Internet. There seems little doubt that growing links can lead to a more cost-effective health care system.

The field of pharmaceutical coverage is the most advanced for a number of reasons. Pharmaceuticals have been regulated for efficacy and safety for more than 40 years, leading to a great deal of information that can be used in making coverage decisions. Clinical trials in the area of pharmaceuticals are more customary and accepted than in other areas of health care. Also, groups of patients and clinicians, and consumer advocates, have worked together to assure better information on the efficacy and safety of pharmaceuticals. Increasingly, these experiences are being followed in other areas of health technology.

Ultimately, all parties at interest, including physicians and nurses, patients and the general public, policy makers, and industry must be involved in the processes.

Beyond that, HTA should be part of all policy making and clinical decision-making. The ultimate end of such activities is to develop a "culture of assessment" in each country involving all such parties.

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