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Technology assessment, priority setting, and appropriate care in Dutch health care

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This article provides a critical analysis of the impact of health technology assessment (HTA) on priority setting in The Netherlands. It describes the limited steering powers of the Dutch government; its complex interactions with insurers, health-care providers, and patients; and the role of HTA in this context as an attempt to rationalize the debate about cost-effectiveness issues. HTA has been drawn upon for decision making on the health insurance package. Also, HTA findings have been linked to the national guideline development programs of the medical community. However, these impacts by no means have been straightforward. We argue that the political nature of the priority-setting debate asks for a broader approach to what constitutes HTA, and how it should be drawn upon in priority setting. Suggestions are made on how to do justice to the social dynamics of decision making and the behavior of stakeholders in health-care systems.

Keywords: Health technology assessment, The Netherlands

Over the past few decades, health technology assessment (HTA) has received much interest from the research community and policy makers. In this article, we provide a critical analysis of its impact on one of the major health policy challenges: priority-setting. We will describe how HTA has been used as an input from the scientific community to rationalize the debate about cost-effectiveness issues. After describing the role of government and the development of HTA, we will discuss the use of HTA for decision making on the Dutch health insurance package and the attempts to link HTA findings to the national guideline development programs of the medical community. We argue that the political nature of the priority-setting debate asks for a broader approach to what constitutes HTA. Several suggestions are made on how to complement the economic and epidemiological assumptions in HTA with the social dynamics of decision making and the behavior of stakeholders in health-care systems.

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POLICY ENVIRONMENT

The Dutch state has a major constitutional responsibility for the accessibility, efficiency, and quality of health care. But the Dutch government is not the power center from which social processes are organized or corrected. In fact, an important feature of the Dutch health-care policy-making system is the government's powerlessness. It does not directly control the main financial flows driving the health-care system; nor are there clearly legitimated and fully equipped governing institutions for implementing decisions on the arrangements for health care.

The historical basis of this bounded power can be found in a strong preference for a plurality of values and the involvement of actors outside the government in health-care

policy making (representative bodies of physicians, service organizations, insurers, and social partners). One key concept is "self governance": that what can be handled in the private sphere should not be undertaken by government. Thus, the implementation of welfare state arrangements has historically been kept as far as possible outside the political and governmental sphere.

This combination of strong government responsibilities, limited government power and heavy reliance on private (not-for-profit) initiatives has been reflected specifically in health care, not only in the way in which care is financed (insurance-based) and delivered (by free-standing professionals and private service organizations), but also in the way in which health care is administered. As a consequence of their marked mutual dependencies, the three key stakeholders in the system—government, providers, and insurers—are all fully dependent on one another for achieving their own objectives. These interdependencies are at the root of the most notable feature of the Dutch health-care policy-making system: the participation of the associations of hospitals, doctors, and insurance companies in public policy-making and, more recently, the contribution of individual hospitals, for-profit home-care organizations, and other private institutions to the production of public goods like health care. The roles of private organizations in the public domain are embedded in the broader public-private cooperative traditions of the Dutch welfare state (31;32).

Examining in more detail the way that Dutch policy on health-care choices has been conducted and decisions reached in recent years brings us to a significant paradox. The rhetoric and deployment of this policy is permeated with the need to be as rational and explicit as possible in decision making concerning medical treatment at the various levels. Evidence-based and explicit knowledge—that is what is at issue. But this strict approach is applied in a real-life situation that is heavily dependent on professional involvement at the lowest level of care, on the barely enforceable cooperation of institutions and care-insurers at the meso level, and on a consensus-building type of policy-making at the macro-level. In practice, priority-setting becomes a joint affair of public, private, and professional stakeholders, who have to act within the complex intermingling of responsibilities and decisional power. Although the positions in this system are changing, these strong dependencies and the associated policy practices of consensus and cooperation still characterize most of the decision-making processes in Dutch health care.

Over the past few decades, patients and their organizations have increasingly become a fourth stakeholder involved in health-care policy processes. They have become part and parcel of the consensus-based policy processes, especially at the macro-level of the health-care system. This finding has further increased the complexity of the interdependencies; the questions of who should speak for "the patient," and how far the influence of patients ought to reach, remain controversial issues.

In light of this, it is striking that formal policy documents emphasize the rational underpinning of decisions. Science (in the form of "evidence" and "technology assessment"—see below) is given a large role in determining the health-care choices to be made. Fields such as "medical decision making," "evidence-based medicine," and "technology assessment" have had, from the beginning, a great appeal to policy makers. The apparent promise of such fields, that a rational grasp of, and thereby "control" over, health-care decision making is possible, is hard to resist (3;28). However, contrary to the evidence-based culture of policy making and policy debates, the collaborative and political nature of *actual* decision making and implementation is hardly emphasized. This is unfortunate, we will argue, because this quest for a rational means of making decisions on health-care choices will always remain an illusion. In addition, by downplaying the actual way choices are made within the current system, policy makers cannot learn from what currently goes right or wrong. Thus, they neglect the potentialities within the complex of interdependencies that has evolved over time, and the implicit or tacit knowledge within this system, especially at the meso- and micro-level. Formal policy fails to draw upon the repertoire of personal skills of those concerned in health care, and their experience, imagination, and intuition. There is a preoccupation with erasing these "subjective" factors so that it becomes possible to manage on the basis of explicit knowledge laid down in rules, procedures, protocols and manuals (35). Thus, these two worlds coexist, and their potential interrelations are not adequately drawn upon. The formal policy process fed by (scientific) evidence threatens to remain locked up in streams of government reports and policy discourses. On the other hand, the political world of on-going debates between stakeholders with different interests threatens to remain unaffected by the lessons that these scientific tools could bring.

DEVELOPMENT OF TECHNOLOGY ASSESSMENT IN DUTCH HEALTH CARE

The active role of technology assessment in Dutch health care dates from the early 1980s. Its emergence was closely connected with the development of priority setting as a deliberate policy. Especially important were the delineation of the basic health-care package covered by social insurance at the national level and the stimulation of appropriate use of health care at the decentralized levels.

Inspired by the activities of the Office of Technology Assessment in the United States, "technology assessment" was initially introduced as part of national endeavors in health-care forecasting. It stood for a broad assessment of the "impacts" of a technology, including economic, organizational, social, and ethical considerations. Yet it rapidly became synonymous with the performance of economic evaluations in health care, notably cost-effectiveness analyses (and this is what we mean by HTA here). In The Netherlands, these

evaluations were introduced in the early eighties by the Health Insurance Council (the statutory body that administers the two social health-care insurance acts—the Sickness Fund Act and the Exceptional Medical Expenses Act—as a response to hi-tech, hi-cost health technologies such as heart and liver transplantation (27). All major new technological innovations, the Council suggested, were to be subjected to cost-effectiveness analysis before coverage in the benefit package could be considered. The notion that HTA could be of vital help for government priority setting was broadly underwritten by other advisory bodies, leading to the establishment of the Fund for Investigative Medicine (*Fonds Ontwikkelingsgeneeskunde*) in 1988 (7;27). This Fund, administered by the Health Insurance Council, constitutes the main Dutch HTA program. Its aim is to fund original research that will generate the evidence required for evidence-based policy making at the national level and evidence-based use of health-care technologies at the practice level (11). It obtains its resources (approximately 16 million Euros per year) mainly from the Ministries of Health, Welfare, and Sport, and Education, Culture, and Science.

In 1992, the Dutch Committee on Choices in Health Care produced what has since become known as the *Dunning Report*, named after its chairman (9). The main focus of the report was the assessment of the basic benefits covered in the social insurance package. A set of core principles was argued for:

- it is fairer to ensure necessary health care for all than for just a proportion of the population to have access to all conceivable medical facilities;
- an explicit and publicly accountable choice is better than covert rationing;
- in setting priorities in health care, authentic social values must be combined with professional and expert opinion as to what is meaningful and meaningless medical treatment.

The report developed four criteria to apply in succession so as to remove obsolete existing types of care from the benefits package and to prevent inappropriate new types of care from entering the system. Taken together, these criteria were called "Dunning's funnel."

1. Is it necessary care (from a community point of view)?
2. Has it been demonstrated to be effective?
3. Has it been demonstrated to be efficient?
4. Can its payment be left to the responsibility of the individual?

Criteria one and four explicated the political choices of deciding whether a (cost-effective) medical intervention also had to be paid for by collective means. Simultaneously, it emphasized that certain forms of care (such as long-term care for the chronically handicapped) should be part of the collective domain both because they are too expensive and because it is the collective's moral duty to do so. These two criteria were much debated, but left little concrete impact on policy discussions. Criteria two and three, on the other hand, emphasized the Committee's desire for an explicit, rational approach to priority-setting. This coincided well with the increasing promise of HTA for priority setting, and further strengthened the desire to stimulate economic assessments of new and current technologies.

Although the resources of the Investigative Medicine Fund are substantial, they are far from sufficient to investigate *all* new major health technologies. Therefore, priorities have to be set here as well: which technologies should be subjected to HTA to maximize HTA's potential benefits on overall health-care quality and costs? At first, the Fund focused on new, sophisticated technologies, such as heart transplantation and in vitro fertilization (25). These priorities were not selected in advance; rather, they were suggested by researchers submitting proposals (who, of course, had to substantiate why their choice would be a relevant one for the Fund to subsidize).

After several years, dissatisfaction with this "bottom-up" generation of priorities led to an attempt to determine priorities in a more top-down manner. For this purpose, in 1993 the Health Insurance Council involved some thirty experts (including medical advisors of insurance companies) in a two-round Delphi procedure, generating a list of 126 routinely used services of doubtful cost-effectiveness (such as diagnosis and therapy of herniated lumbar disk, long-term psychotherapy, treatment of leg ulcers, and palliative treatment in oncology) (25). The technologies on this list were then ranked according to the following criteria: degree of uncertainty concerning efficacy, effectiveness, or efficiency; frequency of use; costs; extent to which the concerned technology could potentially decrease morbidity or mortality and increase quality of life; extent to which technology assessment results could change the rate of use of the technology. The top five priorities based on these criteria are listed in Table 1A. This was the first attempt to rationalize priority-setting for HTA in The Netherlands. Other advisory bodies subsequently generated their rankings, resulting in several wholly new lists. During 1994 to 1995, the Advisory Council on Health Research (*Raad voor Gezondheidszorgonderzoek*), which advises the government on policy issues regarding health research, including HTA, consulted approximately 140 experts in health research and medical practice on priorities for health research using both societal and scientific criteria. Fields of interest were then prioritized in a Delphi-like procedure, resulting in a hierarchy, of which the five most important are listed in Table 1B. In 1996, the Minister of Health asked this Council to prepare a report on priority setting for HTA. For this purpose, the Council organized a workshop in 1997 to identify critical issues in setting priorities, resulting in several HTA subjects nominated for further priority ranking (see Table 1C). In 1997, the Health Council (*Gezondheidsraad*), the statuary body that advises

Table 1. Top Five Priorities Indicated by Different Actors Involved in Identification and Setting Priorities for Health Technology Assessment

A. Priorities from the "126-list" as published by the Health Care Insurance Board (1993)
   1. Ultrasound treatment for problems of the locomotive system.
   2. Treatment and cure of nonhospitalized acute psychiatric patients.
   3. Specialist care for chronic patients.
   4. Diagnosis of suspected hernia nucleus pulposa.
   5. Diagnostic arthroscopy of the knee compared with diagnostic magnetic resonance imaging (MRI).

B. Priorities from the Advisory Council on Health Research, as published in a report on exploring priorities in health research (1996)
   1. Diagnosis and treatment of the chronically ill; e.g. mental problems in children and adolescents; adults and depression.
   2. Adequate care of diseases which occur in the elderly; impairments; endocrine aspects of ageing, dementia, and cerebrovascular accident.
   3. Stimulating autonomy and self-care: the patient as actor in health-care and home-care technology.
   4. Primary and secondary prevention: innovative prevention, effectiveness and efficiency of preventive technologies, and implementation.
   5. Quality and efficiency of care: evaluation of medical practice, clinical decision-making regarding diagnostics and quality of care.

C. Priorities from the Advisory Council on Health Research as described in the advice on HTA (1998)
   1. HTA research into the economic aspects of existing technologies (especially topics on the "126-list," new technologies including medical aids, and drugs).
   2. HTA research that covers not only the efficacy (and possible costs) but also other aspects such as regional and individual differences in the care provided, highly complex care, and the macro-economic impact of (new) health technologies and/or care technologies.
   3. HTA research into prevention and diagnostic procedures.
   4. HTA research into nursing- and paramedical-care facilities.
   5. HTA research into mental health-care facilities.

D. Priorities from the Health Council derived from the "126-list," as described in the annual working program for 1999
   1. Incontinence.
   2. Chronic use of benzodiazepines.
   3. Decubitus.
   4. Use of devices in physiotherapy.
   5. Long-term psychotherapy.

HTA, health technology assessment.
Source: Oortwijn, W.J. (2000).

government on the scientific state-of-the-art with respect to health care, public health, and environmental protection, identified emerging technologies needing assessment through a type of Delphi process. Their top five are listed in Table 1D.

These lists are drawn upon to set novel priorities for new Investigative Medicine Fund rounds (29). In addition to this Fund, the Dutch Health Research and Development Council (ZON), which is accountable to the Ministry of Health, and The Netherlands Organization for Scientific Research (NWO), accountable to the Ministry of Science and Education, also fund HTA research. Here, topics for funding are generated in a variety of ways, including direct input from the Ministry or input from expert working groups that formulate funding programs. The different priority lists help shape these agendas as well. The Health Research and Development Council also funds HTA research on some public health interventions.

Overall, the "system" (if we can call it that) for deciding on the use of new health technologies is very loose. First of all, there is no central direction on *which* technologies are targeted for HTA. Dunning's first criteria, "necessary care," did not lead to any obvious exclusions. There was the 126-item list of the Health Insurance Council, which is by itself just a list to which other organizations may or may not orient themselves, and which has been regrouped and renewed in different ways. The Health Insurance's Investigative Medicine Fund has, in fact, recently been taken over by the Dutch Health Research and Development Council, which has several research and implementation programs running alongside this one. In addition, there are many other local and national initiatives, funded through different routes, which undertake HTA studies or set up trials. The Health Council of The Netherlands (*Gezondheidsraad*), for example, issues HTA reports on a regular basis. With the Investigative Medicine Fund as a major source for funding and with policy makers being interested in the results, HTA has developed as a research field in the academic community (notably, all eight academic hospitals now have some sort of HTA unit). The boundaries between fields such as medical decision making, clinical epidemiology, quality of care research, implementation research, public health research, health services research, the Dutch Cochrane Centre, and the overall movement of evidence-based medicine, however, are blurred.

USING HTA AT THE NATIONAL LEVEL

It is clear that in The Netherlands HTA research (narrowly defined as "economic evaluation") has flourished both academically and as a necessary starting point for government discourses on health-care choices. This does not mean, however, that HTA research findings are widely used in actual

decision making regarding the funding or certifying of health-care technologies. The patchy character of the ways topics are selected for HTA research and the relative lack of coordination between the different agencies prioritizing, funding, and executing HTA research is typical of the Dutch health-care policy arena. Also typical, perhaps, is that the link between the *results* of these studies and the health-care choices implemented by government (or insurance companies, for that matter) remain equally partial.

HTA studies have contributed to the decisions of the government concerning, for instance, the introduction of pancreas and lung transplantation and extracorporeal membrane oxygenation (a heart-lung machine for neonates). Yet these impacts have been far from general; nor have they been unequivocal (11;34). HTA has definitely generated an overall awareness of the importance and relevance of economic arguments. When a pharmaceutical company wants to add a new drug to the Dutch insurance package, they will often add HTA studies to their request to the Commission for Health Insurance. There is still no formal obligation to do so, however. In The Netherlands, despite all the policy rhetoric, there are no categories of technologies—drugs or diagnostic or therapeutic instruments—that have to pass an economic evaluation before they can be admitted to the insurance package. Economic considerations are often brought to the fore, of course, but there are not many examples of tough policy decisions that were decided by input from HTA studies. Sometimes, an HTA study will corroborate a decision already in the making, and then it will be used as such. Sometimes, an HTA study will remain unused because, for example, the research question is too far removed from the policy question at stake. In the case of complex, controversial technologies, the Ministry and/or the Commission for Health Insurance sometimes explicitly call for a HTA analysis. Even in such instances, however, technologies that were proven to be *not* cost-effective have been allowed anyway, as happened in the case of lung transplantation (29). In a recent example, the situation was exactly the opposite: whereas a high-quality HTA study (commissioned by the pharmaceutical company Pfizer and undertaken by an academic research institute) had proven the cost-effectiveness of Viagra as a treatment for erectile dysfunction (the cost per QALY was in fact far less than in the case of many well-established health technologies), the Minister decided to exclude it from the basic package (30). In this case, the expected total financial impact of the introduction of this new technology on the health-care budget (and possibly its symbolic meaning) had more political weight than the outcome of the HTA analysis. More often still, technologies are introduced without any HTA evaluation.

At the national level, then, The Netherlands handles the appraisal of (new) health-care technologies through a patchy assembly of rather different procedures, standards of proof and institutions, in which use is made of a mix of strategies and shared responsibilities, with an important role for the actors at the institutional and professional levels. The identification, priority-setting, and funding for HTA studies is far from streamlined (although a recently established "HTA platform," with members from the involved institutions, is now committed to enhancing mutual coordination), and is heavily dependent on initiatives from (semi-)independent research and funding organizations. HTA analyses are sometimes explicitly performed to guide national policy, and are increasingly drawn upon to back up (or influence) appraisal processes. Yet the list of excluded services is still minimal and highly eclectic. Echoing the experiences in other countries, few services have been excluded from Dutch public health insurance coverage, no matter how thorough and formal the technology's evaluation. The setting of national priorities appears to be a very difficult process, in which political, economic, and moral considerations become intertwined. Nevertheless, HTA and Dunning's funnel have been very significant. There is now widespread recognition that we have to "develop acceptable ways of resolving the tension between increasing demands and limited public financial resources" (25).

THE MESO- AND MICRO-LEVEL: GUIDELINES

At around the same time that the Dunning Committee issued its report in 1991, the Dutch Health Council issued a report concerning the effectiveness and efficiency of medical treatment (15). This report was prepared under the leadership of the subsequent Minister of Health and then vice-chairman of the Health Council, Dr. E. Borst. Because the effectiveness of health care is not so much concerned with the treatments as such but with the application thereof by doctors to patients, medical treatment occupied a central place in this report. The Health Council identified a lack of knowledge about the cost-effectiveness of diagnosis and therapy as the major obstacle to the effectiveness of health care. Many treatments with undemonstrated usefulness are routinely performed. Insurers contribute to this as their payouts are based not on proven cost-effectiveness but on the criterion of established practice. On this basis, the Health Council arrived at the recommendation to stimulate the creation and use of guidelines based on the results of cost-effectiveness research.

As Dr. Borst became Minister Borst, this approach evolved into the main thrust of government policy concerning health-care choices. Instead of setting priorities at the macro-level of the system, the focus of policy shifted toward the meso- and micro-level, where health-service professionals, institutions, and health-care insurers were encouraged to promote the appropriate use of scarce resources (19). The professional community had already broadly invested in peer review, pharmaco-therapeutic consultations, education and training, consensus building, and guidelines. The minister, in turn, supported these efforts by encouraging HTA and the application of its results in medical practice.

In line with developments in other Western countries, government health policy has therefore shifted its focus in the rationing debate to emphasize clinical guidelines. Rather than limiting the basic health-care package through a process of priority setting, the emphasis is now on attempting to influence the individual treatment decisions of clinicians through evidence-based guidelines. As governments do not seem to be able to indicate what "appropriate care" is at the national level, the attention turns to ensuring that the individual health-care professional's activities are "appropriate." In the Dutch setting, "appropriate care" suggests care that "matches" an individual indication, suggesting both effectiveness and efficiency. Referring to Dunning's report discussed above, this has been labeled the "turning over" of the funnel, because the focus shifts from making choices *between* care options in the package at the national level to choices *within* categories of care options at the clinical level (24).

Currently, however, the spheres of guidelines development and HTA are only beginning to approach one another. The most important and established guideline development programs—of the Dutch Institute for Healthcare Improvement (CBO) and the Dutch College of General Practitioners (NHG)—neither fund nor undertake HTA research; they draw upon evidence found in the literature. Both the CBO and the NHG have guideline development programs that were developed in the 1980s and that over time changed their methodology from a consensus-based approach (following the US NIH model) toward an evidence-based approach (following the model of the US Agency for Healthcare Research and Quality [AHRQ]—previously called the Agency for Health Care Policy and Research [AHCR]) (8). (For an overview of CBO guidelines in Dutch, access www.cbo.nl. For English translations of some of the NHG guidelines, see www.nhg.artsennet.nl.) Until 5 years ago, there was no or hardly any formal coordination between the guideline development programs and HTA funding organizations. The need for more cooperation has been recognized, but the Dutch tendency to have the involved stakeholders design the policy rather than the government (this is also referred to as the Dutch "polder model") ensures that concrete changes in actual practices will be slow. Furthermore, until the publication of the AGREE instrument in 2001, there were few guidelines for guidelines (1;2). That is to say, the Healthcare Improvement Institute (CBO), the General Practitioners' College (NHG), and other national or local guideline producing agencies (regional cancer centers, local hospitals, specialist groups, paraprofessional groups, both locally and nationally) produce guidelines in their own ways. Only in the past few years have they started to coordinate activities between one another. On conditions such as depression and hypertension, for example, both NHG (general practitioners) and CBO (specialist) guidelines exist. Only in the past four years have there been attempts to synchronize these guidelines, which usually suggests major discussions about definitions and differences in patient populations.

However, there are few CBO (and no NHG) guidelines that formally incorporate HTA data. Those that do exist were the result of a special program on appropriateness and practice guidelines financed by the Ministry of Health. In this program, in which HTA agencies and guideline developers cooperated, a series of cost-effectiveness studies was undertaken. These were linked to specific cost-sensitive recommendations in a series of guidelines under development. Examples are the use of cost-effectiveness data in formulating the recommendations on the use of cholesterol lowering drugs and the use of recombinant tissue plasminogen activator in stroke. A major finding of these studies was that existing HTA studies are often of little use for making guidelines. Most GP standards, for example, start with patients' symptoms, which makes the application of HTA very difficult: there are hardly any data available for such HTA analyses. Research studies rarely take a collection of symptoms as a starting point; they start out from a clear-cut diagnosis, or focus on the worth of one diagnostic step rather than another. Such typical research questions, however, are not the typical questions that a general practitioner encounters in his everyday work. This mismatch between the requirements of clinical practice and the set up of clinical research is an important problem for the utilization of HTA in clinical guidelines (Cf. [1]).

HTA-based recommendations constitute a minority in the total number of recommendations in these guidelines. Nevertheless, they caused much discussion in the medical community that "owns" the guideline development process. In addition, critical questions were raised in parliament about efforts to express "the value of a human life in money." Political outcries were all the more interesting, because the medical profession, responsible for the guidelines, has felt obliged to take this step partly due to government pressure.

Despite these first experiences with incorporating cost-effectiveness notions explicitly in guidelines developed by and for the medical community, the majority of the recommendations in guidelines are still based only on efficacy or effectiveness data. From a policy perspective, this suggests that guidelines, in their present format, are primarily evidence-based (that is, based upon proof of effectiveness) and based on cost-effectiveness only to a limited extent. In the Dutch context, therefore, guidelines are presently a limited tool when it comes to "steering" the use or acquisition of (new) medical technology. The "appropriateness" agenda toward guidelines has many merits but it cannot replace the political decision making on "choices in health care." Furthermore, ethical questions are raised on the legitimacy of the medical profession as a forum to decide on rationing decisions suggested by practice guidelines (26).

Although cost-considerations are rarely systematically incorporated in guidelines, other normative considerations (concerning, for example, issues of justice, solidarity, the patient's voice in the decision-making process, and so forth) are even less well represented. This comes back to the debate on

the "narrow" definition of HTA that is prevalent in priority debates. Most guidelines may indicate whether an intervention is "evidence based," yet they would rarely state whether and when the intervention would be "necessary" from a broader normative or value perspective (such as the position of Dunning's "community"). An intervention aimed at preventing disease in low-risk individuals may be "evidence-based," but this does not answer the question on whether this intervention is "appropriate." Screening for diabetes might be cost-effective, but such a conclusion leaves unresolved whether this would be a wise way to spend scarce resources, which could also be spent on other, possibly equally cost-effective activities. An evidence-based guideline, in short, is not in and of itself "value-based," and formulating guidelines for "effective care" is not a solution for society's problem of what constitutes "appropriate care" (5).

Apart from the informal networks between guideline developers and HTA researchers, there is little coordination between the guideline-producing bodies and the agencies that set priorities for HTA and fund HTA research. Although the importance of incorporating HTA results in guidelines is widely shared, and although subsidies are given for the creation of evidence-based guidelines, as yet there is no structural financing of the HTA research that should be incorporated into these guidelines. There are, in addition, only limited resources for the actual implementation of any of the produced guidelines. Apart from a few experimental situations, there are no instances where a treatment will only get funded when a specific protocol is followed. Studies that investigate the impact of such guidelines on actual decision making leads one to be rather skeptical (14;20). This is true internationally; there are no indications that the situation is different for the Dutch CBO or NHG guidelines. Professionals are often not even aware of the content of specific guidelines, let alone that their actions are influenced by them. As a result, much work is now done to study how to most optimally implement guidelines (drawing upon techniques from social psychology, diffusion research, and marketing studies), so that health-care professionals will actually start using them (12;13;16).

DISCUSSION

Taken together, the plethora of more or less formal approaches to priority setting—whether targeted at limiting the health package or at ensuring its "appropriate" use in individual cases—has not resulted in the disappearance of the scarcity problem that led to all these activities. As a pragmatic "solution," the government has not yet abandoned the tried and trusted policy of (implicit) national rationing through budgeting. To prevent skyrocketing costs, production capacity is kept within limits, and the actual production is also bound to a maximum. HTA has become an important factor in the scene—but probably more through its indirect, symbolic function of emphasizing the importance of cost-awareness than through a direct, explicit function in policy decision making. The main stakeholders (physicians, industry, insurers, patients, government officials, and politicians) all underwrite HTA as long as its function is mainly symbolic—or as long as the HTA study's outcome underwrites the position they held beforehand.

This is very indirect steering indeed. It is a far cry from a rationalist, explicit approach to health-care technology decision making, in which the ideal situation would be one in which QALYs could be calculated for every possible intervention-per-indication. This is the ideal that often underlies calls for more generalizable technology assessments, for more rational priority-setting: to work toward a fully rational policy in which every Euro spent on health-care interventions buys an approximately equal and optimal amount of QALYs.

Yet we argue in accordance with a growing number of other authors that priority-setting is necessarily messy and difficult. It is inescapably a political process: a decision-making process that takes into account issues of interest and values, taking place under conditions of urgency and uncertainty. There are many reasons for this conclusion; many of which are dealt with extensively elsewhere (10;17;18;22). We have already pointed to a few fundamental observations. First of all, doing HTA involves making all kinds of normatively charged assumptions and interpretations. Rather than undoing the need to make political prioritizing or rationing decisions, the process of HTA can make these choices more visible (in the best case) or hides them from view and buries these choices in the seemingly "rational" HTA (in the worst case). In practice, HTA is usually only about "costs"; and moreover, it leaves all the other normative considerations that go into setting optimal criteria for diagnosis and treatment to be dealt with "implicitly" in the guideline construction or priority-setting process. Dutch HTA researchers argue that the change of emphasis in the evaluation of "effectiveness" toward a more long-term perspective (life-years gained, quality of life) is an important (and successful) aim of their efforts (E. Grijseels, personal communication).

The fundamental problem here is that health care does not have one "goal": it contains a "complex composite of many goals, including fuzzy goals such as maintaining a sense of security in the population" (17). Other "goals" can be more individual, such as reassurance, improvement of quality of life, the need for a last hope, and so forth. These goals are variable and context-dependent, making their explication and formalization over and above individual situations excruciatingly difficult. Most important, however, is that it would be an illusion to think that these goals could be ranked or grouped in any harmonious way. Not only are they fluid—depending on the individual, on the situation—they are also in perpetual tension with one another; always competing for priority.

On a more mundane note, it would be just impossible to do (and keep up to date) all the HTAs and make the evidence-based guidelines that we would like to see. This problem is enormous. It will not even be possible to focus comprehensively on even a few of the most costly and problematic issues

of the 126-list, unless a few crucial decision points are selected. The information ("evidence") is simply lacking; the calculations for comprehensive cost-effectiveness analyses simply become too complex (33). Put in economic terms, the cost of doing so would outweigh the potential benefits.

In our view, the rather technocratic idea that we *can* rationally establish appropriate care and decide on scarcity issues has a problematic edge to it when we look at the move from setting priorities at the national level to achieving "appropriateness" through guidelines for practitioners. This "pushing off" of political responsibility is legitimated by pointing at the "technical solution" that economic evaluations promise (at least in the eyes of many policy makers—most HTA researchers are not so naive). Yet as we said above, these instruments do not *solve* these issues: they bring them into the open, or displace them from one decision context to another. One important danger of this development is that the whole array of normative/political considerations linked to the question of whether a treatment should or should not be available may be pushed down from the macro- to the meso- or micro-level (25). Rather than being technically "solved," hard decisions about whether or not to spend resources to treat individual patients, or the weighing of contrary normative considerations (between equity and cost-utility, for example) will end up in the doctor's office. At the macro-level, in priority-setting debates and attempts, political and ethical considerations are discussed openly: any attempt to delete an intervention or service from the insurance package has always been met with an avalanche of moral, political, economical, and other reasons why it should or should not be included in the package. Often, of course, these issues are so conflict-prone that no solution can be found (indeed, the plurality of values and the politically charged nature of rationing decisions is often mentioned as the primary failure factor for priority-setting attempts). Yet what happens when priority setting is more or less abandoned, and the attention focuses on ameliorating decisions of individual doctors? Rationing decisions will, of course, still be made, but now by individual physicians, or behind closed doors by hospital boards (in the case of budget-shortages for example). Put critically, abandoning the priority-setting attempts at the macro-level shifts the burden of responsibility to individual physicians and institutions. Without any further conditions, this could be highly problematic, first of all because such decisions are thereby made outside of any sphere of public accountability and democratic control. In addition, those having to make these decisions are put in a position that is highly undesirable, both from their own perspective and from a more policy-oriented perspective. They have to make rationing decisions while faced with the needs of individual patients, without having recourse to publicly underwritten criteria. This combination leads to an impossible "double bind" for the health-care professional, and to inequality in the decisions made—an inequality which remains invisible because all these decisions remain implicit.

Bearing all this in mind, we would argue that you cannot make choices at the national level, e.g., on the health insurance package, the starting point of your policy. What could be different routes to health-care technology decision making? How can we improve upon our current "muddling through" while incorporating the well-founded critiques of overly rationalist approaches? One way of achieving cost reduction and quality control could be to pay much more attention to *local* efforts to streamline care, to create "evidence-based" care based not on "universal" figures but on figures locally translated or collected (and thus, are locally relevant and more achievable in terms of data gathering). Based on local information systems, indicators could be generated that are interpretable to local health-care providers, and can be fed back to them, thus stimulating them to constantly rethink their work and decision routines (4;6;21). This of course, is no Grand Solution to scarcity issues—*but that is exactly the point*. It is a means of attempting to reduce costs through local care-innovations and arrangements in which insurers and patients may participate much more effectively than in large-scale (inter-)nationally driven attempts. Discussions about goals, values, and interpretations of data are also much more feasibly settled at the local level—if not through explicit discussion, then through an implicit understanding of the existing local needs and priorities. It is a means of putting professionals, with patients and payers, in the lead in a more fruitful and creative way than as executors of some universal wisdom whose local validity is always contestable.

Importantly, "local" can mean here both locally geographically qua *domain* : as several authors have noted, working "bottom up" from specialty-specific working groups, or as coordinating efforts between HTA-funders and professional guideline makers around specific *topics* (such as, for example, cholesterol medication), which is much more doable (17). In such suitably circumscribed settings, a carefully and modestly selected set of indicators (not yet another "comprehensive" yet unfeasible wish list) could be created. This would be used primarily by local health-care professionals and managers, first and foremost for feedback, not control purposes. Such an approach would be in line with our insights elaborated above because there would be no attempt to transcend the diverse local projects with one, common measure or criterion. QALYs and economic evaluations would not loose their relevance; yet their validity would not be stretched to its breaking point by attempting to generalize between all the (too) diverse contexts.

Yet strengthening such local efforts is not enough, in and by itself. We have argued that government cannot shy away for the responsibility to prioritize, and certainly not under the name of some "technical" solution that would take away the need for difficult decisions. As Klein has argued, "in the absence of national decisions, equity is in danger" (22)—and, we would add, professionals are put in an impossible bind. This, very sketchily, could lead into the direction of more "polder-model-like" bodies (involving patients,

professionals, organizations, etc.) that are active in making allocative decisions, both on the macro- and the meso-level. We need such bodies to make decisions that *have* to be made but that *cannot* be made in a formal, rational, "technical" way. As Latour has argued, it is part and parcel of the nature of such political decisions that they are more about persuasion and conviction than about reason; that they are made under conditions of uncertainty and urgency that thwart any attempts to make them in a formally rational way; and that they are about relative distinctions between "good" and "bad" rather than searches for absolute grounds for such choices (23). In these decisions, the many-layered "costs" and "effects" of new health-care technologies should play a core role. Economic evaluations can be of help here in explicating at least some of these, and the normative considerations that abound. Here again, then, the choice is not "against" more information and "for" new institutions: it is about making such information part and parcel of the political process rather than having it stand outside it, as an impersonal arbiter.

REFERENCES

1. AGREE Collaboration. The AGREE Collaborative Guideline development in Europe. An international comparison. *Int J Technol Assess Health Care*. 2000;16:1039-1049.
2. AGREE Collaboration. Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: The AGREE project. *Quality Safety Health Care*. 2002. In press.
3. Ashmore M, Mulkay M, Pinch T. *Health and efficiency: A sociology of health economics*. Milton Keynes: Open University Press; 1989.
4. Bates DW, Pappius E, Kuperman GJ, et al. Using information systems to measure and improve quality. *Int J Med Informatics*. 1999;53:115-124.
5. Berg M, ter Meulen RHJ, van den Burg M. Guidelines for appropriate care: The importance of empirical normative analysis. *Health Care Analysis*. 2001;9:77-99.
6. Berwick DM. The NHS's 50 anniversary. Looking forward. The NHS: Feeling well and thriving at 75. *BMJ*. 1998;317:57-61.
7. Boer A. Assessment and regulation of health care technology. The Dutch experience. *Int J Technol Assess Health Care*. 1999;15:638-648.
8. Burger, & al e. xxtitle from Niek. 2002.
9. Committee on Choices in Health Care. *Choices in health care*. Rijswijk: Ministry of Welfare, Health, and Cultural Affairs; 1992.
10. Coulter A, Ham C, eds. *The global challenge of health care rationing*. Buckingham, Philadelphia: Open University Press; 2000.
11. Elsinga E, Rutten FFH. Economic evaluation in support of national health policy: The case of The Netherlands. *Soc Sci Med.* 1997;45:605-620.
12. Grimshaw J, Freemantle N, Wallace S, et al. Developing and implementing clinical practice guidelines. *Qual Health Care*. 1995;4:55-64.
13. Grol R. Beliefs and evidence in changing clinical practice. *BMJ*. 1997;315:418-421.
14. Grol R, Grimshaw J. Evidence-based implementation of evidence-based medicine. *Jt Comm J Qual Improv*. 1999;25: 503-513.
15. Health Council of The Netherlands. *Medisch handelen op een tweesprong (Medical treatment at the crossroads) [in Dutch]*. The Hague: Health Council of The Netherlands; 1991.
16. Health Council of The Netherlands. *From implementation to learning: The importance of a two-way dialogue between practice and science in health care [in Dutch]*. The Hague: Health Council of The Netherlands; 2000.
17. Holm S. Goodbye to the simple solutions: The second phase of priority setting in health care. *BMJ*. 1998;317:1000-1002.
18. Hunter DJ. *Desparately seeking solutions. Rationing health care*. Harlow: Addison Wesley Longman Ltd; 1997.
19. Keynote address. Second international conference on priorities in health care; 1998; London.
20. Klazinga NS. Compliance with practice guidelines: Clinical autonomy revisited. *Health Policy*. 1994;28:51-66.
21. Klazinga NS. *Sociale geneeskunde: de derde weg. Oratie Universiteit van Amsterdam*. Amsterdam: Vossiuspers AUP; 2000.
22. Klein R. Puzzling out priorities. Why we must acknowledge that rationing is a political process. *BMJ*. 1998;317: 959-960.
23. Latour B. Socrates' and Callicles' settlement—or, the invention of the impossible body politic. *Configurations*. 1997;5: 189-240.
24. Mulder JH. Terug naar de zorg. Dunning gekanteld. *Medisch Contact*. 1997;39:1219-1220.
25. Mulder JH. Healthcare rationing in The Netherlands: The need for specific guidelines. *Med J Aust.* 2000;172:329-331.
26. Neeling. Eindrapport Passende Medische Zorg. Utrecht: KNMG; 1999.
27. Oortwijn WJ. *First things first. Priority setting for health technology assessment*. Amsterdam: Free University; 2000.
28. Porter TM. *Trust in numbers. The pursuit of objectivity in science and public life*. Princeton: Princeton University Press; 1995.
29. Rutten F. heb ik niet xx. 2000.
30. Stolk EA, Busschbach JJV, Caffa M, Meuleman EJH, Rutten FFH. Cost utility analysis of sildenafil compared with papaverine-phentolamine injections. *BMJ*. 2000;320:1165.
31. Van der Grinten TED. Scope for policy: Essence, operation and reform of the policy of Dutch health care. In: Gunning-Schepers LJ, et al, eds. *Fundamental questions about the future of health care*. The Hague: Sdu; 1996.
32. Van der Grinten TED. XX Heb ik niet. 2002.
33. van Hout B, Goes ES, Grijseels EWM, Quarles van Ufford MA. Economic evaluation in the field of cardiology: Theory and practice. *Prog Cardiovasc Dis.* 1999;42:167-173.
34. van Rossum W. Decision-making and medical technology assessment: Three Dutch cases. *Knowledge Policy*. 1991;4:107-124.
35. Weggeman M. *Kennismanagement: Inrichting en besturing van kennisintensieve organisaties*. Schiedam: Scriptum; 1997.