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THE GREAT ESCAPE?

Prospects for Regulating Access to Technology Through Health Technology Assessment

Mira Johri
Pascale Lehoux
University of Montreal

Abstract

Objective: Health technology assessment (HTA) can be used both to promote access to safe, efficacious, and cost-effective technologies, and to discourage access to undesirable ones. Yet HTA has had less success than might be hoped in pursuing the latter goal. This paper examines the scope of HTA as currently practiced to contribute to regulation of access to undesirable technologies.
Design: The study design is a critical analysis of HTA's methods, based on an exposition of the normative issues involved in restriction of access to health technologies. The paper classifies technologies that might figure as potential candidates for exclusion into five categories and underscores the key social and ethical dilemmas associated with limiting their use.
Results: For four of the five categories of technology outlined, limitation of access necessarily involves denial of benefit. Limitation of access thus inevitably raises difficult normative issues. We show that these are ill-addressed by the range of "evidence" typically considered in technology assessments, which centers predominantly on clinical and technical features such as efficacy, safety, and costs.
Conclusions: If HTA is to enhance our ability to make reasonable decisions concerning the use and diffusion of health technologies, it must better integrate consideration of the social, political, and ethical dimensions of health technologies into the process of technology assessment. We suggest a framework within which to approach this goal.

Keywords: Technology assessment, Biomedical, Health expenditures, Ethics, Diffusion of innovation, Technology, High-cost

Technological innovations are restructuring medical and social practices in ways both profoundly beneficial, and unsettling. While the achievements are undeniable, misgivings persist that the process of technology development and diffusion has escaped our control, with serious implications for the growth of health systems internationally (54).

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Health technology assessment (HTA) represents a potentially countervailing force to these expansionary pressures. As a field, HTA aspires to enhance society's capacity to manage health technologies by providing a sound evidentiary basis for decision making concerning their diffusion and use (3;54). Technology assessment can thus be used both to promote access to safe, efficacious, and cost-effective technologies, and to discourage access to undesirable ones (10).

Despite the impressive scope and quality of efforts made to date, HTA has had less impact in pursuing the latter goal than might be hoped (22). In the words of one recent article, it has proved easier to say "yes" than "no" (46). The aim of this paper is to ask why. We believe that a key part of the response has to do with the unique nature of HTA as a field of study, which aims to contribute to the regulation of technology diffusion by acting as a bridge between the world of scientific research and that of policy making (5). While several types of evidence are necessary for effective performance of this task (5), scientific evidence centering on clinical and technical features such as efficacy, safety, and costs has come to predominate (34). The first and second sections of this paper aim to show why this poses a particular problem for limiting technology diffusion, while the third suggests a framework within which clinical and technical information can be integrated with social, ethical, legal, and political dimensions to more effectively inform policy making.

THE EVIDENTIARY BASIS OF HTA: ADEQUATE FOR INFORMED DECISION MAKING?

HTA aims to bring scientific evidence to bear on policy making, so as to clarify distributional choices. It thereby promises more rational management of healthcare resources and better stewardship of the healthcare system (54). The concept of ability to benefit plays a central role in this process. As Stanley Reiser explains, "Technology assessments centrally address what balance of benefits and harms technologies produce, not only in physical, but in legal, economic and social terms. Thus it provides for all systems not only important evidence upon which to base medical care and policy, but emphasizes a value, ability to benefit, which is highly useful in making difficult allocative judgements" (43).

Two points are worth noting. The first is simply that there has been less success in making difficult allocative choices than hoped (22;46). The second, which we believe is linked, is that the notion of ability to benefit has to date been conceived and assessed in relatively narrow terms. At the present juncture, the scope of HTA assessments, and their subsequent interpretation, is typically limited to the available clinical or epidemiological evidence and to the costs and benefits associated with a particular health technology once it has reached the stage of clinical application (38).

Factors such as safety, efficacy, and costs have come to predominate over broader ethical and social questions, in part because the early years of HTA were marked by a strongly perceived need to establish the scientific legitimacy of the field (4). Because the randomized controlled trial (RCT) was (and still is) typically viewed as the definitive means of assessing the efficacy of drugs (and by extension, all types of health technologies), the RCT acquired a particular significance for HTA (31). Critical syntheses of published results of RCTs became the most popular method for HTA agencies to draw recommendations for policy makers. Methods for the collection and analysis of economic data were also integrated within the RCT framework, since economic evaluations were regularly designed and implemented alongside clinical trials (14). It is often tacitly assumed that these clinical and economic assessments can be carried out relatively independently of normative issues, on which consensus is more difficult to reach.

While scientific inquiry and synthesis of its results is an essential component of technology assessment, HTA's central aim is to contribute to the policy-making process (5).

We believe that in order to perform this role effectively, HTA must consider a broader range of evidence than it typically has done. As we shall argue, the use of technology is shaped by ethical, social, and political dimensions, which influence both the perspective of the assessment and its subsequent uptake (6;7;34). The next section highlights the social and normative dimensions associated with decisions to limit access.

A TYPOLOGY OF TECHNOLOGIES

In its function of discouraging access to undesirable technologies, technology assessment is sometimes conceived as playing the role of "gatekeeper" to the healthcare system (36). This section offers a critical analysis of the scope of HTA as currently practized to occupy this role. It proceeds by systematically categorising technologies that might figure as candidates for restriction of access and using the resulting typology as a heuristic device to highlight the ethical and social issues likely to emerge (Table 1). While the categories are neither exclusive nor exhaustive, we do believe that the use of technologies necessarily involves similar normative dimensions and that a technology assessment based solely on consideration of safety, efficacy, and costs is ill-equipped to reflect on them. Our aim is not to deny the importance of clinical and economic evidence, but rather to challenge the notion that such factors represent a "neutral" core of information, while normative and contextual issues can be satisfactorily addressed after an assessment has been carried out.

Harmful and/or Ineffective

The first category concerns technologies assessed to be harmful to patients, ineffective, or both. In principle, limiting access to technologies and procedures that involve unnecessary risks, or lead to no benefits, should raise few normative issues. Restriction of access to harmful interventions is clearly of *benefit* to potential users and, for ineffective ones, it cannot be construed as detrimental. However, even in this case, a technology assessment based solely on clinical and economic evidence may prove incomplete as a support for policy making designed to limit access. We would like to illustrate the factors commonly involved, taking as an example the case of the electronic fetal monitor.

Electronic fetal heart monitoring (EFM)—a method of monitoring fetal heartbeat for possible signs of distress—became the standard of care in the obstetrical community soon after its development in the 1960s. Its main aim was to serve as a screening test for intrapartum fetal asphyxia, which can cause fetal mortality or cerebral palsy. Moderate and severe fetal asphyxia exposure with newborn morbidity occurs in 3 to 4 of 1,000 births, with brain damage and subsequent disability in at least 1 per 1,000 births (35). The overall effectiveness of EFM, as well as the relative merits of its routine application versus exclusive use for high-risk pregnancies, is questionable. Clinical trials have shown that EFM does not reduce fetal mortality, morbidity, or cerebral palsy rates (45;50). Numerous studies have confirmed that the test leads to increased cesarean section deliveries and surgical interventions (50;53), all of which come at a cost and which may have potentially undesirable health consequences.

It may seem that a decision to limit access should be quite clear in this case, since it apparently represents no loss to the patient and may in fact be of benefit. However, the issues are not so simple. The underlying reasons provide a powerful illustration of the inflationary pressures associated with medical, and in particular, diagnostic technologies.

Four common effects of the introduction of a new test on medical practice and healthcare costs can be identified. First, technologies and procedures rarely substitute fully for one another; once options exist, the tendency is to make use of all of them. Despite the fact that EFM use is quite widespread, the earlier method of establishing fetal heartbeat, intermittent

Table 1. Five Categories of Technology and Their Associated Ethical Issues

Category	Harmful and/or ineffective	Effective, but few beneficiaries	Marginally effective, many beneficiaries	Life prolonging, poor quality of life	Allocationally inefficient
Example	Electronic fetal monitoring	In-vitro fertilization	Dental amalgam	Management of very-low-birth-weight infants	Left ventricular assist device
Rationing issues	Limiting its use should not theoretically pose any problems, although pressures to use it are strong, as it generates both information and uncertainty	Limiting its use poses problems, as it is highly beneficial from the perspective of concerned individuals	Limiting its use poses problems, as both harms and benefits are diffuse	Limiting its use poses problems, as it may run against deeply held moral intuitions	Limiting its use poses problems since it is effective for many individuals, but unsustainable on a societal level
Ethical issues	Few	Defining disability and ability to benefit Reconciling individual and social perspectives Prioritizing outcomes versus prioritizing the worst off	Trade-off: how much of a small benefit to a large group is equivalent to a large benefit to a small group?	Rule of rescue requires that all that can be done, be done Institutions, clinicians, and families may have trouble bearing the responsibility for denial of care Participation of parents in decision making may be limited	Marginal value of investment Opportunity cost of investment and long-term sustainability

auscultation, is also commonly used. This is also the case, for instance, with x-rays and magnetic resonance imaging (MRI) scans. This phenomenon reflects the fact that each technology or procedure usually has its own merits and may be preferred in certain instances or by some health professionals. For example, the most recent Cochrane Systematic Review found only one clinical benefit to EFM as compared with intermittent auscultation for routine pregnancy care, a reduction in the rate of neonatal seizures (50). However, this benefit may be important to some individuals or in some circumstances. Scientific disagreement also commonly plays a role. One study did in fact find that EFM led to a decrease in perinatal mortality (53).

Second, use of diagnostic technologies augments the quantity of knowledge, and patients and clinicians generally view this positively. Since each test or diagnostic procedure relies on specific physiological mechanisms and reveals its own set of information, there are strong incentives in ruling out potential health problems to use all tests available.

Third, the knowledge produced by a given technology is imperfect. It has a certain level of error, in terms both of false diagnosis (false-positive rates) and false omission (false-negative rates). However, once the knowledge exists, it is imperative for the clinician to act on it. Both of these factors can be clearly seen in the case of EFM. EFM has a very high false-positive rate, with approximately 9 of 10 predictive fetal heart rate patterns eventually classified as misdiagnoses. These cases then require supplementary tests, such as fetal blood sampling, to confirm or disconfirm the EFM test result. The enhanced level of uncertainty due to the use of EFM also explains the uniformly higher rates of cesarean section and operative vaginal deliveries seen in clinical trials. Despite these shortcomings, EFM is widely used, suggesting that there is an inherent pressure to acquire the additional knowledge it offers.

Fourth, to resolve or deal with these uncertainties, responsibility for decision making is often returned to individual patients (or their guardians) and their physicians. However, individual decision making is generally a weak strategy for enhancing collective choices and, due in part to an information asymmetry, an agency relationship exists between patients and doctors. It is not clear whether patients always know what their own best interests are, or that their stated preferences match their actual preferences. The issues are more complex when responsibility for the decision lies with a guardian.

Effective, but Few Beneficiaries

We denote here a category of interventions that Oregon, in developing its rationing plan for health care in the early 1990s, called "treatment valuable to certain individuals" (49). As described in the 1991 Oregon rankings, this category aimed to demarcate those treatments that are non-lifesaving, but potentially effective, for a relatively small group of beneficiaries. Examples might include the cochlear implant or infertility services such as in vitro fertilization (IVF), so categorized by Oregon in 1991 (49). Taking as our example the case of IVF, we would like briefly to describe three ethical issues that come to the forefront in assessing such technologies.

IVF, an assisted reproduction treatment designed to help couples experiencing persistent fertility problems achieve a birth, occupies a unique place in health policy discussions. On the one hand, it reflects dilemmas common to the issue of financing expensive medical technologies that benefit a small number of people; while on the other, it is unique both in the nature of the problem that it treats and the benefit it offers (39).

IVF is an expensive treatment, and the success rate associated with the procedure may be relatively low. Many studies report that about 15% of initiated IVF cycles result in a successful live birth; however, success rates vary considerably across populations and centers performing the treatment, type of infertility, and age of the female partner (26;37).

A recent study by Goverde et al. (26), for example, reported a 38% success rate, at an average cost per pregnancy resulting in at least one live birth of US $14,679.

Can We Agree on Definitions of Disability and Ability to Benefit? The case of IVF reveals a common normative issue at stake in technology assessments, which concerns how we assess notions such as disability and ability to benefit. Does infertility represent impaired normal functioning, such that IVF or another assisted reproductive procedure represents a needed response? We can further ask, how pressing is the need? What degree of gain constitutes an adequate benefit, for whom, and at what price? These issues are highly contested by the opposing sides and shape the way in which the evidence is interpreted. For example, although infertility is a medical problem, many insurers have resisted covering IVF on the grounds that it is not medically necessary to preserve a patient's health. Others have argued that infertility is a disease of the reproductive system, and therefore that treatments such as IVF should be viewed just as those for other diseases (39). Since any HTA study of safety, efficacy, and costs must proceed by making assumptions about definitions of disability, need, and ability to benefit, we argue that the controversial nature of such terms needs to be recognized and tackled explicitly.

Can Individual and Social Perspectives Be Reconciled? The second issue concerns the differences in perspective among individuals, who are the potential recipients of care, and society, from whose perspective data are considered. From the societal perspective, a technology is evaluated as a resource that should be allocated as efficiently as possible across persons. The relevant data involves average costs and average probabilities of success. Potential trade-offs between the procedure under study and others may also be relevant, as may the size of the total healthcare budget. However, individual patients and their doctors aim to choose resources to optimize that patient's care. Maximizing care for particular individuals has the potential to restrict resources available for health care for others or to drive up costs (20;21). This tension is, we believe, fundamental.

The case of IVF is highly instructive in this context. From the societal perspective, the least controversial comparisons, at least in principle, are those comparing IVF to other fertility treatments (26). The extent to which the procedure figures in the total healthcare budget has also been cited (12). However, key issues such as the relative cost-effectiveness of the procedure and how it compares to other routinely covered health services, particularly non-lifesaving ones, have proved difficult to resolve satisfactorily, since they require agreement on how the benefit of having a child is to be valued (39).

In contrast, individuals may place a very high value on increasing their chances of having a child. A 1994 willingness to pay (WTP) study by Neumann and Johannesson indicated that survey respondents from a general population in Boston, Mass., would be willing to pay $17,730 on average for IVF if they were infertile and the procedure had a 10% chance of success. The estimated implied WTP per statistical baby, given knowledge of infertility, was $177,730. When fertility status was unknown, WTP for an insurance package including IVF implied a value per statistical baby of $1.8 million (40). The point we wish to make is simply that the benefits and risks associated with use of a technology are evaluated differently at individual and aggregate levels, and that this difference of opinions is rational. Although HTA studies necessarily proceed from the societal point of view, the distinction between perspectives must be kept in mind if recommendations are to be conceived and implemented effectively.

How Much Should We Favor Best Outcomes? How Much Should We Favor the Worst Off? While use of cost and economic information in technology assessments is currently limited, such information is of central importance to decision makers. Use of standard economic evaluation techniques for assessing healthcare programs and interventions has thus been widely recommended as an aid to evidence-based decision making and

is likely to increase. Perhaps the most important form of economic evaluation, cost utility analysis (CUA), assesses the benefit of treatment programs as a function of the change in quality-adjusted life-years (QALYs) brought by the program; that is, by determining patient's average health-related utility with the program versus without. CUA proceeds from a utilitarian perspective, according to which a scarce technology must be allocated to candidates for whom it will achieve the greatest health benefit, so as to maximize the health of the population as a whole (18;23). The anticipated change in QALYs is calculated by estimating the average gain in individual utility, multiplied by the duration of these gains, and summed over the number of persons potentially helped (19;24). The issue of how these benefits are distributed across persons is not usually considered.

The decision to prioritize technologies or procedures offering the greatest health benefits is highly controversial, because this approach may in effect discriminate against those who have worse initial health. The question of how to balance our desire to promote better health outcomes against that to help those who are initially disfavored has been much discussed on an individual level in the bioethics literature, where it is commonly known as the "fair chances/best outcomes" problem (17). However, the methodology of economic evaluation has typically proceeded as though the rule of maximizing aggregate benefits were acceptable. Eric Nord's work on the conceptual and empirical bases of CUA is exceptional in this regard. It suggests that the general public's ethical intuitions contradict the notion that those with limited health potential due to chronic illness should be disfavored in their receipt of treatment. Rather, the general public seems to favor giving some priority to offering individuals a "fair chance" at receipt of treatment, even when this means a sacrifice in total health benefits, provided that the treatment is likely to provide a benefit valued by the individual in question (41). Taking these and similar insights seriously implies that substantial caution will be needed in interpreting evidence concerning cost-effectiveness for purposes of technology assessment.

Marginally Effective, Many Beneficiaries

We group under this heading those technologies that are only somewhat effective but potentially of benefit to a large group of individuals, in order to illustrate the following ethical dilemma: how should benefits for many persons with relatively minor problems compare with the same or fewer benefits for a much smaller group of persons with more serious problems? We illustrate this issue, taking as our example the case of dental amalgam.

Dental amalgam, which contains mercury, has been established for over a century as the most widely used dental filling material. Some worry exists about the potential adverse health effects of long-term mercury exposure even in these low levels, although there is currently little hard evidence demonstrating such effects. There are also a number of alternatives to dental amalgam, all of which incur considerably more expense. In 1997, Sweden became the first country to eliminate dental amalgam for health reasons. This decision has the potential to affect a very large group of consumers, as well as dentists, and the issue is controversial (11).

The conceptual issue we want to raise is that of how to trade off the benefits at stake. We are fairly used to thinking about dilemmas concerning benefits as they arise on a one-to-one basis; for instance, which of two types of patients should receive the heart for transplantation, given a scarcity of organs (8;17;30). Although resolution of such cases is difficult, we have fairly well-developed intuitions concerning the potentially relevant factors, such as the respective likelihood to benefit of the patients, their ages, and their waiting times. However, we have great trouble trying to trade off how much of a small benefit, for how many people, is equivalent to a large benefit for one person. This issue came to the fore during the discussions of the Oregon rationing plan, where some dental

procedures, such as tooth caps, were ranked ahead of lifesaving medical procedures, such as surgery for ectopic pregnancy (21).

The counterintuitive nature of some of the Oregon decisions may be justified in part by the fact that the methodology of cost-effectiveness analysis has the goal of conferring the greatest total benefit to a given population for a specified amount of resources. Volume of services provided has to be an explicit part of this calculus (21). Cost-effectiveness analysis based on QALYs (CUA) represents one potential approach to combining benefits across persons. CUA assumes that individuals' estimates of how they might value hypothetical changes in *their own* health states can simply be aggregated, and decisions for societal resource allocation made on the basis of maximizing this sum. However, there is now considerable evidence to suggest that the relevant assumptions of CUA are not supported by public intuitions and, in particular, that individual valuations of health states may not be a legitimate basis for making rationing choices (51;52). The issue is particularly pressing in the case of lifesaving procedures. In Oregon, those performing the policy rankings eventually adopted a method of establishing lexically ordered categories, where lifesaving interventions were considered separately from others (28;49).

Life Prolonging, Poor Quality of Life

By this category we mean to denote those technologies that prolong life but are not able to ensure a good quality of life. The clinical management of very low-birth-weight (VLBW) infants (<1,500 g) provides a good illustration of the dilemmas involved in this sort of case. Recent advances in perinatal technology over the last two decades have dramatically increased the survival of infants of borderline viability (25), and these improvements have come at a high cost. A California-based study of VLBW infants found that average treatment costs per first-year survivor for infants less than 1,500 g was $93,800 in 1987 constant U.S. dollars. Moreover, treatment costs per survivor were strongly graded according to birth weight. For infants less than 750 g, these costs were $273,900, while the gradient in cost-effectiveness with respect to birth weight drops to $58,000 per survivor for infants with birth weights between 1,250–1,499g (44). Information on long-term medical and educational sequelae for VLBW infants is scanty. This, in conjunction with the fact that neonatal intensive care is very successful in reducing mortality, makes cost-effectiveness estimates appear favorable as compared with other well-accepted medical interventions (57).

The impact of technological advances for health outcomes is less clear. In general, despite the fact that infants born more prematurely are now surviving, severe disability is common among the extremely preterm (56). Health outcomes for such infants are sobering, and they too show a gradient according to birth weight. A prospective 120-day follow-up of VLBW infants (500–1,500 g) showed that respiratory distress syndrome developed in 52% of the infants studied, and that chronic lung disease developed in 19%. In addition, 32% had evidence of intracranial hemorrhage (47). A study of neurological outcomes in a 114-infant cohort of extremely low-birth-weight (ELBW) babies (<750 g) found rates of severe cognitive impairment of 20% and rates of cerebral palsy of 10% after 20 months (27).

Given the rapid advances in medical knowledge and technology in neonatal care, physicians are increasingly likely to be confronted with difficult decisions about starting or continuing aggressive life-sustaining treatments in the face of poor long-term prognosis. A recent European Union study found that physicians' attitudes toward end-of-life decision making vary both within and across countries, and that such attitudes are correlated with self-reported practice (42). From a physician's point of view, the principal ethical issue evoked by denial of care for this category of technologies is commonly referred to in the biomedical literature as the rule of rescue. This can be defined as "the imperative to rescue

endangered life" regardless of the long-term prospects for survival or quality of life, should the means to do so be available (28). Clinicians who have a responsibility for individual patients may feel this imperative particularly acutely (42). Other factors may also contribute to aggressive treatment. A U.S. survey found that, in addition to technological development, physicians frequently felt pressured to overtreat infants due to federal regulations and fear of legal action (32;42).

Responsibility for decision making about aggressive care at birth and thereafter is generally viewed as devolving jointly to physicians and parents (33). However, a recent letter from a group of parents of extremely premature infants paints a different picture of current medical practice. They write: "As parents of extremely premature infants, we were given little information about probable outcomes and few, if any, choices about the treatment. Instead of being encouraged to limit care, many of us were threatened and made to feel like criminals for questioning even the most extreme medical measures" (16).

Efforts to limit care to those unlikely to benefit may also be instituted at the policy level, so as to minimize the burden of individual responsibility for decision making. However, this approach has to date met with limited success. Proposals to contain costs based on restricting care according to birth weight (several policies to deny care to infants less than 500 g to 700 g were studied) have been criticized on the basis that they would not significantly reduce costs for neonatal intensive care units, and that they would result in denial of care to many infants who would otherwise survive (48).

We conclude that the moral intuitions captured in the rule of rescue pose a problem for the generally utilitarian approaches implicit in the evaluation of health technologies and healthcare programs, and that they are likely to pose an ongoing problem for restriction of use for this class of health technologies.

Allocationally Inefficient Technology

The final category represents technologies that should perhaps be categorized as successful ones, in that they are effective and of potentially widespread use. However, they are also expensive. Some of our most difficult ethical and social choices lie in this category, because these technologies necessarily raise issues of setting limits to healthcare spending and of the place of health care in our lives. (9) An example of this sort of technology, now very much on the agenda, is the left ventricular assist device (LVAD), a mechanical pump that can be used in the case of heart failure. This example is taken from the recent AETMIS analysis of whether such devices should be used in Quebec (1).

The LVAD can be implanted in the body of the recipient and take over the heart's function, thus prolonging life for months or years. The device can be used for three purposes: as a bridge to heart transplantation, as a bridge to recovery, or as a permanent alternative to transplantation. Estimates of efficacy are encouraging, as is information on quality of life. According to the AETMIS assessment, many patients on long-term LVAD support can lead a near normal life, taking part in work and recreational activities (1).

Noting that the technology has been demonstrated effective and is no longer experimental, the report focuses on the likely cost impact of the LVAD. Assuming that the direct cost to the Canadian healthcare system of installing an LVAD is $138,000, if the LVAD is employed strictly as a bridge to transplantation (i.e., used for approximately 10 procedures per year), the total annual LVAD-related costs would be $1.4 million. However, the report notes that it will be difficult to limit the use of this technology, and that there will be social, political, and medical pressures to expand its use to all persons whom the technology might benefit. In the event that some of the implants are used as a permanent substitute to transplantation, the report foresees annual expenditures after 12 years on the order of $570 million (to sustain the lives of approximately 9,500 patients) (1).

The critical question raised by this class of technologies, which includes some very expensive drugs, concerns the marginal benefit we receive for our healthcare investments. While cost alone has historically not been seen as a legitimate reason for limiting access to technologies, the case of the LVAD sharply raises questions concerning the appropriate allocation of resources, particularly collective resources, in the healthcare field (1).

TOWARD A BROADER CONCEPTION OF HTA

If HTA is to enhance our ability to make reasonable decisions concerning the use and diffusion of health technologies, it must, we believe, be more closely informed by the needs of the policy-making process. In our view, the array of issues that should figure in determining the desirability or undesirability of a technology extends far beyond those that have to date dominated assessments. To put the point succinctly, what is at stake in the introduction of a technology is often not what HTA examines. We believe that HTA should use a variety of methodologic approaches to consider what is at issue when, for example, a technology is developed and promoted by industry, used by healthcare providers, introduced into patients' lives, and paid for by third-party payers (34). Many assessments have begun to do so, by augmenting stakeholder involvement in the assessment process and attending to the social and organizational context in which the proposed decision will be enacted (see recent work by HTA agencies in Canada, Spain, Sweden and the United Kingdom). We hope to act as a catalyst for this enlargement of perspective in HTA, both by offering some arguments in its favor and by rendering the proposed approach somewhat more explicit.

The expression "social impacts" is sometimes used to describe the dynamics that occur after a technology has been introduced in health care and put to use. This wording is misleading, because these social dimensions do not result from the use of technology but are rather constitutive of it. As recent work in science and technology studies has stressed, the conception, development, and diffusion of technology take place within (and potentially reshape) a particular social context in which monetary incentives and power relations are clearly at play (15;29). Madeleine Akrich (2), for example, argues that the development of any technology entails the construction of a "user-representation": an image of the user's putative characteristics, values, and skills. According to Akrich, the process of development and diffusion involves a series of informal "assessments" in which the potential value of a given technology and its compatibility with the interests and priorities of different groups is debated and redefined. This implies that the "impacts" of technology do not necessarily happen "afterwards"; many are present at the very moment a particular device or system is conceived (2). Clearly, the ethical dilemmas associated with screening tests for cancer of the prostate do not emerge only after such tests are available over the counter in every community pharmacy.

The development and diffusion of medical technologies thus entails more than negotiation over the use of limited healthcare resources. As Langdon Winner's now-classic analysis of the political nature of technology suggests, the efficient diffusion of technology into which substantial investments have been made "necessitates" particular social, economic, or political arrangements, and will (re)shape social relations around its use (55). For instance, prenatal genetic tests for specific diseases such as trisomy 21 transform the way not only a pregnant woman will experience her pregnancy "before the test" but, more importantly, how society will react to a woman who gives birth "voluntarily" to a handicapped child. In general, the conception and use of medical innovations has a number of ethical and social consequences. New technologies may reinforce hierarchical relations (e.g., computerized information systems), contribute to the exclusion of certain groups (e.g., designated services and programs for AIDS patients), impede the social development of individuals (e.g., genetic screening for "noninsurable" conditions), or extend questionable social

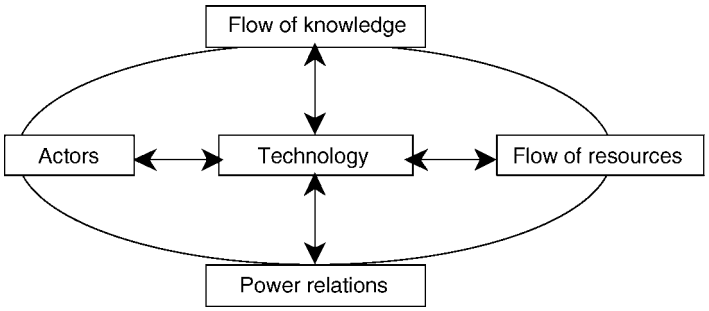

Figure 1. A heuristic framework for examining social, ethical, and political dimensions of technology.

practices (e.g., ultrasonography leading to selective abortion of female fetuses) (34). Technologies may also challenge paradigms of medical practice and professional roles (neonatal care for VLBW babies), and may significantly alter the flow of resources (LVAD).

We hence believe that technology assessments that consider social and ethical elements in conjunction with technical information may prove more effective as a support to decision making (5). While there is admittedly no algorithm for coming to consensus on analysis of normative and ethical concerns, we believe that the level of policy discussion will be enriched by considering how the issues have been framed, who stands to gain and lose (and in what terms), and how use of a given technology may potentially influence the local context. We employ a heuristic framework developed in Lehoux and Blume (34) to help identify the actors who will potentially be affected by a new technology, and to draw attention to the implications it might have for their control over material, financial, and cognitive resources and for their autonomy (Figure 1). We briefly illustrate how these issues might be addressed, making reference to the five categories of technology previously discussed. Two detailed case studies are offered in reference 34.

Table 2 describes the key considerations that emerge when we view each of the five categories of technology presented in this paper in light of the proposed framework. As might be expected, the category of harmful and/or ineffective technologies—notwithstanding the inflationary pressures previously specified—is the least problematic for HTA as usually practiced. For this category, the framework suggests that decisions can be made on the basis of safety, efficacy, and cost data to introduce more accountability into clinical practice and to support patients' participation in decision making. In the case of the second category—that of effective technologies, with few beneficiaries—consideration of the actors involved, including control over resources and power relations, may highlight the potential for very high individual costs or benefits and contribute to public discussion of these issues. It may also show the importance of producing assessments comparing a broader set of alternatives (i.e., health problem–based assessment). In the case of IVF, for example, these may range from other assisted fertility procedures to adoption. For the third category of marginally effective technologies, potential users are likely to be more widely scattered. However, manufacturers and others with a financial interest are much less so. In a suitably broad approach to technology assessment, their role in shaping public dialogue should be closely examined. For the fourth category of technologies—those prolonging life but with a low likelihood of good outcomes—we see a need for more comprehensive economic and quality-of-life assessments. Further research about how relatives of patients may be supported in their decision-making role, and for how society views the future development of such interventions, is also needed. Finally, in the case of "allocationally inefficient" technologies, the social, organizational, and economic consequences of prioritizing one technology over

Table 2. Dimensions Examined Under a Broader HTA Framework

	Actors	Flow of knowledge	Flow of resources	Power relations
Harmful and/or ineffective	Clinicians should be accountable for developing, implementing, and monitoring guidelines	Evidence about efficacy and safety should be disseminated to a broad audience	Should be reimbursed only in patient groups for whom proven effective	Patients' knowledge of effectiveness and safety, and their ability to refuse treatment, may be limited
Effective, but few beneficiaries	Views of potential patients should be weighted against values of the general public	Different valuations of outcomes should be made explicit and debated	A health problem-based HTA analysis should be favored over a technology-based assessment Financial interests should be made explicit, and avenues of cost-reduction explored	Concerned individuals may feel powerless, isolated, and unfairly denied benefits
Marginally effective, many beneficiaries	The concept of "public demand" should be critically examined Actors with economic interests should be identified	A "political" use of effectiveness data should be balanced by critical analyses	Overall costs may increase while (marginal) benefits remain diffuse	Dynamics between industry, specialists, and decision makers should be scrutinized
Life prolonging, poor quality of life	All parties concerned may seek to "pass the buck." Specialists may tend to be too interventionist; concerned individuals may experience ambivalence	Probabilistic evidence and fuzzy definitions of ability to benefit may enhance ambivalence and foster an interventionist approach	Evaluation of benefits of immediate intervention should include long-term costs	Patients' relatives may feel overwhelmed by decision-making responsibility Clinicians may also find responsibility problematic
Allocationally inefficient	Claims of concerned parties should be weighted against a just redistribution of resources approach	Effectiveness data should be supplemented by analysis of organizational impacts	Economic evaluation should make explicit systemic consequences of favoring interventions	Companies, specialists, and interest groups may unduly influence decision makers

other services should be made explicit, particularly when the choice concerns public resources. Consideration of the implicit opportunity costs, based on an awareness of the social determinants of health, should play an important role in assessing the soundness of such investments (13).

POLICY IMPLICATIONS

This paper has argued that a central reason for HTA's relatively limited success in contributing to the regulation of undesirable technologies concerns the narrowness of the evidentiary basis on which it relies. This is not to say that we do not need the information that HTA currently provides—we need that, too. However, we have argued in this paper for a broader approach.

We see two key ways in which an expansion of perspective might positively affect current practice. First, by encouraging us to systematically identify stakeholders and to consider the likely impact of a technology on interests, outcomes, and resource flows, this approach provides policy makers with a richer portrait of reality. While this may seem initially to increase the complexity of decision making concerning introduction of a new technology, we believe that it can serve to enhance the understanding of policy makers, and thereby the quality of their decisions. Second, this approach encourages us to look beyond the scientific rigor of the evidentiary basis and to attend to the procedural features that are also relevant in the technology assessment process. It may, for example, encourage greater public consultation and participation, and increase the transparency of decision making. In conclusion, we believe that a broadened approach to HTA can foster public dialogue conducive to mutual understanding. While there are no guarantees that this will result in consensus on societal value choices, we believe that it is the most fruitful route available. We remain guardedly optimistic.

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