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Reflections on the social epidemiologic dimension of health technology assessment

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Certain key parameters such as safety, efficacy, effectiveness, and cost effectiveness have long been established as key in HTA analysis. Equally important, however, are sociolegal and epidemiologic perspectives. A comprehensive analytic framework will consider the implications of using a technology in the context of societal norms, cultural values, and social institutions and relations. The methodology in which this expanded framework has been developed is termed 'Strategic HTA' to denote its power for the decision-making process. In addition to systematic reviews of published evidence, it incorporates analyses of the influence of dominant social relations on technological development and diffusion. This essay discusses the social epidemiologic aspects of health technology assessment, which includes factors such as sex and gender. It seeks to show how it is possible to bring data from wide-ranging disciplinary perspectives within the parameters of a single scientific inquiry; to draw from them scientifically defensible conclusions; and thereby to realize a deeper understanding of technology impact within a health care system. Armed with such an understanding, policy officials will be better prepared to resolve the competitive clamor of stakeholder voices, and to make the most "equitable" use of the available resources.

Keywords: Strategic HTA, Comprehensive HTA framework, Sex and gender, Cultural values, Social actors

Certain parameters have long been established as key in health technology assessment (HTA) analysis. In deciding what dimensions to include, investigators have traditionally looked along clinical and economic dimensions, taking into consideration safety, efficacy, effectiveness, and cost-effectiveness. Equally important, however, are sociolegal and epidemiologic perspectives. If these aspects are not explored, the great body of social determinants, including cultural norms, beliefs, and expectations, known to be significant in population health remains excluded from the inquiry. Put simply, only by opening and exploring these avenues can individual technologic interventions, and the health-care system at large, be understood.

A comprehensive analytic framework will consider the implications of using a technology in the context of societal norms, cultural values, and social institutions and relations, as well as burden of disease and population impact, because in any given instance, these may be powerful determinants of appropriate or inappropriate use. The methodology in which this expanded framework has been developed is termed "Strategic HTA" (Figure 1).

Strategic HTA may be described as an open discussion of health care in a way that highlights societal and political implications. In addition to systematic reviews of published evidence (as produced by the Cochrane Collaboration), it incorporates analyses of the influence of dominant social relations on technologic development and diffusion. Strategic HTA is grounded in critical theory and is empowered to explore politics, power, professional authority, and community beliefs and values. It is consequently able to expand the limits of clinical epidemiology so as to describe the relevance of technologic change to population health needs and its impact on the burden of illness.

It is hardly controversial or novel to assert that, in the processes of technology diffusion, health-care providers and patients themselves are important social actors. Their influence

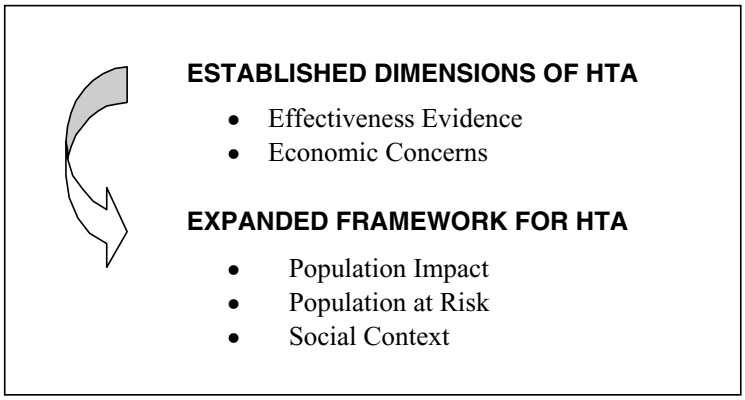

Figure 1. "Strategic" framework for health technology assessment (HTA), incorporating epidemiologic dimensions.

and their individual experiences of clinical practice and of health and illness determine patterns of care provision, or care seeking, and, to some degree, service consumption. Human biology is understood within the context of human culture, and the interaction of social and biological factors has been known to affect men's and women's health outcomes in different societies (2;6). Research has shown that, for example, the difference in morbidity rates between women and men may be largely explained by nonbiologic factors, including socioeconomic and psychosocial variables. Other research in physician practice patterns indicates that gender and age influence the scope of practice and related patterns of clinical intervention (4;5).

Yet the influence of social determinants on patterns of care and on disparities in health outcome have received inadequate attention in health research. The present edition of the IJTAHC seeks to redress this somewhat, by exploring different aspects of health intervention with particular reference to sex and gender. But if such inquiries offer scope for an understanding of the complex processes, the question of why they are so neglected arises. Part of the problem may be the sense that, where support from scientifically valid analytic models is lacking, it is virtually impossible to formulate research questions that probe seemingly unquantifiable social processes.

It is clear that rigorous HTA models require recognition and examination of the complexities and diversities within a population, and population groups; for example, in the context of the present issue, in the lives of women relative to men, and the impact of gender on health status and outcomes (8). How gender roles across the life course affect differently the respective patterns of health-care utilization by men and women are important factors in understanding patterns of technology diffusion and disparities in health status or health outcome.

This essay discusses the social and epidemiologic aspects of health technology assessment, with special emphasis on examples that highlight the importance of sex and gender. It seeks to show how it is possible to bring data from wide-ranging disciplinary perspectives within the parameters of a single inquiry, to draw from them defensible conclusions, and thereby to realize a deeper understanding of technology impact within a health-care setting.

The value of using such comprehensive evaluative tools is not merely in elucidating abstract research questions; it is also practical: to enable understanding of the population-based need for a given technology and the impact on the population its diffusion will have. Armed with such an understanding, policy officials and other decision-makers will be better prepared to resolve the competitive clamor of stakeholder voices and to make the most "equitable" use of the available resources, that is, to provide the greatest benefit for the greatest number.

ESTABLISHING THE SOCIAL EPIDEMIOLOGIC DIMENSION

There are several relevant measures in exploring the social context, both individual and collective. Key individual characteristics to be examined are age, sex and gender, and socioeconomic status pertaining access to health programs. Sex and gender are highly prominent factors, and it should be noted here that they are separate considerations, not always scrupulously differentiated. Sex is the biological difference between male and female. Gender is the social construct, in which the sexes are differentiated according to patterns of interaction that characterize social processes.

A comprehensive consideration of the population should also incorporate collective characteristics, which include the natural history of the disease or health problem, and relevant social determinants, such as measures of income disparity or literacy rates. Together, the individual and collective factors comprise the social epidemiologic dimension.

Once the appropriate key factors have been identified, strategic technology assessment can proceed beginning with two main aspects: the population-at-risk (that is, who needs this technology?) and the population impact (how is the identified population likely to be affected?). These twin

dimensions identify the breadth of the health problem addressed by the proposed technology, the burden of disease under consideration, and the evidence on whether that burden will be reduced or eliminated by the intervention.

Population-at-Risk

The magnitude of a health-related condition is gauged by defining the population-at-risk for that condition. In health research, this population is usually defined epidemiologically in terms such as morbidity rates, including the incidence of the disease or condition (that is, the number of new cases), or prevalence (the number of existing cases). Such rates are known with varying degrees of precision in developed countries and may be more crudely estimated in developing countries. The available statistics may be compiled at national or local levels. Population-at-risk can also be defined in mortality statistics (general death rates or cause-specific death rates).

A helpful first step in assessing the health technology is to identify the *population of interest* relative to the technology under consideration. It is important to be inclusive at this stage, so as to determine the magnitude of the phenomenon under examination. To use an illustrative example, if the technology under consideration were prenatal ultrasound, the population of interest would comprise all women of childbearing age (say, 15–45 years). The more likely population-at-risk to be identified, however, would be those women among the population of interest who are in fact pregnant.

Simple empirical evidence can be gathered to determine the size of this group. In the case of ultrasound, this would include for example, the proportion of women in the age groups of interest, and fertility rates. More elaborate estimates of the potential population of interest can also be obtained by factoring in average family size, number of multiparous women, and other relevant demographic variables. The number of factors that suggest themselves for inclusion might potentially be large, but the availability of information is likely to be much more restricted. The important point is to determine the level of empirical precision required for the particular decision under consideration and then to seek this research.

Although accuracy and precision of data are desirable objectives, variations in availability and accuracy should not be regarded as fatally detrimental. For example, it would be important to ascertain the geographic or ethnic distribution of the population of interest if services are delivered in a decentralized manner or if cultural factors are known to contribute to risk factors and social determinants. Otherwise, aggregate statistics, expressed as actual counts or estimated rates would be sufficient.

Depending on the intended use of the technology, other statistical indicators pertaining to the technology parameters may be of interest; for example, whether the evidence supports the use of prenatal ultrasound as a screening tool to all pregnant women (positive predictive value) as is current practice in developed countries, or whether it will be used solely as a diagnostic tool, available only to women whose pregnancies are identified by primary-care providers as high-risk.

In summary, the first step in the assessment process should raise two basic questions: what is the population-at-risk, and what qualitative and quantitative empirical evidence is available to describe that population in epidemiologic terms? Gender, as well as sex, should be taken into consideration as a social determinant that may be a risk factor. The extent to which answers to these questions can be provided will indicate the clarity with which the magnitude of the problem at hand is defined, and the degree to which an empirical appreciation of the problem exists.

The picture can be significantly enhanced with a statistical profile of current service-use and, if possible, a measure of the demand for such services. Researchers may need to gather the empirical evidence, or to establish the relative quality of evidence, and consult with other interested parties for assistance with broad or specific definitions of population-at-risk.

Population Impact

The second main element for review in comprehensive assessments is the study of *population impact*, which takes into account the expected consequences of the intervention. The impact on the health of the population is often measured by examining both functional ability (physical and social), and psychological status (quality of well-being). There is abundant literature on differences by *sex* in functional ability and health-related quality of life; yet the role of *gender* in understanding such differences for specific conditions such as CVD or population groups such as women in rural areas remains largely unexamined in health research.

Measures of functional status and well-being can be either generic or system-specific. A wide range of narrowly defined health status measures has been described in the literature, and discussion generally includes information about the purpose, reliability, and validity of the measurement instrument. It is important to note whether the particular measures are gender-sensitive or not, that is, whether they incorporate elements that reflect normative notions of maleness and femaleness. Contingent on the answer, a special effort might be required to address any research gap that emerges at this point.

Other useful measures of impact include quality-of-life and "potential" impact. Measures of potential impact reflect the expected effect of changing the distribution of one or more risk factors in a particular population. Although the utility of this measure may be somewhat limited, it has important value in decision-making related to public health issues. This measure would be valuable, for example, in a proactive assessment of public health programs aimed at eliminating medical and nonmedical risk factors in a population.

The purpose of this step is to examine and understand fully the burden of illness. If the expected consequences of using, say, a screening technology has a disproportionate

effect (positive or negative) on a population group, deriving from gender-based factors, it is important to be aware of this. Even where a precise answer proves elusive, an attempt to obtain some quantifiable measure, for example in the case of obstetric ultrasound, reliable maternal and infant morbidity, then the decision process will be better informed.

The ability of technologies to relieve the burden of disease in a population group and improve disparity in health is often overlooked, and it is perhaps one of the most elusive considerations. Often, expert clinical opinion or consensus statements may be the only available information, but even low-grade evidence of this kind should be explicitly taken into consideration if none other is available.

An important consequent issue in relation to screening or diagnostic interventions is the availability of therapy or cure, once problems have been identified. Do health-care or other measures exist capable of attenuating the burden of illness? A principal question in the use of prenatal ultrasonography is whether it is able to provide the type of diagnostic information that, if acted upon (through treatment), would make a difference to women's and babies' health and quality of life. As direct intervention to treat a fetus in utero is unusual, identification of abnormalities at this stage may not be of great value, except to raise the option of abortion.

Finally, questions should be raised regarding the potential health risk of the technology and whether any risk is offset by potential benefits. This is similar to risk assessment. In the example of prenatal ultrasound, wide attention has been given to recent evidence suggestive of some harmful effects to the developing fetus. Even if this is not confirmed, however, problems of false diagnosis (due to machine or human error, or both) and subsequent investigation and treatment may be significant practical concerns. Factors such as objectification of fetus and mother are not even included in assessment of costs and benefits, yet may contribute substantially to stress and psychological morbidity.

It is also important to note that the choice of statistical indicators and quantitative measures to depict the epidemiologic dimension can have a powerful effect on the way an issue is viewed. For example, maternal mortality rates are expressed as maternal deaths per 100,000 (or 10,000) live births. Rates of 100–200 per 100,000 are considered very high. But these rates pale when compared with a different expression of the same situation, namely Years-of-Life Lost (YLL). The YLL statistic would take into account age at death and the average life expectancy for women of that age, and present the cumulative figure for the 200 women at, roughly, 7,000–8,000 YLL.

Social Context

As the health-care sector is a subsector of the larger social system, the diffusion of a technology in health care should be analyzed in that context. The development and take-up of a single health technology has implications for consumers, health professionals, tax-payers, service agencies, educational institutions, and industry, as well as social institutions such as the family, the community, and the economy, among probably many other defined groupings. The nature and direction of these relations have not been well investigated in a comprehensive and systematic way in health technology assessment. In fact, health technology assessment only infrequently examines culture and values.

Social impact analysis is a way to understand, explain, and predict the potential effects of technology on social systems. Social indicators, the quantitative measures of interest, can be expressed at the level of the individual, family unit, community, organization, or system. However, the boundaries between social and ethical, ethical and legal, or legal and political aspects are not always clear, and interactive effects can occur. For example, the use of health technology may have potential to effect demographic change in a given region, effecting alteration in the regional economic base, and in turn, consequences for the power of regional political institutions.

Understanding the relations between social structure or social norms and health technology is equally important in the assessment of that technology. For example, in the case of obstetric ultrasound, where good epidemiologic information is available to show that the burden of disease is not alleviated by this particular technology. Consequently, the proliferation of this sex-specific technology raises gender-based implications, and begs the question, Who is this procedure for? In the developing world, there is powerful evidence to suggest that the driving force behind its increased use is primarily the wish for identification of the sex of the fetus, and consequential selective abortion. In the developed world, this technology is largely used to get "a first picture of baby" (7). In either case, the tendency is to objectify and separate the fetus from its "host," the mother for whom no health benefit may be discernible.

Another example of a sex-specific technology is the electronic fetal monitor, used in obstetrics as the basis for a clinical decision between natural delivery and cesarian section. Why has this technology become firmly established in obstetrical practice, despite high-quality evidence from randomized trials of harm to pregnant women (by causing a doubling of the cesarian section rate through routine electronic monitoring)? Legal implications are often cited, and research has suggested that practitioners are powerfully influenced by successful lawsuits and the need to follow what is understood to be "standard practice." But the circular influences of litigation and medical practice tend to operate in an orbit outside the sphere of individual patient interests (1;4).

Another example of a socially conditioned phenomenon is the desirability of every birth being of a "perfect" child. The meaning of "perfection" is powerfully socially determined, but it is clear that, where "perfection" is highly valued, technology perceived as promoting it is wholeheartedly adopted. Nowhere is this more evident than in the growing demand

for genetic screening techniques (examined more fully elsewhere in this Section); yet even in professional circles, the ethical and social implications have barely emerged, let alone been seen to influence or modify practice.

The social context and gender impact are even more pronounced later on in the life cycle. The phenomenon of population-based screening for bone-mineral density, and consequent labeling large cohorts of pre- and perimenopausal women as "suffering from osteoporosis" is only explicable when set in the social context of the fear of aging and its association with disability, dependency, and immobility. Such images are fostered by women's mainstream media, and they have been central to the remarkably successful marketing effort to promote bone-density testing and drugs aimed at recovering the bone health of "lost youth" (3). In the "strategic" framework of health technology assessment, it should be a high priority to have some understanding of these forces, which are as important from a social-policy standpoint as from a health-care delivery perspective.

The Ethical Context

An increasingly important component of health-care evaluation concerns expected effects of new technologies, or technology transfers, within the spheres of medical ethics and social justice. The indeterminacy of their boundaries makes these elements no less important to full assessment than hard statistical data. Appropriate indicators within each of these dimensions can be compiled from published research, ranked according to relative importance by panels of experts and patients, and then taken to the community (or interested parties) for consultation. In the strategic-HTA approach outlined here, social values and technical expertise are considered complementary to a process that strives for justice and fairness.

Specifically, constituencies and interested parties should be consulted regarding their views of the relative importance of what have been described as the four major tenets of medical ethics: autonomy, beneficence, nonmalfeasance, and justice. Of particular importance in gender issues is *autonomy*, the extent to which patients and their families are able to remain in meaningful control of their care, including decisions about which interventions to undergo (or to refrain from undergoing) as part of their care plan. In many societies, from the poorest to the richest, women are expected "to submit gracefully" to the wishes of others. How medical interventions support or challenge this status quo will clearly be an important element in the diffusion of the technology.

Beneficence relates to the extent to which technologies provide true health benefits in the areas most favored by patients, such as enhanced quality of life and prevention of disease. The social context may emerge more clearly through a comparative perspective. For example, anthropologists have long known that, in societies where ageing is not regarded as debility, menopause is not marked with aggressive medical interventions (6).

Nonmalfeasance refers to the potential for certain technologies to produce a net harmful effect on patients. Certain painful or risky procedures of dubious or minimal benefit may fall into this category.

Ethical implications are focal points in all reproductive technologies. Questions need to be raised, for example, about the "commodification" of women and babies, that is, the reduction of the mother to the status of a womb, or the baby as serving the interests of the society. Such issues are particularly relevant to decisions on obstetric ultrasound, a technology that has been adopted throughout the world, even where fundamental health-care measures are absent.

This technology may arguably be viewed as promoting commodification of fetus and pregnant woman, by reducing her relative place in, and control over, the process. If the fetus can be examined before birth, the clear implication is that its "acceptability" can be externally determined. The ultrasound expert intermediary has maximized the power for intervention of an expectant father or of other societal forces. Thus, to obtain an image of the fetus is equivalent to bringing it into the world in a way almost as significant as carrying the fetus itself. This represents a hindrance to a pregnant woman's autonomy, as defined by medical ethics.

The extent to which ultrasonography provides true health benefits to the pregnant woman and her fetus has in itself been seriously challenged. Even more problematic, however, are issues of consistent misuse or abuse of the technology. The routine use in some countries of ultrasound for sex-selection has now been clearly documented. Consequential abortion of female fetuses raises serious questions regarding beneficence as well as morality.

Yet what may seem superficially as concerns primarily in less-developed countries are in fact of universal concern. Indeed, such issues are likely to become more acute in the developed world, as social relations progressively come to be determined by technologic processes. We have already noted how in the Western medical model of menopause, an aggressive approach is both offered and demanded, because of the perception of ageing in a society that looks for productive capability. Ethical issues are intrinsic to health care, and the significance of each technologic intervention needs to be understood.

Finally, considerations of justice are increasingly important in technology assessment because of growing tension in some countries between a tradition of egalitarianism in health-care delivery (universal public coverage), and the shrinking pool of resources available to pay for all effective services. This consideration is of particular importance where new technologies prove to be very expensive or are of potential benefit to small numbers of patients or specific subpopulations.

Equity is of great importance in the ethical context: will all those able to benefit from a publicly funded technology

have equal access to it? In the case of fetal ultrasonography, two questions can be raised. First, assuming it is desirable to do so, can this technology be made available to all pregnant women? If so, particular attention should be given to designing a service-delivery structure that will reach all pregnant women and allow equal access. Second, if this technology is to be made available only for certain medical indications (for example, previously defined high-risk pregnancies), the question of equal access becomes even more important, especially for rural or isolated areas or disadvantaged groups.

To limit availability will require a technology "gatekeeper" who must first be consulted, requiring perhaps initial travel or forgone earnings and further displacement for those seeking the necessary services. Viewed in this light, gender and other social determinants assume an evident significance that will not be apparent if the assessment process is narrowly confined. If such issues are to be made transparent to public policy-makers, it is essential that they should form a part of comprehensive HT assessment. The discourse on health inequities has many constituents; public policy officials, health-care providers, and research funding agencies are all engaged in this discourse. Health technology assessment has been removed from these debates.

Assembling the Evidence

Although several distinct dimensions are subsumed in the single category of social context, the framework is not intended to simplify the complex phenomena so embraced. For the sake of brevity, and because they each provide the context within which public policy decisions ought to be examined, these dimensions are presented collectively. Depending on the situation, some permutation may be appropriate, and it is likely that all these concerns may in varying degrees be relevant.

In the exampled case of fetal ultrasonography, the social and ethical dimensions may be more important than the legal and political. To ground the technology in its social context, the question should be asked: Is this technology socially acceptable? Determining the answer requires both empirical (objective) and subjective information.

Thus, social scientific research may be available on whether use of a technology is congruent with given social values, pertaining, in the case of ultrasound, to the care and welfare of pregnant women. By providing visual access to the fetus, ultrasonography accommodates a growing trend in obstetrics to give the fetus patient status, somehow distinct from its mother. This may or may not be acceptable within the social values of the population in question.

The impact of technologic change on social relations can vary greatly from one group to another, precipitating different degrees of social change. Inversely, different types of social change can culminate in different levels of technologic development. Critical feminist analysis has provided valuable insights regarding issues of power, control, and dominance pertinent to this field.

In addition to examining empirical evidence, the decision-making process should ensure consultation of relevant groups to obtain their assessment of the issues and gain their particular perspective. The dimensions already elaborated have potential to develop a strong set of base criteria, sufficient to enable a greatly facilitated consultation process with interested parties.

CONCLUSIONS

With strategic HTA, a very different picture can emerge about a technology from that painted by an assessment limited to its clinical effectiveness (i.e., alterations of a measurable parameter within a disease model). Questions are prompted regarding how and why it has been developed, which population is receiving it, and what wider implications are likely to follow from its use. Research has shown many determinants lead to promotion, introduction, and diffusion of technologies. Social (legal and ethical), economic, epidemiologic (population), and clinical and technologic determinants have all been found to affect the degree to which interventions are adopted. Moreover, these determinants vary over time and from context to context.

To reiterate, it should be borne in mind that the aim is to provide practical assessments that offer meaningful choices to decision-makers; decision-makers herein include patients, physicians, hospital administrators, and provincial health policy-makers. The rationale for the development of an expanded, strategic, health technology assessment framework is centered on basic principles of justice in health care: equitable access to all and effective health care which society can afford. But, as the examples of obstetrical technology illustrate, the strategic framework also recognizes that social expectations and demands can determine technology despite absence of evidence of clinical benefit and clear evidence of harm.

This suggests that, while utility as well as equity are important in making a decision, neither equity nor utility necessarily lends itself easily to the formulation of policy. Adjudication and interpretation are needed if principles are to be translated into action.

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