

# HEALTH TECHNOLOGY ASSESSMENT: THE CONTRIBUTION OF QUALITATIVE RESEARCH

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## Abstract

The pragmatism in health care has made health technology assessment (HTA) restrict its scope to a particular set of problems, c.q. methods. The “*multidisciplinary and comprehensive nature*” of HTA, as the concept is presented in certain definitions, is lacking. Health care is also dominated by a positivistic-rationalistic approach of evaluation. In contrast, social studies of evaluations learn that a major difference has to be made between scientific research on (potential) impact of a technology and *valuing* these effects. In this contribution, we will discuss how the positivistic scientific bias of current HTA practice can be made up with other research traditions. More specifically, we focus on the question of how social scientists and particularly how qualitative research can contribute to HTA, complementary to positivistic studies of evidence and efficacy.

**Keywords:** Health technology assessment, Qualitative methods, Evaluation

In this contribution, we present a rather “academic” approach of health technology assessment (HTA). By approaching an applied field of policy research from a theoretical point of view, we realize we run the risk of being criticized of “not understanding the real world”. Indeed, this contribution could encounter the prejudice that “academics” do not understand the daily constraints of HTA practice. However, we think we do understand them. We do understand that HTA is practiced within institutional and financial constraints, as are other programs related to policy making. We are aware of the “pragmatic limitations” of performing HTA. It is precisely this understanding that made us think that a more theoretical paper could contribute to the development of HTA. Historically, the practice of HTA developed pragmatically more than conceptually (26). The pragmatism and specific tradition of evaluation research in health care has made HTA restrict its scope to a particular set of problems and limit itself to specific methods. Economical and clinical studies dominate the research agenda. Clinical studies; cost-effectiveness, cost-benefit, and cost-utility studies are predominant. A clear imbalance is perceptible with social and ethical studies on the impact of health care technologies. Integral assessments based on a conceptual

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framework in which medical, societal, economical, organizational, ethical, and legal aspects are considered together are lacking (23;35). Due to medical and economic research traditions that dominate the HTA agenda, the “*multidisciplinary and comprehensive nature*” (15[page 135]) is not apparent. It is this perceived discrepancy that drove us to this contribution. Instead of falling back into a position in which HTA is being considered as an activity necessarily *determined* by “external” (policy making) factors, a more theoretical approach aims at contributing constructively to the broadening of the practical agenda setting of HTA. We raise the question on how qualitative findings could be used within the HTA process. This contribution discusses how the positivist science tradition of current HTA practice (and research tradition) can be made up with other research traditions. We focus on the question of how social scientists and, more specifically, how qualitative research can contribute to HTA, complementary to positivistic studies of evidence and efficacy. To develop the argument, we will first summarize the different tracks on which “general” TA and HTA evolved.

## TECHNOLOGY ASSESSMENT: ITS HISTORY IN BRIEF

The developments of modern science and technology have historically always been accompanied with euphoria as well as criticism (38;39). Science and technology are considered to fulfil a multidimensional goal: problem discovering, problem solving, but also problem inducing. It formed the basis for emerging societal controversies about technologies and scientific developments. Since the end of the 1960s, critical reflections developed on the relationship between policy making and scientific and technological developments, and arguments were made for controlling negative effects of technological developments. TA developed as a kind of evaluation and policy research as a reaction against the unintended environmental, health, and societal consequences of the exponential growth and use of technology (e.g., Softenon, nuclear energy, nuclear military technology, environmental problems, etc.). In its early phases, TA was intended as an early warning system. The idea was that technological development and innovation should be steered more deliberately, using scientific knowledge about different aspects the technology could affect.

Technology assessment was a policy support method to provide the information that enables policy makers to manage the potential impact of technology on society. In the beginning of TA, one hoped to anticipate all potential (negative) consequences of a technology from the very early stages of a development. One learned that this ambition was impossible to realize because technological innovations are affected by a multitude of factors (see, e.g., the theories of social construction of technologies). As a consequence not everything can be foreseen. Furthermore one learned that valuing the impact of a technology has to do with diverging interests and values of different stakeholders and cannot solely be assessed on rational grounds (17;42).

Together with the shift of TA from the United States to Europe, the ambitions and aims of TA were revised. In general terms, the approach evolved from “*evaluation of effects*” toward “*valuing*” (potential) impact of technology. TA was more and more considered as a process consisting of analyses of technological developments and their consequences *as well as* a debate with different societal actors on the basis of these analyses. Different “approaches” of TA developed (42;17[pages 11–27]). TA was broadened toward more participation and involvement of citizens and other stakeholders, in addition to research and assessment activities of different scientific disciplines. The “rational-sequential” approach of TA was replaced by models in which the assessment of a technology gets form through a continuous dialogue between different stakeholders and researchers from different scientific domains. Those directly and indirectly affected by decisions about a technology are being

involved in the analysis and evaluation process of a technology. The understanding grew that the TA process is very much affected by *whom* and *how* a “problem about technology” is defined. The ambition of TA, therefore, has been to develop methods and approaches in which these different interest values, and scientific knowledge are brought together. The debate between experts in different disciplines and nonexperts on the basis of scientific analyses creates a process in which different actors need different kinds of information. It creates openings for confrontation of different perspectives and expectations about a technology. The “new” forms of TA recognize that stakeholders have diverse power to steer a technological development, have different access to knowledge, have different interests, different values . . . An assessment, therefore, cannot be approached as a rational-logical sequential process. This new approach of TA was, amongst other experiences, inspired by social theories demonstrating that technology was embedded and constructed in society (6;7;13;24;27).

### **Technology Assessment in Health Care: On a Different Track . . .**

HTA developed as a kind of policy research in the second half of the 20th century. HTA is getting established against the background of rising expenditures, quality questions and efficacy, efficiency and utility questions of technologies in health care. The report “*Development of Medical Technologies: Opportunities for Assessment*” (31) is generally considered as the starting point of the debate about technology assessment in medicine. In this report, objectives, subjects, and methodology of health technology assessment were outlined for the first time. The report is a typical exponent of the so-called “old” TA tradition. In health care matters, the fundamental ideas of this report can still be traced, although it has to be acknowledged that things are changing, be it slowly.

HTA, as TA in general, aims at supporting decision making by providing comprehensive information on the preconditions for, and consequences of the implementation of new technologies. Due to budgetary problems in the 1970s and ‘80s, policy pressure increased to reduce the rising expenditures in health care. An important part of the rising expenditures resulted from technological developments. Considerations about costs were combined with questions about quality of care, because choices *between* technologies would be necessary due to budgetary restrictions (1). The question of how expenditures can be justified by the benefits realized was becoming more important (14). Although initially a broad definition of technology was put forward in conceptual contributions, in the early stages, the assessments focused on devices (especially on the costs and effectiveness). In that period, the concept of “*medical TA*” was common. Very quickly, the insight grew that technology and the use of technology should be assessed considering specific characteristics of health care, especially if alternative technologies were to be compared. From that stage, the concept *Health Care TA* was introduced. Shortly after this shift, the idea emerged that a broader use of the concept “technology” had to be used in assessment activities or that a more “problem oriented” approach should be used. The attention of HTA activities shifted to the question on how optimal health can be guaranteed. Attention was no longer focused on devices or pharmaceuticals as used within health care services but more and more on all “technologies” used in health care to realize good health for all. From that moment, the concept of health TA became common. The concept of technology was also put into practice as “all interventions” in health care (26).

However, the historical development made that questions of costs and effectiveness are being studied a lot more than social or ethical consequences or questions of acceptance (23;35). Policy pressures on budgetary questions made that research was especially commissioned about clinical and cost (efficiency, effectiveness) questions. This tradition has had a major effect on both the research methods as well as the TA approach as such. The

scientific culture of medical and economic research traditions have been dominating the agenda. Moreover, theories about HTA are very poorly developed (26;36). There is clearly a trend of labeling different kinds of research concerning health interventions as HTA (an illustrating exercise is to perform a search in on-line HTA databases). The use of the concept is very often limited to the “research” dimension, and the “multidisciplinary part” is focussing solely on very specific clinical or economical aspects. What is seldom discussed is that different groups (professionals, scientists from different disciplines, patients, industry, insurers, and so on) have different expectations with respect to HTA.

There are potential problems as a result of the current development of HTA practice: First, the agenda of HTA will potentially be solely defined by (economical and clinical) experts and research traditions. Second, no efforts are made to develop methods to incorporate *values* and interests of different stakeholders. This contribution tries to illustrate why social scientists and qualitative researchers should contribute more to the HTA debate and why health care professionals and policy makers could learn from experiences and debates in social sciences.

## EVALUATION RESEARCH, EVALUATION AND HTA: CONCEPTUAL CLARITY MAKES A DIFFERENCE

TA started as a specific form of evaluation *research* aiming at early warning about unintended and negative effects of scientific and technological developments (2;4;8). In its early stages, it was a specific form of applied research, that developed, as did other forms of evaluation, into a specific kind of policy research (42). Although TA and HTA have specific characteristics, from a conceptual point of view it is interesting to compare with knowledge gained about evaluation in general.

Evaluation and evaluation research have developed and institutionalized in the 20th century as activities to support policy and decision making. But the conceptual blurring between “evaluation” and “evaluation research” has had far reaching consequences on the theorizing about evaluation (18;37) This conceptual debate is important for theory and methodology development in HTA.

### Defining Concepts

Evaluation *research* is the systematic acquisition and assessment of information by scientific teams to provide useful feedback to a variety of audiences about a program, policy, technology, person, need, activity, and so on. The major goal of evaluation research is to support decision making or policy formulation through the provision of *empirically* driven feedback.

The most important conclusion of the discussion in social sciences is that a conceptual distinction has to be maintained between research activities and evaluation (18). Evaluation research does not differ from other research in the *methods* it uses. Its basic characteristic lies in the support it has to offer for “evaluation” activities. This makes that the funding agencies and the evaluators decide whose (and thus what) questions are to be addressed and whose interests are to be served. Knowing that evaluation research and evaluation are closely connected but distinct, enables one to avoid a position in which the contribution of science and research is condensed into the rational, objective, and politically neutral stance (37;40). Critiques on “the scientific rationality and political neutrality” of evaluation research is at the same time a basis for arguing how qualitative methods can contribute to evaluation.

*Evaluation* goes beyond the boundaries of research. It refers to the systematic examination of (potential) events or effects of a program or technology. The evaluation (and the agenda of evaluation) is primarily defined by all kinds of people involved. Evaluation is not simply a matter of good measurement or design. It is political in nature because the

question of *valuing* by the people involved is crucial. Interpretation, interaction, and political processes are crucial in this process. “Objective” analyses are seldom possible (16;18).

Evaluations are being conceptually distinguished (see 30;32;37). Distinctions are made between (a) summative and formative evaluations (summative evaluations, examine the effects by describing what happens subsequent to the use and implementation of a technology or program. Formative evaluation is a method of judging the worth of a technology or program while activities are forming or happening); (b) between outcome and process evaluations (outcome evaluations attempt to assess the effects of a policy, program, or technology. Process evaluations aim at understanding the interactions and dynamics occurring when a programme or policy is implemented); and (c) a very particular form are impact evaluations (impact evaluation assesses the effects, intended or unintended, of all aspects of a technology and a programme). This distinction can be of particular interest for the conceptual debate about HTA, because it can help in differentiating between the aims of HTA and HTA research.

TA is a particular form of evaluation: (a) it is a policy-supporting methodology focusing on technology; (b) technology is not solely evaluated in technical and economical grounds but also in social, ethical, environmental aspects, etc; (c) it is monitoring technological change at all stages of technological development and diffusion, but it is mainly future oriented: the evaluation of a technology is not happening “after” the introduction but focuses on assessing (short or longer time) future consequences when implementing technology; and (d) it suggests dealing with controversies because scientific and technological developments are characterized by complex dynamics in which people develop different perspectives due to interests and values (25).

### Specific Character of HTA

Health is a domain around which a specific tradition of TA developed. General TA and HTA do use different perspectives (see also 34;36). HTA has the purpose of providing decision makers with reliable and scientifically defensible findings on the likely overall effects of a technology (EUR-ASSESS methodology workgroup, 15). Generally, it is said that HTA has five main tasks: *Identification* (monitoring technologies, setting priorities), *Testing* (data collection and analysis), *Synthesis* (collecting and interpreting existing information), *Dissemination* (providing HTA information to users), *Implementation* (helping to assure the application of HTA results). Coordination of these tasks is considered as crucial (4;5). HTA contains research activities as well as practical implementation of these findings. HTA, thus, is conceptualized as an approach that should not be political but, in the first place, scientific. Research activities are considered as “objective” evaluation findings. The core of an HTA is considered as to systematically review research evidence on the efficacy, effectiveness, safety, and costs of the technology. Its scope is generally limited to a single device or a specific procedure.

The majority of HTA *research* activities currently performed tries to assess the efficacy of a technology (in clinical and economic terms) by providing scientific data for decision making and allocating means. This concept can be explained by the fact that policy makers have a very specific agenda of guaranteeing good health by allocating limited resources. Assessing criteria are most of the time limited to those typical for medical and economical research culture. Because of this practice, HTA is developing quite sophisticated methods to assess costs and benefits of a technology in a quantitative way. Very little qualitative research is performed to contribute to the debate. Furthermore, HTA is often based on positivistic assumptions such as the following (30):

- Policy making is a rational and not a political process in which compromises are realized between different interests, different goals, in which changes occur over time

- experimental designs such as randomized clinical trials are considered as most desirable evaluation techniques
- all stakeholders could develop a kind of “unique” and uniform view on a problem. These assumptions can be criticized on several grounds. As Murphy et al. (30[page] 221) say:

*If the conventional assumptions are adopted, than quantitative approaches would seem appropriate to most of the questions asked in HTA. This model can work when we have a rational specification of goals in an environment where all relevant variables can be identified and controlled and where there is a consensus that makes the assignment of numerical values to the variables uncontested. The nearer that this model is approached, the more successful a purely quantitative approach will be, as in drug trials. Conversely, the further the actual research situation departs from this model, the less appropriate it becomes”.*

Social and political sciences, decision making studies, and insights from psychology learn that decision making and policy making is not a logical-rational process, but a process in which people have limited cognitive capacities, in which emotional factors play a role, and, certainly not least, power processes have a crucial impact on decisions taken. Only in more conceptual contributions, methodological experts recommend “to involve experts, users, and others in the formulation of questions, identification of problems with the data, and the reaching of judgements on the implications of the findings” (15). The EUR-ASSESS dissemination and implementation working group also recognized the political nature of decision making in health care. It is argued that implementation involves not only dissemination of information, but attention to factors that promote change, such as physician preferences, patient preferences, regulation, and financial incentives. Because broad social influences have an impact on health, evaluation activities should expand to incorporate such influences. But, the “political aspect” is not only relevant in the stage of implementation, but already in the stage of problem identifying and formulating. Specifically HTA should pay more attention to the social embedding of technology. In addition to quantified answers to clinical or economical questions, other kinds of knowledge should be developed. Banta and Luce (3[page 132]) already noticed that TA cannot be totally objective or value free, because it is an activity that is influenced by culture and values. At this stage, not enough distinction is made between scientific research on (potential) impact of a technology and the problem of *valuing* these effects. The recognition of interests, values, and norms of all stakeholders is seldom discussed in the practice of HTA *research*, resulting in an overemphasis on the importance of “technical” analyses, overconfidence in quantification techniques, and reduction of the assessment to a “rational scientific” activity or question.

However, more theoretical recommendations hold necessary to expand the scope of HTA studies by including social effects and social objectives of the health care system (EUR-ASSESS methodology group, 15). From this perspective, qualitative data can contribute valuable information for evaluation of context, process, and impact (see also 30). Assessments in which a wide range of members of society, organization representatives, researchers, policy makers are, at least, considered and can collaborate, could enhance better understanding of phenomena by introducing new research questions and could lead to formulations of specific recommendations. Participatory forms of evaluations will necessarily consider *context, process, outcome, and impact of a technology*.

HTA holds “*assessing short and long-time consequences of the introduction and use of technology*” (3[page 61];15[page 135]). Because no scientific data (in terms of “evidence”) can be made available about the future, a lot of decisions will be made based on values about what is judged as more or less important and what is considered as unwanted or unacceptable. Future effects and impact of technologies are far too complex to

forecast solely by scientific positivist research. The use of qualitative research methods and participative-qualitative forms of evaluation are indicated for *valuing* future impacts. The “valuing” aspect of different stakeholders is very crucial, in forecasting wanted and unwanted impacts and to compare the future effects of alternative technologies.

## HEALTH TECHNOLOGY ASSESSMENT: HOW CAN QUALITATIVE RESEARCH CONTRIBUTE?

Specific methodologies have been put forward to evaluate technology in health care. Technical properties, clinical safety, efficacy and effectiveness, economic impact, and ethical, legal, and social impacts may be addressed. However, the question of *valuing* and how values can be considered in the assessment based on an explicit methodology should be elaborated further.

First we address the question of the potential contribution of qualitative research for delivering specific kinds of data. Qualitative research can contribute to HTA by offering and summarizing the perspectives, meanings, values, interests different stakeholders have about a particular technology. Qualitative research may be particularly useful to policy makers, because it enables the understanding of the context in which technology is implemented (“the social embedding of a technology”). As Murphy et al. (30[page iii]) stated:

*“The methods as such are not novel, but the application of these methods within HTA is quite novel for the practice of HTA”.*

Second, we look at experiences of how qualitative evaluation takes form. In addition to the question of the use of qualitative methods in evaluation, different qualitative evaluation methodologies can be identified. We will very briefly discuss how the ideas behind these evaluation methodologies evolved.

### “Nature” of Qualitative Research

Qualitative researchers study things and social relations in their natural settings attempting to make sense of, or interpret phenomena in terms of the meanings people bring to them. The word “qualitative” suggests an emphasis on *processes* and *meanings* that are not rigorously examined or measured in terms of quantity, amount, intensity, or frequency (“numbers”). Most analysis is done with words. (28;29;33;43).

Qualitative researchers stress the socially constructed nature of reality. Because data are gathered in close proximity of a specific situation, influences of the local context can be taken into account. That such data are collected over a sustained period makes them powerful for studying processes, and qualitative data are particularly suited for identifying the meanings of people about events, structures, processes, and so on. Quantitative researchers seldom are able to capture these meanings and processes (10–12;29).

A rather common misunderstanding is the interchangeable use of “qualitative research” and “qualitative methods” (33). Methods refer to the techniques used to gather data. Broadly speaking, the methods used in qualitative research include (participant) observation, interviews (individual or group), content analysis of text, documents, photographs, and audio- or videotapes. The procedures and techniques for gathering and analyzing data have been described in different source books (e.g., 28;29;41;43). These source books show that gathering and analyzing data demand particular skills, very distinct from superficial and subjective daily observations.

The choice for a research strategy (choice for methods) might be influenced by the theoretical perspective on the social world: qualitative methods, therefore, are used differently. Because “theoretical perspectives on the world” are divergent, qualitative *research*

is very difficult to define as such. Different theoretical stances do exist, and differences are not always clear cut (20;41). In general terms, qualitative research is grounded in an interpretative approach, based on flexible methods of data gathering sensitive to the social context in which data are produced and based on methods of analysis aiming to produce understanding of complexity, detail, and context (28).

The divergent theoretical perspectives on the social world learn that there are several ways of telling a story about the (same) world, and they make problematic what is to be considered as “truth” and “reality” (9).

### **Qualitative Research and the Question of Bias**

Because qualitative methods and qualitative research have traditionally been used in the social sciences, health care professionals and researchers with biomedical backgrounds are often unfamiliar with it. Qualitative research is from the lack of knowledge about the methods and the positivistic tradition or scientific culture of medicine, often approached as an assault for a “value-free objective science”. It is resisted and called unscientific, full of bias and in the best case only exploratory. Qualitative empirical data are judged unreliable, subjective, difficult to replicate, and limited to anecdote and impression. Especially the question of validity and bias is used as an argument to consider qualitative research as problematic.

The use of the term *bias* relies on a very specific concept of “validity” and “truth” that is closely linked to the concept “objectivity”. In positivism, the idea prevails that research, when properly executed, is producing conclusions that are valid, because “data” are given: sources of data are treated as “given”—as independent of—and data are imposing themselves upon the researcher. What is required to avoid error or bias is the objectivity of the researcher. Therefore, a researcher should pursue the research in a way that ‘anyone’ would do it.

Especially under the influence of constructivism and postmodernism in social science, this notion of “objectivity” and validity is debated (9;21). The debate is especially about the way of thinking about social reality and interpretation more than on the question of validity, reliability, objectivity, and technical procedures and techniques of gathering data. Hammersley and Gomm (22) argue that the term *bias* generally refers to any systematic deviation from validity or to some deformation of research practice that produces such deviation. Quantitative researchers, for instance, would refer to measurement or sampling bias as a systematic error in measurement or sampling procedures that produce false results. Bias can also be used as a term to identify a particular source of systematic error: a tendency of researchers to collect an interpret data in favor of results that are in line with prejudice and political or practical commitments. Qualitative research is often criticized as being very vulnerable for this kind of bias. There are also sources for bias in the research process itself. Qualitative research is thought to be particularly vulnerable for this, because of the interplay between the researcher and the data. Once a particular form of interpretation or explanation has started to develop, there is a tendency to interpret data in terms of it, or only look for data to confirm an interpretation.

There is considerable debate among methodologists about standards for judging qualitative research. The debate is complex, precisely because of the variety of approaches in qualitative research (33). Denzin and Lincoln (9) have made a classification of the different positions taken and distinguish (a) scientists who want to apply the same criteria to qualitative and quantitative research (positivists), (b) those who argue that a specific set of criteria specific for qualitative research needs to be developed because qualitative research is a distinctive paradigm (postpositivists), (c) postmodernists who state that the development of criteria for assessing qualitative research is impossible because “reality” and “truth” is made in the heads of people, (d) poststructuralist who state that an entirely new set of criteria should be developed away from the positivist and postpositivist tradition.



Personally, we agree with postpositivist that all research involves subjective interpretations and that different methods will produce different images of reality but accept the point that there is some reality that we attempt to understand and study. The role of (qualitative and quantitative) research is to *attempt to represent* that reality, rather than “truth” can be attained.

This point of view also suggests that criteria can be put forward for judging qualitative research. The debate about truth, validity, and bias should not be done in terms of the *kind* of data qualitative research is generating, but as is the case for quantitative research, the “craft” of doing qualitative research is important, and permanent questions should be raised about what is judged as being an *appropriate* way for gaining knowledge. One can conduct a data audit that examines the data collection and analysis procedures and makes judgements about the potential for bias or distortion. Reproducing *exactly* the same research is difficult, not to say impossible, and interpretations are constructed by researchers. Bias can best be approached, therefore, as a systematic error in terms of procedures of research (data gathering, analyzing, and interpreting). The most important question for assessing a research is *how* the process of data filtering or reduction, data display and conclusion drawing is taking form.

Guba and Lincoln (19) identify four criteria: *Credibility* involves that the results of qualitative research are credible or believable from the perspective of the participant in the research; *Fittingness* or *transferability* refers to the degree to which the results of qualitative research can be generalized or transferred to other contexts or settings; *Auditability* or *Dependability* emphasizes the need for the researcher to account for the ever-changing context within which research occurs; *Confirmability* refers to the degree to which the results could be confirmed or corroborated by others.

### Qualitative Methods, Evaluation and HTA: Conceptual and Technical Issues

A distinctive feature of HTA is its inherent political nature, because evaluations and assessments are conducted in the public domain. Program evaluation and HTA are linked to political decision making, including setting priorities, resource allocation, power, etc. As we mentioned earlier, HTA is too much affected by rationalistic scientific assumptions. Even by broadening the research agenda by incorporation by using qualitative methods in qualitative research, the specific nature of evaluation and assessment should be continuously discussed. Not solely research methods are important, but also the methodology for “valuing” the consequences should be discussed more openly. In health care, HTA is still too much considered a tool for obtaining (valid) data for *subsequent* evaluation (see also 36). Evaluation theories show that this approach can be criticized.

The rationalist “positivistic model” of evaluation burst into being in the 1980s, because plenty of variables were not taken into account when evaluating (16;30). Quantification models of evaluation lack the ability to grasp contextual factors and processes. Much evaluative reasoning is nondeductive, because plenty of information is lacking to draw conclusions on the basis of (quantitative) data. Moreover, scientific experts are not always drawing similar conclusions when analyzing the same research question and research findings are also often used very selectively when taking policy measures.

Greene (16) distinguishes four major approaches to program evaluation. A first and dominant genre [sic] is oriented around macroquestions of program effectiveness and cost-efficiency. A second genre of evaluation is much more pragmatic and oriented to provide timely and useful information for decision making and management. In this tradition, a more eclectic methodological stance is used: methods are selected pragmatically to study the practical problems at hand. The third cluster she distinguishes is evaluations in which

qualitative approaches have found their home. It is a tradition seeking to enhance contextualized program understanding for stakeholders closest to a programme. A fourth cluster of evaluation has its roots in a more normative approach, aiming specifically at emancipation, empowerment, and social change. These are forms of evaluation that are “openly ideological”. Important in the approach of Greene is that she is not labeling differences in evaluation based primarily the methods that are used:

*“what importantly distinguishes one evaluation methodology from another, is not methods, but rather whose questions are addressed and whose values are promoted” (16[page 378]).*

We think Guba and Lincoln’s (18) “fourth generation evaluation” is particularly interesting to link with the practice of HTA. It is an alternative constructivist approach in which facts are considered meaningless outside a particular framework of norms and values. Credibility of research findings can be optimized by triangulation of methods, and openings should be created to discuss “facts” with different stakeholders, to confront opinions, raise new research questions, etc. The authors reject the position that the use of proper methods are a guarantee to avoid bias and ensure objectivity and truth in evaluation. They hold the view that knowledge is constructed during inquiry and necessarily embedded in the values and perceptual frames of the inquirer as well as the stakeholders. It is, therefore, not enough to rely solely in the role of the researcher, but one should also pay attention to the needs, values, and interests of the stakeholders. Their “fourth generation evaluation” offers a constructivist framework for evaluation, which can be of particular interest for HTA. Their theory of evaluation can also be compared with the ideas of “constructive TA” (or interactive and participatory forms of TA). Here, TA is considered as being more than a decision making *tool*; it is considered as a specific form of evaluation in which the separation of technology and social embedding is avoided. Whenever stakeholders take part, they are more likely to bring in social aspects at an early stage (25;26;38;39).

A very pragmatic approach is made by Patton (32[pages 44–45]). He makes a distinction between conceptual and technical issues in evaluation. This distinction may be very valuable for setting up research strategies and selection of methods in HTA. Methods choices in evaluation and assessment should primarily match the information needs of the stakeholders that are identified.

- Conceptual issues include questions such as Who are the primary stakeholders?, What is the purpose of the evaluation? What approach or model will be used to provide direction for the evaluation?, What are the primary evaluation issues?, What political considerations should be taken into account?, By what standards and criteria will the evaluation be judged?, What resources are available for the evaluation?, and so on.
- Technical design issues include the plan for data collection and analysis: What will be the method? What will be the primary unit of analysis?; What will be the sampling strategy? What comparisons, if any will be made?, What kinds of data will be collected, when, from whom, and using what instruments? How will the quality of the data be ensured?, and so on.

## CONCLUSION AND POLICY IMPLICATIONS

It is uncommon to address a very practical field such as HTA from a rather “academic” point of view. It could give the impression of not considering, or not being aware of, the practical constraints in which HTA is getting form (including the question “who is funding what kind of research?”). Initiating a more theoretical debate, however, should not be considered as blunt criticism on the activities of HTA. On the contrary. We hope, by introducing

some theoretical considerations, that the perspective on HTA could broaden, which should stimulate researchers as well as those who put out HTA research (by nature of the field: policy makers), the scope of HTA activities. It could also help in identifying the specific field of HTA, vis à vis, activities such as evidence-based medicine (health care), quality of care research. Daily practice of health care research shows that the “conceptual boundaries” of these fields are blurring (especially in the minds of policy makers, but often also in physicians minds).

The major point we wanted to develop is that new developments in science and technology confront public authorities, professionals, and the public with uncertainty about the consequences of these developments, including the values and interests about technologies. The complexities of health problems (including questions about appropriate use of technologies) require data from a spectrum of qualitative and quantitative data. In HTA, the idea is still predominant that policy makers or professionals should get access to independent and “objective” scientific information on scientific and technological issues. This is a fundamental and truly important approach, but problematic is that stakeholders are (if they are) only involved afterward and that critics can be formulated on the notion of objectivity and truth in policy research. This finding does not mean that looking for clinical evidence or efficacy should be abandoned. But the scope of looking for “evidence” should be broadened. HTA falls short if it comes to the assessment of social, ethical, and legal consequences of the application of health technologies. The data-driven scientific culture in HTA needs to be broadened by approaches and methods giving insight in data that cannot be quantified easily. Qualitative methods are more appropriate for *certain* evaluation questions and purposes, especially those where depth and detail are needed. Especially in the stage of implementation, in which a technology is getting embedded in certain local conditions, methods to study implementation should be open-ended, discovery oriented, and capable of describing developmental processes. These methods allow analyzing of how a program or technology is perceived by those involved. Using the appropriate scientific qualitative techniques, a variety of perceptions can be traced and confronted with each other.

Apart from the question of the use of methods, specific debates should be initiated on the notion of assessment and evaluation. Because HTA is offering a specific form of policy support, one should overtly discuss the value of the “evaluation findings” and by whom these were developed. We are convinced that a lot can be learned from critical appraisals in the social sciences and newer forms of “general” TA, to broaden the methodological debate. We are convinced that HTA should primarily be practical action and implementation because it has to support policy making, but a lack of theoretical discussion could inhibit potential success of the method. Social scientist have to play a more important role in this process. They urgently have to make a larger effort to contribute to the HTA debate and development of HTA methods. The debate about the contribution of qualitative and quantitative methods would also run a lot smoother if more multidisciplinary collaboration is realized for the full cycle of HTA activities. Although the problem of multidisciplinary collaboration is often discussed, it is, especially in health care, necessary to *actually* cross disciplinary borders.

## REFERENCES

1. Banta D. Health care technology as a policy issue. In: Battista R, et al., eds. *Health care technology assessment*. Washington: Office of Technology Assessment; 1995.
2. Banta D, Gelijns AC. The future and health care technology: Implications of a system for early identification. *World Health Stat Q*. 1994;47:3-4, 140-148.
3. Banta D, Luce B. *Health care technology and its assessment: An international perspective*. Oxford: Oxford University Press; 1993.
4. Banta D, Oortwijn W. Special issue: Health technology assessment in the European Union. *Int J Technol Assess Health Care*. 2000;16:2.

5. Banta D, Oortwijn T. Health technology assessment and health care in the European Union. *TA Datenbank Nachrichten*. 2001;10:29-37.
6. Bijker W, Hughes TP, Pinch T, eds. *The social construction of technological systems: New directions in the sociology and history of technology*. Cambridge: MIT-Press; 1986.
7. Callon M. Society in the making: The study of technology as a tool for sociological analysis. In: Bijker et al., eds. *The social construction of technological systems*. Cambridge MA: MIT-press; 1986:83-103.
8. Coates JF. Technology assessment: A tool-kit. *Chemtech*. 1976:375-383.
9. Denzin N, Lincoln Y, eds. *Handbook of Qualitative Research*. Thousand Oaks: Sage; 1994.
10. Denzin N, Lincoln Y, eds. *Collecting and interpreting qualitative materials*. Thousand Oaks: Sage; 1998.
11. Denzin N, Lincoln Y, eds. *Strategies of qualitative inquiry*. Thousand Oaks: Sage; 1998.
12. Denzin N, Lincoln Y, eds. *The landscape of qualitative research: Theories and issues*. Thousand Oaks: Sage; 1998.
13. Dosi G. Technological paradigms and technological trajectories: A suggested interpretation of the determinants and directions of technological change. *Research Policy*. 1982;11:147-162.
14. Drummond MF, O'Brien B, Stoddart GL, Torrance GW. *Methods for the economic evaluation of health care programmes*. Oxford: Oxford Medical Publications; 1997.
15. EUR-ASSESS. Special issue. *Int J Health Care Technol Assess*. 1997:13.
16. Greene J. Qualitative program evaluation. In: Denzin N, Lincoln Y, eds. *Collecting and interpreting qualitative materials*. Thousand Oaks: Sage; 1998:372-399.
17. Grunwald A, ed. *Rationale Technikfolgenbeurteilung: Konzepte und methodische Grundlagen*. Berlin: Springer; 1999.
18. Guba E, Lincoln Y. *Fourth generation evaluation*. Newbury Park: Sage; 1989.
19. Guba EG, Lincoln Y. Competing paradigms in qualitative research. In: Denzin N, Lincoln Y, eds. *The landscape of qualitative research*. 1998:195-220.
20. Hammersley M. *What's wrong with ethnography: Methodological explorations*. London: Routledge; 1992.
21. Hammersley M. *The politics of social research*. London: Sage; 1995.
22. Hammersley M, Gomm R. Bias in social research. Available at: [www.socresonline.org.uk](http://www.socresonline.org.uk). Accessed 1997.
23. Hennen L. TA in biomedicine and healthcare: From clinical evaluation to policy consulting. *TA Datenbank Nachrichten*. 2001;10:13-22.
24. Latour H. *Science in action. How to follow scientists and engineers through society*. Milton Keynes/Cambridge: Open University Press/Harvard University Press; 1987.
25. Leys M. Technology assessment: Wetenschappelijke kennisoverdracht als probleem. In: Van der Meeren W, Van Langenhove L, eds. *Management van wetenschap*. Utrecht/Mechelen: Polygon/Lemma; 1987:137-159.
26. Leys M. Technology assessment in de gezondheidszorg. Betere Praktijk door een duidelijker begrippenapparaat. *Acta Hospitalia*. 1997;4:19-32.
27. MacKenzie D, Wajcman J. *The social shaping of technology*. Milton Keynes, Open University Press; 1984.
28. Mason J. *Qualitative researching*. London: Sage; 1996.
29. Miles MB, Huberman AM. *Qualitative data analysis: An expanded sourcebook*. 2d ed. Thousand Oaks: Sage; 1994.
30. Murphy et al. Qualitative research methods in health technology assessment: A review of the literature. NHS R&D HTA programme. *Health Technol Assess*. 1998;2:16
31. Office of Technology Assessment. *Development of medical technology: opportunities for assessment*. Washington: Office of Technology Assessment; 1975.
32. Patton M. *How to use qualitative methods in evaluation*. Newbury Park: Sage; 1987.
33. Pope C, Mays N, eds. *Qualitative research in health care*. 2nd ed. BMJ-books; 2001.
34. Perleth M. Possibilities for partial integration of health technology assessment and technology assessment. *TA Datenbank Nachrichten*. 2001;10:55-58.
35. Perry S, Gardner E, Thamer M. The status of health technology assessment worldwide: results from an international survey. *Int J Technol Assess Health Care*. 1997;13:81-98.

36. Reuzel R. *Health technology assessment and interactive evaluation: Different perspectives*. (PhD-thesis). Nijmegen: University of Nijmegen; 2002.
37. Rossi P, Freeman H, Lipsey M. *Evaluation: A systematic approach*. London: Sage; 1999.
38. Schot J. De inzet van Constructieve Technology Assessment, *Kennis en Methode* 1996;20;3:265-293.
39. Schot J, Rip A. The past and future of constructive technology assessment. *Technological forecasting and social change*. 1997;54:2-3, 36-56.
40. Scriven M. Hard-won lessons in program evaluation. *New directions for program evaluation*. 1993;58:1-107.
41. Silverman D. *Interpreting qualitative data: Methods for analysing talk, text and interaction*., London: Sage; 1993.
42. Smits R, Leyten J. *Technology assessment: Waakhond of speurhond*. Kerkebosch/Zeist: TNO; 1991.
43. Strauss A, Corbin J, eds. *Grounded theory in practice*. London: Sage; 1997.