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The paper presents a set of principles that cover the broad scope of HTA from formulation of the question to effects on the decision-making process. It also provides goals for HTA programs to aim for in producing assessments. The principles are supported by material that includes illustrations from the experience of several programs. The authors have had long contact with the field and are well able to authoritatively discuss a range of methodological and other topics. The paper includes a range of views and details that are relevant to those involved with HTA.

However, some aspects of the paper might be questioned, starting with the need for this quite extensive overview. Most or all of the principles have been discussed in detail in various other articles, some of them published in the Journal. Also, many of the points made in support of the principles will be very familiar to those engaged in HTA. It is perhaps valuable to raise these points again, but is a further publication of this sort really needed?

Further uncertainties are the intended targets of the paper and how it would be used. The purpose of the principles is given as use in assessing existing or establishing new HTA activities. This is qualified by having the principal focus on activities that are linked to, or include a particular resource allocation decision. Some of the messages in the paper are particularly applicable to large programs and "full" HTAs. Other players in the HTA world would have difficulty in following all the proposals that are made.

Many of the activities proposed in support of the principles are worthy but also likely to be resource and time intensive. There could be doubts as to the practicalities of some of the suggestions for a typical HTA program which has limited resources and is under time pressures from clients. There is little recognition of likely constraints on programs. The paper might be seen as presenting a package that is more relevant to programs of the sort that feature in the examples than to the work of other HTA centers. Also, some of the suggestions made seem to be matters for decision makers in health care rather than for HTA programs.

Some of the material in support of principle 2 (HTA should be an unbiased and transparent exercise) could be taken to exclude some areas of HTA, for example, within-hospital activities. The lengthy supporting detail is informative but to some extent considers the role of decision makers rather than that of HTA.

In the material on principle 3 (HTA should include all relevant technologies), the suggestion that investment and practice will gravitate toward those interventions that are free of evaluation might need some qualification. Limited assessment of rehabilitation technologies does not appear to have led to an unwarranted proliferation, for example. Other factors have to be considered. It would be interesting to consider how in practice principle 3 would be matched with principle 4 (A clear system for setting priorities for HTA should exist). In practice, many technologies might have similar priority ratings, but not all could be assessed because of limited HTA program capacity. Further inputs to priority ranking are likely, including perceived policy and administrative imperatives of the decision makers.

In the section on principle 5 (HTA should incorporate appropriate methods for assessing costs and benefits) the paragraph on recruitment and training of assessors raises a separate issue to that in the principle. It points to an obvious difficulty facing those who wish to implement all the suggestions made in the article. Not all stakeholders might be persuaded by the call to invest in capacity building for HTA.

Interesting matters are raised in the discussion on principle 6 (HTAs should consider a wide range of evidence and outcomes), but in applying this principle and others an overriding consideration will be the question that the HTA program has been asked to address. In practice, many HTA programs address a wide range of topics of varying complexity. A very wide range of evidence and outcomes may not be needed to provide appropriate advice on a particular issue. Judgment is required.

Principle 10 (Those conducting HTAs should actively engage all key stakeholder groups) would be a hard act for many HTA agencies to put together consistently. Such an approach would have major implications for program resources and for timing of assessments. Similar considerations apply to suggestions made under principle 1 regarding circulation and discussion of a draft scoping document.

With principle 11 (Those undertaking HTAs should actively seek all available data), the effect of seeking confidential information on the timeline of an assessment would have to be a consideration. There are often difficulties and delays in getting confidential information.

Many in the HTA community would have much sympathy with principle 12 (The implementation of HTA findings needs to be monitored), but who is it aimed at? It is important for HTA programs to consider the influence of assessments that they produce. However, monitoring implementation of HTA findings suggests some appraisal of the decision-making process, which will typically have several inputs other than HTA. Such broader monitoring approaches are outside the scope of the typical HTA program. Also, evaluating HTAs on their clinical impact over time appears ambitious, given the many other influences on clinical practice and outcomes.

Principle 13 (HTA should be timely) gives a fundamental point from HTA 101, but how likely is it to be achieved if all provisions under the other principles are followed? The call for timely studies by manufacturers and other advocates is another message for those outside HTA programs and might have limited impact. The material on conditional reimbursement is useful in indicating a practical mechanism for HTA and decision makers but does not get to grips with the issue of timeliness of the original HTA.

Some of the discussion on principle 14 (HTA findings need to be communicated appropriately to different decision makers) is more about content than communication. Development of interactive models is getting well outside the scope of many HTA programs and seems more a matter for certain types of decision maker. However, more might have been said here about the importance of an interactive approach to the HTA dissemination process. The lengthy discussion on principle 15 (The link between HTA findings and decision-making processes needs to be transparent and clearly defined) is in terms of decision thresholds. No further perspective is offered on the various political and other agendas that inform real-life decision making in health care. The principle appears to be more appropriately directed to decision makers than to HTA programs.

Application of the principles to regional and particularly local HTA, as suggested in the Conclusions, would need some further consideration of inevitable trade-offs between rigor, resources, and relevance to the decision-making process.

The paper presents a set of principles and supporting detail that re-state many important issues of relevance to HTA. Some of the principles and associated suggestions will be of most relevance to those HTA programs that have the resources, data, time, and mandate to meet them consistently. Other areas of HTA could find useful guidance in the paper but will be likely to frame their assessments more modestly and with greater flexibility. The messages in the paper that seem to be aimed more at decision makers than at HTA programs may need to be delivered using other approaches.

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THE PROCESS OF HEALTH TECHNOLOGY ASSESSMENT (HTA)

"Key principles for the improved conduct of health technology assessment for resource allocation decisions." The title says it all. I am amazed that such a summary is even possible and that it defines this field so well. Perhaps this report will be cited for years to come as the best and central definition of HTA. A field like this can be defined in other ways.

THE SOCIAL CONTEXT OF HTA

Governments and Insurers must decide what care and treatments to pay for. HTA undertakes to answer this perennial question in a reasoned way. Because there is this ongoing need the economic basis for HTA is secure. There will always be funding for this kind of work. It will primarily be carried out by government agencies and by consultants and not so much by academia. HTA answers must be rapid and accurate enough to stand up to challenge.

THEORY AND HTA

Some academic disciplines define themselves by theory. Molecular biology, physics, statistics, and economics come to mind. Some fields like epidemiology are a body of methods devoid of theory. HTA is some where in between. Read that wonderful title again. ". . . for Resource Allocation Decisions." The implicit theoretical framework here is based on economics and management: resource scarcity, rational choice, the management of innovation, and biostatistics. Theory is important. It allows for generalization, which in turn allows for replication, which is the basis for evidence with in the scientific method. If HTA is primarily a body of methods, then it is this process of assessment not the specific content of any assessment at one moment of time that is repeatable.

THE CHANGING WORLD

HTA exists in a world of change; new evidence about specific therapies and new methods of evaluation. There are four new methods that could radically change this body of