Chapter 7
Discussion: Attending to Values and Quality of Patient Involvement in HTA

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7.1 Introduction

This chapter discusses Part I of this book, which has provided an introduction to the history and development of HTA and to the various rationales for, and forms of, patient involvement within it. One of the points that recurred in the introductory chapters was the sense that patient involvement in HTA is 'still contentious' to some people (Sect. 5.4), and in part because of concerns such as 'scientific debate gets softened by inclusion of patients' perspectives' (Table 5.1), and patient involvement is 'a potential hazard in achieving independent evidence-based decisions' (Sect. 3.1). To address these concerns effectively, we suggest it will be important both (1) to identify, challenge and avoid perpetuating any unfounded assumptions or faulty reasoning that might lie behind them and (2) to ensure that advocates of patient involvement in HTA avoid overstating its merits, acknowledge variability in its quality and promote the most robust and defensible approaches. In what follows, we offer a few suggestions to support both kinds of endeavour. We do this in the interests of ensuring that, moving forward, patient involvement is discussed and developed in ways that not only fulfil its advocates' aspirations that it will improve HTA but that can also convince those who are currently sceptical about its value. Our comments apply primarily to patient involvement in assessments of particular health technologies rather than in HTA policy or the development of HTA processes more generally.

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Recognising that ‘patient involvement’ and associated terms are used to refer to various things and in confusingly inconsistent ways, we follow the editors’ stipulation that in this book, ‘patient involvement in HTA’ will be used as an umbrella term for two main types of activity: the use of ‘patient-based evidence’ and more direct ‘patient participation’ in HTA processes.

7.2 Tackling and Avoiding Overgeneralisation

Perhaps the most obvious form of faulty reasoning about patient involvement to be tackled and avoided is overgeneralisation. It is clear from the chapters in Part I that people with diverse and multiple experiences and social positions can be counted among the patients who might be involved (Chap. 3), that there are diverse forms of ‘patient-based evidence’ that can be introduced into HTA in diverse ways (Chap. 4, Parts II and III) and that diverse forms of more direct patient participation, including various kinds of ‘patient input’, can be used across a range of HTA activities (Chaps. 5 and 6 and Part III). These all have a number of context-sensitive strengths and weaknesses, so generalisations about patient involvement can very quickly become inappropriate.

The contingency of some experiences with and ‘impacts’ of patient involvement also needs to be recognised. Critics should not be able to use particular historical examples, for example, of some patient groups being unwilling to consider changing their views in the light of research evidence about the effects of a technology or of patients’ perspectives having contributed to particular decisions that subsequently had problematic implications (Chap. 3), to jump with faulty inductive reasoning to the conclusions that all examples of patient involvement will have such problems. But similarly, advocates of patient involvement should not rely on examples in which particular forms of patient involvement have contributed highly distinctive and useful insights to an HTA to imply that such positive contributions will be so clearly evident whenever those (or other) forms of patient involvement are used.

7.3 Recognising HTA as Inherently Value-Laden Even in the Absence of Patient Involvement

The concern that patient involvement is a hazard in the pursuit of good HTA seems to rest to some extent on the idea that without patient involvement, HTA would be a value-free scientific endeavour—or an endeavour in which decision-makers other than patients could readily and sure-footedly adopt the right values. This kind of thinking seems to stem from utilitarian and technocratic interpretations of the basic idea that the purpose of HTA is to ensure that when questions are asked about whether and how particular technologies should be introduced into or continue to be

used within health systems, the answers are informed by systematic assessments of the health benefits, harms and costs of using those technologies. A utilitarian interpretation of this is that HTA should help ensure that health systems provide the maximum (health) benefit, with the minimum possible attendant harm, within available resources. A technocratic interpretation then assumes that these goals can be achieved using standardised methodologies such as cost-effectiveness analyses based on the results of randomised controlled trials of the technologies of interest.

However, there are several reasons to believe that these utilitarian and technocratic interpretations are insufficient. First, there are questions to be asked about what should count, and as how significant or weighty, as a '(health) benefit', 'harm' or 'cost'. Answers to these questions are, of course, value-laden. And although there are some strong areas of consensus at a general level (e.g. that reducing the burden of disease or illness is beneficial for health), the labelling and valuation of particular biomedical states and experiences as examples of disease or illness are often contested, and technologies often impact on several of these simultaneously and in different ways for different population subgroups and individuals. Evaluative research, including scientific studies of clinical and cost-effectiveness, has a normativity built into it, even if that normativity is implicit (Molewijk et al. 2003).

Secondly, other values, for example, transparency in policy decision-making, fairness in resource or benefit allocation and support for personal autonomy, can also be held to be important in society. Some stakeholders reasonably expect that HTA (in its processes and/or its outcomes) should reflect and reinforce commitments to these or other additional values—although again there is room for debate about which values, how they should be interpreted and how they should be considered in relation to each other when it is not possible to fully realise them all (Chap. 2).

Value judgements are integral to and pervasive of HTA, as has been very well argued by Hofmann and colleagues (Hofmann et al. 2014). We suggest it is further important to recognise that HTA is a value-laden enterprise *whether or not patients are involved*. Highlighting this could be one of the most important contributions and, indeed, strategies of the patient involvement movement. Once the value-laden nature of HTA is acknowledged, the field of values that is recognised as relevant can be expanded, and the need to attend to the perspectives of patients and other stakeholders (including citizens) should become more apparent.

7.4 Looking Critically at Approaches to Patient Involvement in HTA

In the inevitably value-laden process of HTA, patients are legitimate stakeholders. Writing on patient involvement should—it seems to us—start from and reflect this assumption. But this does not mean that every possible approach to or instance of patient involvement will contribute equally well as stakeholder participation, to

good HTA or to the broader fulfilment of the purposes of participation and/or HTA in society. As Hansen and Street indicated in Chap. 3, there is a clear need for humility about what patient involvement can achieve and for ongoing research and development to help improve it.

It was noted in Chap. 1 that there has been a tendency in recent years to reduce the scope and scale of assessments of particular health technologies and to rely on more direct forms of patient participation, rather than reviewing and using 'patient-based evidence'. We agree that this is worrying because it seems likely to significantly reduce the quality of patient involvement in HTA overall. Assuming a reasonable range of research studies have been conducted among people with the health conditions of interest, a careful review of these is likely to uncover a more diverse range of experiences and views than it might be reasonable to expect a few patients, or even patient advocates, to be familiar with.

A reliance on relatively direct forms of patient participation can make it particularly difficult to integrate particular patients' inevitably partial perspectives on a health condition or technology within a broader assessment of the relevant issues. The appropriateness of particular approaches to such integration will, of course, depend on who participates, under what circumstances and how. There are, however, likely to be a number of uncertainties and value tensions to be faced by HTA staff and committee members as they strive to develop a well-rounded knowledge base and appreciation of what might matter and why to key stakeholders. For example, HTA committee members will often be aware that health technology developers and others who might profit from the widespread use of a particular technology seek HTA support for its use. They know that to that end, they will often identify patients whose experiences are particularly likely to encourage a decision in favour of their technology and encourage and support them to provide input or otherwise participate in an HTA process. When these committee members hear or otherwise experience patients' input or participation, they need to bear this in mind. It would be inappropriate to dismiss these patients' accounts completely: there is a need for HTA staff and committees to try to understand what matters from patients' perspectives, and submitted accounts and comments will often be based on experiences that are deeply felt and personally important. Staff and committee members must, however, deal somehow with their recognition that participating patients are perhaps carefully selected and accounts presented to suit one set of interests and that, of course, participation can be limited in other ways. The appropriate use of patient participation is far from simple.

A recognition of the limitations of contributions made by direct forms of patient participation does not need to imply a disrespect of the people on whose accounts they are, just that an awareness that there can be constraints and other influences that tend to limit and shape what can be seen from particular positions. One combination of influence and constraint that seems particularly important at the moment is relevant to technologies to screen for and diagnose cancer. When people who live in a society with a strong culture of emphasising the importance of catching and treating cancer early experience a cancer, they are understandably likely to speak in favour of more sensitive screening and diagnostic technologies for detecting that

cancer. They cannot personally and directly recognise the overdiagnosis and overtreatment that such technologies might lead to, because these are often only evident from analyses of population level data. Thus, unless they have engaged with such analyses, these patients are unlikely to know or speak against interventions that could harm them.

The limitations of what can be seen from particular positions will also affect the insights that can be generated by research into patients' experiences, so it is important that these limitations are considered critically when that research is reviewed as well. One of the advantages of including rigorous reviews of such research within HTA processes is that critical questions, for example, about which questions the research set out to answer and how its design and execution might have influenced the completeness and robustness of its answers, can be (required to be) more explicitly considered. Reviewers (who might include or otherwise be sensitised by people with relevant experience as patients) can consider, for example, which patients were and were not included and how the ways they were recruited, observed or questioned and interpreted might have shaped what was reported about their experiences and perspectives. This form of patient involvement can be strengthened by the use and development of methodological traditions for distinguishing better quality from poorer quality work and input for all kinds of research—not just that which has tackled questions of clinical and cost-effectiveness.

7.5 Considering Talk About 'Patient-Based Evidence'

The phrase 'patient-based evidence' appears to us to have some potentially unhelpful features and implications. The appeal of adopting the term in connection with HTA is understandable as since the rise of 'evidence-based medicine' it has become rhetorically powerful to refer to 'evidence' when shoring up a decision or action. There are reasons for caution, however. The (over)use of the term 'evidence' as a near synonym for 'research', and the (over)simplistic equation of 'evidence based' with 'justified' or 'good', means the word now often fails to differentiate between what is more and less useful and so can seem rather hollow. The relationship between 'evidence about x' and 'evidence for doing y' is not always completely clear and straightforward, and the tendency for 'evidence' to be associated in health service contexts with particular kinds of 'science' also runs the risk of obscuring rather than encouraging openness about the values at play in research studies.

The distinction that is sometimes drawn between effectiveness research 'evidence' and 'patient-based evidence' is also not as clear-cut or significant as it might first seem. Good quality effectiveness research should arguably always reflect outcomes that matter to patients, and some of these will be patient reported (in which case the effectiveness research will fulfil the criteria stipulated in Chap. 4 for 'patient-based evidence').

There is also a danger of encouraging an assumption that patients will or should attach more weight to 'patient-based evidence' than to the research it is contrasted

with. We think it is important to recognise that the effectiveness and affordability or otherwise of health technologies for addressing their problems usually matter a lot to patients and perhaps especially for influencing societal decisions about the availability and use of particular technologies. Setting information about clinical and cost-effectiveness apart from [other] patient-based evidence potentially implies more of a division between patients' and others' concerns than is useful.

7.6 Concluding Remarks

We hope we have made it clear that, like other authors in this volume, we strongly endorse the need to recognise and consider how to integrate the perspectives of patients as well as those of citizens, health professionals and other experts, in important decisions about the use of health technologies in health systems and societies.

In a book about patient involvement in HTA, it makes sense to focus attention on how and how well patient involvement can contribute to HTA. However, a reorientation to a focus on the broader questions of how and how well HTA can incorporate the value concerns and insights of all legitimate stakeholders, including those of patients and citizens, might be more helpful for moving debate and action forward. Reminders that HTA is an intrinsically value-laden endeavour can bring more of the challenges of the endeavour into view. HTA requires the identification, critical analysis and defensible synthesis of a plurality of value concerns and insights relating to a potentially diverse array of relevant questions that are interlinked in complex ways. This can't be achieved by 'purely' technical means, and it might not be realistic to expect it to yield a singular universal recommendation about the use of a particular technology. Taking the perspectives of multiple stakeholders, including diverse patients, seriously may in the end require greater flexibility to be built into the recommendations made by HTA agencies. This may further complexify HTA processes, but could bring them closer to 'recognis[ing] what is best for all patients across the board' (Sect. 3.1).

References

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