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An equity checklist: a framework for health technology assessments

CHE Research Paper 62

An equity checklist: a framework for health technology assessments

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Abstract

Despite the inclusion of equity ideals in the design of many health care systems, pragmatic tools for integrating them into the efficiency categories of cost-effectiveness in HTA remain under-developed. This paper reviews approaches used to incorporate equity in HTA methods and develops a framework to help decision makers supplement the standard efficiency criteria of HTA and avoid building inequities, explicit or implicit, into their methodology. A 'checklist' is provided to alert decision makers to a wide range of equity considerations for HTA. This checklist is intended to be used as part of the process through which advisory bodies receive their terms of reference; the scoping of the agenda prior to the selection of a candidate intervention and its comparators for HTA; the accompanying background briefing for decision makers; and as a tool to help to structure the discussion and composition of professional and 'lay' advisory groups during the assessment process. The checklist is offered as only a beginning of an on-going process of deliberation and consultation, through which the matters covered can be expected to become more comprehensive and the record of past decisions and their contexts in any jurisdiction adopting the tool can serve to guide subsequent evidence gathering and decisions. In these ways, it may be hoped that equity will be more systematically and fully considered and implemented in both the procedures and decisions of HTA.

Introduction

A challenge was recently presented to Health Technology Assessment (HTA) practitioners to address equity better in their analyses [1]. In this paper we attempt to meet that challenge, at least in part. HTA is the systematic evaluation of the consequences of the use of a health care intervention (henceforth 'technology'). Its principal purpose is to inform decision-making. Ethical considerations and non-economic social consequences were included in early general formulations of HTA [2]. However, it is only recently that attempts have been made to develop frameworks for considering methods of integrating ethics and a wider set of social consequences into HTA [3-7]. comprehensive attempt to give practical guidance is that of the National Institute for Health and Clinical Excellence (NICE) in England and Wales [6]. One important ethical consideration is equity. Despite the significance of equity ideas in the design of many health care systems, pragmatic tools for integrating them into the efficiency categories of cost-effectiveness in HTA remain under-developed [8]. We attempt here a first step towards a pragmatic solution by providing a framework of equitable considerations of potential relevance in HTA decision making, giving examples of the ways in which such considerations might arise, and providing a summarized checklist which may itself be used as a decision tool by HTA decision makers or which could be further abbreviated as a desk-top aidememoire. The framework is primarily intended for high-level decision makers who specify the criteria to be used by HTA advisory committees. The checklist if offered as a first approximation to a practical tool for use by such advisory committees.

Equity has many meanings in both academic and lay contexts [9-12]. The absence of an agreed theory of equity arises out of the absence of a general or monist theory of morality. There are moral theories that claim to be general, such as utilitarianism, though utilitarianism in its classical form is not directly concerned with equity. Non-utilitarian theories hold, variously, that the equitable distribution of health care resources is that which is to the advantage of the least advantaged person - so-called maximin theory. Deontological theory posits that an equitable distribution arises out of the duty each has to provide for others. Entitlement theory holds that an equitable distribution is the outcome of an equitable economic and social system (for a review of rival approaches see Veatch [13]). We do not attempt the Sisyphean tasks of selecting from or reconciling rival philosophies but suggest instead that equity issues concerning the use of health care resources in a decision-making context are best considered explicitly as pluralist. Rather than defining a priori what 'equity' is, we draw on a multidisciplinary literature and our own practical experience, to create an eclectic list of equity issues, which, if left unaddressed by decision makers, could be deemed by a reasonable person to be unfair or to lead to unfairness in the adoption, diffusion or consequences of a health technology.

Two domains of equity are especially relevant in HTA. One is fairness of the procedures used in the conduct of HTAs. The other is equity as a decision criterion, like efficiency, for ranking health care interventions. Equity in the first sense has, at least in part, been conceptualized as 'accountability for reasonableness' [10, 14-16] and has been adopted by some agencies (e.g. NICE 2008). Equity in the second sense is a statutory requirement in several jurisdictions and is likely to be increasingly required: illegal discrimination will need to be addressed in all jurisdictions, such as the UK, where such legislation exists. However, such imperatives typically address only a subset of the concerns for equity that can arise in HTA. Unfortunately, there exists no substantive body of principled thinking that can serve as a sure, or even moderately agreed, foundation for a more comprehensive treatment of equity in HTA [11].

Equity in the sense of fairness in the way health care is financed, produced and distributed has been a founding principle of many health care systems throughout the world, and has resulted in systems that broadly fund activity according to ability to pay and distribute it according to need (especially in middle and high income countries). It would therefore seem appropriate for HTA equity criteria in such jurisdictions to be at least consistent with these broader ideals of health care. Unfortunately there are major differences between definitions of 'need', measures of it and its application in HTA decisions [12] and it is far from clear what a criterion of need would require over and above the criteria of effectiveness and cost-effectiveness.

The standard approach to equity within HTA seems to operate at two distinct levels. The first is general, such as being aware of the difference between horizontal and vertical equity (noting that only the former involves attempting to achieve equity through the equality of something [9, 17]) or having an equal respect for everyone. Since not all inequalities are inequitable, nor all equalities equitable,

we agree with Whitehead (1991) in making equity and inequity the focus of our attention rather than equality or inequality [18]. The second is specific, such as the application of differential weights to costs and benefits according to particular equity-related characteristics of those likely to be affected by the decision [19-27]). While there is merit in this outcome-based approach, in practice decision makers have difficulty in identifying circumstances in which departures from strict equality in the value of units of outcome could be justified, with the possible exception of end-of-life benefits which NICE, for example, explicitly treats as warranting special weights, but without specifying them in quantitative terms, and which others, such as Ontario's Committee to Evaluate Drugs (CED), favour - though only implicitly¹. Equity-focused 'impact assessments' are examples of procedures that have a focus specifically on the distribution of outcomes (e.g. Kemm et al 2006 [29]).

There is little guidance concerning what, justly, ought to constitute either the characteristics in question or the size of the weights. Some gather evidence regarding the public's preferences. stakeholders' perspectives or experts' advice on either of these matters [26, 27, 30-36]. Empirical efforts to discover what 'the public' thinks about appropriate ways of trading-off benefit with cost also raise the fundamental ethical question of the extent to which HTA *ought* to embody such values, even when participants are well-informed. It is possible that preferences may be unstable or that the values elicited change according to the amount of information that is given, the technology considered, whether the health state in question is merely anticipated or actually experienced. Even when all such confounders have been taken into account it is possible for there to be considerable variance around population means and the distribution of ethical values need not have a single mode. Ethicists might raise the objection that what is just or fair is not to be determined by populist vote, while others might contend that the preferences of elected representatives of the community in question should count rather than the preferences of those who elected them. Other methods have sought generalizable trade-offs between equity and efficiency [37, 38]. However, not all equity issues involve trade-offs with efficiency² [40] and none of these approaches addresses what ought to be done nor attempts to address the many other dimensions of equity that ought to be taken into account. The dimensions of equity typically considered (at least by health economists) are quite restrictive, being mostly concerned with distributive fairness and focused on health, the geography of health care, and income. Further, irreconcilable differences in values are glossed over, hidden stereotyping happens and reliance, save in the case of legislated requirements, is almost entirely upon intuition.

We propose the creation of a pluralist [41] 'checklist', that might be expanded and developed in the light of experience, consultation, deliberation and the transparency that ought to accompany it. In any specific decision context, not all the items in the checklist will be relevant – and perhaps none will be – but the intent is to minimize the risk of overlooking considerations of equity that might be relevant by ensuring that minds are open to matters that can easily be overlooked or, if not overlooked, that may be difficult to articulate, appraise or measure.

¹ In the UK the Department of Health's recent call for proposals regarding value-based pricing for pharmaceuticals explicitly invites proposals regarding weights (see [28]).

² Equity is commonly perceived as in conflict with efficiency. The existence of any trade-off hinges, however, on the concept of 'efficiency' employed. If being efficient is to maximise aggregate population health with *fixed* weights for its members' health states (say, equal weights), then any such weights are potentially inequitable, and could generate a clash (say, on grounds of neglecting previous histories of ill-health, or of treating a given health gain as of equal social value regardless of the starting health state of individual members). But this clash is between different approaches to weighting health states, and less to do with efficiency. If, on the other hand, efficiency is of the conventional kind in economics (e.g. Barr 2004 [39]) – a state of affairs in which no one's health can be increased without the necessity of reducing someone else's, then there is a virtually unlimited set of differently weighted combinations of members' health states, any one of which is efficient but only a few equitable. The real trade-off is again between rival conceptions of what it means to be equitable.

A proposed initial checklist

We propose a practical and adaptable initial framework (the 'equity checklist'), as the basis for the development of a more comprehensive typology³. It is practical because it is intended as a sequence of 'red flags' to alert decision makers - and the designers of the systems within which they work - to matters of equity that might warrant integration into the usual efficiency analysis of HTAs. It is adaptable because the checklist as it currently stands is intended only as an initial step and what may be added is currently unknowable (at least, by us).

The checklist is an initial framework to inform discussion and decision at a relatively high level, to set criteria, and ensure that lower tier decisions - and the reasons for them - are incorporated into minutes and notes of the meetings at which they are taken, thereby enabling a dynamic process of comparison and consolidation as cases accumulate. In our approach, what is equitable or inequitable is less a matter for a priori definition than for discovery and subsequent categorization by those appointed by legitimate means to make such decisions. We hope that the checklist will help the process of discovering whether a consensus does exist and, where it does not, what the nature of the conflict may be and how it might most appropriately be dealt with. Although the exercise is not intended to generate a consensus, establishing that there is no consensus on some of these questions is as important as seeking one [45]. While it may be possible to develop a consensus over time in a jurisdiction, or at least a consistency in the way equity matters are considered, it seems unlikely that such a consensus would ever be achieved across jurisdictions, where prevailing standards, cultures and political values could vary greatly.

The object instead is to enable all potentially relevant factors to be clarified and considered, along with any evidence pertaining to them, including any evidence generated in the actual process of consultation and deliberation. The process is intended to affect both the procedures of the HTA as well as the 'final appraisal determination'. It may also be used by agencies to determine the scope of equitable issues to be considered by advisory committees, with the consequence that some of the matters identified in the list would not in practice be open for discussion.

We propose that the equity checklist should: (a) be used as part of the process through which advisory bodies are given their terms of reference, (b) form a part of the scoping agenda prior to the selection of a candidate intervention and its comparators for HTA, (c) accompany the usual efficiencyrelated statistical and analytical, research and background briefing for decision makers, including systematic and other reviews, incorporating any anticipated equity issues in the scoping stage; and (d) where appropriate (e.g. when equity issues of sufficient weight are identified to warrant detailed consideration) help to structure the discussion and composition of multi-disciplinary, multi-professional and 'lay' advisory groups during the assessment process.

We anticipate that the checklist will be developed in a variety of ways. One is through academic research and discussion, which will in turn inform the methodological guidance of HTA agencies. Others, which we have previously characterised as casuistry, are through the gradual building up of case studies of actual decisions, their reasoning, and their eventual analysis, synthesis and consolidation into statements of good practice at various levels of the decision making process. This will normally require digging deeper than the mere on-line consultation of the recommendations and decisions of advisory committees. In this fashion, we expect to see an accumulation of case-based precedents that will help decision-makers achieve consistency across interventions, constantly remind them of factors that might otherwise be overlooked, together with suggestions of how they could be handled.

of its Technology Appraisal Advisory Committee.

³ It is intended to complement rather than supplant other checklists such as those being developed by the Campbell and Cochrane Equity Methods Group (Ueffing et al. [42] and Tugwell et al. [43]). It could also be used as a complement to audits of equity such as that operated in England by the Department of Health [44]).

This is the term used by NICE to describe the recommendation or final product of its evidentiary review process: the guidance

Elements of the checklist

Equity versus equality

Decision makers may need reminding that equity and inequity are not the same as equality or inequality. When, however, inequalities are linked with postulated causes as when, for example, a concentration curve links health or ill-health to income, an inequality might be judged as also inequitable. Some inequalities are actually equitable as when, for example, someone with an urgent need to treatment receives it before another who is a less urgent case. In all cases, however, it is worth asking 'equality (or inequality) of what?' Common candidates include: need; deservingness or responsibility; capacity to benefit or be harmed; degree of incapacity or current health state; history of past health or ill-health; prognosis with and without the technology; health outcome - quality of life; and dependents (e.g. care-giving responsibilities). The ethical element derives from the postulated cause of the health inequality. Empirical causes judged to be ethically relevant commonly include income and wealth; social class; social deprivation; and life-style and behaviour. While the solution to inequity is likely to require addressing the underlying causes, an assessment of their mutability and the balance of cost and benefit in changing them, the range of remedies in HTA is typically narrower, lying within health care and typically within a rather small subset of health care technologies.

The language of equality and inequality is explicitly quantitative and it is always worth seeking empirical and quantitative information about *how equal or unequal* the relevant factors, outcomes or causes are and how equal or unequal it is felt they ought to be. Major unjust inequalities may rightly be perceived as more important to remedy than minor ones, though the relative costs or redress ought normally also to be taken into account. In all cases a judgement should be made as to whether the evidence on equity warrants any significant departure from the implications of the efficiency analysis, such as recommending the use of an intervention when its incremental cost-effectiveness ratio is above that normally deemed to be the maximum allowable, or not recommending one that is below that threshold, on grounds of its inequitable consequences.

Domains of equity

The matters for discussion under this category of the checklist relate to the appropriate focus on equity, for example, whether it should relate to health care inputs, processes or outcomes; whether it is the direct or indirect (perhaps unintended) consequences of the use and diffusion of the health technology that matter; whether there should be a disease focus, with patients being classified by, say, diagnostic group, or in some other way (say, by socio-economic status (SES)). If the identification of subgroups within a larger class of individuals could generate inequities, these should be explored. It is at this stage that some groups who might be affected by a technology can be (innocently but mistakenly) overlooked, as might be the case in interventions for parents that have significant side-effects on children. Such an omission would, of course, also bias an efficiency analysis as well as raising potentially significant equity issues [46]. For example, if we consider a screening technology that distinguishes between cancer patients who would benefit from a particular treatment from those who would not, then one domain of equity pertains to the consideration the implications for both sub-groups: not only the sub-group that benefits but also those who are disappointed.

Legal obligations

Most jurisdictions will specify statutory requirements to consider justice and equity and there may be further administrative obligations placed on agencies by higher tier organizations or their own governing bodies. Anti-discrimination legislation may be quite specific in requiring specific factors to be taken into account and may go so far as to specify how and the discretion that is permitted the decision makers. Legal obligations may be absolute, in the sense that any inequality of the sort in question is illegal, or relative in the sense that discretion may be exercised regarding the extent to which a given inequality violates a principle of equity. Common dimensions include discrimination by age, religion, gender, disability, ethnicity, race, socio-economic status, nationality, language and sexual orientation. Other dimensions may have regulations we cover under other headings.⁵

⁵ NICE has gone further than most agencies in identifying groups of people for whom special treatment may in some circumstances be appropriate. They are: race (ethnicity) only when clinical effectiveness cannot be identified in any other way;

General principles

Despite the difficulty in obtaining universal assent to specific ethical principles, it is always worth establishing whether some (probably simple) principles would in fact be agreed for all cases or in the context of the case under consideration. Some may be inherently broadly applicable and become embodied as standard in the consideration of equity. Principles that might be worth discussing could include:

- (a) The domain of equity shall be 'current and prospective health' not past health.
- (b) Equity requires either the attainable equality of something or else its fair inequality.
- (c) Fair inequalities in treatment exist when the inequality arises from a fair claim for being treated differently, such as an accepted claim of higher need.

It may also be possible to agree specific axioms relating to equity, such as the following cockshies:

Weak equity axiom 1: 'if person A has a worse state of health than person B, then in determining the equitable allocation of an intervention having a given impact on a population including A and B the equitable solution ought to increase A's health more than B's, or reduce it less'.

or

Weak equity axiom 2: 'if person A has a worse state of health than person B, then in determining the equitable allocation of a budget for interventions on a population including A and B the solution ought to include only interventions that on average increase A's health more than B's, or reduce it less'.

Embedded inequity

By embedded inequity we mean inequities arising from inherent characteristics of the analysis or intervention. This might arise from the use of specific concepts or tools. For example, it is generally recognised that the use of EQ-5D might discriminate unfairly against clients with cognitive impairment or with sensory deficits for whom it is not well-designed. Unfairness might also arise in the detail of the measurement process - EQ-5D may omit significant dimensions and thereby unfairly discriminate against patients for whom the omitted factors are key outcomes, such as relief of fatigue for people living with rheumatoid arthritis or anaemia. Time costs may not properly reflect opportunity costs for different social/employment groups, as when salary earners do not lose income when attending a clinic compared with the self-employed. Practical measurement and experimental methods may contain inequitable framing biases, or measures of inequality may over or underweight the extremes of a distribution of benefits or harms [48] or exclude relevant dimensions [49].

The systematic exclusion of vulnerable groups from clinical trials/research can lead to an absence of evidence on effectiveness in those groups, which in turn can result in inequitable denial of access. A now classic case of this bias is the exclusion of women from cardiovascular clinical trials despite the prevalence rate of cardiac disease amongst them (see Kim et al. 2009 [50]).

Embedded inequity might also arise from the inherent character of an intervention, such as denial of choice that can arise in some interventions such as water fluoridation, population-screening programs or (healthy) fixed school lunch menus, where the affront to freedom may bear more heavily on some than on others, such as those with religious dietary restrictions. The commonly made assumption that a quality-adjusted life year is of equal social value to whomever it accrues is an embedded assumption that may need modification if it is thought that the value (weight) placed on a QALY gain for one who is currently very sick ought to be higher than for one less sick [23].

Inequity may arise when the valuation basis of health outcomes is variable as when, for example, those who have actually experienced a condition (and its treatment) value its avoidance less than

disability, especially where there are obstacles to their benefitting from a technology; age, sex or sexual orientation, if they are an indicator of benefit or risk or clinical effectiveness cannot be identified in any other way; stigma, to the extent that it affects behaviour and the probability of benefit; behaviour-dependent conditions only if continuing behaviour affects the probability of benefit; socio-economic status only if effectiveness is linked to status or there is a legal requirement to favour this group [47].

those who anticipate but have not experienced it [51]. More generally, if the prevalence of unstable valuations of outcomes is related to other characteristics, such as education or social class, then a suitable precaution might be to discover the views of those most directly affected by the intervention in question. There is a great deal of evidence of the considerable variability of preferences and valuations, and their susceptibility to framing and other effects, in the literature of cognitive psychology and experimental economics (e.g. Kahnemann and Tversky 2000 [52]).

Institutional bias

Institutional biases are those that are also embedded but in organizations rather than analytical methods or interventions. The equity issue here is whether the jurisdictional scope of agency or of its parent organization causes any costs or benefits that might be significant for equity to be omitted or distorted. For example, if major outcomes include effects such as reductions in teenage pregnancies or a reduction in the frequency of j-walking, these may not be a part of a Ministry of Health's remit, belonging instead to a Ministry of Social Work or the Ministry of Transport. Conversely, the jurisdictional scope of 'partner' agencies or ministries might cause significant costs or benefits for health equity to be omitted or distorted (such as impacts on life expectation).

Other skews may exist in the distribution of the costs and benefits of interventions across 'stakeholders' that create inequity, as when workplace interventions have costs that fall mainly on owners and benefits that fall mainly on workers [53]. Institutional biases may cut across a myriad of domains, including the highest institutional levels such as health ministries, within agencies conducting technology appraisals, in provider institutions, in workplaces and other locations of care or intervention.

Implicit stereotyping

Implicit stereotyping occurs when assumptions are made about a condition and the desirability of treating it so as to ascribe those living with that condition as 'abnormal' or 'undesirable' [54]. For example, individuals who are deaf like to consider themselves as a group distinguished not only by deafness but also by a language (Sign) and resist the descriptor 'disabled' on the grounds that deafness is, in effect, a socially-constructed 'disability', and therefore need not be 'treated'. Implicit stereotyping is especially likely when the culture of the 'patient' differs from that of the analyst. A dramatic example of the way in which 'disease' can be socially constructed is pinta (dyschromic spirochaetosis). This skin disease produces distinctive rose-coloured spots on the skin, which some Indians in South America once believed to be a sign of being healthy, and which was so prevalent among some tribes that the few single men *not* suffering from it were regarded as pathological to the point of being excluded from marriage [55]⁶. To treat it therefore according to concepts of disease which are external to that culture is likely to imply that the value of treatment thus estimated would conflict with a value based on local Indian concepts and values. The danger for HTA in implicit stereotyping is that the externally perceived health gain relative to that perceived by the patient can be substantially different, and subsequent implementation becomes patronising or even stigmatizing.

Implicit stereotyping may be particularly expected for congenital and other chronic conditions. A check is actually to ask the target populations concerned through consultation and deliberation whether the measure or conceptualization of the health benefit or state is biased – or whether there may be some members of the target group for whom this might be the case.

Contexts, behaviours and circumstances

This category includes aspects of the context of technology use that could, at least in principle, disadvantage some people relative to others (e.g. traveling from a remote home to a clinic or hospital) and thereby render an intervention cost-effective for one group but not for another (e.g. [31]). Any of the following circumstances could affect the balance of negative and positive consequences: demographics (age, sex, ethnicity, socio-economic status (SES)), location of delivery of care (e.g. home or institution), language, religious beliefs, sexual orientation, or multiple deprivation.

⁶ This interpretation is not uncontroversial, see Frankel (1986) pp 2-3 [56], but the social construction remains.

Some effects occur in unanticipated ways. For example, it was found in Rich et al. (1976) that the reliability of self-administered dipslide measures of bacteriuria taken at home by girls without symptoms varied significantly with the age and socio-economic status of the children performing the tests compared with costlier supervised sampling of the same girls [57]. In such cases, the costeffectiveness of an intervention that is in all other respects the same will be higher for the younger and/or lower SES children.

There is considerable evidence that differential behavioural responses to public health measures according to SES may actually contribute in an unintended way to inequity, especially when utilization of an intervention is lower among more disadvantaged and 'hard-to-reach' populations or by ethnic minorities [8]. It can be all-pervading, for which the term 'staircase effect' was coined by Tugwell et al. Unintended inequality-widening interventions have been termed 'intervention generated inequalities' [59]. These are widespread phenomena and have been found to exist, for example, in many preventive interventions [60, 61]. There is also, needless to say, abundant evidence that many interventions also generate greater health equality [58].

More generally, equity concerns may arise whenever a particular technology is cost-effective for some subgroups of clients but not others [38] whether for behavioural or other reasons, depending again on the social and economic characteristics of the subgroups.

Processes in HTA

Anticipated equity effects that require adaptation of the usual review processes of the agency need to be considered and addressed as early as possible in the HTA, including the scoping stage. Thus, all questions concerning rights of different groups to be consulted, represented or to participate in decision making processes should be considered not only in terms of the expertise, knowledge and understanding that they may bring to the process but also with regard to fairness. For example, if a manufacturer or a patient group may be affected for good or ill by the HTA process, it is likely that fairness would at least require their right to participate to be considered.

If the outcome measure of choice may not be valid for some patients, perhaps because some aspect of health benefit is not included among the dimensions of the measure, then the procedure should ensure that decision makers have access to patients and informal carers with experience of the condition and its treatment to enable the construct validity of the measure to be assessed and, if necessary, to enable appropriate adjustments. This approach was employed recently by the Medical Advisory Secretariat in Ontario during their scoping stage of an HTA, where they sought patient input on the research questions to ensure that they captured relevant patient outcomes in their evidentiary review [31].

Hidden opportunity costs

These are costs imposed on those affected by the intervention and anonymous people who are affected through consequential changes in the distribution of resources. The identity of the individuals who lose may not be known. The weight to be attached to any such opportunity cost might vary according to what is known about who are most likely to lose compared with those directly affected by the intervention. One group of stakeholders that is almost invariably omitted from the deliberative processes is the 'ordinary' or potential consumer of health care - that is, members of the public (as distinct from representatives of specific patient advocacy organisations). By definition, these are anonymous individuals whose stakeholder status arises from the fact that their taxes or premiums fund health care budgets, and if some of these budgets are spent on one intervention, those parts are not available for others including interventions for these ordinary and potential consumers. While this opportunity cost provides the underpinning argument for using a test incremental cost-effectiveness ratio (ICER) and is a conventional part of the efficiency element of an HTA, the possibility arises that there may also be equity considerations. For example, when the beneficiaries of a proposed new intervention are relatively privileged or underprivileged members of the community (or few in number) compared with the 'ordinary' consumer. Similarly, the 'ordinariness' of those who bear the opportunity costs of newly introduced interventions ought to be tested. Empirical ways in which this might be done are, however, very much at the research stage.⁷

Processes in the delivery of care

Processes in the delivery of care might have inequitable consequences even in the absence of institutional bias of the type already outlined. For example, the way in which care is delivered may be demeaning or unduly revealing, as when a patient enters an HIV or STD clinic having a sign publicly indicating its purpose. There may be processes at local delivery sites that deny opportunities for patients to reveal equity-related factors. For example, it is commonly charged that middle class clients of health care systems are more adept at managing their way through administrative processes and hence of receiving effective health care [62]. A flagrant breach of equity arises when health care providers select out patients deemed to be less financially advantageous to the organisation by virtue, for example, of the chronicity of the disease or their insurance status.

Special claims

There is a range of frequently heard specific equity claims that ought to be anticipated and appraised both in the scoping of an HTA and at subsequent stages. A position should be taken as to what categories of claims will be entertained. Commonly met claims include: claims of need, such as low initial health status; claims of responsibility, which may be positive if, say, the likely beneficiaries are deserving by virtue of their roles as, for example, parents, or negative if, say, the likely beneficiaries are deemed 'undeserving' by virtue of behaviour such as pursuing life styles hazardous to health; claims of history, such as past endurance of ill-health or previous receipt of the intervention; claims of desperation, as when the intervention in question represents a 'last chance' for a cure; claims of unfair innings, such as a short already-lived life-span [63]; claims related to non-health consequences (other effects on welfare) or on multiple deprivations; claims of willingness to pay such as a willingness to 'top-up' to compensate the provider for providing care that is less cost-effective than the third party payer's threshold requires.

Special claims and possible inequity may arise in connection with individuals who are not themselves patients. While it is commonplace in efficiency studies to recognize the importance of taking account of the impact of technologies on informal carers, carers too may have circumstances or characteristics that warrant special consideration on grounds of equity, especially if they have carried very heavy physical and emotional burdens while caring [64]. It is important not to be misled by spurious special claims from interest groups but it is equally important not to allow the strongest of special claims to go unappraised or to overlook the interests of those who are not organized or equipped to ensure that their claims are.

Cumulative effects

The consideration of cumulative past disadvantages or advantages that might be relevant in assessing benefit or cost or their distribution across affected parties would enable a broad view to be taken and help to ensure that the 'whole' was not taken uncritically to be merely the sum of the individual 'parts'. The accumulation might be across many equity categories, or over time, or both. The possibility ought to be considered that such accumulation strengthens any case for redress.

These categories are summarized in the following 'checklist', in which we have included 'prompts' to stimulate discussion and the assessment of the relevance of the category in question.

⁷ The topic is being investigated by a group led by Karl Claxton and Mark Sculpher at York (UK) researching value-based pharmaceutical pricing.

Conclusions

We have provided a framework for developing a checklist of equity considerations to complement the standard efficiency calculus of HTA. It is intended be used as part of the process through which advisory bodies are given their terms of reference; the scoping of the agenda prior to the selection of candidate interventions and their comparators for HTA; the accompanying background briefing for decision makers, including systematic and other reviews; and as a tool to help to structure the discussion and composition of professional and 'lay' advisory groups during the assessment process. Its effective development and implementation depends upon the creation of an on-going research program that identifies omissions and on HTA processes that provide, through appropriately detailed minuting and note-taking, accounts of decisions taken by decision making agencies that can be interpreted as precedents and analyzed retrospectively to promote consistency and to understand the reasons why apparently similar cases have been adjudicated differently on different occasions. Periodic reviews and updating guidance for decision makers are also recommended. In these ways, it may be hoped that equity will be more systematically and fully considered and implemented in both the procedures and decisions of HTA.

Table 1 A Checklist of equity considerations for health technology assessment

Domain	Elaboration	Questions
1 Equity and equality	There can be fair inequalities and unfair equalities. Equity ought not to be equated with equality (of something) but, if it is, the ethical 'weight' to be attached to the 'something' needs consideration. 'Equality' and 'inequality' imply a degree of quantification (minimally an order of states of 'more' or 'less'). Check on empirical research for quantified measures of inequity. In the absence of good quality research, identify other sources such as 'expert opinion' but be alert to the possibility of 'expert prejudice'.	Equality (or inequality) of what? Common candidates include: need, deservingness or responsibility, capacity to benefit (or be harmed), degree of incapacity or current health state, history of past health or ill-health, prognosis with and without the technology; health outcome - quality of life; and dependents (care-giving responsibilities). Need to seek empirical and quantitative information about <i>how equal or unequal</i> the relevant factors are.
2 Adequacy of the domains of equity	The focus of the analysis of equity. This could be on health care inputs, processes, direct outcomes, indirect outcomes, disease patterns, patient types, subgroups. The desired focus is likely to be context-dependent and may depend on the rulings of a higher tier authority.	Should the domain of equity relate to health care inputs, processes or outcomes? Might there be unintended consequences that raise equity issues? Should the domain of analysis be disease focused; or should some other basis for differentiating individuals and subgroups be used? What are the equity-related consequences of this categorization?
3 Legal obligations	Common offences include discrimination by age, gender, disability, ethnicity, race, nationality, language, sexual orientation, in the workplace, in education; there are also institutionalized discrimination, implicit and indirect discrimination.	Have the relevant local legal obligations concerning age, gender, disability, ethnicity, race, nationality, language, sexual orientation, etc. been considered? Are there any legislative requirements concerning institutionalized, implicit or indirect discrimination, in the respective jurisdiction?
4 General principles	Minimal requirements for 'equity', axiomatic statements, applicability of such principles in current context.	Have a set of guiding principles or axioms been established concerning what constitutes equality (or fair inequalities) in the current context? Is it possible to infer specific equitable guidance in the current context from the general guidance? Are their precedents that could guide in the present context?
5 Embedded inequity	Possible unfairness 'built in' to concepts (e.g. omitted dimensions of outcome or cost), framing effects in experimental approaches, possible unfairness inherent in the intervention (e.g. threat to autonomy).	Are there inequities in the measurement or methodological processes informing the HTA? For example, does the outcome measure omit significant dimensions and thereby differentially exclude key outcomes for some groups? Are the standard weights attached to gains and losses affecting different people (usually but not necessarily, unity) deemed suitable in the current context? Do the measures of inequity weight distance from the average in an acceptable way? Are there any aspects of the intervention, in addition to the direct effects, that may raise equity concerns?
6 Institutional bias	Inequity resulting from jurisdictional scope in clinical practices, provider institutions, workplaces, or in the distribution of consequences.	Do any of the following cause particular costs or benefits to be omitted or distorted: the agency's parent organization, the culture of the HTA agency itself, provider institutions, workplaces?
7 Implicit stereotyping	Definitions and concepts that exclude or prejudice individuals. Aspects of the effects of the intervention that have differential impact on individuals, or which make in untested assumptions about what does and does not 'matter', or are stigmatizing.	Is the measure or conceptualization of the health benefit or cost or state biased? Have assumptions about what 'matters' been tested by consulting those affected? Is the current context one in which there are likely to be marked differences in culture between analysts and client groups that could give rise to implicit stereotyping? Are there people who might be affected but whose interests have not been taken into account?

8 Contexts and circumstances	Aspects of the context that could disadvantage some relative to others (e.g. geography, culture), tests for whether any of the following could affect the balance of advantage: Usual demographics (age, sex, ethnicity, SES), location of delivery (e.g. home or institution), language, education of clients, religious beliefs, sexual orientation, stigma, multiple deprivation. Aspects of the context that render the proposed methods of HTA inappropriate (e.g. methods used in a high-income country being applied in a lowincome country, 'western' values being applied in an aboriginal or 'first nations' context).	Do any of the following circumstances affect the balance of negative and positive consequences: geography, demographics (age, sex, ethnicity, socio-economic status), location of delivery of care (e.g. home or institution), education, language, religion, sexual orientation, or multiple deprivation? Are methods developed in one culture being appropriately applied in another?
9 Processes in HTA	Process that deny suitable representation to people with a legitimate interest, processes that deny consideration of the interests of absentee stakeholders.	Has the scoping of the HTA caused a bias in the processes through which information germane to equity is gathered or considered? Is the current guidance devoid of any implicitly biasing elements, such as the exclusion of relevant consultation groups, in the current context? If not, can the matter be addressed and rectified? Are the appropriate health outcomes measures and stakeholders included in the HTA process (including patients and members of the public)?
10 Hidden opportunity costs	These refer to costs inflicted on those affected indirectly by the intervention and those anonymous people who are affected through consequential changes in the distribution of resources if the recommendations of the HTA were implemented. The identity of the individuals who lose may not be known. It may also be that the weight to be attached to any such opportunity cost might vary according to what is known about those most likely to be losers relative to those directly affected by the intervention.	Has due regard been had to the interests of the anonymous clients of the health care system from whom resources will be removed as a consequence of the implementation of the recommendation of the HTA? Do those most likely to be affected in this way have distinctive characteristics suggesting that differential weights ought to be attached to the impacts on them? Are there any empirical estimates of any such relevant effects?
11 Processes in delivery of care	Processes in the delivery of care that are prejudicial to, demeaning of or embarrassing for some who are affected. Some processes favour those adept at managing their way through complex or unfamiliar processes. Thus, other inequities for those lacking such social skills or that impose differential costs/burdens on some clients and stakeholders relative to others might not be known or even revealed.	Are there processes in the delivery of care, apart from those that are embedded in institutions that discriminate unfairly? Are any of the likely delivery processes prejudicial to, demeaning of or embarrassing for some clients relative to others? Is there a 'middle class' bias that favours those with skills at dealing with receptionists, bureaucrats, professionals and other unfamiliar groups of people?
12 Special claims	Claims such as claims of need (e.g. low initial health status?), claims of responsibility (e.g. life styles hazardous to health), claims of history (e.g. past endurance of ill-health, past receipt of the intervention), claims of desperation (e.g. 'last chance'), claims of unfair innings (lived life-span), claims of non-health consequences (other welfare effects), claims of willingness to pay (e.g. top-ups).	What, if any, special claims ought to be considered? Are there claims or interests not being heard but deserving of voice? Are their claims that are not ethically significant? Can the claims that might carry weight bear empirical testing for their veracity and size? Are there precedents for dealing with claims of the sort in the current context? How do special claims compare to the putative claims of those not represented in the HTA process?
13 Cumulative effects	Consideration of cumulative past disadvantages or advantages that might be relevant in assessing benefit or cost or their distribution across affected parties.	Has a holistic perspective been taken, or merely the sum of the individual 'parts'? Have historical disadvantages been considered? Are there any other respects in which the cumulative experience or the combination of experiences of those affected may be of equitable concern?

References

- [1] Culyer AJ. Hic sunt dracones: The future of HTA one economist's perspective. *Journal of Medical Decision Making*. In press.
- [2] Office of Technology Assessment. *Development of medical technology: opportunities for assessment.* Washington DC: U.S. Government Printing Office 1976.
- [3] Lehoux P, Williams-Jones B. Mapping the integration of social and ethical issues in health technology assessment. *Int J Technol Assess Health Care*, 2007 Winter;23(1):9-16.
- [4] Hofmann B. Toward a procedure for integrating moral issues in health technology assessment. *Int J Technol Assess Health Care*, 2005 Summer;21(3):312-8.
- [5] Saarni SI, Hofmann B, Lampe K, Luhmann D, Mäkelä M, Velasco-Garrido M, et al. Ethical analysis to improve decision-making on health technologies. *Bull World Health Organ*, 2008 Aug;86(8):617-23.
- [6] National Institute for Health and Clinical Excellence. Social value judgements: principles for the development of NICE guidance; 2008.
- [7] Johri M, Norheim OF. Can cost-effectiveness analysis integrate equity concerns? A systematic review of current approaches. Paper presented at ISPOR 12th Annual European Congress, Paris, October, 2009.
- [8] Cookson R, Drummond M, Weatherly H. Explicit incorporation of equity considerations into economic evaluation of public health interventions. *Health Econ Policy Law*, 2009 Apr;4(Pt 2):231-45.
- [9] Culyer AJ, Wagstaff A. QALYs (quality-adjusted life-years) versus HYEs (healthy years equivalents). *J Health Econ*, 1993 Oct;12(3):311-23.
- [10] Daniels N. Just health care. Cambridge: Cambridge University Press 1985.
- [11] Brock DW. Ethical issues in the use of cost-effectiveness alanysis for the prioritisation of health care resources. In: Anand S, Peter, F, Sen A. ed. *Public health, ethics, and equity.* Oxford: Oxford University Press 2004:201-23.
- [12] Culyer AJ. Need: the idea won't do--but we still need it. Soc Sci Med, 1995 Mar;40(6):727-30.
- [13] Veach RM. Ethical dimensions of the distribution of health care. New York: Praeger 1982.
- [14] Daniels N. Accountability for reasonableness. BMJ, 2000 Nov 25;321(7272):1300-1.
- [15] Daniels N, Sabin J. The ethics of accountability in managed care reform. *Health Aff (Millwood)*, 1998 Sep-Oct;17(5):50-64.
- [16] Daniels N, Sabin JE. Accountability for reasonableness: an update. BMJ, 2008;337:a1850.
- [17] Culyer A. Need an instrumental view. In: Ashcroft R, Dawson A, Draper H, McMillan J. ed. *Principles of health care ethics*, Chichester: Wiley 2007:231-8.
- [18] Whitehead M. The concepts and principles of equity and health. Copenhagen: WHO; 1991.
- [19] Bleichrodt H, Quiggin J. Characterizing QALYs under a general rank-dependent utility model. *Journal of Risk and Uncertainty*, 1997;15:151-65.
- [20] Bleichrodt H, Diecidue E, Quiggin J. Equity weights in the allocation of health care: the rank-dependent QALY model. *J Health Econ*, 2004 Jan;23(1):157-71.
- [21] Dolan P. The measurement of individual utility and social welfare. *J Health Econ*, 1998 Jan;17(1):39-52.
- [22] Dolan P. Desperately seeking numbers: the not-so-holy grail of the 'Super QALY'. *20th Nordic HESG* Reykavic 1999.
- [23] Dolan P, Shaw R, Tsuchiya A, Williams A. QALY maximisation and people's preferences: a methodological review of the literature. *Health Econ*, 2005 Feb;14(2):197-208.
- [24] Dolan P, Tsuchiya A. The elicitation of distributional judgements in the context of economic evaluation. In: Jones A, ed. *Companion to health economics*. Cheltenham: Edward Elgar 2006.
- [25] Johannesson M, Gerdtham U. A note on the estimation of the equity-efficiency trade-off for QALYs. *J Health Econ*, 1996 Jun;15(3):359-68.
- [26] Johannesson M, Johansson PO. Is the valuation of a QALY gained independent of age? Some empirical evidence. *J Health Econ*, 1997 Oct;16(5):589-99.
- [27] Johansson-Stenman O, Martinsson P. Are some lives more valuable? An ethical preferences approach. *J Health Econ*, 2008 May;27(3):739-52.
- [28] Department of Health. A new value-based approach to the pricing of branded medicines: A consultation: United Kingdom Department of Health; 2010.
- [29] Kemm J. Health impact assessment and health for all policies. In: Ståhl T, Wismar M, Ollila E, Lahtinen E, Leppo K, ed. Health in all policies: prospects and potentials. Helsinki: Ministry of Social Affairs and Health 2006:189-208.

- [31] Bombard Y. Public engagement pilot study on point-of-care International Normalized Ratio (INR) monitoring devices; Final Report to the Medical Advisory Secretariat, Ontario Ministry of Health and Long Term Care: 2009.
- [32] Abelson J, Giacomini M, Lehoux P, Gauvin FP. Bringing 'the public' into health technology assessment and coverage policy decisions: from principles to practice. *Health Policy*, 2007 Jun;82(1):37-50.
- [33] Bombard Y, Abelson J, Simeonov D, Gauvin FP. Eliciting social values and ethics in health technology assessment: A participatory approach *Social Science and Medicine*. Submitted.
- [34] Nord E, Enge AU, Gundersen V. QALYs: is the value of treatment proportional to the size of the health gain? *Health Econ*, 2010 May;19(5):596-607.
- [35] Nord E, Daniels N, Kamlet M. QALYs: some challenges. *Value Health*, 2009 Mar;12 Suppl 1:S10-5.
- [36] Cropper ML, Aydede SK, Portney PR. Preferences for life saving programs: How the public discounts time and age. *Journal of Risk and Uncertainty*, 1994;8:243-65.
- [37] Williams AH, Cookson RA. Equity-efficiency trade-offs in health technology assessment. *Int J Technol Assess Health Care*. 2006 Winter;22(1):1-9.
- [38] Ubel PA, Loewenstein G. Distributing scarce livers: the moral reasoning of the general public. *Soc Sci Med*, 1996 Apr;42(7):1049-55.
- [39] Barr N. Economics of the welfare state. Oxford: Oxford University Press 2004.
- [40] Culyer AJ. The bogus conflict between efficiency and vertical equity. *Health Econ*, 2006 Nov;15(11):1155-8.
- [41] Brody B. Life and death decision making. New York: Oxford University Press 1988.
- [42] Ueffing E, Tugwell P, Welch V, Petticrew M, Kristjansson E, for the Cochrane Health Equity Field. C1, C2 Equity checklist for zystematic review authors.; 2009.
- [43] Tugwell P, Petticrew M, Kristjansson E, Welch V, Ueffing E, Waters E, et al. Assessing equity in systematic reviews: realising the recommendations of the Commission on Social Determinants of Health. *BMJ*, 2010;341:c4739.
- [44] Department of Health. Health equity audit: a guide for the NHS: United Kingdom Department of Health; 2003.
- [45] Karpowitz CF, Mansbridge J. Disagreement and consensus: the need for dynamic updating in public deliberation. *Journal of Public Deliberation*, 2005;1(2).
- [46] Perry CD. Does treating maternal depression improve child health management? The case of pediatric asthma. *J Health Econ*, 2008 Jan;27(1):157-73.
- [47] Littlejohn P, Rawlins M. Social value judgments: implementing the Citizens Council reports. *Patients, the public and priorities in Healthcare.* Oxford: Radcliffe Publishing 2009:109-23.
- [48] Allison P. Measure of inequality. American Sociological Review, 1978;43(6):865-80.
- [49] Atkinson A, Bourguignon F. The comparison of multi-dimensioned distributions of economic status. *The Review of Economic Studies*, 1982;49:182-201.
- [50] Kim ES, Menon V. Status of women in cardiovascular clinical trials. *Arterioscler Thromb Vasc Biol*, 2009 Mar;29(3):279-83.
- [51] Kahneman D, Tversky A. Choices, values and frames. *American Psychologist*, 1984;39(4): 341-50.
- [52] Kahneman D, Tversky A. Choices, values, and frames. New York: Cambridge University Press 2000.
- [53] Culyer A, Tompa E. *Economic evaluation of interventions for occupational health and safety: developing good practice.* Oxford: Oxford University Press 2008.
- [54] Reuzel RP, van der Wilt GJ, ten Have HA, de Vries Robbe PF. Reducing normative bias in health technology assessment: interactive evaluation and casuistry. *Med Health Care Philos*, 1999;2(3):255-63.
- [55] Ackerknecht EH. The role of medical history in medical education. *Bulletin of the History of Medicine*. 1947;21:135-45.
- [56] Frankel S. The Huli response to illness. Cambridge: Cambridge University Press 1986.
- [57] Rich G, Glass NJ, Selkon JB. Cost-effectiveness of two methods of screening for asymptomatic bacteriuria. *Br J Prev Soc Med*, 1976 Mar;30(1):54-9.
- [58] Tugwell P, de Savigny D, Hawker G, Robinson V. Applying clinical epidemiological methods to health equity: the equity effectiveness loop. *BMJ*, 2006 Feb 11;332(7537):358-61.

- [59] White M, Adams J, Heywood P. How and why do interventions that increase health overall widen inequalities in populations? In: Babones SJ, ed. *Social inequality and public health*. Bristol: The Policy Press 2009:65-82.
- [60] Katz SJ, Hofer TP. Socioeconomic disparities in preventive care persist despite universal coverage. Breast and cervical cancer screening in Ontario and the United States. *JAMA*, 1994 Aug 17;272(7):530-4.
- [61] Alexander FE, Anderson TJ, Brown HK, Forrest AP, Hepburn W, Kirkpatrick AE, et al. 14 years of follow-up from the Edinburgh randomised trial of breast-cancer screening. *Lancet*, 1999 Jun 5;353(9168):1903-8.
- [62] Dixon A, Le Grand J, Henderson J, Murray R, Poteliakoff E. *Is the NHS equitable?* A review of the evidence. London; 2003.
- [63] Williams A. Intergenerational equity: an exploration of the 'fair innings' argument. *Health Econ*, 1997 Mar-Apr;6(2):117-32.
- [64] Zivin K, Christakis NA. The emotional toll of spousal morbidity and mortality. *Am J Geriatr Psychiatry*, 2007 Sep;15(9):772-9.