Procedural justice and democratic institutional design in health-care priority-setting

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Abstract

Health-care goods are goods with peculiar properties, and where they are scarce, societies face potentially explosive distributional conflicts. Animated public and academic debates on the necessity and possible justice of limit-setting in health care have taken place in the last decades and have recently taken a turn toward procedural rather than substantial criteria for justice. This article argues that the most influential account of procedural justice in health-care rationing, presented by Daniels and Sabin, is indeterminate where concrete properties of rationing institutions are concerned. Such properties inscribe substantial norms into institutions. These norms can derive validity only from democratic majority decisions, which must be seen as an instance of pure procedural justice. We therefore have to move the discussion to a meta-level and ask how concrete properties of institutions are being chosen. I suggest four criteria for sufficiently democratic institutional design choice and conclude that as institutional properties are likely to have effects on the resulting distribution of health care, design choices should be empirically informed and taken both democratically and deliberately.

Health is important to all of us; it is vital to the pursuit of our individual goals in life, whatever these may be. A good that is significant, or even indispensable, for the achievement of other goals is typically described as a 'conditional good'. The conditional qualities of health as a good provide a strong argument for the realization of a public health-care system that provides access to health services. However, progress in medical research has produced an ever wider range of costly health technologies and services, which meets with respective demands from patients. Given that health care competes with other public goods, such as education or environmental protection, even highly industrialized and

wealthy societies reach a point where it becomes impossible to publicly provide all services that patients demand. This is the point where limits and priorities have to be set in health-care service provision and where health-care goods need to be rationed. At this point, we are confronted with issues of distributive justice. 'How can we meet needs fairly if we can't meet them all?' asks Norman Daniels (2008, p. 103).

The debate on the necessity and justice of health-care rationing has been contentious in the United States since the 1970s, reached the state health-care systems in Europe and Australasia in the 1980s and 1990s and is at present beginning to gain momentum in the Bismarck-style health-care systems of continental Europe. During this time, the focus of the debate has shifted from mainly philosophical questions about the acceptability and ranking of abstract principles of justice to more practical questions as to how decisions on the public coverage of specific medical services are to be taken. In this process, the question of how decisions are to be made, and thus the question of procedural justice in allocation, has begun to replace questions of substantial distributive justice. This procedural turn of the debate attracts interest from empirical researchers such as political scientists, for whom the case of health-care rationing can be seen as exemplary for the challenges of decision making under conditions of uncertainty and complexity in conflicts that concern fundamental values and material interests alike. Uncertainty and complexity are also motives for the delegation of decision-making powers to non-majoritarian bodies, the legitimacy and justification of which is a contested issue in the study of governance.

This article explores the relationship between substantial and procedural justice in the allocation of health care by first pointing out the peculiar properties health and health care have as goods before turning to general issues of justice in distributive conflicts, arguing that such conflicts can in practice rarely be resolved by recourse to abstract principles of justice. The next section outlines the procedural turn the priority-setting debate has taken and considers the most influential model of procedural justice in health-care rationing, Daniels and Sabin's (2002) 'accountability for reasonableness' (AFR) model (Daniels, 2008). I consider this model in light of three forms of procedural justice Rawls has differentiated: pure, perfect and imperfect procedural justice, and argue that AFR remains indeterminate when it comes to choosing more concrete properties of priority-setting institutions.

My central argument, presented in the next section, is that by choosing concrete institutional properties, we inscribe appointed bodies (in health-care rationing and

elsewhere) with substantial norms. Although the decision-making procedures of appointed bodies must thus be viewed as an instance of imperfect procedural justice, the norms inscribed into them can only derive validity from democratic decisions – which, in modern pluralistic societies, can and should only be viewed as realizing pure procedural justice. In the final section, I therefore outline criteria for democratic design choices and discuss the British National Institute of Health and Clinical Excellence (NICE) as an example. I conclude that as procedural decisions are inevitably also distributive decisions they should be taken democratically, deliberately and in light of information on the distributive consequences of institutional design.

Health and Health Care as Goods with Special Properties

Health is a 'conditional' good, meaning that it is important to the achievement of many other goals in one's life. John Rawls (1999 [1971], p. 62) has characterized health as a 'natural primary good'. The distribution of natural goods is unequal, but to begin with, this distribution is neither just nor unjust: 'What is just or unjust is the way institutions deal with these facts' (Rawls, 1999 [1971], p. 102). Health-care goods – drugs, medical treatments, procedures and devices – can potentially protect and restore health and thus render the distribution of health more equal. However, anything near real equality is out of reach: people are born with differing chances for good health and suffer from consequences of diseases or accidents that cannot be completely reversed. Nonetheless, the conditional properties of health as a good provide strong arguments for the realization of public institutions that provide access to health care regardless of status and ability to pay. All industrialized countries spend a considerable share of public revenues on health care and regulate its provision. In most countries, access to health services is either organized by the state (NHS-type systems, for example, United Kingdom and Sweden) or through mandatory social insurance schemes (for example, Germany and France). Even in the United States, whose present health-care system is typically described as market-driven, the state-funded programs Medicaid and Medicare protect some (although not all) vulnerable groups from the risk of poor health.

Questions of distributive justice arise on two levels: first, societies have to weigh health and health care against other social goods such as education, culture or social security. All public expenses generate opportunity costs elsewhere – money that is spent on

health care is money that cannot be spent on schools, libraries or programs to fight poverty. Questions on the weighting of competing social goods are also questions on the weighting of claims and interests of different social groups. Claims of patients to appropriate or even maximal health care need to be weighed against claims of schoolchildren to a good education and weighed against claims of the poor to fair social inclusion. Given that the question of how to weigh competing social goods is decided in a way that sets limits to the amount of resources available for health care, questions of distributive justice arise on a second level, namely, within the health-care system itself (cf. Calabresi and Bobbit, 1978). It is on these questions that the debate on health-care rationing focuses; this article contributes to this debate.

The definition of health varies both between different actors (such as the WHO, the pharmaceutical industry or public health administrations) and between different strands of bioethical theorizing. The famously broad definition of health as 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity' applied by the WHO may be contrasted with Nussbaum's (2006) capability approach or Daniels's (2008, pp. 36–42) understanding of health as 'normal species functioning'. The more important aspects of the discussion on health-care rationing, however, are the special properties of the goods whose distribution is controversial, that is, the special properties of health-care goods.

Health care is instrumental to the protection of health, which as a good has conditional qualities. However, it does not follow that health-care goods are of conditional character themselves; they remain instrumental. Given that the decision on the weighting of health care against other social goods has been taken in a way that makes limit-setting in the public provision of health care necessary, health-care goods become scarce. With a few exceptions (such as transplantation organs), this scarcity is not insuperable in principle, as the goods in question remain available on the market. Rather, scarcity only concerns the public provision of health goods and services without charge or below market prices [1]. A common categorization of health services is the distinction between preventative, curative and rehabilitative services. Although the under-provision of preventative and rehabilitative services can mean that significant health benefits are foregone, this article will focus on curative services, where scarcity is most painfully noted and distributional conflicts are most evident.

Further central properties of health-care goods are that they are often indivisible and heterogeneous. Although the monetary resources spent on health care are in principle divisible, the single hospital bed, infusion or surgery is not so. Heterogeneity of goods means that the utility derived from a good depends on the recipient and his or her condition (cf. Elster, 1995): an appendectomy only has utility for patients with an inflamed appendix; for all other patients it would constitute substantial harm. Finally, many health-care goods have a decreasing marginal utility at the collective level, but not at the individual level, which is due to the fact that from the patient's perspective, many drugs and particularly diagnostic procedures have only negligible side effects, but always at least a potentially positive effect. A yearly (or even monthly) CT scan, for example, might detect cancers in patients without symptoms in an early and treatable stage, but at a tremendous price. Moreover, in NHS-type systems as well as in most social insurance systems, services are provided without charges or at a very low price, meaning that their actual cost is not transparent to the patient. But even in private, for-profit insurance schemes, consumption of health services can be excessive, meaning that patients consume more goods than they actually need (Aaron and Schwartz, 1990).

Scarcity and excessive consumption make priorities and limits, or simply rationing in the public provision of health care inevitable. By rationing I mean that goods or services that are available on the market are not available in national health services or funded within social insurance schemes. As my interest is primarily in political priority- and limit-setting decisions, I will focus on cases of explicit rationing rather than on bedside rationing that is enforced by tight budgets and carried out by doctors and nurses. For reasons of simplicity, I also focus on decisions to include or exclude a good or service in a public health basket, neglecting the issue of co-payments as well as meanstested allowances for specific services (such as glasses or dental prosthesis).

Rationing, and more generally, the just distribution of health-care goods are rendered difficult by the indivisibility and heterogeneity of these goods. These properties rule out equality in distribution (everyone receiving the same goods), which, from a perspective of substantial justice, might seem the ultimately just solution in the distribution of other goods. They also rule out distribution by means of a lottery, which might, from a perspective of procedural justice, seem to be the ultimately unbiased and therefore fair

allocation procedure. So what principles and criteria are available to guide allocation in complex distributional conflicts like those over the distribution of health-care goods?

Justice in Distributional Conflicts

On the search for a just distribution of scarce resources, normative philosophical theories, such as utilitarianism or variants of egalitarianism, offer possible principles and sometimes even concrete solutions. Among philosophers, healthcare rationing has been a popular example to illustrate the practical implications of different theories of justice. However, the cases considered were typically of hypothetical nature – such as the allocation of a drug that could serve to cure one sick patient or vaccinate 10 healthy ones. But are these hypothetical cases sufficiently similar to empirical ones to derive solutions to practical conflicts? Do theories of justice offer distributive principles that could solve the allocation problems faced in day-to-day practice?

Normative principles offered by theories of justice are typically insufficiently specified to guide allocation: although they can be referred to for the evaluation of distributive decisions, they cannot justify the selection of one among the numerous possible allocations. In this case, more concrete distributive principles seem to be required. Authors such as Michael Walzer (1984) and David Miller (1999) assign different distributive principles to different societal spheres of interaction: although a principle of desert may legitimately hold on the job market, the distribution of civil and democratic rights must be led by a principle of equality. For the health-care sector, distribution according to a principle of need seems most acceptable. But even if we could achieve a consensus to allow a single principle to guide allocation, questions regarding the explication and contextualization of the concept of need remain open. Do we understand need simply as urgency and accordingly apply a 'rule of rescue' (McKie and Richardson, 2003)? Or do we recognize different forms of need: the need to be rescued from potentially fatal diseases and injuries, the need to be protected against diseases (through vaccinations), the need to receive psychological help in personal crises, or even the need for fertility treatments? And if we do recognize such different forms of need, how do we weigh them against one another? Should we, under conditions of scarce resources, prefer to fund a cancer therapy that prolongs the life of a terminally ill patient for a few weeks, or artificial fertilization for a couple with an eager wish for children?

It thus becomes doubtful as to how far abstract normative theories and the distributive principles they suggest can instruct practical political decisions. A theory of justice that claims to define consensual distributive principles, which would make the political decisions and the democratic management of conflicts unnecessary, seems both naive and presumptuous. And in fact most philosophers would neither deny the challenges arising from the contextualization of abstract principles nor dispute that the success of suggested solutions in distributive conflicts eventually depends on their acceptance within a given society.

In political practice, a number of different interest groups as well as numerous differing conceptions of justice compete for acceptance where the fair distribution of health services is concerned. Distributive decisions require the weighting and aggregation of these interests and values, which can hardly be attributed to specific social groups. By contrast, the interests of citizens – as taxpayers, patients or relatives of patients – are in most cases as complex as their normative values and attitudes. Few people would be willing to attribute priority to one principle over all others in all possible conflicts. Rather, most regard different principles and criteria as legitimate in different spheres and situations. Although the allocation of health care may at first sight seem comparatively clear-cut, principles like need, efficiency or equality will conflict in theory as much as in practice and will require weighting and contextualization.

The difficulties that normative theories and principles encounter where they are to be put into practice can be illustrated with the empirical experience in priority-setting gained in the 1980s and 1990s. In this period, several countries undertook the attempt to define consensual principles for the allocation of scarce resources in the health-care sector, typically by way of respective expert commissions and public hearings. In 1985, Norway set up the first Lønning Commission to define priorities (Norheim, 2003). New Zealand initiated a comprehensive participatory process for the same purpose (Manning, 2005), and discussions in The Netherlands were shaped by the Dunning Commission's report published in 1992 (Berg and van der Grinten, 2003). Only the US state of Oregon, however, attempted an explicit ranking of so-called conditiontreatment-pairs (Jacobs et al., 1999).

These commissions, which I label 'principles commissions', were led by the hope that a broad societal consensus on basic principles of just distribution could be achieved. This would free 'tragic choices' (Calabresi and Bobbit, 1978) in single cases from their

contingency and painfulness. Potentially explosive decisions would no longer be necessary once a consensus on principles from which to derive solutions has been found: information on needs and treatments would simply need to be entered into a kind of 'distribution automat' (in practice an expert commission or even a computer program), which would calculate a priority list according to consensually defined principles.

Quite contrary to these expectations, the results that these various commissions produced did not result (except in the Oregon case) in a more explicit definition of priorities or justified cut-backs in service lists. In most of the countries concerned, health-care expenses, in particular for high-tech medicines, continue to rise. In the year 2000, Søren Holm (2000) announced a procedural turn in priority-setting with a paper titled 'Goodbye to simple solutions'. Holm's diagnosis is based on the experiences, particularly of the Nordic countries, which were the first to politicize priority-setting through the setting up of principles commissions. It has led to the insight that any singular decision on whether to fund or not to fund a treatment for a specific disease, and perhaps even any decision to fund treatment of a specific patient's disease, requires a new assessment and weighting of claims, interests and values. Accordingly, the focus of the debate had to shift from abstract principles of justice to procedures and also to the bodies taking decisions on the financing and prioritizing of medical services. After the procedural turn, considerations of justice are no longer addressed at the distributive results themselves but rather at the way in which they are produced, thus applying criteria of procedural rather than substantial justice.

Procedural Justice in Health-Care Rationing

How can procedural justice in decisions on the allocation of health services be conceptualized? As argued above, the idea that an objectively fair distribution can be achieved by deriving just decisions from abstract higher-ranking principles appears to have failed. In recent years, models of deliberative decision making have become highly popular both in theory and in practice and can be convincingly justified (Dworkin, 2000; Daniels, 2008; Fleck, 2009). Deliberation is a widely used concept in political science, and theories of deliberative democracy dominate contemporary democratic theory [2]. Although a number of different specifications can be found in the literature, most authors would probably embrace a basic definition of deliberation as a mode of political interaction that is based on

a reciprocal exchange of arguments and aimed at both achieving a superior information base for decisions and solving, or at least managing, conflicts of value and interest.

What I want to show by reference to the most famous model of deliberative decision making in the allocation of health care – the model AFR developed by Daniels and Sabin (1997) – is that the relationship between procedural and substantial justice remains underspecified in this enterprise. This is because the understanding of procedural justice applied in Daniels and Sabin's model, as well as in many other models of deliberative decision making, oscillates between what Rawls has described as 'pure' and 'imperfect' procedural justice.

Rawls (1999 [1971], pp. 73–78) has drawn the following, extremely helpful distinction between types of procedural justice. Perfect procedural justice, according to Rawls, obtains where both an independent standard of justice exists, and where the decision-making procedure guarantees that its results are, according to this standard, just. Procedures in real-life politics are unlikely to qualify as examples of perfect procedural justice. However, the setting up of principles commissions described above seems to have been driven by conceptions of perfect procedural justice: if only a consensus on principles of just distribution could be achieved, perfect procedural justice could be realized by correctly deducing decisions from the agreed-upon, just principles. As noted before, this hope has failed.

In contradistinction to perfect procedural justice, Rawls distinguishes imperfect procedural justice, where a procedure can promote, but not guarantee decisions that comply with the agreed-upon standard of justice. The idea of imperfect procedural justice is illustrated with the example of a criminal trial in court: the defendant's guilt constitutes the independent standard, but the trial, however fair, cannot guarantee never to convict an innocent or to acquit a guilty defendant.

Much depends on whether political decisions are understood to be analogous to judicial ones, that is, whether political decisions are ultimately seen as instrumental to the realization of pre-defined ideals of justice. Rawls (1995, p. 170), as a theorist of justice, eventually views democratic politics as an instance of imperfect procedural justice (Lafont, 2003, p. 164), whereas Habermas, like other theorists of democracy, insists on a different kind of procedural justice, which Rawls has characterized as pure procedural justice.

In pure procedural justice, the output of a procedure derives its justice (or legitimacy) solely from the procedure itself. The prime example of pure procedural justice is the lottery; another one, in the eyes of many, is democratic majority voting. Despite the fact that different voting systems have different outcome effects and thus lead to different kinds of voter inequalities, majority decisions can be viewed as an instance of pure procedural justice simply because the addressees of decisions regard the procedure as a just way of decision making (presumably because they assume that it gives each of them more or less equal chances to determine the collective decision).

In the search for fair procedures in the distribution of health services, pure procedural justice is at stake where democratic legitimacy of decisions is concerned. Imperfect procedural justice, by contrast, is at stake where the assessment of evidence and arguments in a process resembling a fair trial is concerned. The AFR model developed by Daniels and Sabin (2002; Daniels, 2008) is the most influential approach to procedurally just decision making in the distribution of health services, and the authors have advised governments in several countries on the design of respective decision-making procedures and institutions. I argue that, although presented as a case of pure procedural justice, their model blinds out the matter of democratic legitimacy [3].

The AFR model consists of four conditions that a procedure needs to fulfill in order to qualify as just (Daniels, 2008, p. 118ff.). The central one among them is the relevance condition, requiring decisions to be based on reasons that fairminded people would accept as relevant and that all relevant reasons are considered in the decision-making process. The other three conditions, requiring publicity of reasons and decisions, the possibility of revision and appeals, and a regulation that ensures that these conditions are met, eventually seem to be instrumental to ensuring that relevant reasons are discovered and brought to bear on decisions. But how do we identify relevant reasons?

Rid (2009, p. 13) has argued that Daniels (2008, p. 109), who regards AFR as a case of pure procedural justice, uses the relevance condition to introduce a substantial criterion through the back door: reasons can be more or less relevant only with regard to an implicitly entailed criterion. One could of course define relevance purely empirically and argue that relevance depends on what a societal majority regards as relevant. Daniels, however, is rather skeptical with regard to the often volatile judgments of random majorities (see Daniels, 2008, pp. 111–113). Instead he defines relevance by reference to the opinions of

fair-minded people – but who is fair-minded, and by what criteria do these people judge relevance?

The central reference point in Daniels' theory of just health care is the Rawlsian principle of fair equality of opportunity. The extension of Rawls's theory to the subject of health care, which Rawls explicitly decided not to address, is one of Daniels's central contributions to political philosophy [4]. Understanding health as 'normal species functioning' and as a requirement for the creation, use and protection of opportunities, Daniels (2008, p. 23) argues that Rawls's principles of justice 'capture the key social determinants of health' and includes health care among the social institutions that protect fair equality of opportunity. Moreover, the moral importance of health care that derives from its being essential to opportunities has consequences for the set-up and regulation of the system that provides it: 'Because meeting health-care needs has an important effect on the distribution of opportunity, the health-care institutions should be regulated by a fair equality of opportunity principle' (Daniels, 2008, p. 57).

Despite this avowal of fair equality of opportunity as a regulatory principle in the health-care sector, Daniels (2008, p. 108) rejects its application where the coverage and distribution of specific services is concerned, arguing that it is not fine-grained enough to resolve real-life rationing problems. Daniels (2008, p. 108) thus takes the step from substantial to procedural justice by arguing that abstract principles (like fair equality of opportunity) 'cannot substitute for a fair process for resolving disputes in the real time of decision makers'. However, given that the AFR model's relevance condition does not specify with regard to what principles or criteria reasons have to be relevant, there remains room for the suspicion that the principle of fair equality of opportunity eventually constitutes a hidden criterion of relevance in Daniels's account (as argued by Rid, 2009). This may be indicated by the wording of the revision and appeals condition: decisions should not only be revisable when procedural errors can be proved (as would be the case in instances of pure procedural justice, such as a lottery), but also 'in the light of new evidence or arguments' (Daniels, 2008, p. 119) – in other words, in the light of new reasons that have turned out to be relevant with regard to an agreed-upon criterion.

As long as its relevance condition lacks an explicit criterion of relevance, though, the AFR model itself remains underspecified where the design of concrete rationing institutions is concerned. Although they are reasonable and well justified, the AFR conditions are

insufficient criteria for the set-up of a procedure that ensures pure procedural justice. In practice, numerous institutional solutions are conceivable that fulfill these criteria. Are they equally good, are they likely to lead to the same results – and how are we to choose between them? This is the central question Daniels and Sabin leave unanswered. Thus, as much as the principle of fair equality of opportunity is too unspecified to guide concrete distributive decisions, the AFR conditions are too unspecific to derive a decision for a concrete institutional solution. For Daniels, procedures that fulfill the AFR conditions can apparently be regarded as equally fair and be expected to produce decisions equally worthy of acceptance.

As I will argue in the following section, however, design choices inscribe substantial norms into institutions and they have effects on outcomes, which is why ensuring procedural justice both within appointed bodies and in their design is the challenge to be met.

Procedural Justice and Appointed Bodies

In nearly all developed democracies, decisions on the content of publicly financed 'health baskets', that is, decisions on which services are publicly financed and which are not, are delegated to specialized committees (cf. Landwehr and Bo¨ hm, 2011). In some cases, these committees are based within the responsible ministries or the public health administration. In these cases, committees remain hardly visible to the public, while at the same time the respective minister, and eventually the government, remains to some degree accountable for decisions. In an increasing number of countries, however, decisions are delegated to more or less independent appointed bodies, ranging from bureaucratic–expertocratic ones (for example, Pharmac in New Zealand) to negotiation rounds between payers and providers (for example, the Federal Joint Committee in Germany) to highly pluralistic institutions (for example, NICE in the United Kingdom). Looking at the variety of different institutional design solutions, the question of whether and how substantial and procedural justice is realized in them arises naturally. Assuming that the principle of fair equality of opportunity is a well-justified and widely accepted one where the distribution of scarce goods is concerned, why can we not simply design institutions to produce decisions in keeping with it?

The answer is that designing political institutions to produce decisions that accord with specific conceptions of justice is problematic in modern, pluralistic societies in which decisions can derive legitimacy only from impartial majority decisions. For modern pluralistic

societies there is no justifiable independent standard of a 'correct' decision to which majority voting can or should be instrumental. One may hope for decisions in keeping with one's own particular preferred principles of justice – but in a democracy, the same hope must be granted to those who hold different views on justice and who do not accept the same principles as a standard for the fair distribution of goods. If we regard majority rule as realizing pure rather than imperfect (or even perfect) procedural justice, any principle of just distribution applied in decision making can thus claim validity only on the grounds of the pure procedural justice.

How are we to institutionalize procedural justice in the appraisal of medical services then? The problem is that in practice any decision-making structure seems to be to some degree creative, meaning that it has effects on resulting decisions. Even if we consider majoritarian decision making as such, procedural choices are necessary and likely to have effects on outcomes. Even in a directly democratic decision, someone has to decide which options are put to the vote and in what order, or what majorities are required to accept an option. As soon as we introduce representation, it gets even more complicated. Whether to use a majority voting system or one with proportional representation, how to define constituencies and their boundaries – these decisions have effects on outcomes and inevitably benefit some groups and interests more than others. Looking at non-majoritarian institutions like the appointed bodies involved in rationing decisions, it becomes clear that an outcome-neutral procedure is probably impossible to realize in practice. Any procedural decision will have effects on the resulting distribution and is thus in part a distributive decision in itself (see Scharpf, 1989).

My point here is not that decision-making procedures have to be outcomeneutral in order to ensure procedural justice. On the contrary, it seems that the procedures and institutions used to decide which services and drugs should be publicly financed need (and should) not be outcome-neutral in the sense that any service or drug assessed has the same probability of being approved. One might reasonably hope for highly effective, efficient and essential services to be more likely to be covered than ineffective treatments for trivial diseases. At the same time, most people would hope a drug specifically aimed at women to have the same chance of being approved, all other things being equal, as one specifically aimed at men. The problem lies in establishing the outcome effects of different procedures, in discriminating desirable biases (against ineffective drugs) from undesirable ones (against,

for example, women) and in choosing from a set of non-neutral, and in this sense biased, procedures.

If, from the set of conceivable (and outcome-biased) procedures, we choose one that favors effective over ineffective drugs, we should be clear about the fact that the procedure is inscribed with a norm of clinical effectiveness, and we should be equally clear that the validity of this norm can only be derived from a democratic decision. But how can a procedure that is deliberately inscribed with substantial norms (such as a norm of clinical effectiveness) be an instance of pure procedural justice? My argument is that through the inscription with substantial norms, the decision-making procedure becomes an instance of imperfect procedural justice: its decisions could be judged with regard to the chosen norms (for example, clinical effectiveness) and challenged with regard to unwanted (not chosen) outcome biases. The choice of the norms to be inscribed into institutions, however, can only be based on pure procedural justice as long as we lack a consensus on a superordinate principle like the principle of fair equality of opportunity – and such a consensus, as argued before, cannot be expected in modern pluralistic societies.

This argument may seem to lead into a regress: if political institutions are inevitably inscribed with norms, the majoritarian democratic procedures used to take decisions on the institutional design of appointed bodies will equally be inscribed with norms, which need to be chosen at a higher level, and procedures used at this higher level will be inscribed with norms that need to be chosen at a level above it and so on. In social contract theory, this regress is stopped by the less realistic assumption of consensus at the constitutional level. To some degree I would nonetheless accede to this assumption, arguing that the challenge of designing bodies appointed with specific tasks (such as priority-setting in health care) is categorically different from the challenge of constructing majoritarian democratic institutions. In the first case, decisions are effectively not only procedural, but substantial ones, concerning the values to be inscribed into procedures and institutions. In the latter case, at the constitutional political level, the norms at stake are mainly procedural ones, for which broad public support (if not consensus) is a more plausible assumption than for substantial norms.

To sum up, the institutional design of appointed bodies is a matter of choosing substantial norms to inscribe into procedures and institutions. The norms to be inscribed can gain validity only from democratic majority decisions, which need to be seen as a matter of

pure procedural justice. Decision-making procedures in appointed bodies then become an institutionalization of imperfect procedural justice, in which the selected norms function as an independent standard. Given that consensus on a single norm to guide decisions is not realistic (or desirable), several norms will conflict in application and the decisionmaking process will involve the weighting and contextualization of these norms. Procedural fairness is thus an important aspect here, too. Moreover, as designing appointed bodies is a matter of deciding how to decide, it follows that manipulation, exclusion and unjustified biases will have more far-reaching consequences than they would have in ordinary political decisions (on specific regulations rather than decision-making procedures). In the following section, I therefore suggest an approach to ensuring democratic legitimacy, challengeability and deliberative decision making in institutional design choices.

Criteria for Democratic Institutional Design Choices

I assume, as argued above, that substantial norms will necessarily be inscribed into institutions and will function as criteria of relevance in decision-making processes. Directing the focus from procedural justice to the justice and legitimacy of institutional design choices, what might a democratically legitimate institutional design process for rationing institutions look like?

To begin with, we may ask how deliberative, non-majoritarian procedures as advocated by Daniels and Sabin and currently in place around the world can in principle meet standards of democratic legitimacy, or whether majoritarian procedures might not be superior. After all, majoritarian procedures, even if they cannot be entirely outcome-neutral either, seem to have fewer outcome biases than deliberative ones, and they are widely accepted as realizing procedural fairness. Nonetheless, there are reasons to insist on the comparative advantage of deliberative designs over majoritarian ones where appointed bodies are concerned. First, the exchange and assessment of evidence and arguments can potentially serve to correct misunderstandings and turn superficial, myopic and self-centered judgments into more justified, farsighted and other-regarding ones. Second, the norms inscribed into procedural rules can be addressed, and unwanted biases can at least partially be corrected within the decision-making process itself. Finally, not only the complexity, but also the sheer number of decisions required in health-care priority-setting renders delegation to deliberative institutions more feasible than majority decisions. At the

same time, non-majoritarian bodies can never involve all potential stakeholders, and deliberative decision making may undermine the equality of participants, as the more articulate members of a forum will find it easier to construct successful arguments for their positions. This is why the principle of 'one person one vote' must retain its importance in a democracy, and why the delegation of decision-making powers to deliberative bodies needs to publicly justified.

If we opt for the delegation of rationing decisions to deliberative bodies, a general avowal of deliberation as a mode of interaction and decision making leaves room for many concrete options with differing distributive effects – a normative framework like AFR is, as noted above, too unspecified to guide institutional design here. In the choice of any one of these possible options, majoritarian legitimation and democratic accountability should be brought to bear. I therefore suggest four criteria for democratic institutional design choices in the set-up of appointed bodies – particularly for the case of health-care rationing, but eventually also for other cases in which informational requirements and distributive conflicts are entangled in similarly complex ways.

Democratic legitimacy and accountability

At the level of procedural and institutional design choices, decisions have far reaching consequences, as this is where the parameters that determine decisions on the coverage of single services are established. Ordinary political decisions are one-time decisions against some interests and in favor of others. Losing in one case may in the long run be balanced out by winning in another. In institutional design, by contrast, decisions against specific groups and interests are more significant, as they tend to reproduce the disadvantage in any decisions that follow on lower levels.

In institutional design choice, it is therefore particularly important to ensure legitimacy through essentially egalitarian democratic procedures. In practice, this means that it must be made clear to the public that bodies to which decisions are delegated are set up and sanctioned by governments and that their legitimacy and continuity thus eventually depends on democratic majorities. A minimal requirement for accountability is that rationing institutions are publicly known and their decisions transparent. Moreover, accountability might be improved by building a requirement for ministerial approval into decision-making processes. Finally, it seems easier to ensure accountability if a new body is

established to deal with the rationing task than when an existing institution is charged with new responsibilities. In the best case, public scrutiny should prevent governments from both shifting blame to appointed bodies and engaging in strategic institutional design that promotes partisan interests.

Challengeability and revisability of institutional solutions

Appointed bodies to which decision making is delegated must not only be entrusted with their tasks by democratic majorities, they must also be democratically challengeable. Daniels and Sabin stress the importance of challengeability of decisions with their 'revision and appeals' condition. However, the possibility of challenges must not be restricted to single coverage decisions, but must apply to meta-level decisions as well. If meta-level decisions are revealed to have been driven by partial interests or subjected to the undue influence of powerful groups, the case for appeal and revision is clear. In other cases, unwanted biases may only become apparent in practice. For example, relevant stakeholders may be found not to have been included in the decision-making process. If institutional design produces persistent losers and leads to perpetual disadvantages for specific groups, it must be possible for these groups to challenge it.

One may doubt, of course, whether subjecting institutional design choices to majoritarian procedures is likely to protect minorities. Nonetheless, I am cautiously optimistic in this regard where rationing decisions are concerned. If a specific patient group, say cancer patients, is systematically disadvantaged in a given decision-making procedure, this disadvantage is a potential reason not only for the affected patient group, but for anyone else as well to challenge the procedure. After all, we find ourselves behind a kind of 'veil of ignorance' with regard to our future health, not knowing whether we might be cancer patients ourselves sooner or later. Although the interests of others may be interpreted as our own for widespread diseases that we are likely to suffer from ourselves, compassion is a strong motive to object discrimination even for rarer or congenital conditions [5]. Given this, the set-up of bodies charged with distributive decisions seems not only a possible, but also a desirable topic for public debates and even election campaigns.

Coherence with societal values

Assuming that decision-making procedures of appointed bodies are always inscribed with substantial values, institutional design choices determine criteria of relevance for priority-

setting decisions. They determine which reasons will count as relevant in the weighting of competing principles of justice and in the assessment of available evidence. The choice of a specific institutional design, including, for example, the decision which stakeholders to involve, is thus also a decision about what reasons will count in decision making, and can in this sense be regarded as a specification of Daniels and Sabin's relevance condition.

How can the inscription of substantial norms into decision-making procedures meet a benchmark to be regarded as sufficiently democratic? Eventually, values and criteria of relevance and the procedures in which they are applied must be coherent with the conceptions of justice held by those addressed by decisions. That is, the specific empirical community in which health services are o be allocated has to determine the reasons that are relevant for allocation decisions. These reasons will be different ones in different cultural, political and historical contexts. The broad societal values to which these reasons relate are too unspecific to guide concrete decisions on single services, and they will conflict in application. However, societal values may be thought of as defining a space in which decisions are to be sought by just procedures [6] The delimitations of this space of potentially acceptable decisions constitute the most important inscriptions into the decision-making procedure.

Admittedly, it is difficult to determine which values are considered important in a given society and how they are weighed against one another. Although opinion polls such as the European Social Survey, for instance, can tell us something about the relative weight of different values in different societies, survey research cannot replace democratic approval. The selection and weighting of values in parliament or in a referendum, though, do not seem to be viable options either. It will therefore be notoriously difficult to determine whether the values inscribed into a specific institution are coherent with those of the society for which it takes decisions.

It is easier, however, to find indicators for incoherences between societal values and institutions. If an appointed body's decisions are repeatedly challenged by the public and fail to be accepted and implemented, this may indicate not a failure of the body itself but deficiencies in its institutional design. For example, if a panel of health economists is asked to suggest priorities, it is hardly surprising if decisions are dominated by efficiency considerations. If these decisions fail to win public approval, it is not the health economists who are to blame, but the institutional design that is incoherent with societal values. An

appeal against this design might result in a revision that involves different experts (philosophers, lawyers, social scientists) and stakeholders (doctors, patients).

Eventually, a series of appeals and incremental revisions may be required to achieve and maintain coherence between societal values and institutional inscriptions. Moreover, societal values are not stable but subject to perpetual change, and they should not only drive institutional design but are also influenced by institutional design themselves. Thus, the institutional design process cannot so much be aimed at achieving a once and for all solution, but rather at finding an equilibrium between values and institutions.

Public meta-deliberation [7]

Authors such as Daniels (2008) and Fleck (2009) have made strong arguments for deliberative institutions in the allocation of health care, and I have argued above that in appointed, non-majoritarian bodies deliberation has considerable advantages. However, not only the decision-making procedure used to take rationing decisions should be deliberative, but the meta-level process in which the procedure is designed should be so as well. If coherence between societal values and the criteria of relevance inscribed into procedures is at stake, these values and criteria must be deliberated upon in broad public debates.

What does this imply for a practical benchmark of sufficiently democratic institutional design? I regard deliberation first and foremost as a mode of interaction that is discursive and aimed at coordination (Landwehr, 2010). Interaction is discursive if the reasons named by actors are general and transferable to other actors and where actors have equal opportunities to contribute to the interaction. What is more important, however, is that deliberation is essentially aimed at decisions on what the collective is to do, rather than on what is 'objectively' fair or correct. Although the discursive quality of deliberation may be assumed to increase the quality of decisions, this coordinative quality implies that participants engage in the coordination of preferences and intentions rather than in the politically pointless pursuit of ultimate truths.

Deliberation may be viewed as democratic in so far as it is inclusive, that is, in so far as it involves all relevant stakeholders. Where the allocation of health services is concerned, any citizen is a potential stakeholder. Democratic deliberation in large-scale democracies thus cannot be institutionalized in a single forum, but must be conceived of as a process involving numerous different forums as well as the media [8]. For the case of health-care

rationing, this kind of discourse would require institutions and their design to be transparent to the public and their decisions to be explicit. Broad and inclusive public deliberation could then address not only principles to guide allocation, but also the question of how acceptable principles could be brought to bear on decisions through institutional design.

Although the principles commissions discussed above have failed to determine consensual principles of justice from which just distributive decisions could simply be derived, they are likely to have contributed to public deliberation on health-care rationing in the respective countries. What they did was to politicize the rationing topic, showing that it is a matter for democratic rather than technocratic decision making. Moreover, and precisely in their failure to achieve consensus, they have made it clear that the determination of criteria for just allocation cannot be delegated to experts, but requires an ongoing and democratic dialogue.

The National Institute of Health and Clinical Excellence (United Kingdom)

To illustrate the potential use of these benchmarks for democratic institutional design, consider the British NICE, which constitutes a seminal institution in the field of health-care priority-setting. NICE was set up in 1999 by Tony Blair's Labour government that had come into office 2 years earlier. The establishment of NICE was accompanied by considerable media attention, and today, NICE and its tasks are widely known to the British public. In addition, the government made it clear that NICE, although statutorily independent, would report to the ministry of health, thus acting in the 'shadow of hierarchy' of majoritarian institutions. In the way NICE was set up, the criterion of democratic legitimacy and accountability thus seems to have been fulfilled.

In the following 13 years, the institutional set-up of NICE was reformed several times. This reform process may partly be viewed as a process of institutional learning and adaptation that most institutions undergo. However, revisions also seem to constitute a response to appeals for greater transparency and broader stakeholder participation. For example, meetings of technology appraisal committees (where services are evaluated) were rendered public and advisory citizen councils were set up to improve democratic participation. These reforms indicate that the institutional set-up of NICE is indeed challengeable and revisable, although there may be institutional parameters that are more immune to challenges.

Regarding the coherence between societal values and the allocation criteria applied in NICE decision-making processes, the case is somewhat more difficult. NICE was explicitly set up to assess the cost effectiveness of health services and uses an informal threshold of d30 000 per Quality Adjusted Life Year, meaning that services that are more expensive and less effective are unlikely to be covered (see Appleby et al., 2009). Although generally the need to apply efficiency considerations in the provision of health care appears to be widely consensual in British society, the threshold has been repeatedly challenged. Following a series of protests against single decisions, it was suspended for end-of-life treatments in 2008 – a measure suggested by the citizens' council [9]. This revision of the decision-making process may be viewed as a case in which institutionalized criteria of just allocation had to be brought into a new equilibrium with societal values.

Finally, NICE decision-making procedures and decisions have been subject to comparatively broad public debates. Decisions are explicit and reports easily accessible. Although there has not been anything like a principles commission at the national level in the United Kingdom, numerous citizen forums at the communal level have engaged citizens in deliberation on health-care provision and priorities. Clearly, health policy and priority-setting compete with other issues on the public agenda so that the degree to which the public deliberation benchmark is met may alternate. On the whole, however, the establishment and design of NICE seem to meet standards of sufficiently democratic institutional design – although there are certainly reasons for criticism, it may be described as 'democratic enough'.

Conclusions

The 'procedural turn' in priority-setting has proved that solutions to the empirical challenges in the allocation of scarce health services cannot be derived from abstract principles of justice. Justice in the allocation of health care has increasingly come to be viewed in terms of procedural rather than substantial justice, and rightly so. However, the appointed bodies charged with rationing decisions cannot be outcome-neutral empirically, but will always be inscribed with substantial norms. The norms to be inscribed into procedures and institutions, I have argued, can only derive legitimacy from democratic majority decisions. This is why the institutional design of appointed bodies in health-care rationing and elsewhere must

become subject to democratic debates and decision making – and I have outlined criteria for institutional design choices to qualify as sufficiently democratic.

If we aim to ensure pure procedural justice in health-care rationing, the substantial norms and relevance criteria inscribed into institutions need to be made visible and challengeable, and the institutional design of appointed bodies itself must become subject to public scrutiny and democratic decision making. Democratic control and deliberation require knowledge of the way in which the norms are inscribed into procedures and on the effects institutional design choices have on distribution. Evidence on the correlation between institutional design and distributive decisions thus constitutes an important basis for the future design and revision of priority-setting and rationing institutions: if a society seeks to inscribe substantial norms into appointed institutions, it needs to know whether the selected institutional design does indeed bring these to bear or whether it leads to unwanted and unjustified biases.

Acknowledgements

The author thanks three anonymous reviewers and the editors for helpful comments on earlier versions of this article, as well as the VolkswagenStiftung for funding the research that this article is based on through a Schumpeter Fellowship.

Notes

[1] Whether health-care goods that are not publicly available should remain tradeable on the market is a controversial question. Some philosophers (for example, Gutmann, 1981) have argued that the private purchase of rationed health services should be forbidden to prevent inequalities. The problem with such 'hard rationing' solutions is that it is often difficult to distinguish health goods from ordinary consumption goods: how should we classify massages or cosmetic surgery?

[2] For accounts of deliberative democracy, see, for example, Gutman and Thompson (1996) or Dryzek (2000), as well as collections edited by Bohman and Rehg (1997) or Gastil and Levine (2005).

[3] The model was originally used to evaluate procedures in health insurance companies, meaning that the decisions studied were not political ones, and democratic legitimacy could

not be a central issue. In his latest book, however, Daniels (2008, pp. 111–113) explicitly rejects majoritarian decisions on the distribution of health care.

[4] Rawls simplifies his assumptions by postulating normal functioning, thus factoring out the issue of inequalities resulting from differences in health status. Daniels (1985) has extended Rawls's theory to address issues of health and health care in Just Health Care, but has revised some of his earlier arguments in Just Health (Daniels, 2008, see especially, pp. 46–63).

[5] Although much of the argument made here can be transferred to other policy areas, I would be less optimistic with regard to the protection of minority interests in meta-level decisions on the set-up of appointed bodies in, for example, education policy. Much depends on the degree to which we can conceive of ourselves as placed behind a veil of ignorance and on our capacity for compassion with, and responsibility for, negatively affected groups. I believe that both differ for different policy areas.

[6] A somewhat similar argument is made by Rid (2009), who views AFR as a case of 'constrained pure procedural justice'.

[7] In a different context, Dennis Thompson has argued for democratic deliberation on the institutional design of political systems at large, using the term 'meta-deliberation', which I adopt here (see Thompson, 2008, p. 515).

[8] This kind of two-track model of deliberative democracy, in which public discourses are not institutionalized but nonetheless exert pressure on political institutions, is advocated by Jürgen Habermas (1996) and James Bohman (1996).

[9] See www.nice.org.uk/newsroom/features/CitizensCouncilReport.jsp.

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