Prioritization in Medicine

An International Dialogue

Eckhard Nagel
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Editors

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ISBN 978-3-319-21111-4 ISBN 978-3-319-21112-1 (eBook)
DOI 10.1007/978-3-319-21112-1

Library of Congress Control Number: 2015952827

Springer Cham Heidelberg New York Dordrecht London

Printed on acid-free paper

Springer International Publishing AG Switzerland is part of Springer Science+Business Media (www.springer.com)

Preface

This contributed volume goes back to the interdisciplinary research group FOR 655 “Setting Priorities in Medicine: A Theoretical and Empirical Analysis within the Context of the German Statutory Health Insurance.” Two volumes associated with this research group have been published in German language earlier. Edited by Wohlgemuth/Freitag (2009), the first volume focused on the presentation of objectives and methods of the research group’s subprojects. The second volume, edited by Schmitz-Luhn/Bohmeier (2013), discussed particularly relevant and controversially assessed prioritization criteria. This volume addresses normative dimensions of methodological and theoretical approaches, international experiences concerning the normative framework and the process of priority setting as well as the legal basis behind priorities. It also examines specific criteria for prioritization and discusses economic evaluation.

The contributing authors are in parts members of FOR 655 and other scientists from various academic disciplines and different parts of the world. Some of them came together at an international conference in Bayreuth, Germany, in November 2013 were the idea for this book originated. Editors invited further colleagues to contribute, aiming to encourage a comprehensive discussion about different approaches and methods within this volume and beyond.

Prioritization is necessary and inevitable – not only for reasons of resource scarcity, which might become worse in the next few years. But especially in view of an optimization of the supply structures, prioritization is an essential issue that will contribute to the capability and stability of healthcare systems. Therefore, our volume may give useful impulses to face challenges of appropriate prioritization.

We acknowledge the excellent cooperation and fruitful exchange with contributing authors who made this book possible. We would also like to thank members of FOR 655 who encouraged us to realize this book project. Special acknowledgment is made to the German Research Foundation (DFG) which financed the work of FOR 655 as the first large-scale project on prioritization in healthcare between 2007 and 2015.

Finally, we are especially grateful to Valentin Schätzlein for his editorial assistance, expert consulting, and for managing all issues along the way to this volume.

Bayreuth, Germany
October 2015

Eckhard Nagel
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Introduction to an International Dialogue on Prioritization in Medicine

Michael Lauerer, Valentin Schätzlein, and Eckhard Nagel

Molière did not have prioritization in mind when he expressed his focal thoughts about responsibility: “It is not only for what we do that we are held responsible, but also for what we do not do.” However, being aware that health is one of the most essential goods and that resources in health care systems are limited clearly shows us that Molière’s aphorism is of major importance for allocation decisions in health care. This applies to the decision whether or not to set priorities explicitly as well as to the process and consequences of priority setting.

Prioritization in medicine can contribute to face the urgent challenges that arise from scarcity in health care worldwide. The present volume offers an international dialogue on prioritization in medicine initiated by the German research group FOR 655.[1] May it be helpful to meet the responsibility for what we do and for what we do not do.

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[1] FOR 655 “Setting Priorities in Medicine” was the first research project financed by the German Research Foundation (DFG) concerned with prioritization in medicine (2007–2015). Nationwide 14 universities and research institutions participated in 10 working groups: Theoretical projects focused on legal, philosophical, and economic aspects, frameworks, and implications relating to the process of setting priorities in the statutory health insurance. Empirical projects analyzed stakeholder preferences concerning prioritization in medicine. (For more details, see http://www.priorisierung-in-der-medizin.de)

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_1

1 Prioritization in Medicine

Topics such as "Priority Setting in Medicine" and "Rationing in Health Care" are widely used in the discussion about allocating scarce resources. Thereby, priority setting and rationing are sometimes used interchangeably. But they can at least indicate different stages in the process of resource allocation (Williams et al. 2012, p. 6). While rationing regularly refers to actual withholding of health services, priority setting describes a systematic approach to figure out what is more and what is less important in health care. It leads to a ranking order and prepares decisions (Meyer and Raspe 2012, p. 73). Prioritizing can be understood as a prerequisite of rationing (Raspe 2001, p. 32).

Priority setting does not necessarily have to refer to scarce resources. It can also be used for quality assurance, for example (Meyer and Raspe 2012, p. 73). But whether or not explicit priority setting in medicine is desirable or even inevitable has been discussed particularly in the light of scarce resources.

Basically, limited resources lead to a competition between publicly funded health care and other sectors, as well as among different health needs and claims within health care (see chapter "Accountability for Reasonableness and Priority Setting in Health"). Demand or claims on resources always exceed available resources and therefore the meaningfulness of priorities appears regardless of whether resources are available in very large or very small quantities (Mitton and Donaldson 2004, p. 4). It appears regardless of whether available resources increase, decrease, or remain constant (Williams et al. 2012, p. 6). Nevertheless, setting priorities seems to be the more important, the scarcer resources are. Unanimously a growing demand, particularly in consequence of demographic and epidemiological transition as well as medical progressions, is held responsible for an aggravation of scarcity. Accordingly, allocation decisions are gaining in importance.

Certainly explicit priority setting is not the only option responding to limited resources in health care. But each alternative (such as increasing efficiency or the overall amount spent for health care, rationing by delay, rationing implicitly) goes along with problems in principle, respectively, practice, and is not sufficiently narrowing the gap that occurs between demand and supply (Williams et al. 2012, p. 8–12). In particular there is a wide consensus that an explicit approach for framing health care is preferable over implicit rationing when tight budgets force clinicians to make allocation decisions in their day-to-day workload. If doctors must offer inferior medical interventions without society taking responsibility for this circumstance and without taking care that allocation criteria are established and accepted, this overtaxes clinicians, possibly leads to unfair distribution patterns and jeopardizes the physician-patient relationship (German Ethics Council 2011, p. 30). Explicit priorities are considered to avoid these negative consequences of implicit rationing as it happens in clinical practice.

Explicit priority setting helps to allocate scare resources fairly and transparently. Since health care systems around the globe are faced with challenges along with setting priorities, it is obviously reasonable to discuss prioritization in an international dialogue.

2 An International Dialogue

Across nations setting priorities is an important and essential part of the debate on managing resource scarcity in health care. Thereby, countries diverge in regard to their experiences with discussing and implementing systematic prioritization. While some European countries already have a long history of priority setting (e.g., Norway), the discussion is still in its infancy in other countries (e.g., Germany). Additionally, those countries that have already implemented systematic priority setting are following fundamentally different approaches (see chapter "Prioritisation: (At Least) Two Normative Cultures").

Experiences that have been made with prioritization in several countries can contribute to a mutual learning process by revealing success and failure. Therefore, this book project aims to stimulate an international dialogue on prioritization. Contributors bring together experiences from arround the globe. They present a broad range of professional perspectives and scientific disciplines (such as religious studies, philosophy, medicine, (health) economics, law, psychology).

This international and interdisciplinary concept enables readers to get a comprehensive and balanced insight into the complex issue of setting priorities in medicine. Hence, the structure of this volume reflects essential topics and challenges along the way to priorities.

3 Structure of This Volume

This volume encloses six parts which, in turn, consist of two to five chapters. Numerous cross-references indicate that a topic is discussed in greater detail in another chapter. Some chapters introduce or comment on other contributions within this volume.

Part I, *Evaluation and Decisions in Modern Healthcare*, addresses elemental aspects of evaluation in medicine and (prioritization) decisions in health care: In Chap. 2, Jim Cochrane reflects prioritization in a larger environment of *Fundamental Evaluation Criteria in the Medicine of the Twenty-First Century*. Rather than offering an in-depth discussion of legal frameworks, medical choices, or financial challenges, he discusses the setting within these topics must be placed. Assuming that the distinction between "vertical prioritization" and "horizontal prioritization" is incomplete, he suggests a third category "system prioritization" described by a dynamic adaptive system. To contextualize this general framework, Cochrane comments on themes that he characterizes as central to questions of prioritization: the bounds of science and the limits of rational choice theory. In Chap. 3, Sir Muir Gray discusses resource allocation as *Hellish Decisions in Healthcare*. He initially provides an overview of changing paradigms in health care from 2nd World War until the recent Global Finance Collapse. Subsequently, he characterizes (evidence for) significant variations in access, quality, outcome, and investment that led to a historical drift, respectively, an attempt to make resource allocation more explicit in NHS. In this context, Sir Gray critically examines utilitarianism as influential principle of British thinking and deduces the need that decision makers are accountable for reasonable resource allocation. Finally, he introduces program budgeting as a basis for priority setting in health care.

Part II, *Normative Dimensions of Methodological and Theoretical Approaches*, focuses on the concept of Accountability of Reasonableness and the critique of priority setting as a maximization task. Its coherence is enhanced by a comment on both issues. Norman Daniels brings together *Accountability for Reasonableness and Priority Setting in Health* in Chap. 4, He suggests the concept of "Accountability for Reasonableness" as an appeal to a type of procedural justice that can improve the legitimacy as well as fairness of priority setting, particularly in the environment of a far-reaching ethical disagreement about allocation decisions. Therefore, Daniels proposes conditions that should be met at various levels where priority setting proceeds. His contribution considers the implications of the suggested concept for health technology assessment and for efficiency frontiers (German alternative for cost-effectiveness analysis). Finally, he assesses the feasibility of "Accountability for Reasonableness." In Chap. 5, Weyma Lübbe discusses the *Social Value Maximization and the Multiple Goals Assumption*. She considers the focal question: *Is Priority Setting a Maximizing Task at All*? To answer this question, the contribution first addresses the multiple goals assumption: It is frequently assumed that decision makers pursue the target of fair allocation beside health maximization. Combining both goals is understood to involve a trade-off. It is often argued that its quantitative form should be grounded on data collected in social preference studies. Accordingly, the modification of the health maximizing approach is thought to involve an alteration in the direction of social value maximization. Lübbe suggests that an appropriate conceptualization of fair allocation includes a break that goes beyond breaking with health maximization. This break refers to the notion of maximizing any value(s) in any way. This means to break with the tie that connects preference and value. Then, integrating fairness would be beyond the paradigm. Lübbe exemplifies this by discussing the concept of equity weights for QALYs. In Chap. 6, Andrea Klonschinski addresses *The Trade-Off Metaphor in Priority Setting* and thereby provides *A Comment on Lübbe and Daniels* (chapters above). Her contribution aims to help the reader to evaluate the arguments presented by Daniels and Lübbe. It strives to strengthen and complement Lübbe's critique of the multiple goals assumption and to connect her considerations with Daniels' account. It shows that Lübbes' objections pertain to Daniels' contribution. Above, the contribution itself provides important input to the debate on priority setting. Klonschinski pleads to pay more attention to conceptual issues in the course of discussing priority setting.

Part III, *International Experiences: Normative Basis and Process of Priority Setting*, provides an international perspective on prioritization. Thereby, authors take into consideration both the normative basis and the practice of priority setting. Heiner Raspe analyzes in Chap. 7, *Prioritisation – (At Least) Two Normative Cultures*, different models of prioritization and their normative basis: Models from Oregon and England serve as examples for the Anglophone type. Norway and Sweden illustrate the Scandinavian approach. Based on this, he contrasts "clinical solidarity” with “social solidarity.” Furthermore, Raspe provides remarks on working with the Swedish national model particularly in the German debate on prioritization in medicine. In Chap. 8, Gustav Tinghög discusses *Seven Unresolved Problems* of *Healthcare Priority Setting in Practice*. Additionally to the contribution of Raspe, this chapter outlines four lessons learned from Oregon and three lessons learned from Sweden. These experiences of explicit priority setting in practice exemplify approaches that have emphasized two contrasting perspectives on distributive fairness from the start: maximizing health benefit, on the one hand, and giving priority to the greatest need, on the other hand. Frode Lindemark analyzes *Recent Developments on the Issue of Health-Care Priority Setting in Norway* in Chap. 9. Particularly he refers to work of the third committee on health priorities that delivered its report “Open and fair –priorities in the health service” to the Ministry of Health and Care Services in November 2014. This committee suggests that the aim of priority setting could be to strive for the “greatest number of healthy life years for all, fairly distributed”. Lindemark gives an overview of present developments and discussions against the background of prioritization in Norway.

Part IV, *Legal Basis of Setting Priorities*, highlights aspects of legal regulation with a focus on Germany and UK. Gerhard Dannecker outlines *Prioritization in Health Care* from a *Normative Perspective* in Chap. 10. His contribution is an introduction to the chapters in the following. With a focus on Germany, it emphasizes the importance of ethical and legal principles, the meaning of the (constitutional) admissibility of prioritization and prioritization criteria, and the necessity to consider the interdependence between different areas of law. In Chap. 11, *Rebalancing the Rationing Debate – Tackling the Tensions between Individual and Community Rights*, Christopher Newdick attends to the tension that occurs when choices that favor needs of individuals disfavor needs of communities: He discusses limitations of the individual perspective and the necessity of clearer population-based targets. His contribution alleges examples from the English NHS, though the questions it reflects are global in scope. In Chap. 12, Bjoern Schmitz-Luhn and Christian Katzenmeier discuss *The Law Behind Priorities* with a focus on the *Implementation of Priority Setting in Health Care* using *The German Example*. They emphasize that prioritization cannot forgo instruments of implementation: Transforming allocation concepts into practice requires mechanisms for the steering and governance of prioritization principles. Changing the ways of allocation can diversely impact health systems and their legal framework. The underlying regulatory frame may even be a barrier toward the application of prioritizing schemes or raise questions of permissibility and impact on present regulatory equilibria. Schmitz-Luhn and Katzenmeier show some of the challenges to introduce a scheme of prioritization in Germany.

Part V, *The Role of Age and Personal Responsibility*, provides a discussion on two controversial criteria for prioritization. Both, theoretical and empirical analyses contribute to this discussion. Greg Bognar focuses on *Priority Setting and Age* in Chap. 13. He stresses the importance of elucidating the role that age can play in resource allocation since age considerations permeate health systems worldwide. Therefore, Bognar presents a broad outline of notions that defend the relevance of age. Furthermore, he reflects on the recent Norwegian discussion about the role of age in priority setting. In Chap. 14, Sarah M. Watters analyzes *Fair Innings as a Basis for Prioritization* from *An Empirical Perspective*. She differentiates two versions of the fair innings argument that advocates for age-based prioritization. Her review of empirical evidence indicates that the acceptance of intergenerational equity due to the fair innings principle is mixed and support appears to be dependent on context. In Chap. 15, *Just Caring: Fair Innings and Priority Setting*, Leonard M. Fleck raises the pointed question: *Does a 90-Year-Old Have a Just Claim to an Artificial Heart?* He suggests that some form of age-based rationing, vindicated partly by fair innings aspects, is not unjust: Relevant, he argues, is a flexible contextual interpretation of fair innings in a spectrum of conditions for the determination of just claims to health care for the elderly. Fleck emphasizes in this regard that a complex theory of rational democratic deliberation as well as according political practices are required. In Chap. 16, Harald Schmidt analyzes *Personal Responsibility as Criterion for Prioritization in Resource Allocation*. This contribution first outlines how one could think about the normative groundwork for policies that have reference to personal responsibility. It takes a closer look at major rationales underlying its promotion in resource allocation. Moreover, Schmidt discusses several essential dimensions of incentives for promoting personal responsibility. Adele Diederich completes this part of the present volume with her contribution in Chap. 17, *Age and Personal Responsibility as Prioritization Criteria? The View of the Public and of Physicians*. Rather than focusing on philosophical debates, she reports the views of a representative sample of the German population and of a sample of physicians as well: The contribution first presents citizens' and physicians' attitudes towards age, then towards personal responsibility. Moreover, it brings together the other contributions in this part of the volume.

Part VI, *Economic Evaluation*, addresses, on the one hand, the role of economic evaluation in priority setting in general. On this basis, it discusses, on the other hand, a special type of evaluation in Germany. In Chap. 18, *Using Economic Evaluation in Priority Setting: What Do We Know and What Can We Do?,* Iestyn Williams and Stirling Bryan comprehensively examine cost-effectiveness analysis (CEA) in priority setting. At that, they comment on the evidence base and highlight two types of barriers toward the use of CEA (accessibility and acceptability). They reflect the neglect of context when it comes to explanations of the use of CEA. Focusing on the context, they argue, contributes to explain the disparity between national and local decision making tiers in regard to using CEA. Williams and Bryan suggest that for the purpose of CEA to have an increasing impact at local levels, analysts should consider more the restrictions in which decision makers act and that greater clearness over roles, responsibilities, and relationships is necessary in the process of resource allocation. Moreover, they plead for researchers to focus on closing theoretical gaps as well as empirical gaps in comprehension across health systems and contexts. In the last chapter (Chap. 19), *Let's Talk About Health Economic Evaluation: Relevant Contextual Factors for the German "Sonderweg,"* Lars Schwettmann draws on the contribution of Williams and Bryan. First, he comments on selected aspects raised by their analyses of barriers toward the usage of health economic information. Beyond, he outlines the limited role of economic evaluations in the German statutory health insurance system. In this, Schwettmann also sketches the special methods of evaluation evolved by the German "Institute for Quality and Efficiency in Health Care." By summarizing findings of qualitative research, his contribution in addition identifies possible reasons for the specific limitations and regulations in Germany.

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Part I

Evaluation and Decisions in Modern Healthcare

Fundamental Evaluation Criteria in the Medicine of the Twenty-First Century

James R. Cochrane

It is an extraordinary gesture, and a significant risk, to be asked as a religion scholar to keynote a meeting on prioritization in medicine. At the outset let me state clearly that I have no expertise to address specific legal frameworks governing health care, to discriminate scientifically between medical choices, or to analyze the financial challenges involved. At the same time, I will say something about the larger environment within which these matters are necessarily placed.

Similarly, it is beyond my province to judge the problem in the terms used by this research group, namely, "vertical prioritization" (a hierarchy of choice within a special field or group of patients) and "horizontal prioritization" (a hierarchy of choice between special fields or types of illness or disease). I will suggest, though, that this distinction is incomplete and offer a third "system prioritization."

My remarks come from an engagement over the last decade with an international transdisciplinary collaboration of people engaged in researching health care, health systems, and public health with a view to unpacking the interface between health and "religion." Broadly understood, the key questions here have revolved around a double recognition: that religious entities of one kind or another are widely and deeply involved in delivering health care and medicine in most corners of the world, often where there are few or no other formal state or private facilities or services, and that religion, as an efficacious worldview linked to particular cultural and traditional constructs of health and healing with practical implications (more often than is usually granted), plays a significant role in how health care and medicine is received and understood.

To be clear, the point for the purposes of this discussion is *not* to put religion on the agenda (though there are instances where that might not be a bad idea). Rather, it so happens that dealing with the interface between religion and health rapidly

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_2

forces one to consider crucial issues that are often sidelined by the problematic yet pervasive Cartesian split between mind and body or spiritual and material reality. That split dominates a great deal in governance, policy, and practice in the field of medicine and health care, and it often confounds their aims and objectives. That religion is invoked (and it is in any case a tricky notion[1]) should not derail us. Besides challenging the Cartesian split, our work on the interface between religion and health has also spawned general concepts that I wish to reflect upon of some relevance to the most fundamental issues around health-care provision that also concern this research group, in particular, ideas about health assets, healthworlds, causes of life, and deep accountability.

The approach I adopt places the question of medical prioritization within a larger framework of evaluation criteria for medicine in the Twenty-First Century. Here I suggest an additional category of prioritization that cuts across the notions of vertical and horizontal prioritization, namely, that described by a dynamic (or emergent) adaptive system. To provide some necessary context to this general framework while simultaneously highlighting some important fault lines that bedevil many attempts to solve the major challenges we face, I first wish to comment on two topics that mediate much discussion around medicine and its organization and generate considerable controversy: the bounds of science and the limits of economics or, more specifically, of "rational choice" theory as a defining viewpoint.

1 The Lure and Allure of Science

Undoubtedly one cannot but be mesmerized by the astounding science and the breathtaking technologies of our time. As an example of one typical piece of magic at an institution to which I have connections, Dr Anthony Atala and his team at Wake Forest Medical Center in North Carolina are responding to a growing crisis in organ availability resulting from in medicine: an aging population and a lack of sufficient organ donors. They engage in regenerative medicine to produce artificial bladders, spinal bones, and more; with three-dimensional printers, they are building, layer-by-layer, an artificial kidney, with the promise of other organs to come. One may cite many other remarkable scientific innovations in fields such as genetics, neuroscience, nanotechnology, and the like.

Such empirical science, given its evident power, is alluring. It is hard not to be fascinated by it, to place one's hopes in it, to promote it, and to invest in it. So the demand grows to allocate major human, intellectual, material, and financial resources to its work through every relevant institution, private or public.

Where, however, does this often impel us? Even if the manifest intention is to heal, the explicit practice is often reminiscent, metaphorically speaking, of

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[1] Smith (1998).

veterinary science or perhaps bioengineering. More generally, one could say that we embrace one of the four "sins" of global health,[2] namely, the lust for technological solutions (the other three sins being "coveting silo gains, leaving broad promises largely unfulfilled, and boasting of narrow successes"). I would portray this as an instrumental, technical response to setting priorities. It is best captured in the idea of a "magic bullet" and raised virtually to a Holy Grail in the form of randomized controlled trials which are less reliable than are widely believed or acted upon.[3] Pushed in this direction, it is easy to set aside fundamental questions about which or, more tellingly, *whose* interests drive research and technological innovation.

Another side of the lure and allure of science is its potential hubris. This rests not just on its undoubtedly effective utility but also on an epistemological and ontological conviction: that "causes" (e.g., of disease or illness) can be determined with great and increasing certainty and that only the ignorant or the disingenuous person would reject the superior authority of science. Science, it is assumed, uncovers reality "as it is" and gives us an increasingly firm grip on it.

Yet, as the best scientists well know and Kant long ago theorized, we never perceive causes directly but only via a world of appearances. To these appearances we necessarily add inferences of order, but we do so only by making fundamental (supersensible) assumptions we cannot prove. Irrespective of our powers of invention, this places a fundamental limit on our grasp of reality. We never see fully. And the order we place upon reality has, can, and will change, not simply according to a rule of diminishing ignorance and increasing knowledge but in principle and always. We have and can have no "God's-eye view" of the real.

In short, though we do grasp the real with greater adequacy and increased power (which is not inconsequential and can indeed can be profoundly exciting), we never do so other than by means of generating "laws," that is, by overlaying a unity and an order on the appearances that is not intrinsic but of our making—which is why paradigm shifts in our understanding are both possible and inevitable. At the same time, this capacity is a measure of our creative freedom, which we exercise in ordering the appearances of both the natural order and the human order, inseparably. Both must thus be comprehended together, as the interplay between theoretical reason and practical wisdom. This applies to the sphere of medicine and health as much as any.

One challenge, then, is how to grasp the complexity with which we are thereby confronted without reducing it to an instrumental, technical logic. We tend to look for an order that, to be manageable, is necessarily simplified, made legible, and measurable—in a word, reductionist. Paraphrasing James Scott's *Seeing Like a State*[4] and thinking not of polity but of the field of medical science, we may then

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[2] See Panter-Brick et al. (2014).

[3] Ioannidis (2005).

[4] Scott (1998).

speak of its practitioners being disposed to "seeing like a medic": imagining that they have grasped reality through their deeply rooted training in instrumental knowledge and the powerful tools it gives them, supported by powerful accrediting and grant agencies who see things similarly. In fact it simultaneously tends to blind them, as Scott notes, to "essential features of any real, functioning social order," demoting or setting aside "the indispensable role of practical knowledge, informal processes, and improvisation in the face of unpredictability."[5]

Why is this so important? From a complexity theory point of view, for the simple but rather profound reason that life is uncontrollable, at least in the sense that its dynamic, emergent, and unpredictable properties, however much we may grasp them in one way or another, always exceed that grasp. Whereas it is possible to understand this complexity in part, sometimes even with astounding depth (say, in neuroscience), in principle and for epistemological reasons it can always only be grasped partially.

One way to think of this partial kind of understanding is to regard it as "sufficient for the purpose"; in many situations we do not require anything more. Yet increasingly, across many fields of inquiry and professional practice, we are realizing that this is not enough: that linear analyses or diagnoses of a particular lived reality (say, a health condition) are in many cases misleading and potentially capable of undermining the very thing one seeks to achieve. This becomes obvious in the case of diseases or illnesses like HIV and AIDS or obesity and diabetes and in the face of the rapidly growing reality of long-term chronic conditions.

To think otherwise is to ensure that we will continually be confounded by our attempts to control life. This is true even when our focus is death—or mortality and morbidity—and our knowledge and action are urgently geared toward addressing pathologies.

2 On the Rationality of Choice and the Question of the Common Good

In several publications the research group on prioritization in medicine has addressed the crucial decisions in the economics of health provision and care to be made about the generation, appropriation, and allocation of resources. In a time when the economic version of rational choice theory, supplemented by game theory, has largely been taken as standard wisdom, I wish to raise an old, seemingly antiquated, and often disparaged question of the common good.

It has been heavily undermined by the penetration of market rationalities into all spheres of life. Some even speciously equate it with notions of social engineering or command economies (not a necessary equation at all, as is clear in the alternative phrasing, "common weal" or commonwealth). What largely now holds sway is a philosophy, perhaps more accurately an ideology, that gives heavy or even

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[5] Scott (1998): 6.

hegemonic priority to a calculus of opportunity costs and preferences and thus to a particular mathematical modeling of reality that aspires to define and guide all decisions that humans make. Like those who imagine that science is the answer to our problems, a similar hubris attaches to this effort.

As with the hubris of science, it is fundamentally reductionist and similarly fails at the level of its anthropological assumptions (and probably its ontology as well) to take into account the complexity of human beings or of life per se. It prioritizes the autonomy of individual "rational" choice, a limited and morally misleading understanding of autonomy. Specifically, the autonomy associated with choice or preference is what is limited. Preferences are rooted in desire and inclination and, as such, are incapable of transcending self-interest; yet the capacity to do so and the capabilities that go with that capacity suggest that a much richer view on autonomy is needed, one that is able to transcend self-interest.[6] Finally, it is forcefully used to promote private enterprise as a determining reference point in governance in particular and in social life in general. This extends very widely. In South Africa, for example, pharmaceutical companies, so central to medicine, are patenting and placing a price on bits of nature per se, "privatizing" many of South Africa's unique and ancient indigenous medicinal plants and claiming rights over their properties. The trend is toward privatization and includes the move in many public or semi-public facilities to outsourcing activities to private enterprise. Defensible only on limited economic grounds, this attitude is ruled—an appropriate metaphor—by a market logic of exchange relations. In turn, this posits a clearly reductionist view of the human being as, par excellence, a unitary, isolated, or "point-like" ego with no history or context involved in rationally weighing up opportunities and balancing costs and benefits as the basic strategy of life.

This calculating, ahistorical creature establishes the anthropological basis of many key decisions about how to set priorities in society. Characterizing the human as having a price rather than intrinsic worth,[7] it supports the talk and practice of rationalization. Narrowed definitions of efficiency and effectiveness, based heavily on economic and bureaucratic rationality, accompany it. Such a gaze, only partially accounting for the human being and his or her agency, cannot help but turn toward an instrumental approach to the real—or to use Habermas's language (taken from Weber) to a purposive-rational rather than communicative action logic.[8] And so, it turns our view decisively away from what efficiency and effectiveness might mean

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[6] See Jaggar (2006), Nussbaum (2001).

[7] This Kantian distinction, linked to the second form of his categorical imperative ("treat persons as ends in themselves and never as means to another end"), has recently been explored with considerable profundity in relation (inter alia) to the new South African Constitution, German Basic Law, and the Canadian Constitution in (2012).

[8] Habermas (1984). Here his distinction between the "system imperatives" of money (markets) and power (state bureaucracies) and their driving logic—inherently instrumental and purpose-rational rather than communicative—is evoked.

for a relationally embodied human being defined as person (where the concept of “decency” becomes helpful).[9]

The ideology has another deleterious effect too. The public, as such, disappears from view. At best, it emerges in the form of representation at the level of governance or the state. But this sphere, too, is easily overtaken by an increasingly restricted group of actors who have the expertise or means to act and who do so through highly planned, if volatile, interlocking affiliations, groupings, and interactions that ironically can, and sometimes do, contain elements of a command economy with little accountability to anyone but themselves (notwithstanding the supposed democratization of ownership that shareholder or stakeholder approaches are purported to bring).[10]

When the sphere of the public is diminished and progressively brought under the control of entrepreneurs, technocrats and bureaucrats, what might we understand by the health of the public per se? What becomes of the common good; that is, what becomes of our accountability not just to ourselves but also to all and indeed to that which nurtures and sustains us in our environment?

Whether we consider (1) the current, destructive casino logic of financial capital or (2) the disappearance of the “real human being” from the sphere of economy in favor of a “virtual person” that is a shareholder without face or responsibility beyond self-interest with regard to dividends accruing in the market or (3) the troubling effects of our presence on the earth that have begun to change it in ways we may not be able to manage, the question of the common good confronts us. The common good now cannot be understood in nation-state or similarly narrow terms but only with respect to humanity as a whole in our interdependence and dependence upon the earth we inhabit in consort with its other creatures. Nor can it be understood as giving priority to those who seek to socially engineer our lives “from the top down,” so to speak, always legitimated on the grounds that they have the expertise, the mandate or the wisdom to know what we all need and want. Yet the search for a new understanding of the common good cannot be set aside either.

Perhaps this question provides us right now with no specific criteria for how we prioritize medicine in the time ahead. But it does suggest that some criteria must be found that enable us to measure the science and practice of medicine in terms of its contribution to the common good. At least one clue to this is provided by an element of the contemporary form of the Hippocratic Oath, namely, the Declaration of Geneva or “Physician’s Oath” which includes a commitment to human rights. Like the basic injunction that one should do no harm, it is phrased in the negative, however, requiring that one not violate any rights. There is no suggestion that one seek to enhance such rights, which would imply a proactive role.

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[9] See Karpf et al. (2008).

[10] See Letza et al. (2004); also Ireland (2005).

In any case, a rights approach has particular limits, especially given the de facto reality that they are largely articulated juridically as individual rights negatively defined (what should not be done) and with difficulty as social rights positively defined (what should be done). Can decisions about prioritization in medicine find a meaningful relation to a deepened understanding of human rights? This would mean pushing beyond first-generation or negative rights into the tricky legal territory of second- and third-generation rights. First-generation rights are largely individual rights, whereas second- and third-generation rights are more general and include, for example, those of unborn generations. To consider the impact of our actions on unborn generations is to begin to think in terms of the common good through time.

Another related limit to any consideration of the common good is the notion of contractual rights, a legal articulation of rights that dominates jurisprudence in most contexts today—notably (given the context of this discussion), in the use of medicine, the provision of health care, and the status of private corporations (such as the ultimately bizarre predilection to define corporations as "persons with rights," legally entrenched in some places in law with seriously negative impact on democratic life). It also contains within it certain dangers. A contract is inherently an expression of exchange relations and not of any common good. Hence, even though a contract may formally appear symmetrical, those who have greater power, wealth, access, or authority readily leverage it to their advantage and self-interest. In practice, then, especially where a great deal is at stake in terms of influence and money, a contractual right readily expresses deeply asymmetric power relations.

We once had a notion of covenantal rights. This evokes a relationship that goes beyond contractual limitations. It appeals to a foundation that transcends self-interest (individual or corporate). Avoiding the religious constructs within which the term originates, we might now refer to this as the priority of the Just,[11] the "law above the law" (Kant) that transcends specific particular constructs of justice.[12] Clearly, there is a normative dimension here, and though it is not defined culturally or contextually (it is universal, in that regard), it would not find favor with those who adopt a merely empirical or pragmatic view of law.

This, then, describes in shorthand the alternative before those responsible for the provision of health and medicine in any society: either autonomy understood as the discrete nature of an individual who, out of self-interest, makes free choices from among available goods according to a calculus of costs and benefits (opportunity costs included) or autonomy understood as the exercise of the will to maximize the benefits accruing from the use of our creative freedom (in the form of science and

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[11] Ricoeur (2000).

[12] This transcendental law, it should be clear, is not rooted in nature, but in the conditions of possibility that define the human being (at least) as of intrinsic worth. It is also, in principle, the basis for the expression of any particular law (culturally, contextually, historically established) and for its criticism.

of moral judgment) for all—in ways that cater for but also transcend self-interest. I believe the latter holds greater promise for the health of all.

3 Another Direction

How, given my general remarks on the allure of science and the question of the common good, do we now look at prioritization in medicine differently? Not, I am sure, by setting aside scientific, technical, operational, economic, financial, or managerial questions but by reframing them. In what follows, I articulate some ideas that are an attempt at such reframing.

3.1 Health Assets

First, then, let's consider the notion of health assets. I refer now to research carried out in Zambia and Lesotho for the WHO in 2005–2006.[13] It had commissioned us to provide some reliable data on otherwise anecdotal claims that religious entities were significantly involved in health care and necessary to scaling up the response to HIV and AIDS.

Using GIS instruments, the WHO Services Availability Mapping tool, and our own instruments matched to (but extending) the WHO's HealthMapper coding, we mapped 434 sites in four areas in Zambia and three in Lesotho. Remarkably, of these 434 sites, 432 were new to HealthMapper. They were, in other words, invisible to those who define and enact policy in the relevant health systems. The graphic below is one example of numerous formal health-care facilities in Chipata in Zambia; only two are visible on either government or WHO maps. There were little or no knowledge of the others, mostly with some religious backing or inspiration, and virtually no alignment with them in serving the area (Fig. 1).

Yet despite their widespread invisibility to authorities that govern or agencies that serve formal health systems, such "invisible" bodies represent vital new entities for engagement, the table below indicating their diversity (it also tabulates how participants, particularly health seekers, ranked such facilities in terms of their perceived credibility and value, with some clear differences in Zambia and Lesotho) (Fig. 2).

The entities we mapped also spanned a wide range of (sometimes overlapping) health-related activities. In Zambia, this included prevention (155), care and support (145), networking (38), treatment services (20), and ARV treatment (7) and, in Lesotho, HIV education and life skills development with VCT (44), home-based care (22), and treatment (8).

In short, we uncovered a substantial range of people organized in one way or another to deliver health, including medical treatment, to a very large section of the populace that could not have been reached if one paid attention only to the formal

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[13] African Religious Health Assets Programme (2006).

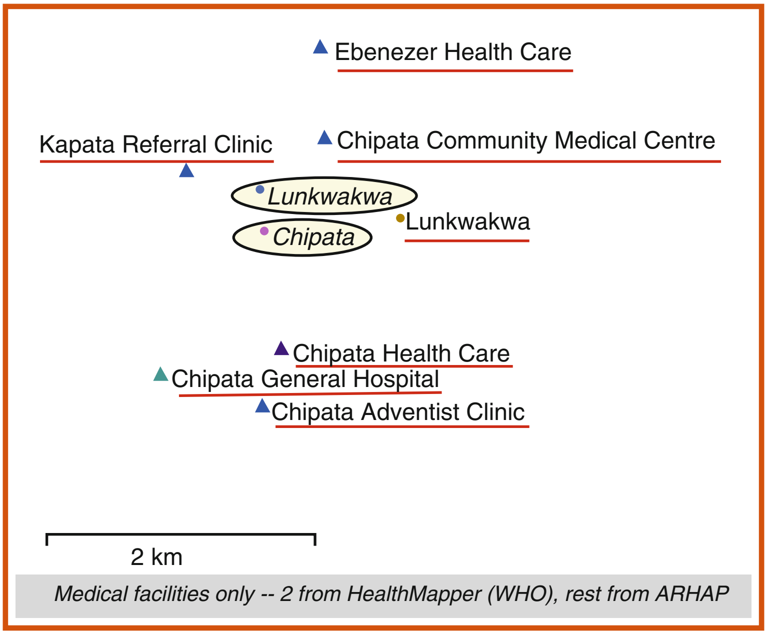
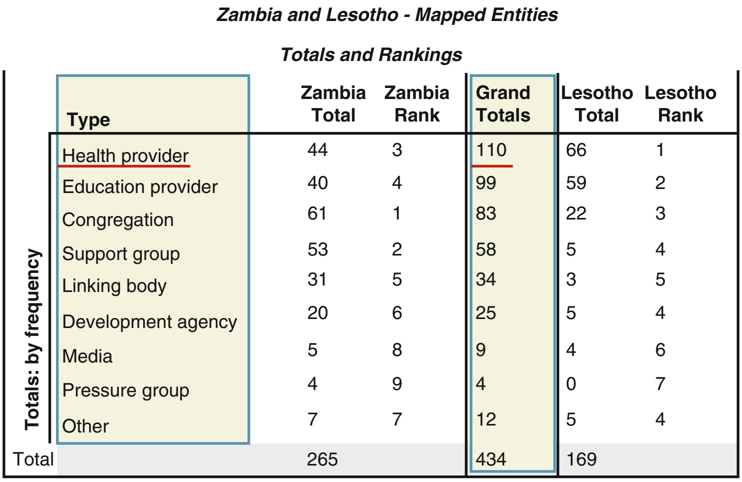


Fig. 1 Chipata, Zambia—visible/invisible entities



Zambia and Lesotho - Mapped Entities

Totals and Rankings

Totals: by frequency

Type	Zambia Total	Zambia Rank	Grand Totals	Lesotho Total	Lesotho Rank
Health provider	44	3	110	66	1
Education provider	40	4	99	59	2
Congregation	61	1	83	22	3
Support group	53	2	58	5	4
Linking body	31	5	34	3	5
Development agency	20	6	25	5	4
Media	5	8	9	4	6
Pressure group	4	9	4	0	7
Other	7	7	12	5	4
Total	265		434	169	

Fig. 2 Mapped entities in Lesotho and Zambia—diversity

health facilities. Clearly, beyond the doors of such facilities lies a great deal of other related activities, much of it embodying crucial assets for any health system.

If visibility is important, so too is the distinction between tangible and intangible assets. Much that we unearthed pointed to the import of intangible factors for the effectiveness and efficiency of any intervention. Trust is one such intangible asset, as are credibility, motivation, compassion, mentoring, accompaniment, and many more. These factors are hard to measure directly and difficult to capture through proxy measures. Yet all bear upon whether or not available health care is accessed, regarded as acceptable, or properly utilized, perhaps on their affordability too regarding how costs are carried and shared.

Paying attention to the full range of assets available well beyond those defined in economic or clinical terms is thus of obvious consequence. Formal health systems, private or public, cannot and never will meet all the demands and needs that exist.

3.2 Healthworlds

The term "assets," commonly associated with financial accounting, allows us to add another dimension. An asset remains at rest and of no immediate significance if it is not acted upon. In short, agency is essential, meaning the active engagement of a person or persons in using or leveraging an asset (intangible and tangible).

Though an asset-based approach to health care is gaining some ground,[14] in medical practice and in health interventions generally such agency is seen largely to reside with the provider, the expert, or the trained professional. We sought in our research to explore the hypothesis that durably effective health interventions—whether at individual, community, or public level—need to account not just for the agency of the provider but also that of the health seeker. Prior evidence from various fields of research and practice, including clinical, prompts the hypothesis.[15]

Here we face a practical conundrum. To take into account the agency of a health seeker is to step into another world than the one largely occupied by the clinician, epidemiologist, or health provider. This is a world not governed by rigorous science, standard protocols, or bureaucratic controls but one where those canons may not be trusted or where they may be viewed as too limited: a world of the health seeker's own individual or communal construction of health and illness and of their etiology. This often plays a key role in the choices that individuals, families, or communities make about their health.

The health provider who simply wants to get the job done as best as he or she knows how may not find this of immediate interest. To treat the health seeker as an agent means to take into account their subjective standpoints. These are shaped by lifeworlds that take for granted a valued background store of knowledge and experience passed down through generations. They are mediated by traditions that both conserve and evolve. And they occur in always changing local circumstances that are often well understood endogenously. Such realities may not always fit well with what a health provider knows, sometimes quite the opposite. It is easy then to set

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[14] See, for example, Glasgow Centre for Population Health (2011), and Foot and Hopkins (2009).

[15] A small sample: Akintola (2008), Barry et al. (2001), Dejong (2006), Hausmann-Muela et al. (2003), Morgan and Ziglio (2007).

aside or even denigrate and demean the health seeker's perspective. Besides anything else, this may well undermine durably meaningful interventions.

A classic example: An African woman in South Africa, provided with ARV's after acknowledging her condition and agreeing to testing, knew fully well that the drug protocols required her to take one tablet twice a day; yet she also knew that her sister was probably infected though, in shame, unwilling to admit anything publicly. Because her African cultural values place a high priority on relationality at least as much as on individuality, her personal health would not trump that of her sister. This expresses itself in a deep ethic of sharing. So, clearly noncompliant, she shared her ARVs. It might be said, perhaps with annoyance, that she acted stupidly, irresponsibly, and irrationally. From her point of view, however, within the framework of her primary values, she acted entirely rationally.

Most of us, actually, when faced with particular health challenges act according to our own understandings of what and whom we can trust and we appeal to experiences and authorities (e.g., a grandmother) that lie well beyond the walls of any medical practice or institution. More, as a recent high-level report on disease eradication notes. "Even when the biological, technical, and operational criteria are by and large favorable," any successful eradication intervention will also depend upon non-biological "critical enabling factors," including strong ethical arguments, effective communication strategies, and societal support.[16]

In sum, as HIV and AIDS has taught us if we did not know it already, the *reception* of interventions or of services impacts on their utility and value. It is unhelpful—perhaps even counter-productive—simply to insist on the agency, or power, of the health provider over the health seeker. Trust and credibility are won not by force, but by intelligent encounter.

To capture the complex reality confronting health provider and health seeker, we conceived the idea of the healthworld.[17] It alerts us to what is really a continuum, regularly to be assessed in accordance with circumstances. At one end is a purely instrumental, technical view of the intervention. Here priority is placed on science and its application; all decisions about resource allocation, funding, and policy are made accordingly. At the other end is the human perspective, one that prioritizes subjective, relational, and cultural possibilities. To focus only on one end of the continuum is to fail. To pay attention to both ends is to anticipate an intervention that has a greater chance of succeeding (appropriately thoughtful about circumstances, of course: e.g., arrested breathing must be dealt with instrumentally and quickly; but other conditions will require more, as the example of sickle cell treatment discussed later demonstrates).

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[16] Cochi and Dowdle (2011): 99. Other critical enabling factors include financial feasibility, strong economic arguments, an effective governance structure, political commitment, and the ability to positively impact health systems.

[17] Germond and Cochrane (2010).

4 The “Memphis Model”

Can ideas about assets, agency, and healthworlds be operationalized and their impact assessed? A serious effort to answer these questions using the approach and appropriately adjusted tools from the WHO study has been undertaken by colleagues at Methodist Le Bonheur Healthcare in Memphis, Tennessee. A high-quality seven-hospital system, it kept its main facilities in the inner city to serve the poorest and most hard-hit citizens of Memphis when most others were leaving for the wealthier suburbs. Despite world-class medicine and facilities, though, it was clear that a profusion of providers in the area had little long-term impact upon the overall health profile of the city and its population.

What, asked a senior executive, if we were to see our responsibility as extending beyond our doors to the community as a whole? What would we do if we were to pay attention, say, to the 30 days before patients arrive at our door and the 30 days thereafter? How would *that* change our practice, our mission, and our financial calculations?

The question cannot be answered if one’s gaze remains focused on the internal life of the hospital. Nor can one give up what people within the hospital are charged and trained to do. One has to turn to others outside of the formal health-care system. This what the Methodist Le Bonheur did. It accepted the idea that community health assets understood in relation to their particular healthworlds might be relevant to the formal health-care system as such, as well as to the overall health of the population at large. It thus sought to understand where those assets lay and how they might be leveraged. It was an untested gamble.

The result over several years has seen the growth of an extended, financially valued, and professionally supported partnership with local communities, mostly congregations of one kind or another, but not all (Fig. 3).

Recent figures show that about 600 such community-based entities representing well over 15,000 individuals are now joined with the hospital and three ancillary providers in what is called the Congregational Health Network (CHN).[18] Having gained the attention of Health and Human Services and the White House, this has helped spawn a nationwide collaboration of many more similar facilities through the Health Systems Learning Group,[19] now known as Stakeholder Health.[20] A further enhancement at state level is currently underway in North Carolina.

Why has this gained so much attention? Early outcome data from the first 2 years of operation using a controlled, matched comparison between CHN and non-CHN patients (based on electronic medical records) suggests that CHN patients cost the hospital over $8000 less per head (probably because earlier referrals lead to better

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[18] Cutts (2010).

[19] Health Systems Learning Group (2013).

[20] See http://stakeholderhealth.org/, accessed 20.04.2015.

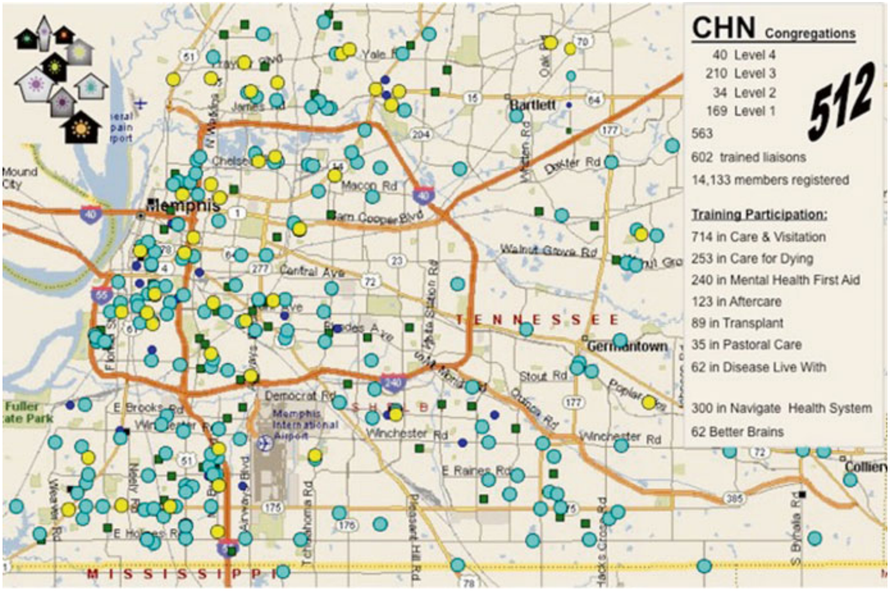

Fig. 3 CHN partners in Memphis, TN

results and less intervention). Significantly longer periods before readmission were also evident for the most frequent diagnoses (including congestive heart failure, other cardiovascular diseases, strokes, and diabetes). Crude mortality rates of CHN patients were less than half of those of non-CHN patients.[21]

The data was early and needed additional methods for probing its validity and durability. Much more recent figures[22] of patients between 2008 and 2011 matched on 14 variables show that CHN patients, for all diagnoses (all APR-DRG),[23] took 120 days longer to readmission than non-CHN patients for first the quartile. The median time to readmission for CHN patients with congestive heart failure was 141 days longer than for non-CHN patients. Statistically significant crude mortality

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[21] Cutts (2010): 204.

[22] The latest data, not yet published, is from a private communication from the person tracking CHN data.

[23] "The All Patient Refined Diagnosis Related Groups (APR-DRGs) expand the basic DRG structure by adding two sets of subclasses to each base APR-DRG. Each subclass set consists of four subclasses: one addresses patient differences relating to severity of illness and the other addresses differences in risk of mortality. Severity of illness is defined as the extent of physiologic decompensation or organ system loss of function. Risk of mortality is defined as the likelihood of dying." See http://www.ahrq.gov/professionals/quality-patient-safety/qualityresources/mortality/Hughessumm.pdf, accessed 19 November, 2013.

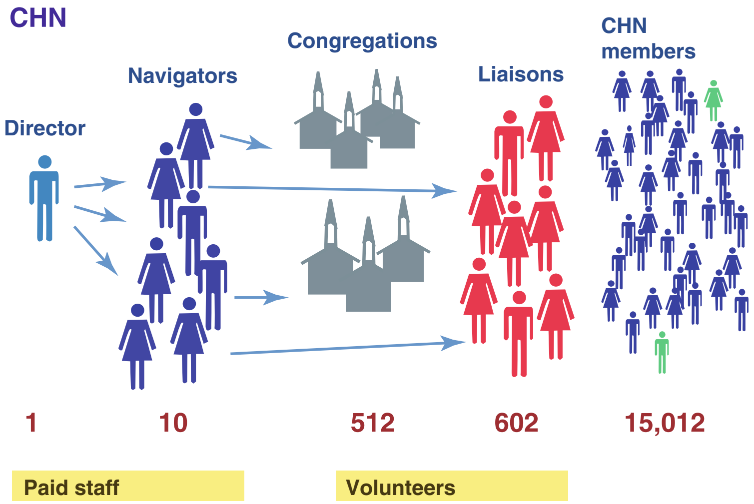

Fig. 4 CHN structure

rates in archived data for CHN patients remained at roughly half of non-CHN patients. Further, CHN patients were markedly more likely to be appropriately navigated to hospice or home health care than the total population served by the system. Write-off costs for uninsured patients, treated in large numbers, have also decreased, producing significant savings.

Why does this work? Certain key factors are clearly crucial. First is the recognition that "The predominant trajectory of anyone's journey of health is located outside traditional hospital settings," which requires an approach that deliberately decenters the role of traditional health-care settings "to give equal credence and weight to care offered intrinsically within the community by nonmedical personnel"[24] (Fig. 4).

Second, to enable this to happen transparent communication with all concerned is vital. For the CHN this has meant including community representatives on the hospital board (albeit without voting powers). Trust, here, is the most crucial asset of all. Clearly intangible, trust cannot be measured as most health systems like to measure things. It is also hard won, and it must be sustained; once lost it is very difficult to recover.[25]

A third critical element is a commitment to what the originators of the CHN call "blended intelligence"[26]—a focused process of taking into account the wisdom and knowledge of all stakeholders, especially those usually excluded from the policy

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[24] Cutts (2010): 196.

[25] Gilson (2003, 2005), Thiede (2005).

[26] Cutts (2010): 199.

and experts circles of decision-making, that is, those to whom the health services are formally targeted.

One could ask here whether or not the CHN represents a venture in public health as such or in health care understood primarily as medicine and its practice. This division, prevalent in many university faculties, tends to view public health as “soft science” and even perhaps inappropriately located within the health sciences (“they really should be with the social sciences”). Such compartmentalization is probably not sustainable, especially in the light of life-span chronic conditions, and where it occurs it misses precisely what the CHN recognizes: the journey of health for any particular person or community is one, indivisible. The blending of intelligence that it requires to make this apparent simultaneously binds medical science and population health. The hospital or clinic, to put it another way, is not a separate entity with a separate practice along the way but a way station that will work better even in its own terms when it sees itself aligned with that journey and with all actors and stakeholders that are relevant to that journey. The CHN represents such a view.

One cannot assume that the CHN model is applicable everywhere. Yet many pressures that led Methodist Le Bonheur to move in this direction do apply elsewhere. They include the high costs of care and cutting edge technologies, health insurance gaps, demand on available beds, shortages of medics and nursing personnel, the relative demise of the general practitioner (especially away from urban or peri-urban areas), limits to the reach and capacity of parish nurses (*Diakonie* or *Sozialstationen* in Germany), the negative impact of financial rationalization, frequently inappropriate use of the emergency room, the increasingly chronic nature of diseases that are now managed, aging populations, and more.

The CHN represents a shift in thinking about these problems. Particularly important is its conception of the journey of health as involving a lifespan, probably transgenerationally. Simply expanding services and facilities to meet this reality, even where possible, is not enough. It is crucial to see that the medical component in the cycles of care that mark the lifelong journey of health is not just on a continuum of *clinical* care. It is dependent on many other things that live outside of what one might call medical spaces.

Here a brief historical note is worth recalling. In 1968, a propitious gathering took place in Tübingen under the auspices of the German Institute for Medical Mission (Deutsches Institut für ärztliche Mission).[27] Reflecting on a growing awareness of crisis in medical missions across the world, it ultimately inspired and, through the establishment of the prestigious Christian Medical Commission in Geneva, fed directly into the famous 1974 Alma Ata gathering that defined the WHO’s primary health-care (PHC) mandate.[28] Its most fundamental judgment than was that the focus of medicine and health provision must expand from the

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[27] McGilvray (1981).

[28] World Health Organization (1978).

individual to include the community.[29] This meant designing an integrated system of care that linked formal health facilities to community care. The thinking behind Alma Ata was pregnant with new possibilities that are still not met. There are multiple reasons for this, not least the constraints placed upon innovative ideas by limited resources and selective appropriation and the failure to integrate medical facilities and community health initiatives.[30] The CHN is one contemporary expression of the conviction that new ways must be found of addressing what was already visible then, now with additional insights and experience.

Here I have spoken about of health assets, agency, and healthworlds. Yet, the whole is much better understood within a larger framework to which I shall now turn. It begins not with what damages or kills us but with what allows us to survive in the first instance and to thrive in the second. Turning standard epidemiological language on its head, we may speak of "the leading causes of life."

5 Dead or Alive: Schrödinger's Cat

Long ago, having studied organic chemistry, I was able to solve Erwin Schrödinger's quantum cloud equations; now I would have difficulty telling between those equations and his cat. The fate of that cat has often been discussed and it is a useful allegory for how medicine tends to work. Most of health science and practice assumes that the cat, if not dead (when it would be of little interest other than to a pathologist or anatomist), is dying or in danger of dying and that something must be done to control, retard, or prevent that state. But what if we assume that cat is alive, that finding ways to enhance its life—not necessarily seeking only to prevent its death—is equally crucial to its health and well-being?

Taking such a view is not entirely original, of course. Aaron Antonovsky, for example, began his investigation in Israel of a cohort of women holocaust survivors, two thirds of whom were not thriving, by asking a different question: what enabled those who *were thriving* to do so? Would that not provide crucial insights into the direction health care or medicine needs to take? Calling his approach "salutogenesis," he found that a "sense of coherence" (SOC)[31] was crucial to health and healing. Physiological, mental, and relational coherence are important at one level. At another, the incoherence for many patients of a medical or hospital experience also has relevance in the stress it causes and the misdirection that may result. The CHN, for example, thus places high priority on its "navigators" within the hospital system and in its voluntary community-based liaisons outside its walls. Coherence can thus be described as one "cause of life." Many indications suggest that a SOC gives a

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[29] McGilvray (1981): 46.

[30] See, for example, Cueto (2004), Hall and Taylor (2003).

[31] Antonovsky (1987), Eriksson and Lindström (2005).

people the capacity to be agents in their own healing: to have reasons to take their medicine, do their exercise, leverage their energies, and generate their own vitality. It can also have a clear positive impact on the human immune system long after the intervention.[32] Coherence may not be enough but it can tilt the balance.

Antonovsky's basic insight can be significantly expanded, however. For example, the human child develops in the context of complex bonds of nurture, dependency, and affection that impact upon sickness and health. Relational constructs, beginning already in the womb and extending in webs of connections, accompany us throughout life.[33] We can call this *connection*, and it is another leading cause of life. It applies to the human being as person and his or her ties to other persons, to the body as an intricate weave of systems, to the psyche as relationally molded, and even to the brain as a dynamic web of interacting neural networks.

Earlier, in discussing health assets, a third "cause of life" had already been introduced: that of *agency*. It is the power to do, to act, and to establish some control over one's life even in the most heinous or constrained circumstances.[34] It is no coincidence that one way to assess the state of a patient's health is by looking for signs of vitality that include his or her capacity to express agency. If absent, we call it a "vegetative state"; if seriously diminished, one becomes worried. The effects of agency can be extraordinary. Many years ago in a seminar with Elizabeth Kübler-Ross of "death and dying" fame,[35] I recall her describing how a cancer-riddled man whose physicians believed should be long dead kept himself alive for a full year to await his son's graduation. He died the day after. It is not far-fetched to imagine that agency has direct positive clinical implications in all sorts of other ways too that are not at all linked to a terminal illness. Its value is evident in other ways too. The wise nurse, for example, nurtures the agency of his or her patients, finding ways for them to express choice, even if only between cereal and oatmeal for breakfast; and the physical therapist pulls patients onto their feet after a brief period of passive rest because the human body is designed to exercise its own capacity, failing which it atrophies.

To take a less individualist view, let me cite an example at Wake Forest Baptist Health in North Carolina. The hospital's financial advisors had recommended that the jobs of its Environmental Services Workers be outsourced to a private company. Others viewed them differently—as agents in the health of the patients whose rooms they cleaned. It could be shown that on average they spent 12–15 min with each patient daily compared to 3–5 min by a nurse or a doctor. Why not call on their agency and ask them to use their interaction with the patient to help assess his or her

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[32] This is clearly demonstrated in Pennebaker (1997).

[33] Here attachment theory finds its locus. See Bowlby (1982), Fricchionne (2002).

[34] A seminal early discussion of this point is Bandura (1982).

[35] Kübler-Ross (1969).

needs or state, training them in what to look for? Why not designate them, in this role, as health workers in their own right? And because they went home to the places whence the hospital's patients came, why not have them trained to play basic early warning and post-hospital observation roles in their community? One division of the hospital proposed this plan and agreed to cover the additional costs involved, the personnel division then agreed, and in due course so did the board.

So was born the Supporters of Health, as those who now represent this new initiative designate themselves. Already after a year or so initial indicators point to a significant positive impact in morale, patient outcomes, alignment of services, and cost benefits from the work in the communities from which they come that the Supporters of Health do. This is without even taking into account the costs of the almost certain loss of morale and trust in the hospital that would have resulted from outsourcing its services personnel, including the attendant resentment and the passive resistance on the job that one could expect to follow. It also enhances the hospital's ability to link to the communities from which its patients come with benefits of its own for all concerned.

There is clearly a changed basis for financial accountability here, one that goes beyond (though it does not exclude) the standard "bottom-line" position that usually dominates. There is a deliberate and conscious leveraging of agency among those who in the standard model would not be seen in that way at all, but rather, as a price factor. Yet what one sees here is in fact much more than agency. It is a superb example of how the "causes of life" overlap and integrate with each other—in this case, agency, connection, and coherence—and of how paying attention to one strengthens the other.

It also points indirectly to a fourth "cause of life" that emerged through the process: that of hope. More than an abstract philosophical idea but grounded in neurobiology through our "prospective brain,"[36] hope is anticipatory consciousness. We anticipate, expect, weigh the likelihood of a new possibility and then act as if that is what is unfolding. This links hope to agency: as anticipatory practice and as responsible action. It would have been easy—in fact, it is the default position—simply to have accepted the view of the financial advisors trained to look at the matter instrumentally that outsourcing was the most rational route to take, leaving everyone and not just the environmental services workers somewhat depressed. Through hope, to cite David Harvey, we "construe ourselves as embedded within an ongoing flow of living processes that we can individually and collectively affect through our actions."[37] A capacity already present in the early child, it reflects an ability to transcend the given.

A final "cause of life" is "intergenerativity." Inherently not about one life, it remains highly relevant to one life. It refers to the generative relationship that cuts

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[36] Schacter et al. (2007): 657.

[37] Harvey (2000): 218.

across and between generations. It is negatively visible in the long-term transgenerational effects of historical trauma, such as the destruction of Native American First Nations or the history of Germany in the twentieth century to name but two. It has clinical effects too as studies of the punitive "Dutch Hunger" in 1944–1945 clearly show.[38]

There are other ways to construe the "leading causes of life" though the theory suggested does have a certain robustness to it and a sizable and growing body of science across several disciplines does feed into its elements. Not just poetry, the model is actually best seen as one version of the emerging sciences of complexity. Many events poorly understood merely as medical transactions are better grasped as life processes. The phenomena are real enough; to understand them we add explanation and a theory. The "causes" describe certain recurring functions and relations in the phenomena we observe. They operate on many levels, including the biological level, and they have significant value for the medical field both in its science and its practice.

Still, the main point is not a particular theory or set of concepts. More important is the challenge they represent. It can be put as simply as this: can we think about life with the same precision and rigor we use to analyze and beat back or postpone death? There is no reason in principle why medicine, with the vast amounts of energy and money that it wields, should focus less on supporting life than it does working against death. Thus Bill Foege, one-time head of the Centers for Disease Control and Prevention and indelibly associated with smallpox eradication, speaks of a "reverse epidemiology."[39] It is not much of a stretch, then, to think of "reverse medicine." The breaking of the human body and of life is relatively simple. That which is broken—life—is highly complex with many facets that exist in exquisitely rich relationship with each other. One can see this going on in the lives of patients, families, and communities if one knows how to look. The human system with its organic and emergent qualities seems less a construct to be managed and more one to be nurtured or healed.

Case Example[40]

Rethinking Sickle Cell Anemia: Life Logic at Work

Sickle cell anemia is not infectious. Transmitted genetically, it is unaffected by behavior or choice. Named after the sickle shape that red blood corpuscles assume as the condition advances, it originates in Africa where it is thought to have evolved by conferring some resistance to endemic malaria.

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[38] See http://www.dutchfamine.nl/index_files/study.htm, accessed 19 November, 2013.

[39] See Gunderson (1994): 1; refer also Foege et al. (1985).

[40] Taken from Gunderson and Cochrane (2014).

With its pattern of episodic, variable, and unpredictable but wrenching pain and limited to people of African descent, it was not even universally considered a real disease until midway through the twentieth century. It gained global attention as one of the archetypal diseases only when new tools of molecular research found sickle cell to be a perfect candidate for scientific investigation.

The first sickle cell clinic in the United States was opened in 1958 at the public hospital in Memphis, now known as the Regional Medical Center at Memphis (the Med). This made sense for reasons that are not pretty: a lack of alternative sources of medical care for African American patients ensured that researchers would have access to an practically endless supply of people who could be diagnosed early in their life and kept in treatment throughout their life as they "graduated" from children's care at Le Bonheur and St. Jude's hospitals to the adult wards. World-class molecular researchers came to Memphis to conduct extensive research on sickle cell anemia and associated medical conditions. The research engine that ran on the fuel of available patients expanded throughout the medical center of Memphis, lifting the University of Tennessee with it.

That story belongs to another book. For our purposes, it is enough to note that Memphis has a long history of engagement with people living with the excruciating pain of sickle cell. A new chapter in that engagement was the acceptance by Methodist Le Bonheur Healthcare of responsibility for adult treatment. With the roughly two thousand adult sickle patients now coming to a faith-based university hospital instead of the Med, for the most part this is simply a change in destination, not in paradigm.

Using a simple outline of best treatment practice, we can ask if the LCL theory could add anything to what is already known about how to care for those experiencing a sickle cell crisis. If we treat the engagement between a patient and a medical delivery system as part of a process and not just an event, what would advance life and simultaneously improve treatment outcomes?

Sickle cell is a curious and oddly brutal disease. The life of someone living with sickle cell is marked by unpredictable cycles or "crises" of extreme pain coursing throughout the body. The best evidence-based practice in treating a sickle patient, largely limited to pain management, usually involves a combination of powerful medications. Any adult sickle cell patient knows which medicines in what combination are most effective in controlling their crisis events.

However, the emergency room (ER) clinician, faced with an adult complaining of severe pain and wanting narcotics and showing no broken bones or obvious medical condition, has a problem figuring out whether this is just a drug-seeker, someone living with sickle cell, or something else. Any sickle patient has stories of being treated as a drug-seeker and, at best, being given an unhelpfully low dosage painkiller and then being put into observation. Even the Le Bonheur hospital finance committee chair's son was treated this way in a university hospital ER in California where he was attending a conference on sickle cell. Many adults living in the unpredictable chaos of sickle cell are also unable to hold down a good job with insurance. This adds sizable negative economic implications to treating someone who might inappropriately be abusing the limited resources of the hospital.

The decision to treat or wait also has big consequences for all concerned. If appropriately treated and controlled within 2 hours of onset, the painful crisis can be limited to 8 or 12 hours per episode as an outpatient. If not controlled within that period, it will likely end up being a 3- to 5-day inpatient admission. As many adult sickle patients lack insurance (if male, even under government programs), their care will be unreimbursed, a loss for the hospital.

LCL theory notices that more than medicine determines the likelihood of getting that 2-hour window right. Many decisions are involved and the most important ones are not necessarily made by an overworked ER clinician in a hurry, but by those making daily life decisions rather than medical ones. What affects a decision to come to the ER at the early onset of the crisis?

The decision to navigate to the ER is a choice to expend one's agency knowing it may well end with a demeaning, incoherent, and ineffective result given one's profoundly disruptive dependency on a hospital that regards one as a financial burden. Other burdens rest on family or friends who inevitably need to be involved by providing transportation and attending to the details of one's life while in a hospital for a few days. As every crisis event is unpredictable, the sensible thing to do is usually to wait until the visit to the ER simply cannot be avoided—exactly the opposite of what "evidence-based medicine" recommends. Then ER staff may have only minutes to get the diagnosis right before the 2-hour window passes, making more likely the 5-day inpatient stay that everyone dreads.

LCL theory suggests many opportunities for dramatically improved management of this situation, beginning with noticing that sickle cell sufferers—who, after all, are alive—have many mediating connections beyond the ER. They are not just patients but members of one or another social association. Probably at least seventy percent of the two thousand people living with sickle cell in the range of Memphis are known and cared for by somebody in one of Methodist Le Bonheur's hundreds of Congregational Health Network (CHN) partners. Those congregations are connected with many other mediating networks that penetrate every neighborhood and social network, reaching far beyond those who show up to weekly worship.

The link of a sickle cell person to any CHN congregation can be registered in the hospital computer, enabling those at the admissions desk to connect the two meaningfully. This simple act changes an unknown person who may look like a drug-seeker into a human being who is part of an existing, covenantal relationship with the hospital through the CHN. It allows one to trigger an automatic visit from a chaplain and, if desired, a request to the congregation to come alongside and share in the care. Alternatively, the sickle cell person may remember to call their congregational liaison, trained to either accompany them to the ER or arrange for someone else from the congregation to meet them there.

An experience that is normally fraught besides great pain with appropriate fear and embarrassment can now be expected to take place with some assurance of respect, understanding, and community. The pain will not be less, but since a decision to come quickly is much easier and a diagnosis will not be confused by suspicion, that 2-hour window is likely to be more successfully navigated with the person returning home later the same day. Correct diagnosis within the window can mean the difference between giving away 8 hour of outpatient care (roughly \$1500) or 5 days of inpatient care (roughly \$20,000). Naturally, the chief financial officer enjoys the fact that the hospital has avoided \$18,500 of unreimbursed expenses; but that is by far the crudest measurement of what has actually happened.

Antonovsky would also quickly note the dramatic improvement in the patient's SOC which draws from an encounter that is indeed more coherent for everyone involved—the congregation, ER staff, hospital administration, spiritual care staff, friends, and family. All experience themselves as participants in the event with an opportunity to share in the successful passage through a crisis of one they care about, in a way that reinforces everyone's SOC, connection, and agency. Rather than diminishing the life force, as Antonovsky predicted the stressful passage actually builds the consciousness that a person has of his or her extended social networks and of the resources necessary to deal with a circumstance that cannot be predicted or avoided.

Conclusion

The "different way of seeing" I have sketched via notions of assets, healthworlds, and causes of life is not that radical a shift in paradigm—many people, including medical practitioners, health scientists, policy makers, and community activists, are applying their minds to a view that redresses the balance between pathology and salutogenesis in the search for a richer and more scientifically complete understanding of illness and health. They do so aware of the limits of what we have achieved to date, the extent to which our existing trajectory fails to meet the "wicked problems"[41] we face, and the consequent need for innovative, breakthrough ways of comprehending the issues with greater complexity and new

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[41] Kreuter et al. (2004).

methods. Like Sir Muir Gray whose work in health in the United Kingdom has gained recognition in this regard, I take the view that neither markets nor bureaucracy, both of which rest on a far too limited instrumental and purposive-rational logic rather than a communicative rationality, can solve the challenges of complexity.[42]

Even as we take account of the increasing costs of medicine alongside budget pressures, of the hugely sophisticated sciences of the human body and striking new technologies, of aging populations and greater means of prolonging human life, and of growing demand from health seekers alongside significant and not always misplaced fears of the abuse of power by medical and pharmacological interests, we might consider some basic paradoxes identified by Paul Ricoeur in what he calls "the medical contract":

> First paradox: the human person is not a thing, and yet his [her] body is a part of observable physical nature. Second paradox: the person is not merchandise, nor is medicine a form of commerce, but medicine has a price and costs society money. Final paradox (which overlaps the first two): suffering is private, but health is public.[43]

Ricoeur's second paradox was already clear in nineteenth century to German health reformer Rudolf Virchow when he argued that "medical science in its innermost core and being is a social science" and that "politics is nothing less than medicine write large."[44] Linked to a refined notion of the common good, this prompts another distinction: between consumers and clients on one hand and citizens on the other. The absorption of the latter by the former is one of the most destructive developments of our time, to which we have yet to find the solution.

In our context we may indeed speak metaphorically of the "sins and virtues" of global health, primarily those of "coveting silo gains, lusting for technological solutions, leaving broad promises largely unfulfilled, and boasting of narrow successes."[45] In this context, my colleague Gary Gunderson and I speak of "deep accountability." Beyond accountability for particular services and treatments, we seek a more rigorous standard that includes all involved in the journey of health, taking the complexity of that journey into account. The patterns and processes described by the language of health assets, healthworlds, and causes of life help define that complexity. Helpful for understanding health interventions and goals, they also open up significant areas of inquiry that are largely undeveloped and poorly understood. They are best understood not in the light of

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[42] From a videoed presentation by Sir Muir Gray at the conference at which this paper was given.

[43] Ricoeur (1999): 208.

[44] Albrecht (2009). My translation of "Die medizinische Wissenschaft ist in ihrem innersten Kern und Wesen eine sociale Wissenschaft" and "Die Politik sei weiter nichts als Medizin im Grossen"

[45] Panter-Brick et al. (2014).

a theory of disease but in the context of a living person in a social system that is itself alive.

The institutional reality of a health-care facility will change if it takes this view as it shifts from seeing itself as a fixed a point of service to that of a landmark on a longer journey of health. To account for this institutionally new questions arise: how does any medical intervention fit into that longer journey? To what does it need to be linked? How do we enable that link? Accountability thus shifts from a focus on the autonomous quality of an event in one place to an optimal alignment with other institutions, upstream and downstream, in the different places that a person occupies in space and time.

On these grounds I argue that notions of "vertical prioritization" and "horizontal prioritization" are insufficient. They need to be supplemented by a third view, one that both escapes the linear, nonsystemic implications of the first two possibilities and that takes into account the relationship of medical provision through formal facilities to the tangible and intangible assets and agency that lie outside of them. Thinking in terms of the science of complexity (systems thinking), we would need to imagine how to think of the prioritization of medicine in relation to dynamic complex adaptive systems—not just institutions but living systems.[46]

In this light I would call for a view in the medicine of the twenty-first century that begins with "systems prioritization," with the clear understanding that this does not refer to the narrower and common terminology that defines health systems primarily in terms of formal facilities and services. Rather, broad and encompassing, it incorporates the entire spectrum of assets and activities that energize and impact on anyone's health through the lifespan.[47]

The examples I have provided around the WHO work in Africa and the CHN in Memphis or its current reinvention in North Carolina may be seen as expressions of such prioritization in practice. At the same time, it is clear that new ways of accounting for what one is doing are needed. Here it is useful to consider how the Health Systems Learning Group to which I have referred conceives of the matter (here the term "system" does indeed refer primarily to formal facilities, but the vision the group embodies begins to break this limit). The group regards several innovations as necessary. One is a turn to what it calls "integrated care for

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[46] Muir Gray (2011).

[47] Only very recently have global health agencies such as the WHO, the CDC, the Global Fund, GAVI, and several others begun to pay attention to this issue, if still in a somewhat limited sense, in the holding of symposia on global health systems research, the first of which took place in Montreux, Switzerland, in 2010 (http://healthsystemsresearch.org/hsr2010/) and the second in Beijing in 2012 (http://www.healthsystemsresearch.org/hsr2012/), with the third in Cape Town in 2014.

socially complex people in socially complex neighbourhoods."[48] Another is a shift from the standard return-on-investment (ROI) accounting model to one described as "social return on investment" (SROI, to some extent already adopted in the United Kingdom, particularly Scotland).[49] Finally, this in turn requires the introduction or invention of new tools and techniques by fiduciary agents in formal facilities, together with appropriate digital and data infrastructure, to account differently for costs and benefits.[50]

In moving in this direction, it is important to note that we do not need to start from scratch. A vast amount of data from patient records, demographics, census tracks, epidemiological surveys, and much more is already available for us to mine. It is not data that is missing (though some new data might be valuable) but appropriate ways of modeling the data, using a different lens.

As one example, a team from Indiana University took months to reframe the information from electronic medical records in Memphis to make visible what is now much clearer. Similarly a team at Wake Forest, adapting methods and algorithms used to study brain network activity, is parsing a year's worth of patient data with fresh eyes, looking for new patterns and the way they shift as a tool for operational and clinical decision-making, discovering in the process that "outliers"—a few people with multiple health challenges both biomedical and social—absorb a hugely disproportional amount of resources at high costs (indicating where prioritization should occur). On another level entirely, biologists at a recent meeting in Frankfurt on early child development[51] noted that new research, going beyond traditional ways of understanding the executive function of the cortex, is seeking better to understand what we might call "the agentive mind." The data is largely the same, the view on its altered.

A shift in paradigm is possible and necessary. I have suggested some ways in which this might be taken up or enhanced. The specific notions introduced—assets, healthworlds, causes of life, and deep accountability—are not determining.

They may be taken as ciphers and can be replaced by other appropriate terms. What matters is the way of seeing they depict and project. Such a way of seeing might be essential to meeting the challenges we face, in health and medicine as much as anywhere. There are indications that such a shift in paradigm is underway. It is time to contribute to it.

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[48] Health Systems Learning Group (2013): 38–63.

[49] Health Systems Learning Group (2013): 19–23.

[50] Health Systems Learning Group (2013): 33–36.

[51] Ernst Strüngmann Forum on "Formative Childhoods: A Path to Peace?," held at the Frankfurt Institute for Advanced Studies from 13 to 18 October, 2013, at which 48 experts from various disciplines and around the world met to discuss innovations and possibilities linked to the theme.

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Hellish Decisions in Healthcare

J.A. Muir Gray

For the last 10 years, health services worldwide have been focused on quality and safety, and rightly so with the reports of quality and safety failures such as the two reports from the Institute of Medicine in Washington D.C. one on quality and the other on safety-stimulating action (Ham and Robert 2003; Austin 2007). These reports changed the paradigm of healthcare which started after the Second World War with priority being given to provide universal coverage to whole populations, either through insurance-based or tax-based systems. In the 1980s and 1990s, the paradigm changed again with the focus on effectiveness and evidence-based decision making. The quality and safety paradigm embraced these previous paradigms, and it seems as though health services in every country had reached, if not Nirvana, at least a reasonable consensus. The USA of course remains a notable exception because of its lack of consensus and commitment to cover the whole population and although ObamaCare has changed that in principle there is still a long way to go.

Then came the shock from outside – the Global Financial Collapse. In many countries, the Global Financial Collapse or GFC led to an appreciation of the fact that public expenditure, either directly on healthcare or through subsidy of insurance companies, could not continue to rise at the rate at which it had risen in the previous 40 years. During these decades, most developed countries had seen an expansion of investment in healthcare until it reached about 10 % of the GMP, with the USA again a notable exception.

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_3

1 Historical Drift

The NHS started producing Atlases of Variation based on the wonderful work of Jack Wennberg at Dartmouth. The team that produced the Atlases were able to predict what they would find, namely, large amounts of variation much of it unwarranted, but they decided to produce the Atlases and publish them on paper, as well as on the web, for their emotional impact. What was found was no surprise. There were significant variations in access, quality, investment and outcome. None of the populations could guess where they stood in the league table. In addition, we found significant variations in expenditure usually at least 1.5-fold from the highest to the lowest, and this happened after taking out the data from the top five and the bottom five for fear of being accused of overemphasising the magnitude of variation. Of course, as is always the case, the outliers claimed that the data were wrong and that they had special needs, but we came to the conclusion that the magnitude of variation was so great that data errors alone could not explain it.

What has happened is obvious. Over the last 40 years, some services have grown faster than others, probably principally due to the effectiveness of committed clinicians in lobbying for additional resources. In addition to variations in expenditures between programmes, there was also significant variation within programmes. For example, within the Eyes and Vision Programme, there are six major systems, glaucoma, cataract, retinopathy, macular degeneration, children's service and support for people with lower vision, and the amount of investment in each of these six, within the overall Eyes and Vision budget, also varies widely from one population to another.

What is happening now in the English NHS is an attempt to make this process more explicit, and not surprisingly there is resistance to doing this because, to use the title of a workshop that was organised on prioritisation and programme budgeting, these are *Hellish Decisions in Healthcare*. The terms *Hellish Decisions* was chosen because it is often applied to difficult end-of-life decisions in clinical practice, but decisions are just as hellish when it comes to allocation of resources.

Two points emerged at our recent workshop, one of them on a good British principle, the principle of utilitarianism, and the other on the need for accountability for reasonableness.

1.1 Utilitarianism as a Weak Point

John Stewart Mill and Jeremy Bentham dominate many aspects of British thinking still with their essays. 'On Liberty' and 'On Utility' and with the term utilitarianism, often summarised as 'the greatest good for the greatest number', is a long established and a much loved principle, not surprisingly because it brings a warm glow to the health of the decision makers and takers. However, the greatest good for the greatest number overlooks the fact that others must suffer. This has been most closely brought out in Dostoevsky in his challenge from Ivan to Alyosha from The Brother Karamazov.

> Tell me frankly, I appeal to you – answer me: imagine that it is you yourself who are erecting the edifice of human destiny with the aim of making men happy in the end, of giving them peace and contentment at last, but that to do that it is absolutely necessary, and indeed quite inevitable, to torture to death only one tiny creature, the little girl who beat her breast with her little fist, and to found the edifice on her unavenged tears – would you consent to be the architect on those conditions. Tell me and do not lie! (Dostoevsky (1958), p. 287; italic added)

The greatest good for the greatest number can be expressed in another way as the least harm to the least number, but we must not delude ourselves. The allocation and reallocation of resources always involves adversely affecting some groups of the population. For this reason, we need to be accountable for the decisions. We need to be accountable for reasonableness.

1.2 Accountability for Reasonableness

This is the concept developed by Norman Daniels and James Sabin in their book *Setting Limits Fairly* (see also chapter "Accountability for Reasonableness and Priority Setting in Health"). It is defined below:

> *Accountability for reasonableness* is the idea that the reasons or rationales for important limit-setting decisions should be publicly available. In addition, these reasons must be ones that 'fair-minded' people can agree are relevant to pursuing appropriate patient care under necessary resource constraints. This is our central thesis, and it needs some explanation.
>
> By 'fair-minded', we do not simply mean our friends or people who just happen to agree with us. We mean people who in principle seek to cooperate with others on terms they can justify to each other. Indeed, fair-minded people accept rules of the game – or sometimes seek rule changes – that promote the game's essential skills and the excitement their use produces. (Daniels and Sabin (2008), p. 44)

The public are not unreasonable. They do not expect the judgement of Solomon. When offered the opportunity to get involved in decision making and decision taking, they see what the difficulties are, but when they see reasonableness, namely, that the decision makers have, for example, listened to all the groups that will be affected and taken some steps to exclude bias and conflict of interest, they can accept that decision making is reasonable and fair.

1.3 The Future of Decision Making

Looking to the future, we will still have some relatively easy prioritisations to make, for example, should we put money into treatment A rather than treatment B for a disease when both come of the production line at the same time. However, when need and demand continue to outstrip resources, we will face much bigger decisions. For example, should we move money from cancer to mental health or vice versa, should we shift resources from services for old people to services for children or vice versa. These are the hellish decisions that face us in a new era of prioritisation.

2 Prioritisation and Rationing

For the last 50 years, health services in Britain and most other countries have made priority decisions when faced with the challenge of how to spend the annual increase in budget. When additional money becomes available, as it has done year after year, with only a few blips, then a decision has to be made about which service and therefore which group of patients should be given priority. Various approaches have been used but the focus has always been one of benefit that one group of patients will receive. A value judgement is made over whether or not there would be a better result if the resources were allocated to another group of patients. There is however another aspect to priority setting, the other side of the coin – rationing.

In their book called *Reasonably Rationing*, Chris Ham and Glyn Roberts use the terms 'healthcare rationing' and 'priority setting' interchangeably throughout (Ham and Robert 2003). These authors recognised that even in the days of growth of 2003, before the Global Financial Collapse, we were making decisions implicitly or explicitly which affected different population groups. By giving priority to one group, you ration care to the second group. In 2007, the NHS Confederation published a report written by Daphne Austin, and she emphasised that need and demand always exceeds funding with a consequence that Primary Care Trusts, the jurisdictions responsible for allocating resources, had to prioritise (Austin 2007). Also in 2003, the National Health Service in England introduced a new way of budgeting called programme budgeting, and this brought the choices out more clearly.

2.1 Programme Budgeting as a Basis for Priority Setting

The origins of programme budgeting are eloquently described by Alain Enthoven in his book on the introduction of programme budgeting to the Defence Department in Washington with Robert S McNamara as the Secretary of State for Defence. Enthoven was one of the 'whizz kids' from RAND who were brought in to the Defence Department by Robert S McNamara to challenge the current way of spending resources which was by service. Instead of simply thinking of putting more money into the army or the navy or the air force, the debate was to identify what the objectives of the programmes were and which programme, for example, the defence of the homeland or the ability to invade another land, should have high priority. Alain Enthoven had a significant influence on Margaret Thatcher which led to the introduction of purchasing or, as it was later called, commissioning. The NHS has therefore been collecting financial information on the basis of programmes for a number of years.

They used as the taxonomy the International Classification of Diseases, and the result is shown in Table 3.1:

There are of course weaknesses in this approach because it does not allow the citizen or the decision maker to see the allocation of resources by social class, by ethnic group or by age to give three other possible ways of cutting the cake. Nevertheless it is much more challenging that simply allocating resource to

Table 3.1 Expenditure per million population by NHS England in 2011/2012

	£M/Million pop
Mental health	225
Cardiovascular disease	160
Cancer	117
Genitourinary	95
Musculoskeletal	95
Respiratory	92
Gastrointestinal	92
Neurological diseases	82
Trauma	74
Maternity	72
Social	70
Dental	66
Learning disability	63
Endocrine	58
Healthy	42
Skin	42
Vision	40
Infectious diseases	40
Blood disorders	28
Adverse effects	21
Hearing problems	10
Other	65
Subtotal	**1649**
GP/PMS	154
SHA	92
Miscellaneous	226
Total	**2121**

‘primary care’ or ‘secondary care’. The reports of programme budgeting, however, showed how little explicit and evidence-based priority setting had actually taken place as the variation in expenditure clearly shows.

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Part II

Normative Dimensions of Methodological and Theoretical Approaches

Accountability for Reasonableness and Priority Setting in Health

Norman Daniels

1 The Problem of Priority Setting

Priority setting is required whenever a society must provide for the needs and welfare of its population and resources are limited, which is always. However important most people may feel that health and health care are they are not the only goods that compete for collective or individual resources, for these are not the only things people value. Thus, health competes with other goods, such as education, housing, and income support (through job creation and schemes to support people unable to work for various reasons, including aging and disability). This competition means that however wealthy a society is, it cannot meet all the legitimate claims for assistance people within it have. In addition, health needs compete with each other for resources in a world in which demand grows quickly, fed by the aging of populations and technological advance as well as by increased access to information. Consequently, priorities must be set between health and other goods, as well as within the health sector itself since different claimants have different health needs within any population.

Some form of fair process should be involved in both kinds of priority setting. The competition between health-related resources and other goods is generally left to a political process. The fact that a societal budget for meeting health needs is the result of such a political process means that in all societies, some method of resolving disagreements about priorities is needed. In this paper, I will say no more about this important topic, except to note that many societies spend too little on health, and that the one case I know best where too much is spent, namely, the USA, it is because of incentives and not a collective decision. Instead, I focus here on priority setting about health. Treatment of one illness, for example, competes with the

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_4

treatment of other illnesses as well as with preventive interventions that protect and promote health. There is reasonable disagreement about both kinds of competition.

Priority setting takes place at various levels in a society. Thus, in the context of a national health system, there may be national decisions about what services are included in national coverage. But national budgets must be divided into budgets for local regions (states or districts) and even institutions (such as hospitals). Decisions about priorities must be made, for example, about resource allocation within a hospital, even if the overall budget for the institution is determined by political decisions made elsewhere.

People reasonably disagree about how budgets should be set between health and other goods, and they commonly disagree about what resources should be devoted to protecting health when it is threatened—both by risks and by actual illness. In this paper, I propose a decision process, or rather the conditions that should be met by such a process, which is argued for in more detail elsewhere (Daniels and Sabin 2008). My aim is to reduce disagreement about priorities in health and to enhance the legitimacy and fairness of such decisions. These conditions, I claim, should be met at various levels where priorities are set. We should suppose that decisions about priorities must be made in real time and in conditions where moderate scarcity of resources exists.

I shall argue that we lack economic tools for priority setting that are adequate to the task of making decisions that are both fair and legitimate, though these tools should remain inputs into the decision-making process that I defend. I shall also consider the implications of this proposal for health technology assessment (HTA) in general, with some remarks focused on Germany. Finally, I shall assess the feasibility of proposing a fair, deliberative process when we have little direct evidence about its feasibility: is it a requirement of justice to implement such a system?

2 Reasonable Ethical Disagreement About Resource Allocation in Health Is Rampant

To see the pervasiveness of reasonable ethical disagreement about resource allocation, consider two main goals of health policy: to improve population health in the aggregate and to reduce unjust health inequalities. These goals sometimes converge and sometimes they are in tension. When they are in tension, reasonable people will differ about how much they are willing to give up improvements in aggregate population health to achieve a reduction in health inequalities they believe are unjust. For example, when the introduction of antiretroviral treatments for HIV/AIDS was being discussed by WHO, some argued that many more people would be treated if hospitals that could serve the urban population provided treatments first, and others were intent on reducing health inequalities between the urban and rural populations by locating some treatment centers where they were more likely to serve rural populations even at the cost of reaching fewer people.

One of the most common forms of public disagreement reflects an ethical disagreement about the relative weights to be given to compassion vs. stewardship. All

Table 1 CEA vs. fair distribution

	CEA	Fairness
Best outcomes vs. fair chances	Best outcomes	Weighted chances
Priority to worst off	None	Some
Aggregation	Any	Some

insurance schemes, whether public or private, claim they will cover only proven treatments. This is a form of stewardship of resources. Often, however, the denial of a treatment that has not undergone full experimental testing, but which offers a patient a "last chance" at treatment, is publicly challenged. Many countries have seen successful challenges when public authorities deny coverage for the unproven treatment.

There is also disagreement between important priority setting tools in use in many countries, such as cost-effectiveness analysis (CEA) and commonly held views about fair distribution. This disagreement is illustrated in Table 1, where the rows indicate three pervasive "unsolved" rationing problems (Daniels 1993) and the columns show a disagreement between the approach of CEA and public judgments about fairness. For example, in the top row, CEA always favors best outcomes, but most people believe it is fair to give people fair chances at a significant benefit, even if the significant benefit is not the best outcome. In the middle row, CEA gives no priority to those who are worst off, whereas most people want to give some priority (not maximal priority) to them, thinking that there is more value to giving a benefit to someone worse off than giving an equal benefit to someone better off. In the bottom row, CEA favors aggregating any benefits, however small, so that minor benefits to large numbers of people can outweigh a significant benefit (such as extending a life) to a few. Frances Kamm argues some benefits are "irrelevant goods" and they should not be aggregated (Kamm 1993). Accordingly, fairness favors aggregating only some effects, not all of them. Of course "some" does not identify a principle, whereas "giving no priority to any" and "aggregate any benefit" identify principles that govern the answer CEA gives. These disagreements focus on the distributive insensitivity of CEA, a commonly noted feature that seems to follow from its underlying maximization strategy—it always aims at getting the most effect per quantity of resource invested. The virtue of this approach is that efficiency can be viewed as an ethical consideration—more needs can be met per resource invested. The drawback is that it matters to many who receive the benefit.

In light of this distributive insensitivity, a group authorized to give ethical guidance to decisions about countries expanding coverage in order to achieve universal health care (UHC) gives prominence to cost-effectiveness analysis, but views it, as does the Public Health Service in the USA, as an input to a decision-making process, not as an algorithm for making decisions (WHO Consultative Group 2014). The WHO group modifies the results of CEA by considering other goals of UHC, such as fairness (in this case, giving some priority to those who are worse off) and financial protection. Both of those other goals can compromise the main goal of CEA, which purports to tell us which allocations improve aggregate health in the population the most, for a given intervention.

3 Procedural Justice and Accountability for Reasonableness

The prominence of instances of the unsolved rationing problems in resource allocation for health shows that there is pervasive disagreement about resource allocation decisions and this disagreement rests on reasonable ethical disagreements. In many contexts, when we lack a way to solve substantive disagreements, we rely on procedures we view as fair, and we view the result of using such a fair procedure as itself fair. Of course, as my former colleague, Marc Roberts (Personal communication to the author, February 4, 2014), pointed out to me, this presupposes that it is easier to agree on what counts as a fair procedure than it is to resolve the substantive disagreement. This presupposition is often the case. For example, in some sporting events, we rely on a random procedure, such as the flip of a coin, to determine who goes first when there may be some perceived advantage to going first or last. When the substantive disagreement that exists is important to the people who may be winners or losers in any decision, the decision faces an acute legitimacy problem: what is the authority of those who make the decision to make it, and, their authority aside, how is it being made?

In the philosophical literature, a distinction is generally made between cases in which there is prior agreement on a relevant principle (which is referred to as "impure procedural justice") and cases in which there is no such agreement (which is called "pure procedural justice") (Rawls 1971). A classic example of the impure procedural justice is a criminal trial, where the prior principle is "convict all and only the guilty," but we need the process of the trial to assess who is guilty. Rawls (1971) cites "gambling" as an example of pure procedural justice (also his hypothetical contract), since the outcome of a fair spin of the roulette wheel or throw of the dice is taken to determine the fair winner.

There however are two differences between the resource allocation problems with which we are concerned and the example of gambling. Although it is impossible to conceive of finding a principle that might determine the winner in a gambling case, we can and should leave open the possibility that some argument may eventually persuade all parties that they have a principled solution for one of the "unsolved rationing problems." The possibility of finding such an argument means that the claim that the decision process determines what is fair for this class of cases is "defeasible." A second difference is that we may accept some constraints on the resource allocation decisions that derive from considerations of justice. For example, we may not accept a decision that involves discrimination against a particular gender or race. In contrast, we may think there are no such constraints on the outcome of gambling. Despite these two differences, there is a fundamental similarity—both, resource allocation cases and gambling are cases in which there is no prior agreement on a substantive principle that should apply to them. Consequently, I conclude, if the decision procedure is deemed to be fair, then the decisions made in that process will count as legitimate and (defeasible) fair.

I shall only briefly explain the four conditions that a fair deliberation should meet in this appeal to procedural justice to arrive at decisions about resource allocation in health (Daniels and Sabin 1997). There are three substantive conditions: publicity, a requirement that the rationales for decisions be public; relevance, which requires that there is a search for rationales that are based on reasons all can agree and are relevant to the task at hand; and revisability, which requires that decisions be revisited when there are new evidence or arguments to consider. One formal condition completes the list that Sabin and I constructed: enforcement, which only ensures that the other three conditions are met. The publicity condition is stronger than what a market-based publicity condition would require, since it applies to the rationales for decisions, not just to the options available once a decision is made. The relevance condition is also strong, since it requires that there is agreement on what counts as a relevant consideration in the task at hand, though it does not require agreement on the weight given to that relevant consideration. This leaves room for reasonable disagreement about the weights, and this means that some decisions may require a vote among decision-makers. Whether this is a simple or a supermajority vote is left an open matter. The revisability condition leaves open what counts as the appropriate frequency or review of past decisions and what kinds of new evidence or arguments call for a revisiting of the decision.

Although James Sabin and I were confident that these four conditions had to be met, we did not assume that they were necessary and sufficient for assuring people of the legitimacy and fairness of the process. If good arguments can be made that another condition should be added, we are open to amending accountability for reasonableness in this way. We were also confident that different processes were appropriate at different levels of decision-making, though we think that the conditions that constitute accountability for reasonableness, so amended or not, should be met at any level.

We were also confident that implementing such a process at appropriate societal levels would serve a social educational function by creating a social learning curve. The process would familiarize people with the ethical commitments underlying the health system and the benefit package of services it provides to people. We see this educational function, the social learning the process facilitates, as an essential feature of priority setting: people affected by the decisions that are reasonable and fair to make must understand their rationales. Our view is that this feature is a requirement of justice and not simply an instrumental effect. This public learning is important if the decisions that are made are to be seen as legitimate and fair to all, so that there is public buy-in to the idea that priorities have to be set under resource constraints and that they have to be set in a way that is fair to all people affected by them. In a universal coverage system that defines contingent entitlements, these decisions about resource allocation affect everyone.

One issue that has become clearer to us in the nearly two decades since the main ideas of accountability for reasonableness were articulated is that much needs to be done to understand how to conduct a fair process. Not only is there the obvious issue of whom to include in the process, but also there is the quite common problem of how to conduct deliberations so that they do not get captured by vested interests and are not derailed by common flaws. How can we embrace the partial views of stakeholders without converting the deliberation into a contest among powerful vested interests lobbying for their own objectives? By a “common flaw,” I mean a phenomenon such as the influence of “charismatic” people deliberation by a jury. We know that such figures can distort a deliberation, yet we do not have a clear idea of how to construct the rules of deliberation to counter such effects (Hans 2007). We have become much more aware of how little we know about how to conduct effective deliberations. At the same time that we have learned more about the potential for such processes to be “fig leaves” for the powers that really are at work, we may not yet know how to make those deliberations work as well as they can in theory.

Theory is not enough. I was once asked by a group of health ministers from China if the decision-making process “worked.” Unfortunately, it is too soon to tell. To date, empirical examination of accountability for reasonableness has been limited to assessment of whether the four conditions are met when the system is implemented. A real test of whether the appeal to procedural justice “works” would not stop at seeing whether theoretically defended conditions actually are achieved, but also would look at the effects of such decision-making on the legitimacy and fairness of the decisions that are made.

Herein lies the problem. How do we measure these effects? Without such an empirical assessment, the rationale for the approach is primarily theoretical, but practical agents will want a rationale that shows the approach has the promised effects.

It is easier to measure the effects on legitimacy than on fairness. We may have some agreement on what counts as legitimacy, and that may give us a basis for measuring what we agree upon. But the rationale for appealing to procedural justice in the case of resource allocation is that we lack agreement on what counts as a fair allocation of resources. How can we measure an effect when we do not have prior agreement on what it is? That remains an important issue to address in answering the question, does accountability for reasonableness work?

Another question I have been asked is whether multi-criteria decision analysis (MCDA) provides a method that can replace accountability for reasonableness as a form of procedural justice (see Balthussen and Niessen 2006). I do not have space here to develop my concerns about this proposal, so I shall make only two points. First, the criteria that should play a role in the deliberation should themselves emerge out of a deliberation. Second, the weights assigned to these criteria must be defended by reasons, and there should be some collective process for agreeing on what weights are assigned. Also, the weights given to a criterion may depend on the context, and that variability may undercut the appeal to preferences. In general, I am skeptical of mere preferences being the basis for the selection of criteria or weights, and therefore, I am skeptical about the ability of an approach that relies on preferences to produce a quantitative ranking of options. Such an approach may tell us what a particular group of people likes, but such a result should have questionable normative force. Unfortunately, “being quantitative” is often the main selling point for a method that aims to replace a deliberative process that determines what we should do. Nevertheless, I think some of the practices involved in MCDA can be useful in managing the deliberation, for example, the emphasis it places on determining the criteria for a decision.

MCDA is also not automatically sensitive to questions about distribution in a way that avoids the problems earlier raised for CEA. If a goal of health policy is the reduction of some unjust health inequalities and achieving this goal is sometimes worth sacrificing some maximization of population health, depending on the relative gains for both goals, then CEA, as we saw earlier, cannot tell us whether the sacrifice is worth it in this case, but neither does MCDA automatically improve the situation. We might think that MCDA could add a criterion about unjust health inequality reduction and that would make it sensitive. Raising the issue is clearly an improvement over not even addressing it, but how seriously the criterion is viewed will depend on the weight given to it.

4 Implications for Health Technology Assessment

So far, I have argued that there is significant and reasonable disagreement about resource allocation decisions for health, in part because of multiple goals of health policy and in part because of various ethical disagreements about what fairness requires. My proposal is that we need to retreat to a form of procedural justice to address these issues. This proposal has general implications for health technology assessment.

Health technology assessment began as the assessment of the efficacy and safety of new technologies; in many countries, especially around pharmaceuticals, cost-effectiveness analysis has been added to the assessment of new technologies. But decision-makers have other concerns as well: they are concerned with the impact of a new technology on budgets, and if their health system imposes significant coinsurance on costly new technologies, they may also be concerned about the affordability for families using a new technology. Also, they should be and often are concerned about the equity implications of a new technology. So decision-makers have to broaden their concerns beyond the safety, efficacy, and cost-effectiveness of services. This suggests that health technology assessment may be seen as clearly underdetermining coverage decisions unless it takes a position on these other matters.

This is where the conditions must be met if accountability for reasonableness is to become relevant to HTA. My proposal becomes a way for HTA to address the ethical issues that are pervasive in coverage decisions. The proposal is that HTA expands the analysis it provides to include these broader ethical concerns that are of interest to decision makers in general. HTA so expanded is likely to address the concerns more directly which are important elements of coverage decisions.

5 Implications for Germany

As I understand it, Germany does not use cost-effectiveness methodology in priority setting, and so it may avoid the criticism made earlier that CEA is insensitive to distributive issues. I believe the alternative that is used in Germany, namely, the calculation of "efficiency frontiers" for classes of treatments (usually drugs) in order to price them better (not to make a determination about coverage) does not avoid the concerns, about equity and risks, not addressing some questions that CEA tries to answer (perhaps incorrectly). Let me explain briefly.

To calculate an efficiency frontier requires that there be enough existing instances of a treatment to form a class of which the new treatment is a member. If, for example, a treatment is efficacious for a disease that had no treatment, there is no way to calculate an efficiency frontier for it. Yet decision makers must determine whether it is worth buying it at the price at which it is offered. Also, efficiency frontiers tell us whether a new treatment is producing a health effect at a price that is reasonable—given what has been paid before for treating the same or similar conditions. As a method, it accepts significant cost differences between classes of treatments for different (or the same) condition(s) and can say little about the moral acceptability of those cost differences (CEA did produce a ranking of these interventions, a ranking that is viewed as inappropriate if the question of what it is worth spending to correct one disease rather than another is not addressed). But some ethical issues do surround these cost differences, and arguably they need to be addressed by decision makers. Accordingly, relying on efficiency frontiers leaves some issues unaddressed that decision makers should consider. The point earlier made about MCDA as compared to CEA, that the distributive issues that CEA is not sensitive to may well reappear in MCDA, also applies to the gains made by calculating efficiency frontiers: such a calculation may not be sensitive to distributive issues either, and so CEA and the method of calculating efficiency frontiers may both face problems on this score.

6 Justice, Feasibility, and Accountability for Reasonableness

Accountability for reasonableness, I have argued, is an appeal to a form of procedural justice that can enhance the legitimacy and fairness of decision making about priorities in health, especially in the context of the pervasive ethical disagreement that surrounds decisions about resource allocation in health. Is such an appeal to a form of procedural justice a requirement of social justice?

I have recently argued that discussions of social justice and its requirements assume that requirements of justice are feasible in an appropriate sense (Daniels and Ladin 2014). Consider the fact that we often will condemn a practice or institution as "unjust" yet we generally believe that ethics and justice in particular should take people "as they are" and should not require people to do what they cannot. This is a feature of our moral practice of which we must make sense. We might, for example, condemn an institution as racist even though we do not know how to dislodge those who control it from power; at the same time, however, we do not think theories of justice should assume people are completely altruistic, since we think such a property of people is quite rare. To eliminate this apparent inconsistency in our practice, I have proposed that we distinguish feasibility as achievability, which is what is involved in the condemnation of the racist practice, from feasibility as sustainability, which is what is involved in the judgment about "taking people as they are" in the construction of theories of justice. My claim is that feasibility as sustainability better reveals the relevant capabilities that people must have, especially in regulating institutions, than feasibility as achievability. My goal in introducing the distinction is to eliminate the claim of inconsistency in this common practice, preferring two senses of "feasible" to the charge of inconsistency.

Unfortunately, many of our beliefs about feasibility as sustainability are ones about which we do not have much direct evidence, since we often do not know what people are capable of, especially in the construction of institutions. For example, how sustainable are the nonracist institutions we point to as requirements of just when most of them are only a few decades old? We may believe they are sustainable (and we certainly hope they are), but we do not have direct evidence of that feature of human capabilities as we do about the lack of complete altruism. This leaves plenty of room for trying to push the envelope by inspiring people to set up institutions that we hope will be stable and, say, nonracist, but we must admit that we do not know if they are sustainable, and this means, in my view, that we do not yet know if they are ways of meeting requirements of justice, even if we believe they are.

Where does accountability for reasonableness fit in to this view of what we can claim about institutions and the requirements of justice? First, I must admit that we do not have good, direct evidence that institutions that satisfy the four conditions I have sketched are sustainable. We do have reasons to believe that they are sustainably feasible based on the familiarity of the conditions, taken separately. But, there is a dearth of practical experience with their combined effect, and so I am inclined to think of accountability for reasonableness as the kind of requirement on institutions that could well be sustainable—and the social learning curve such institutions would produce would enhance their sustainability. At the same time, I admit that we do not have direct evidence that such institutions are sustainably feasible. By lacking direct evidence, I mean that we have no experience of such institutions lasting long enough to count as being sustainable. Do I think we should find out if they are feasible, by implementing them and modifying what we implement to make them "work" in the ways that might make them more sustainable? Yes, I do.

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Social Value Maximization and the Multiple Goals Assumption: Is Priority Setting a Maximizing Task at All?

Weyma Lübbe

It is often assumed that decision-makers pursue the goal of fair allocation of health-care resources besides or in addition to the goal of maximizing health (multiple goals assumption). The task of combining the goals is then assumed to involve a trade-off. Its quantitative shape, or so it is usually argued, should be based on data from social preference studies. The amendment of the conventional, health-maximizing approach is thus conceived to involve a change toward social value maximization. This chapter, however, suggests that an adequate conceptualization of fair resource allocation involves a break not only with health maximization but, more generally, with the idea of maximizing any value or values at all. It involves, in other words, a break with the link between ("social") preference and value. If this is true, integrating fairness is beyond the paradigm. The point is exemplified by commenting on the idea of equity weights for QALYs.

1 The Multiple Goals Assumption

As Weinstein et al. summarize, the conventional QALY approach had been developed with the intention to aid decision-makers, assuming that "[…] a major objective of decision-makers is to maximize health or health improvement across the population subject to resource constraints" (Weinstein et al. 2009: S5). The proponents of the conventional approach, they say, would however agree "[…] that decision-makers may also have other objectives such as equity, fairness, and political goals, all of which currently must be handled outside the *conventional* [approach]" (ibid.).

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_5

There is a nontrivial assumption in these quotes. It is the idea that efficiency and fairness are two different objectives that can consistently be held at the same time. Weinstein et al. suggest that the decision-maker will pursue the goal of fairness in addition to the goal of health maximization – an assumption that leads many analysts to presume that the decision-maker will want to make a trade-off when the goals cannot both be fully attained. However, when a decision-maker realizes that health maximization is not fair, her reaction may simply be to drop it as a separate goal. She might take the unfairness of health maximization as proof that this objective is, as such, unethical, and she might then seek for another way to allocate resources, a way that is fair. Fairness, in other words, might be the decision-maker's only goal.

Health economists tend to not perceive the matter in this way because they are used to conceptualize fairness as some sort of distributive equality – equality in health status, or equality in health gain, or perhaps equality in lifetime health. If fairness is conceptualized as distributive equality, it is wildly implausible to imagine that it might be the decision-maker's only goal. The reason is that equality can most successfully be achieved by treating all patients equally bad.[1] Perfect equality in health status is achieved when all patients are dead, and perfect equality in health gain is achieved when no health care is funded at all. Thus, it is concluded that the decision-maker must first have the goal to produce health and that her wish to have that product evenly distributed among the beneficiaries can only be a second goal. However, there are good reasons not to conceive the matter in this way. No decision-maker who is in her right mind would agree that one of her health policy goals, fairness, would be perfectly achieved if all patients were dead, but that she does not agree to let all people die, or kill some, as it were, because her health policy follows yet another goal: that the system be efficient. Instead of making the multiple goals assumption, one should rather conclude that the goal of distributive equality is an inadequate conceptualization of what decision-makers intend when they strive for fair allocation.

These remarks may, so far, indicate to the reader that the multiple goals assumption – the idea that fair distribution is a separate goal besides the goal of health maximization – is a nontrivial assumption. It presupposes, first, a conceptualization of fairness that makes it plausible as a goal in itself. Given such a concept, it further presupposes that the normative basis of this goal is consistent with the normative basis that stands behind the goal of health maximization. This is not trivial, again. The conventional approach cannot be amended by supplementing it with considerations that are critical, instead of complementary, to its own normative basis. The claim that the results of conventional economic evaluations have normative relevance for the decision-maker – a relevance that survives the decision-maker's

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[1] This is known as the leveling down objection. It objects to conceiving equality per se – of welfare, of resources, chances, or whatever – as a valuable property of outcomes, be it within a monistic or within a pluralistic axiology. See, for a seminal text, Parfit (1995). The force of the objection is occasionally recognized in the context of publications that contribute to health economic issues. See, for instance, Broome (2002).

wish to implement fair procedures – depends on showing that such consistency can be achieved.

The question of how to conceptualize fairness can thus not simply be left open or left to others. The multiple goals assumption suggests that it may be adequate to tackle the fairness problem, as Weinstein et al. put it, "outside" the conventional approach – which also suggests, in turn, that one goal, at any rate, is served adequately when the economic evaluation proceeds in the conventional manner. The multiple goals assumption itself, however, remains unwarranted as long as the conceptual and foundational issues are left untackled.[2] It remains completely unclear what sort of relevance the conventional QALY approach has for the decision-maker as long as the objection that the method taken by itself is unfair has not been dealt with.

What has been said so far can be summarized in a first message:

> The fairness problem can only be solved outside the conventional, health-maximizing evaluation approach when fairness and efficiency are indeed separable moral objectives and when their respective normative foundations are consistent. If this is not the case, tackling the fairness problem means correcting, not supplementing the conventional approach. We do then have to look for the source of unfairness within the efficiency objective's own normative basis.

2 Health Maximization

The source of the unfairness of the conventional approach may be superficial and thus easy to remove, or it may lie deep. One of its symptoms arises, or may arise, when productivity losses are included in the cost-effectiveness assessment. Productivity losses, so-called indirect costs, are costs that societies have to bear if people cannot go to work because they are sick. If such costs are included into the assessment, a treatment that brings patients sooner back to work is, other things equal, rated more cost-effective. If, however, the patient group belongs to the non-working population, there are no such costs associated with their sickness. Other things being equal, it is less cost-effective to treat such patients. An economic evaluation handbook concludes: "Under strict application of the principles of efficient allocation, working people must be given the more preference the higher their income" (Greiner and Damm 2012: 33, translation W. L.).

Politicians who publicly call for the efficient use of health-care resources would probably stop to do so if knowledge of a quote like this was widely spread among the population. The unfairness of such a recommendation has, however, not come to

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[2] One indication that they are indeed untackled is the purely intuitive nature of enumerations like "equity, fairness, and other political goals" in the quote given before: What is "equity", and how does it relate to "fairness"? Are these two goals or two names for one goal? Analysts who conceptualize the goals of decision-makers in such a pêle-mêle fashion have no clear picture of what these objectives are and how they relate to the concept and the foundational principles of efficiency.

the mind of analysts as a result of social preference studies. It is rather a matter of moral and political common sense. But why is it that in our public health-care institutions we do not want to prioritize patients by the order of their income? A natural answer would be that we think that sick people should be treated because it is good for their health not because their health is good for society. For this reason, cost-effectiveness analysis looks officially, i.e., on the benefit side, for health effects only, not for indirect benefits. Including indirect costs is a way of circumventing this restriction. It counts the loss of indirect benefits as indirect costs. The problem is not of much relevance in practice because evaluators mostly work with average income figures, if only for the lack of more specific data. One could even legally determine that productivity costs may only be introduced as average values. But such an amendment would be ad hoc. It would mean to shrink away from a consequence of one's evaluative principles without openly apostatizing from the principles.

Some analysts have always doubted that the decision to restrict the benefit assessment to medical benefits has a consistent theoretical basis. If we opt for efficiency, they say, we must count all benefits of health-care allocation and all costs. They are right. Those who choose cost-effectiveness analysis as their evaluation paradigm show thereby (unless they include all foregone indirect benefits as losses in their assessment of the costs) that they do not strive for full efficiency. They should carefully explain why. If something is wrong with efficient allocation when all sorts of benefits are included, it might be something wrong with it when only health benefits are included too.

And there is something wrong with it. A well-known unfairness objection against conventional cost-effectiveness analysis is the severity of diseases objection – the objection that the approach is blind as to whether the QALYs go to severely or to slightly ill patients. Another is the objection of disability discrimination – the objection that the approach is not blind between treating a life-threatening disease when it befalls a disabled patient and treating the same disease when it befalls a non-disabled patient. An ad hoc amendment for fairness problems like these is equity weighting. Equity weights are multiplication factors that are introduced in order to make some patient group's QALYs count more than others. Here is an example for a severity case (Fig. 1).

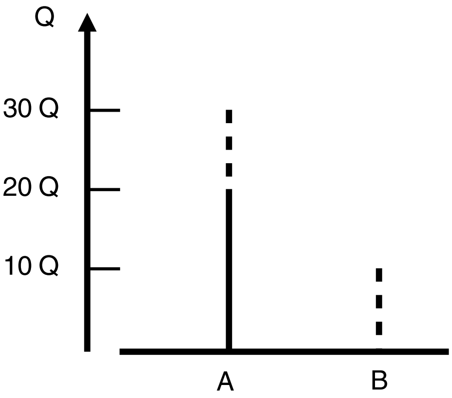

Fig. 1 A severity case

Continuous lines show the QALYs that a patient with a certain disease can expect to have without treatment. Dotted lines show the gains that can be expected from treatment. Gains for a patient with disease A and gains for a patient with disease B are assumed to be alternatively fundable under the given budget constraint. The conventional approach expects the decision-maker to be indifferent between treating a patient with disease A and treating patient with disease B since both options lead to the same total gain of QALYs. In social preference studies, however, people have been found to prefer that patients with disease B be treated – the more severely ill patients. Introduction of severity weights can explain the observed preferences.

An ad hoc amendment is a change in one's evaluation paradigm that serves to reach intuitively and/or socially accepted results for certain decision problems without showing how the newly introduced terms or concepts fit with the paradigm's theoretical frame. QALY weights have been used in such an intuitive manner by national HTA institutions. NICE[3] used weights to keep the funding of some so-called end-of-life QALYs compatible with its cost-effectiveness threshold after having found that such funding was socially wanted. A theoretical interpretation for equity weights has, however, been offered in the literature. So perhaps the amendment is not necessarily ad hoc. Here is a relevant quote: "[S]ociety's overall valuation of health output is a function not only of total output, but also of the distribution of health output across individuals. […] The term *health-related societal value* may be used to designate the overall value that society assigns to different health outcomes and programmes when concerns for both efficiency and equity are taken into account. Equity weighed QALYs are thus measures of health-related societal value" (Nord et al. 1999: 25). We are thus invited to read a weighted QALY term as representing the value, then called "societal value" or "social value," with which that QALY gain contributes to the overall value of the outcome of a funding option. The next section is a comment on this proposal.

3 Social Value Maximization

The given quote defined the social value as the value that "society" assigns to a QALY gain when concern for two goals is taken into account: efficiency, understood as health maximization, and "equity." Social value is thus not meant to be the value that a patient's health has *for society* in the sense that is involved in the issue of productivity losses. The subjects of empirical studies conducted to elicit equity weights are not presented with income data. They are confronted with decision problems similar to the case presented in Fig. 2.

Figure 2 involves a so-called person trade-off. Either care for two patients with disease A or care for one patient with disease B can be funded. The subject is asked whether she would still prefer that the patient with disease B be treated. If she does, she is asked about 3 vs. 1, 4 vs. 1, and so on, until she eventually reaches

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[3] *National Institute for Health and Care Excellence* (formerly *National Institute for Health and Clinical Excellence*), the British official institution for Health Technology Assessment.

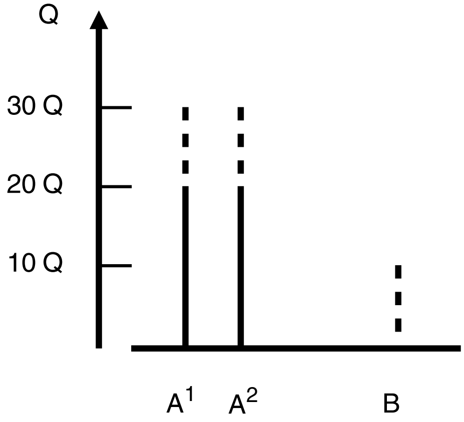

Fig. 2 A severity and number case

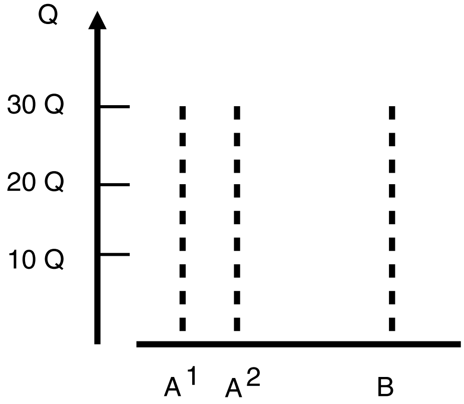

Fig. 3 A number case

indifference. The QALY weights are then determined such that the aggregated social value of the QALY gains in each outcome explains the subject's choices. If the subject, for instance, expresses indifference for the options in Fig. 2, the following weights would explain the observed result (bold lettering refers to dotted lines in Fig. 2):

$$\max\left(\tfrac{1}{2}\mathbf{Q}^{\mathbf{A1}}+\tfrac{1}{2}\,\mathbf{Q}^{\mathbf{A2}}+1\,\mathbf{Q}^{\mathbf{B}}\right)$$

There are, however, social facts (and extensive academic debates in fields that are usually not followed within health economics[4]) that throw some doubt on the method and on its conceptual frame. Consider Fig. 3.

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[4] One such debate is the debate on whether the number of people saved is a morally relevant consideration when persons are grouped in different, non-overlapping groups which can only be saved alternatively. The question is directly relevant for judging the merits, or demerits, of the person trade-off. The seminal text is Taurek (1977). For some contributions, see Parfit (1978), Rakowski (1993), Kamm (1993, Ch. 5–7), Scanlon (1998: 230–241), Lübbe (2008), and Hirose (2015). For

In Fig. 3, disease A is a single organ failure of either the heart or liver. Disease B is double organ failure of the heart *and* liver. There is no difference in the severity of diseases since all patients are about to die unless they get transplanted. To make matters simple, the case example assumes that the patients have equally good prospects for their future health if transplanted. Transplants, as is well known, are scarce and people are dying on the waiting lists. Whenever a patientss with disease B is transplanted, two patients with disease A must die who could have been helped instead. In view of the person trade-off method – which assumes that if other things are equal, more persons treated means more social value – we should expect decision-makers to remove patients with disease B from the waiting lists. However, such patients are in fact transplanted like everybody else when their turn comes before they die. The rules which determine their turn do not even gradually move them back on the list because of their double need to resources. This holds for the Eurotransplant region, and the author of this article is not aware of an allocation system that handles this otherwise. The rules show, in other words, indifference between transplanting one patient with disease B and transplanting two patient patients with disease A.

If the method of eliciting QALY weights from social preferences was sound, the widespread acceptance of such rules would be evidence for the following weights (bold lettering refers to dotted lines in Fig. 3):

$$\max \left(\tfrac{1}{2}\,\mathbf{Q}^{\mathbf{A1}} + \tfrac{1}{2}\,\mathbf{Q}^{\mathbf{A2}} + 1\;\mathbf{Q}^{\mathrm{B}} \right)$$

There is, however, no difference in the severity of diseases involved and in no other so-called context factor except the fact that patients with disease A needs half as much resources. We would have to conclude that society sees double value in the survival of people with double need of resources.

This is of course nonsense. It cannot be the right interpretation of the preferences that are here revealed. There is only one sensible interpretation for such rules: The task of allocating transplants is not perceived to be an exercise in value maximization – neither in health maximization nor in social value maximization. Transplants are one sort of medical resource. It could thus well be that the task of allocating financial resources for medical care is not an exercise in value maximization as well. This suggestion is explained in more detail in the last section. First, here is a second summary message:

> Equity weighting assumes that health care allocation is an exercise in value maximization. Social preference studies do not confirm this assumption empirically. The assumption is a preconception that analysts foist onto their subjects. It may be false, and there are actually reasons to doubt it. Without the assumption, no equity weights can be elicited from preference studies.

an effort to link this foundational debate with the debate on medical priority setting, see the proceedings of the 2009 conference of the *Harvard University Program in Ethics and Health* “Ethical Issues in the Prioritization of Health Resources,” http://peh.harvard.edu/events/2009/priority_resources/, Day Two, Session 1 (3.3.15).

4 Additive Interpersonal Aggregation

Consider again Fig. 3. As we have seen, it is easy to mathematically represent such a choice as a value maximizing choice. However, unless a reason is given *why* a subject would want to value certain QALYs more than other QALYs, this is just playing around with figures. In the transplant example, the only context factor that could be used to explain unequal QALY weights is the different amount of resources which is needed to treat the patients. There is no sense in assuming that a higher need to resources might be a reason to value a person's survival higher. Decision-makers would of course explicitly deny that they value the patients' lives differently. If asked why they still do not prefer treating the patients with disease A, they would rather say that any of the patients has an equal claim to survival and that when not all claims can be satisfied, it is fair to give each patient her chance to survival when her turn on the waiting list has come. Subjects would, in other words, not even speak about the value of the patients' lives. They would speak about the patients' claims.

Talking about claims which are to be satisfied, instead of talking about values which are to be produced, is perhaps the more adequate talk for decision-makers who have to allocate public health-care resources. Evidence for the unavoidability of a concept of claims (or rights) can be found within the health economics literature too, although these concepts have no roots in the intellectual history of welfare economics.[5] The concepts surface, notably, when the problem of disability discrimination is discussed. It is a matter of moral common sense, for instance, that a blind patient, other things equal, has the same right to get a transplant than a seeing patient. The question whether we produce as much value when we transplant the disabled, or in other words whether resources are used as efficiently if we do, is simply not relevant. Disabled patients have the same right to be treated, and that is it. *There is no trade-off with efficiency.*[6] This is further evidence for suspecting that the source of the fairness problem lies within the very basis of the efficiency objective itself and can thus not be solved outside it.

The transplant case indicates that value maximization by (weighted or unweighted) additive interpersonal aggregation as such involves a fairness problem.

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[5] This is due to the utilitarian background of the field and is acknowledged as a problem within modern welfare economics. Two authors who have, over many years, tried to overcome the problems associated with this fact are Amartya Sen and John Broome. See Sen (1981) and Broome (1984) for starting points. Both authors stay, however, within the consequentialist paradigm – the idea that the rightness of choices is determined by the overall goodness (or value) of outcomes. For a foundational critique of the consequentialist assumption, developed out of the debate referred to in footnote 4, see Lübbe (2009) and Lübbe (2015), Ch. 3–5.

[6] The point is developed, with detailed references to the health economics literature, in the overview article of Klonschinski and Lübbe (2011). The relevance of the rights/value distinction for judging the role which has been claimed for the QALY approach in the German debate on the evaluation of medical benefits and costs of drugs – a task with which Germany's official institution for Health Technology Assessment, the IQWiG ("Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen"), has been legally charged in 2007 – is set out in Lübbe (2011).

If this is true, the fairness objective cannot be integrated by manipulating the value of the units that are aggregated. This can be put into a third summary message:

> Equity weighting assumes that fairness can be integrated into cost-effectiveness analysis by manipulating the value of the units that are aggregated. If, however, the fairness problem rests within the additive mode of aggregation, the assumption is wrong. Additive interpersonal aggregation, weighted or not, might as such be incompatible with conceptualizing fairness adequately.

In order to discuss the acceptability of interpersonal addition in detail, one would have to go into the axiomatic basis of the addition theorems that have been presented within the welfare economic tradition. I do indeed believe that their axiomatic basis is untenable.[7] But these are topics that are discussed in other places.

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[7] In particular, the Sure Thing Principle, as applied to social choices, is not compatible with the demands of fair allocation. An argument to this effect, made originally by Peter Diamond (1967), was the starting point of John Broome's endeavors to develop a theory of fairness that could supplement axiomatic utilitarianism without destroying its basis in expected utility theory. See Broome (1984: 624): "It is a popular belief that there is merit in equalising people's utilities […]. The same belief is sometimes extended to *expected* utility too […]. If this is true it is profoundly important for welfare economics. It means […] that 'social' preferences do not obey the sure thing principle, which is generally taken to be an essential requirement of rationality." Broome here acknowledges the force of the objection that Diamond (1967) brings forward against John Harsanyi's (1955) addition theorem; see also Broome (1991:110–117). For discussion, see, among others, Verbeek (2001), Risse (2002), Stefánsson (2015), Lübbe (2015), Ch. 4–5.

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The Trade-Off Metaphor in Priority Setting: A Comment on Lübbe and Daniels

Andrea Klonschinski

1 Introduction

One merit of a compendium such as the present one lies in its potential to encompass different perspectives on a subject. It has the capacity to mirror the complexity of the topic, thus enabling the reader to evaluate the diverse arguments presented and to draw her own conclusions. This is not to say that she or he may not appreciate a little assistance in this process. Providing this help with regard to the contributions of Weyma Lübbe and Norman Daniels to this volume is the aim of the present paper. More precisely, it seeks to strengthen and complement Lübbe's (see chapter "Social Value Maximization and the Multiple Goals Assumption: Is Priority Setting a Maximizing Task at All?") critique of the "multiple goals assumption" in healthcare resource allocation – i.e., the idea that health policy has at least two goals: fostering efficiency and distributing resources fairly – and to establish a connection between her considerations and Daniels' (see chapter "Accountability for Reasonableness and Priority Setting in Health") account. That being said, the paper is also accessible and worth reading for those readers who are unfamiliar with the papers by Lübbe and Daniels, because, first, the latter's relevant aspects will be summarized and, second, the paper makes some general points and provides a relevant contribution to the priority setting debate on its own.

The argument proceeds as follows. After summarizing Lübbe's main arguments, the paper's first part emphasizes that her objections not only apply to a specific health economic discourse but have indeed a much broader scope as they ultimately tackle the economic conception of choices as such. While this notion permeates the literature on priority setting to a large extent, its normative content remains largely unreflected. I surmise that this is because the economic conception of choice is embodied in and carried by so-called "dead metaphors," the metaphorical character

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_6

of which is no longer recognized. The most important dead metaphor in the present context is the notion of choices as *trade-offs* in general and the idea of an *equity-efficiency trade-off* in particular. The claim that the equity-efficiency trade-off indeed constitutes a metaphor, and a misleading one at that, is illuminated by tracing its origins in hedonic consumer choice theory and by carving out the implicit premises on the items to be traded off against each other.

Against the background of these considerations, the paper's second part turns to Daniels' (see chapter "Accountability for Reasonableness") contribution. While he agrees that medical resource allocation on the basis of economic evaluations, such as cost-utility analysis (CUA), leads to ethically untenable results, he is not willing to drop them altogether.[1] Quite to the contrary, Daniels argues that efficiency is a relevant consideration but that other concerns are to be taken into account as well. That is to say, he adopts the multiple goals assumption and, as I will show, the economic conception of choices as trade-offs. Considering the different instances of reasonable ethical disagreement in priority setting given by Daniels, I demonstrate in how far Lübbe's objections can be applied in each case. Thereby, it turns out that Daniels does not coherently stick to a value-maximizing paradigm but also appeals to concerns for fairness stemming from other normative frameworks. Since it seems as if Daniels himself does not realize that he is in fact invoking different frameworks connected with nontrivial assumptions (see chapter "Social Value Maximization"), I take it that his paper constitutes a prime example for the subtle and by now pervasive influence of the "dead" trade-off metaphor on the priority setting discourse. These findings bear implications for his *accountability for reasonableness* approach. First, the examples for reasonable ethical disagreements Daniels offers may not be so "reasonable" after all. That is to say, the disagreements do not mark the end of all possible normative-ethical discourse on the matter but indeed show that more theoretical-conceptual work is required. Therefore, second, a turn to procedural justice in form of a deliberative decision-making process is both premature and unlikely to solve the fairness problems mentioned. These results are of practical relevance, as an example of decision-making in priority setting in Mexico illustrates.

2 On the Scope of Lübbe's Critique: Choices as Trade-Offs

In her contribution to this volume, Lübbe (see chapter "Social Value Maximization") challenges the view that the task of allocating medical resources can be considered as a *trade-off* between the two goals of efficiency and fairness – the so-called multiple goals assumption. She points out that this conception rests on substantive, yet unjustified, assumptions on the issue at stake (ibid.). For one thing, the trade-off notion presupposes that both efficiency and fairness can be regarded as independent goals, each desirable for its own sake. For another, it takes for granted that these

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[1] Note that Daniels uses the term cost-effectiveness analysis (CEA) to refer to the method of health economic evaluation called CUA in this paper.

aims' normative foundations are compatible with each other. Lübbe argues that these assumptions are mistaken since efficiency is in fact no independent goal of health policy and it cannot be consistently amended by complementing it with countervailing concerns for "fairness." At this point, it deserves to be emphasized that the goal of efficiency itself is generally adopted for decidedly normative-ethical reasons in the literature. To give an example, maximizing health in terms of *quality-adjusted life-years* (QALYs) is regarded as being "in line with a particular egalitarian view that everybody's health should be valued equally" (Tsuchiya 2012: 407). Thus, QALY maximization is supposed to have a "strong nondiscriminatory flavor" (Williams 1988: 117). Non-efficient allocations violate this basic "egalitarianism" and since they neglect the opportunity costs of a certain allocation of resources, they are said to be utterly *unfair*. Hence, the alleged equity-efficiency trade-off actually amounts to a conflict between different *conceptions of justice*.[2] Framing the matter in this way stresses the appropriateness of Lübbe's claim that the respective aims' normative foundations may not be commensurable to begin with (see chapter "Social Value Maximization").

Lübbe exemplifies her fundamental argument using the example of the *equity weighting* approach in health economics. As is well known by now, both resource allocations seeking to maximize overall benefits from a so-called social perspective and distributions focusing on QALY maximization lead to serious fairness problems (see chapter "Social Value Maximization"). Health economists have hence tried to integrate concerns for fairness into economic evaluations by means of attaching equity weights to QALYs. Maximizing weighted QALYs, so the idea, would then maximize the *social value* of a resource allocation, taking into account efficiency and fairness at once. Lübbe (ibid.) avers that the weighting approach is not promising since it is based on the implausible assumption that respondents' answers in hypothetical rationing decisions express their "valuation" of the alternatives at stake. In her view, it is much more reasonable to understand distributive decisions in terms of the patients' rights and claims. Then, however, the weights do not capture the reasons behind the choices. In effect, modelling equity weights on the basis of hypothetical prioritization decisions amounts to nothing but "playing around with figures" (ibid.).[3] Lübbe concludes that it is "value-maximization by additive interpersonal aggregation *as such* [that] involves a fairness problem" so that a satisfying consideration of priority setting requires for substituting the value-oriented framework for a paradigm based on the patients' rights and claims (ibid.).[4] Therefore, regarding efficiency as a desirable goal on its own is misguided, and the multiple goals assumption has to be abandoned.

The fact that Lübbe makes use a lot of technical concepts, such as QALYs, equity weights, and social value, might evoke the impression that her critique is confined

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[2] See Schmidt (1994: 48) and Schefczyk/Priddat (2000: 459).

[3] Empirical evidence for this claim is provided by Klonschinski (2013, 2014, and forthcoming). A thoroughgoing analysis of the weighting approaches with reference to the history of economic theory and current issues of moral philosophy is offered by Klonschinski (forthcoming).

[4] Italics added.

to a very particular, health economic discourse on priority setting. In fact, however, her considerations have a much broader scope and ultimately refer to the economic conception of individual decision-making.[5] This conception is embodied in and carried by powerful metaphorical concepts, first and foremost the "trade-off" notion, which permeate the current priority setting debate to a large extent. In fact, it does not seem a stretch to consider the trade-off concept as one of the cornerstones of economics, as the following phrase confirms:

> The discipline is premised on the notion that *every decision* made by a consumer, producer, bureaucrat or politician involves some kind of *trade-off* between the different bundles of attributes that make up each choice. *Implicit trade-offs* can be revealed from decisions made by policy-makers in the public sector, e.g. how the benefits from additional education are *weighed* against the benefits from using those resources to reduce the risk of death or serious injury. By studying such choices, it is possible to infer the implied *value* of different goods […]. (Dolan 2001: 46; Italics added)

The quotation shows that there is a close conceptual connection between the trade-off notion, the concept of "weights," and the "implied value" of the different goods at stake. In economic theory, the latter amounts to the so-called opportunity cost of a decision. That is to say, "the value of a particular choice is revealed by what we are prepared to give up [i.e., to sacrifice] in order to make that choice" (Ryan et al. 2006: 405). Note that this is the rationale behind the approach of attaching equity weights to QALYs as well: the weights are supposed to mirror the "sacrifice to efficiency" it is "worth making to achieve a particular improvement in equity" (Williams/Cookson 2006: 6). By now, this conception of choices as trade-offs is commonly regarded as being "in the very nature of things" (McPherson 1987: 45). And yet, it is by no means in the nature of things but rather in the nature of a particular theoretical approach. As demonstrated more extensively elsewhere, it originates in hedonic consumer choice theory or, more precisely, the indifference curve analysis of consumption choices.[6] A brief consideration of this approach illustrates the decidedly *metaphorical* character of the trade-off notion in health-care resource allocation.

Indifference curve analysis goes back to the end of the nineteenth century but did not gain widespread popularity until the so-called ordinal revolution in the 1930s, during which economists sought to eschew all normative, value-laden concepts from the realm of economic analysis (see Davis 1990: 141ff.). This cataclysm especially affected utility theory. Before, "utility" had been regarded as denoting the amount of satisfaction a consumer derives from purchasing a good. Differences in utility numbers were taken to denote differences in the amount of satisfaction, and within welfare economics, these amounts were commonly assumed to be interpersonally comparable. But since psychological states could not be witnessed, this conception now became regarded as utterly unscientific.[7] It was in this context that the indifference curve analysis gained currency. They have an edge over the

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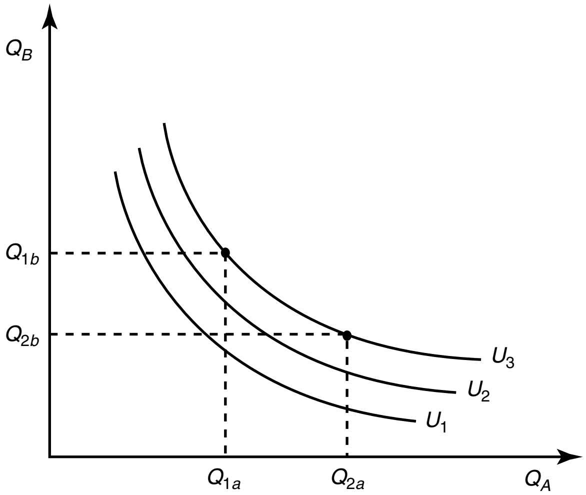
[5] On the relevance of her considerations for the fundamental debate on consequentialism, see Lübbe (2015).

[6] See Klonschinski (2013, 2014, and forthcoming).

[7] The seminal reference here is Robbins (1935), who maintains that there "is no means of testing the magnitude of A's satisfaction as compared with B's", so that interpersonal comparisons of util-

Fig. 1 Indifference curves



formerly used utility functions in so far as they mirror combinations of goods between which an individual *expresses* indifference and, hence, rely on observable data only. Indifference curves can be represented geometrically as follows (Fig. 1):

The curves in the figure could, for instance, epitomize combinations of the number of apples (Q_B) and oranges (Q_A). The respective individual would be indifferent between receiving the combination of Q_{1b} apples and Q_{1a} oranges and a bundle containing Q_{2b} apples and Q_{2a} oranges. The shape of the curvatures directly illustrates the opportunity costs of receiving one more unit of good A in terms of the quantity of good B. Note that the curves can be regarded as embodying a literal trade-off: "The object of the [indifference] map is to demonstrate what quantities of X and Y our consumer will purchase of we give him a certain quantity of Y and then let him trade X for Y at a given price" (Little 1957: 17).

Evidently, the indifference curve analysis and the trade-off notion are tightly connected with each other. In fact, the originator of the *equity-efficiency trade-off* in terms of value, the political philosopher Brian Barry (1965), explicitly took the indifference curve analysis of consumers' choices as a blueprint for his considerations.[8] He regarded the microeconomic analysis of individual consumption choices as particularly apt for analyzing the evaluation of social states in cases when the

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ity are "essentially normative", begging a "great metaphysical question", and, hence, fall "outside the scope of any positive science" (Robbins 1935: 140, 137, 139).

[8] See Le Grand (1990: 555f., 559), Lukes (1996: 41), and Schefczyk/Priddat (2000: 431). In contrast to the trade-off in terms of value, the equity-efficiency trade-off in terms of production refers to the "productive capacities" of social or economic system to bring about different combinations of efficiency (for instance, in terms of the GDP or QALYs) and equity (for instance, in terms of the formers' equal distribution). The idea that each economy indeed faces an empirical trade-off between equity and efficiency was famously put forward by Okun (1975). The equity-efficiency trade-off in terms of value was taken up from Barry by John Rawls (1971: 37f.) and rapidly entered public discourse so that in the midst of the 1980s, it was already widely used, as McPherson (1987: 44) reports: "'Trade-off' is a fairly recent addition to the English language but it is now in common use in business and labour circles and by economists, politicians, and political commentators."

evaluation criteria conflict. For even when different criteria, such as equity and efficiency, were not reducible to a third one, they could be "expected to be to some extent substitutable for one another" (Barry 1965: 6). That is, the "goodness of a state of affairs" to be evaluated is "not a quantity to which efficiency and equity contribute but merely a shorthand expression for the total set of the man's indifference curves expressing the trade-offs between equity and efficiency which would leave him equally satisfied" (Barry 1965: 7). Now, it has become "almost a truism" for economists and political scientists that "equity-efficiency trade-offs prevail in virtually all areas of social policy" (Schmidt 1994: 45).[9]

But do they? As Lübbe (see chapter "Social Value Maximization") pointed out, the trade-off notion bears substantial assumptions on the goods to be traded off against each other. Complementing her considerations, it can be said that the items at stake have to fulfill at least the following four premises. First, they have to be characterizable as separate goals, each desirable on its own account.[10] Second, these goals cannot both be reached to full extent, but are, at least after a certain point, conflicting with each other, making an "either…or"-choice inevitable.[11] Third, the items are comparable according to some common standard and, fourth, the individual's choices reveal her relative valuations of the goods at stake.[12] The third aspect may seem puzzling at first glance, given that Barry (1965: 4f.) endorsed the indifference curve analysis precisely for the reason that it does *not* need a "common yardstick" for evaluating states of affairs. And yet, speaking with Lukes (1996: 41), trade-offs occur when one good "is exchanged for another because they are taken to be equal in value." Assessing this equality in value would certainly be impossible if the goods in question were completely incommensurable to begin with. The very notions of "relative valuation" and "indifference," that is, in fact require for a common benchmark. A closer look reveals that even Barry himself makes use of such a measure in the quote above when he refers to the *satisfaction* yielded by a certain combination of equity and efficiency (see Barry 1965: 7).[13] Summing it up, the trade-off notion presupposes that the goods at stake are "discrete, free-standing, and independently characterizable values the extent of whose realization can in any case be measured according to some scale which enables the agent engaged in evaluation to express a preference between such "extents" or else indifference between them" (Lukes 1996: 40).

In the case of ordinary consumption goods, it seems generally reasonable to take these assumptions as given.[14] Sticking to the example given above, both apples and oranges can be considered as independent goods, desirable for their own sake, and, given stable preferences and rational choice behavior, a series of choices between different bundles of apples and oranges allows for deducing the individuals' relative valuation of these edibles. Furthermore, taking a budget restriction into account, the consumer cannot have any amount he wishes of each but has to allocate his resources

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[9] See also Lukes (1996: 36).

[10] See Le Grand (1990: 555) and Lübbe (see chapter "Social Value Maximization").

[11] See Barry (1965: 7), Okun (1975: 1), and Le Grand (1990: 564).

[12] See Sassi et al. (2001: 20).

[13] Indeed, indifference curve analysis of consumer choices cannot be understood without reference to a hedonistic quantitative entity such as pleasure or satisfaction at all. See Giocoli (2003: 95).

[14] I disregard special cases such as perfect substitutes or complementary goods here.

to the purchase of a certain number of apples and oranges, respectively. Lastly, as a measure according to which the consumer makes his valuations, he could use the fruits' taste of their nutritional value.

The crucial question in the present context certainly is whether the enumerated premises are also met when it comes to distributive choices in health-care resource allocation. As it turns out, the alleged equity-efficiency trade-off fulfills none of the assumptions. To begin with, efficiency and equity do not constitute separate goals, each "valuable" for its own sake, as Lübbe (see chapter "Social Value Maximization") points out. Since fairness, based on a framework of rights, can reasonably be considered the one and only goal of health policy, there is no need to strive a trade-off with efficiency in the first place (ibid.). Also, the assumption that the respondents' hypothetical rationing choices in empirical surveys mirror their relative valuation of the alternatives is beside the point – both empirically and conceptually (ibid.). Finally, it remains unclear according to which common standard equity and efficiency are to be traded off against each other. At any rate, the hedonic concepts used within indifference curve analysis, such as pleasure or satisfaction, are no plausible candidates. The only reasonable understanding of the required benchmark seems to be an interpretation in terms of justice. Still, this makes little sense if the trade-off as such already seeks to combine the goals of efficiency on the one hand and concerns for equity on the other. This conceptual issue points to the inappropriateness of transferring the trade-off notion from individual choices to the evaluation of states of affairs.

In sum, the trade-off notion and associated concepts such as "relative values" or "sacrifices" have their original place in the hedonic consumer choice framework of economics. Hence, their use is not normatively neutral but, *nolens volens*, invokes substantive premises as to the nature of choices and the characteristics of the alternatives at stake. To put it pointedly, transferring the conception of choices as trade-offs to all kinds of choices whatsoever rests on the tacit assumption "that the market provides an appropriate model for understanding decision-making" (Lukes 1996: 37). The normative content carried by the trade-off notion and related concepts remains largely unreflected in the literature because their origin and, therefore, their genuinely metaphorical character are no longer recognized – they have become dead metaphors.[15] To complicate the matter further, the terms "trade-off," "value," and "weighting" are also commonly used in a loose sense in the vernacular, when people "value" friendship or "weigh" reasons for and against a certain decision. In the academic debate on priority setting, however, the concepts are partly used in a quotidian manner *and* partly in a less innocuous way.[16] This leads to serious conceptual ambiguity, as the following section illustrates.

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[15] On dead metaphors, see Henderson (1998: 293).

[16] Papers entitled *Toward a broader view of values* (Menzel et al. 1999) or phrases like "Our goal should be to capture the most important values that will affect most people" (Ubel et al. 2000: 900) suggest the quotidian meaning of "values" in terms of highly valued items or ideals. In doing so, they invoke the impression that these terms and, hence, their approach were normatively harmless. That being said, the quoted papers continue using the term "value" in a more specific, decidedly normative sense and assume that concerns for equity can indeed be represented in terms of stable and consistent "values."

3 Reasonable Disagreement on Multiple Goals in Priority Setting?

Having reinforced and complemented Lübbe's (ibid.) assessment of the multiple goals assumption and the value-maximizing framework of health-care resource allocation, the present section turns to Daniels' (see chapter "Accountability for Reasonableness") contribution to this volume. His general concern is to lay down criteria a decision process has to fulfill in order to lead to fair and legitimate priority setting decisions. Daniels (ibid.) maintains that such a procedural approach of justice is required in view of deep disagreements about how to allocate medical resources. These pragmatic disagreements are pervasive, he argues, since they rest on reasonable ethical disagreements. In the following, some of the examples for such disagreements given by Daniels will be reviewed in order to demonstrate that he partly makes use of the economic conception of choices as trade-offs and the multiple goals assumption, so that Lübbe's critique can be applied.[17] These findings bear implications for the qualification of the respective disagreements as "reasonable" and "pervasive" on the one hand and for the proposed necessity of turning toward a procedural account of justice on the other.

Although Daniels (see chapter "Accountability for Reasonableness") categorizes them differently, the examples he provides for the pervasive disagreement as to how priorities should be set ultimately all boil down to conflicts between the goal of maximizing aggregate population health on the one hand and certain concerns for fairness on the other. This becomes especially evident in the first issue presented:

> To see the pervasiveness of reasonable ethical disagreement about resource allocation, consider the *two main goals* of health policy to improve population health in the aggregate and to reduce unjust health inequalities. These goals sometimes converge and sometimes they are in tension. When they are in tension, reasonable people will differ about how much they are *willing to give up* improvements in aggregate population health to achieve a reduction in health inequalities they believe are unjust. (ibid.; Italics added)

In this passage, Daniels evidently adopts the multiple goals assumption. Beyond that, he frames the problem of resource allocation implicitly as a trade-off between efficiency and equality when he refers to the amount of health people would be "willing to give up" (see chapter "Accountability for Reasonableness") for the sake of reducing inequalities.[18] The quotation thus already indicates that Daniels regards efficiency in terms of the overall sum of health as a relevant goal of health policy. Indeed, he explicitly regards efficiency as "an ethical consideration" of its own

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[17] As Daniels' (see chapter "Accountability for Reasonableness") discussion of the fairness problems is quite short, the analysis is complemented by referring to two other publications of his.

[18] Likewise, he states that achieving a more equitable distribution of health "is sometimes worth *sacrificing* some maximization of population health" (see chapter "Accountability for Reasonableness"; italics added).

accord “since more needs can be met per resource invested” (ibid.).[19] While providing information to this respect constitutes the “virtue” of economic evaluation, their problem is “that it matters to many who gets the benefit” (ibid.). Accordingly, Daniels does not seek to abandon economic evaluations entirely, even though they are facing serious fairness problems. Instead, he argues that since CUA cannot account for a wide range of “reasonable” concerns for fairness, it should not be regarded “as an algorithm for making decisions”; rather, its results ought to serve “as an input to a decision-making process” (ibid.).[20] To be sure, this is exactly the conception Lübbe (see chapter “Social Value Maximization”) explicitly rejects right at the outset as being highly implausible: no decision-maker in her “right mind would agree that one of her health policy goals, fairness, would be perfectly achieved if all patients were dead, but that she does not agree to letting all people die because her health policy follows yet another goal: that the system be efficient.”

As a further sign for the ubiquity of reasonable ethical disagreement, Daniels (see chapter “Accountability for Reasonableness”) enlists three “pervasive ‘unresolved’ rationing problems” connected with CUA: best outcomes vs. fair chances, aggregation, and priority to the worst off. The priority problem consists in the fact that “CEA gives no priority to those who are worst off whereas most people want to give some priority […] to them, *thinking there is more value* to giving a benefit to someone worse off than giving an equal benefit to someone better off” (ibid.).[21] This quotation neatly reveals the economic conception of individual choice delineated above. Although Daniels does not endorse equity weighting as a measure of solving CUA’s fairness issue, he apparently believes that people’s answers to prioritization questions reveal their relative valuation of the alternatives – a prime example for foisting a certain preconception on the subjects, as Lübbe (see chapter “Social Value Maximization”) puts it. That being said, it is doubtable whether Daniels really thinks of distributive choices in this way. Indeed, he does not stick to the value-oriented framework throughout his paper, as his description of the other two unresolved issues elucidates.

To begin with, the best outcomes vs. fair chances problem denotes the issue that while allocating resource on the basis of CUA always leads to the “best outcome” in terms of the maximum sum of health realized, it is commonly regarded a requirement of justice that each patient should have a fair chance of benefitting from health-care resource allocation. In another publication, Daniels (1993: 227) illustrates this conflict using the following example: a treatment T_1 saves the lives of patients in group G_1, but does not restore a particular function, leaving them, say, unable to walk. Another treatment T_2 preserves the lives of patients in group G_2 and also enables them to walk. CUA unambiguously favors T_2 because it generates more

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[19] Recall the considerations on efficiency as a decidedly normative-ethical goal above.

[20] To be precise, in the quoted passage, Daniels refers to the way the WHO consulting group has handled the issue. Yet, on the basis of other utterances, it seems safe to assume that he endorses this view himself as well (see chapter “Accountability for Reasonableness”).

[21] Italics added.

health, thereby denying the persons in G_1 any chance of being treated. Neither this "best outcome" option nor giving everyone an equal chance of treatment seems entirely fair to Daniels (see ibid.). Interestingly, a similar example is also used by Lübbe (see chapter "Social Value Maximization"), who considers the issue of disability discrimination in the case of life-saving treatments. Other things equal, CUA always favors saving the life of a non-disabled person instead of saving the life of a disabled person since in doing so, more health can be produced. Lübbe (ibid.) draws quite a different, less tentative inference from the case:

> It is a matter of moral common sense […] that a blind patient, other things equal, has the same right to get a transplant than a seeing patient. The question whether we produce as much value when we transplant the disabled, in other words, whether resources are used as efficiently if we do, is simply not relevant. Disabled have the same right to be treated, and that is it. *There is no trade-off with efficiency*.

Here, Lübbe emphasizes the categorical difference between normative frameworks focusing on the production of value on the one hand and on respect for each person's rights and claims on the other.[22] These paradigms cannot be consistently combined just like that. Instead, a decision has to be reached: *either* the cost-effectiveness of medical interventions serve as the basis for defining patients' entitlements *or* certain rights and claims restrict what counts as a legitimate "production of value" in the first place (Lübbe 2011: 111ff.). In Lübbe's view, the example of disability discrimination leads the way to unequivocally answering this question: since the aim of producing as much value as possible bears untenable ethical consequences, the value-oriented framework needs to be abandoned and priority setting has to be based on rights and claims instead.

Finally, the aggregation problem points to the question of whether very small benefits to a large group of patients should outweigh huge benefits to a few. Within value-maximizing frameworks and, hence, CUA, no limits are set on aggregation. To give an example, QALY maximization implies "that the benefit of providing ten people with a utility gain of 0.1 for the rest of their life (corresponding to sildenafil treatment for men with erectile dysfunction) is […] equivalent to saving the life of a single (otherwise healthy) person" (Schlander 2007: 537). Such a result is clearly inacceptable. Daniels (see chapter "Accountability for Reasonableness") thus avers that it seems fair to aggregate "some effects, not all of them" but recognizes that this stance can hardly be justified coherently by stating a certain principle. The reason for this is, again, that the aggregation problem results from the impingement of two incommensurable normative frameworks at once. If the generation of units of health matter normatively, as CUA presupposes, setting limits on aggregation cannot be consistently justified. Alternatively, if it is not relevant how many units of health are produced but *how persons are treated*, it is of pivotal importance that the units of health are generated in ways compatible with the demands of justice to treat everyone fairly in the first place.[23] Hence, any QALY

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[22] See, for instance, Lübbe (2005, 2009, 2011, and forthcoming).

[23] See Harris (1987) and Lübbe (2005, 2009, and 2011).

induced in ways violating individual rights and liberties or denying persons equal concern and respect does not count to begin with. This reasoning challenges the normative status of interpersonal aggregation as such and, again, renders the notion of an equity-efficiency trade-off notion pointless (see chapter "Social Value Maximization").

For Daniels (see chapter "Accountability for Reasonableness"), by contrast, the fairness problems enumerated confirm that "there is pervasive disagreement about resource allocation decisions, and this disagreement rests on reasonable ethical disagreement." In view of these substantive disagreements, he avers, it becomes necessary to turn to an account of procedural justice and to rely on a fair deliberative decision-process for priority setting (ibid.). A decision process is fair, in turn, when it satisfies the conditions of publicity, relevance, revisability, and enforcement, which together establish *accountability for reasonableness* (ibid.). And yet, this resort to procedural justice seems premature for the following reason. The previous reflections revealed that in the course of describing the rationing problems, Daniels invokes different conceptual frameworks. On the one hand, he acknowledges the normative dignity of efficiency (ibid.) and endorses the goal of improving "aggregate population health". He also makes use of the value-oriented concept of (prioritization) choices when he regards the task of priority setting as a trade-off between efficiency and concerns for equality and fairness, refers to necessary sacrifices in the form of health for the sake of equity, and couches the issue of giving priority to the worse-off in terms of relative valuations. On the other hand, he concedes that "we may accept come constraints on the resource allocation decisions that derive from considerations of justice", wants to rule out "discrimination against a particular gender or race", and applies decidedly non-consequentialist concepts such as "legitimate claims", "needs", and "fair chances".[24]

Juxtaposing these diverse concerns and proclaiming "reasonable ethical disagreement" at this point, however, are stopping halfway. As both Lübbe's contribution to this volume and the supplementary considerations in this paper illustrate, the fairness issues presented by Daniels embody the clash and, indeed, the incommensurability of different normative frameworks. Hence, they do not provide evidence for reasonable ethical disagreement but rather point to the need for more conceptual-theoretical work to be done. As Daniels does not seem to realize this fact – or at least does not regard it as important – I take it that his paper constitutes a prime example for the subtle and pervasive influence of "dead metaphors," first and foremost the trade-off notion. This claim is reinforced by the fact that he partly uses notions and phrases such as "relative weights" (ibid.) or "things people value" (ibid.) in a loose, quotidian manner of speaking. In the passages quoted above, however, the concepts used are by no means normatively innocuous. Therefore, both the categorically different concepts referred to by Daniels and their respective relationships to each other need to be subjected to a

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[24] As to the priority problem, Daniels (2008: 105) surmises in *Just Health* that one might be induced to give priority to the worse-off on the basis of "the fair equality of opportunity principle."

thoroughgoing conceptual analysis in order to spell out their normative bases and to query whether these bases can be combined consistently at all (see chapter "Social Value Maximization"). Before conceptual clarity on these matters is reached, it cannot be assumed that any deliberative process will be able to solve the "unresolved" problems enlisted by Daniels. Quite to the contrary, it is likely that similar problems will reappear again in the course of the deliberative exercise. This claim shall be buttressed by briefly considering an attempt to actually apply Daniels' *accountability for reasonableness* approach in Mexico (see Daniels 2008: 291ff.).

In 2003, the Mexican government passed a law establishing a national health reform, the *Seguro Popular*, in order to offer health insurance to half of Mexico's population. The crucial question certainly was which conditions ought to be covered in the insurance scheme. In 2006, Daniels conducted a few workshops on decision-making in health care with key personnel from the *Ministry of Health* and the *Seguro Popular*. He reports that in the course of the first workshops, it was suggested that four groups should be involved in the decision-making process:

> A clinical group would provide important information about the clinical course of the disease and the effectiveness of treatments. An economic group would provide information on the costs and cost-effectiveness of the treatments. Since conformance with ethical norms and social acceptability were *also* criteria mentioned in the law, an ethics working group, […] and a social acceptability working group would contribute to the deliberative process. (Daniels 2008: 293; Italics added)

Initially, each of the groups was supposed to rate the different conditions on an ordinal scale from 0 to 5 according to some self-selected criteria. Yet, it turned out that "the two groups assessing values, the ethics group and the social acceptability group" could not quantify their deliberations' results in the required manner (Daniels 2008: 294). Hence, the process was amended to the extent that the clinical and economics group would evaluate the interventions on the basis of criteria such as prevalence, seriousness, and cost-effectiveness and the "ethics group would then base its analysis of the ethical issues on this information" (ibid.). Finally, their results would be assessed by the social acceptability group.

Against the background of the previous considerations, it is especially striking that this decision-process clearly distinguishes between economic concerns on the one hand and ethical concerns on the other. While the ethics group is supposed to assess "values" and to give "normative inputs," the task of the economics group is presented as a purely positive analysis. Crucially, by proposing that the ethics group shall evaluate the information provided by the economic group, it is tacitly assumed, first, that cost-effectiveness is of independent normative relevance and, second, that this criterion can be adjusted by considering other concerns for fairness afterwards. It thus becomes obvious that the conceptual problems arising in a discussion of what a substantial account of justice requires in priority setting are carried over to the procedural account of deliberative decision-making.[25] As a consequence, the latter does not provide a solution to the alleged "pervasive disagreements" but merely reiterates the underlying problems on another level. To make it worse, delegating the allegedly "separate" concerns of efficiency and fairness to different deliberative groups does not foster the required conceptual inquiry but is likely to reinforce the unreflected persistence on the respective framework in the different groups, instead.[26]

Conclusion

This paper sought, first, to strengthen and to complement Lübbe's (see chapter "Social Value Maximization") critique of the multiple goals assumption in health-care resource allocation and, second, to show that her objections apply to Daniels' (see chapter "Accountability for Reasonableness") contribution to this volume. The observation that Daniels does not seem to realize – or is not interested in the fact – that he is invoking different and incommensurable normative-framework at once, I argued, resembles a widespread phenomenon in the current debate on priority setting, which can in part be explained with the ubiquity of "dead metaphors." Ultimately, the considerations provided in this paper boil down to a plea for paying more attention to conceptual issues in the debate on priority setting in general and to the pivotal and subtle influence of (dead) metaphors in particular. Without conceptual clarity, neither substantive agreement on just principles for priority setting nor a pervasive "agreement to disagree" can be reached.

Acknowledgments I want to thank Daniel Quanz for helpful comments on an earlier version of this paper.

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[25] The criticism that Daniels assumes reasonable ethical disagreement far too soon and that the turn to deliberative methods is thus premature has also been raised by other authors. See, for instance, Powers/Faden (2006: 181) and Holm (2009). The question of whether Daniels' accountability for reasonableness approach indeed constitutes an account of procedural justice is discussed by Rid (2009).

[26] Although Daniels (see chapter "Accountability for Reasonableness") is not particularly clear as to how exactly his accountability for reasonableness account is supposed to contribute to health technology assessment (HTA), it seems as if the Mexican example can serve as a blueprint here. As far as I understand it, he basically argues that HTA should be expanded in order to include "broader ethical concerns" (ibid.). Together with other relevant concerns, such as safety, efficacy, cost-effectiveness, and affordability, these ethical concerns should then be subject to a fair deliberative process. The critical remarks in the main body thus apply to this approach as well.

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Part III

International Experiences: Normative Basis and Process of Priority Setting

Prioritisation: (At Least) Two Normative Cultures

Heiner Raspe

1 Introduction

This chapter describes and analyses a limited range of international models (essentially representing two types) of prioritisation in medicine and their normative bases. It separates artificially and for analytic purposes what in reality shows overlap and includes elements of the other.

Two models (from Oregon and England) present typical though differing examples from the Anglophone world; the other two (Norway, Sweden) represent the Scandinavian approach. I will not deal with procedural and organisational aspects of prioritisation and *their* normative bases. It is yet to be proved that our society is already so diverse and fragmented that we cannot find one or more common moral denominators and therefore have to rely mainly on procedural justice and arrangements, for instance, on what Daniels and Sabin (2008) proposed as the 'accountability for reasonableness' – or A4R-concept (see also chapter "Accountability for Reasonableness and Priority Setting in Health").

2 Four Models of Prioritisation

Though – to my knowledge – the earliest publications on 'priorities in medicine' are from England (Butterfield 1968; Godber 1970) and Denmark (Pornak et al. 2011; Pornak und Raspe 2015), Norway was the first country worldwide that considered prioritisation in healthcare in an organised way and on a national level.

According to Inge Lønning, Professor of Theology at Oslo University, everything started with a telephone call in early 1985 (Raspe und Meyer 2012), when

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_7

then Norwegian Minister for Social Affairs invited him to lead a multidisciplinary commission and prepare ‘Guidelines for prioritizations in the Norwegian Health Service’ (Norwegian Ministry of Health and Social Affairs 1987). The ‘Lønning I-Committee’ was followed by a second one called into existence to revisit and improve upon the first report (Norwegian Ministry of Health and Social Affairs 1997; ‘Lønning II’). In 2014, a third government commission, led by Ole F. Norheim, an internist and medical ethicist from Bergen, published again a report ‘Åpent og rettferdig – prioriteringer I helsetjenesten/Open and fair – Priorities in Health Care’ (Helse- og Omsorgsdepartementet 2014, see also chapter “Recent Developments on the Issue of Health-Care Priority Setting in Norway”).

Oregon entered the stage in 1989 and Sweden in 1992.

During this period, in England, discussion was mainly centred on ‘rationing’ of healthcare services. Prioritisation or priority settings were terms understood as synonyms or even euphemisms for rationing. Since about 2005, the situation in England has changed considerably, and after budget cuts (2010) and the introduction of Clinical Commissioning Groups (CCGs, in 2013), there have been even greater changes. CCGs are clinically led organisations and replaced the former Primary Care Trusts (PCTs) assuming responsibility for strategic planning and commissioning of healthcare for regional patients and designated populations. They are dominated by general practitioners but include nurses and other professionals as well. To give their deliberations and decision a sound moral basis, many CCGs from all over England developed or adopted ‘ethical frameworks’. All of them referred in one way or another to ‘priority setting’ and/or ‘prioritisation’. In effect, these terms, clothed with a mantle of respectability by having moral underpinnings, replaced ‘rationing’, an expression abhorrent to many in the context of healthcare.

2.1 Norway

But back to Norway in 1987, The Guidelines of the first Lønning Committee were to be based ‘on generally-accepted values in the Norwegian Society’ (Norwegian Ministry of Health and Social Affairs 1987:23:4) to recall, express and affirm the then valid national morality. Explicitly mentioned were the ‘ideals … justice, equality and liberty’ and ‘the generally accepted social responsibility for socially-deprived and under-privileged individuals’.

Within this context, ‘five principles or dimensions for prioritisation’ were emphasised: ‘the gravity of the health state’ (‘particularly important’), ‘improved efficiency’ (‘most important’ together with ‘gravity’), ‘equality … same opportunity to be as healthy as their condition permits’, ‘health economics … enhancement of productivity at a population level … financial aspects in the treatment of patients at a primary level’ and ‘largely no … (to the question) whether self-inflicted damage to health should have consequences for the prioritization of individual patients’.

Over the next decade, the 1987 Guidelines couched in rather vague and tentative language became clearer and more focused. The number of criteria was reduced to three: gravity, clinical effectiveness and cost-efficiency (Norwegian Ministry of Health and Social Affairs 1997:18:5). Most recently (cf. Helse- og Omsorgsdepartementet 2014), three slightly different criteria were formulated to reach 'as much good life years as possible for all, fairly distributed' (translation HR): health and welfare gain, resource use and past and future health loss over the entire lifespan. The last is meant to replace and extend the former gravity/severity criterion within the context of the 'worse off principle' or 'prioritarianism' (Ottersen et al. 2014). It gives persons and services for persons with severe clinical conditions extra priority even at the expense of efficiency losses.

All three commissions delved deeply into the ethical questions underlying prioritisation issues in healthcare before arriving at their respective guidelines. Nationwide prioritisation without ethical foundation in accord with the national morality ('common set of values'; Mørland et al. 2010) seemed in Norway to be unthinkable.

2.2 Sweden

Though we could not find many explicit Swedish references to the Norwegian approach to prioritisation (already in place in 1987), it seems to have served as a model for Sweden. Inge Lønning told us (Raspe und Meyer 2012) that in the late 1980s, he was more often invited to address Swedish than Norwegian audiences.

Three Swedish documents are of particular relevance: the final report of the Swedish Parliamentary Priorities Commission of 1995 (Swedish Ministry of Health and Social Affairs 1995:5), an act of the Swedish Parliament of April 1997 based on the government's proposition ('Priorities in Health- and Sick-Care'; www.riksdagen.se/sv/Dokument-Lagar/Utskottens-dokument/Betankanden/199697Prioriteringar-inom-hal_GK01SoU14/10.2.2015) and the more recent publication of the 'National Model for Transparent Prioritisation in the Swedish Health Care' (Broqvist et al. 2011).

The model was and still is the basis for the development of an advisory tool in the form of a new type of prioritisation guidelines intended to support the management and governance of healthcare within the country. They primarily address persons and institutions at a level above the clinical microworld. As shown in a recent PowerPoint presentation, their goals are 'support for the allocation of resources, basis for organisational decisions, support for clinical ('behandling') treatment decisions, and contribution to local or regional health care programmes and routines' (www.socialstyrelsen.se/riktlinjer/nationellariktlinjer/nationella-riktlinjer-hjartsjukvard/10.2.2015, translation HR).

Extensive deliberations within the Parliamentary Commission led to the identification of three ethical principles, explicitly in 'ranking order' and related to a 'humanist view of man – rooted in Christian values – in the welfare society' (Swedish Ministry of Health and Social Affairs 1995:5:97, 104, 30). These are human dignity, need and solidarity and cost-efficiency. Based on this 'ethical platform', four prioritisation criteria were chosen, namely, present and future (not past!) severity of the clinical condition of interest (clinical perspective), patient (net) benefit due to the medical intervention (clinical perspective), cost per effect (societal perspective) and, as a meta-criterion, quality of the evidence for each of the foregoing criteria (scientific rationality perspective).

The most relevant criterion was and still is the severity of the patients' clinical state: 'It is only the severity level that is assessed independently of patient benefit and cost effectiveness' (Broqvist et al. 2011:27). This can be seen as a logical consequence of the central position of the 'needs and solidarity' principle in the Swedish approach. In 1997, the Riksdag accepted an extension of § 2 of the Swedish health law: 'Those who have the greatest need for health- and sick-care shall be given precedence'.

In 2009, the Swedish Council on Medical Ethics rejected a proposal of the National Prioritisation Centre at Linköping to abandon the clear hierarchy of the three ethical principles in favour of a more flexible approach.

There has been a decade-long emphasis on patient autonomy, with the healthcare provider expected to educate the patient so that he can make informed choices but is not permitted to make decisions for the patient, thus respecting the patient's right to self-determination. With solidarity being considered as 'an emerging concept in bioethics' in general (Prainsack and Buyx 2011), there is a shift in emphasis, and the Swedish Parliamentary Commission explicitly addressed a tension between solidarity-based prioritisation and individual autonomy: 'Respect for autonomy and integrity is important, but there must be certain limits for autonomy if prioritisation is to be at all possible' (Swedish Ministry of Health and Social Affairs 1995:4:104).

2.3 Oregon

The extraordinary and independent position of the severity criterion is exceptional and differs from all Anglo-Saxon approaches I am aware of. Let us look at the Oregon model first as an example. The following Fig. 1 presents in brief the latest version of the Oregonian methodology to prioritise health services, or more precisely condition-treatment pairs (www.oregon.gov/oha/herc/Pages/Prioritization-Methodology.aspx/last update: 25.10.13/10.2.2015).

It proposes an algorithmic and computational 'technocratic' (Klein and Maybin 2012:10ff) solution – another marked difference to the Swedish model in which the ranking is explicitly to be based on a 'qualitative appraisal', i.e. on deliberation, judgement and consensus within a group of about 25 persons from various backgrounds, mostly medical.

Impact Health Life
+ Impact on suffering
Catetory Weight X
+ Population effects
+ Vulnerable of population affected
+ Tertiary prevention (categories 6 & 7 only)
× Effectiveness
× Need for Service

Fig. 1 Oregon's prioritisation methodology

The very first variable of the Oregon equation is the 'category weight' of different types of healthcare – with values from 100 (for 'maternity and newborn care') over 20 (for 'nonfatal conditions' such as closed fractures) to '1' (for 'inconsequential care'). The second variable addresses the question, 'what is the magnitude of the benefit to the patient from the treatment compared to no treatment for the condition after factoring in harms associated with the treatment', with values between 0 and 10, and only the third considers the question 'to what degree … the condition results in pain and suffering' for patients and family members with a value range from 0 to 5. The result of all calculations is a single value for all 669 entries of the Oregonian 'prioritized list of health services'. Higher scores indicate higher priorities. But more relevant than the relative position of a CIP is the question, is it above or below the so-called funding level (since 1.1.2015: between positions 476 and 477)? This decides whether an item is publicly funded or not.

It is hard to understand that this complex algorithm with composite variables and different value ranges results in more than 90 % of all assessments in solutions that reportedly do not require 'hand adjustment'. It seems to provide uncontested solutions quasi-automatically. Could it be that the algorithm grossly exaggerates the reliability and validity of all measurements and mathematical operations involved?

2.4 England

There is a flood of documents from England on 'ethical frameworks' for 'priority setting and resource allocation', 'decision-making', ' priority setting and decision-making' etc. Many of these frameworks are intended to guide the work of 'Clinical Commissioning Groups' (CCGs) with their responsibility for purchasing most regional health and care services within fixed budgets. Though the National Institute for Health and Care Excellence (NICE) has a nationwide influence, it determines only a small part of all medical services.

One prominent precursor of several CCG frameworks was the 'South Central Ethical Framework' in the development of which Christopher Newdick, Professor at the School of Law, University of Reading, was involved. Its traces can still be found in today's frameworks of, e.g. Portsmouth or the States of Guernsey (www.oxfordshireccg.nhs.uk/10.02.2015).

The South Central Ethical Framework puts forth seven points to consider (see Table 1):

There is no reference whatsoever to the severity of patients' conditions. Instead, the topmost criterion is 'evidence of clinical and cost effectiveness', the second 'equity'. The third criterion 'health care need and capacity to benefit' is explained as follows:

> Health care should be allocated justly and fairly according to need and capacity to benefit, such that the health of the population is maximised within the resources available. The Committees will consider the health needs of people and populations according to their capacity to benefit from health care interventions.

Table 1 Prioritisation criteria of the English 'South Central Ethical Framework'

Evidence of clinical and cost-effectiveness
Equity
Healthcare need and capacity to benefit
Cost of treatment and opportunity costs
Needs of the community
Policy drivers
Exceptional need (of patients in special circumstances)

There are two points about the South Central Ethical Framework to which attention must be drawn: The first goal of prioritisation is health maximisation, and the first determinant of health needs of people and populations is their capacity to benefit and not their clinical status. Maximisation must not be understood in an individualistic sense; the intended beneficiary is not the individual patient nor a certain patient group but the population as a whole, the 'public health'. This seems to be in accord with stated preferences of the English public (Shah and Devlin 2012) and with certain prioritisation methods, e.g. Programme Budgeting and Marginal Analysis (PBMA).

This concept can be visualised by a figure from the 'IMPRESS Guide to the relative value of COPD interventions' of July 2012 (www.impressresp.com/index.php?option=com_docman&task=doc_view&gid=52&Itemid=82/10.02.2015). It was developed by a group of scientists at the London School of Economics (LSE) and is supported by a Learning Report of The Health Foundation (2012) (www.health.org.uk/publications/looking-for-value-in-hard-times/10.02.2015).

Take smoking cessation programmes to treat COPD patients as an example. To whom should they be offered first? To reach a decision, one needs to consider three variables: prevalence of the health state of interest, average individual treatment benefit and costs per effect (see Figure 1 and 2 on page 10 of the guide).

It can be inferred from the scheme (Fig. 2) that priority for a certain service increases with the average individual capacity to benefit (*y*-axis) multiplied by the number of persons who benefit (*x*-axis) at low cost, i.e. with increasing size of the rectangle and decreasing size of the triangle.

If one considers that moderate to severe COPD has a lower prevalence than its mild variant, that average individual treatment benefit decreases with increasing severity, and this despite increasing cost, a potential for discrimination, becomes evident. If not balanced by, for example, a bonus for the clinically worst off, one might easily prioritise mild cases, which are more frequent, over the more severe but less prevalent ones in order to maximise overall health gain and efficiency.

This risk of discrimination evidently increases with the width of the aggregation. If sums, percentages, means, effect sizes etc. are calculated for separate homogenous patient or population subgroups (e.g. COPD patients with moderate disease), it virtually disappears. If on the other hand, the statistics cover huge and heterogeneous subpopulations (e.g. health of all lung patients, health of the public), the risk then is real, and discrimination becomes unavoidable.

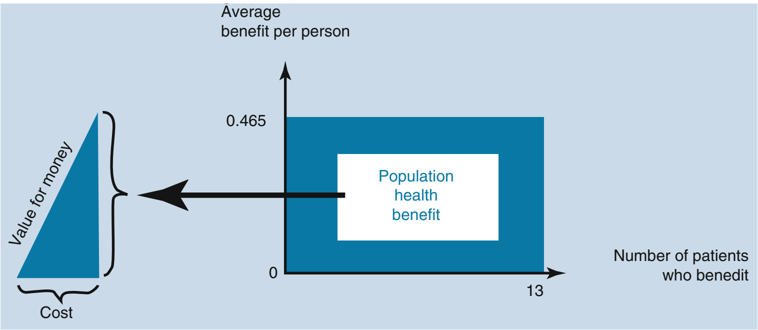

Fig. 2 Graphic representation of population health gain and cost-effectiveness of defined health services

3 'Clinical' Versus 'Social' Solidarity

It is exactly this risk against which the Swedish model tries to protect its population:

> … the Commission rejects a benefit principle implying that the choice prioritisation situations must fall on whatever confers the most benefit to the greatest number of people. In that case the benefit principle rests on the possibility of aggregating the benefit of care for many people with small needs in such a way as to counter balance great benefit to a small number. This can mean, for example, deciding to devote resources to helping a large number of people with mild hip disorders instead of a few with severe traffic injuries. The benefit principle in this sense is incompatible with the principle of need and solidarity. (Swedish Ministry of Health and Social Affairs 1995:5:109)

That this is not a statement from a romantic past can be shown by the following quotation from Broqvist et al. (2011:36):

> An important standpoint in the national model is that if conflicts arise between collective benefit and individual benefit, the collective benefit should never be given greater weight.

To my understanding, the two statements represent implications of the 'need and solidarity principle' of Riksdag's ethical platform.

The Swedish interpretation of solidarity seems to be in accord with clinical deontology. Every clinician 'instinctively' prioritises more severe cases over milder ones, except in mass accidents and similar triage situations where hopeless cases are first to be left without extensive medical care. Under virtually all other clinical circumstances, more severe cases are clearly given priority despite the inherent risk of various efficiencies and welfare losses.

Solidarity that focuses on individuals with certain common clinical characteristics may therefore be called 'clinical (or person-centred) solidarity'. It favours those patients who are clinically worst off and will never regain full health in spite of possibly expensive medical interventions. It will most likely violate the principle of health maximisation.

This type of solidarity is firmly anchored in different ways in the German and many other European societies: The German statutory health insurance, for instance, covering more than 80 % of the population, is expressly organised as 'Solidargemeinschaft' (solidary community). Furthermore, the principle of clinical solidarity is in keeping with the ethics of the main Christian churches and with stated preferences of the German people as evidenced by many population surveys (e.g. Raspe und Stumpf 2013). Solidarity has been identified as one of Europe's 'basic values' (Sedmak 2010).

Solidarity as understood in the English ethical framework mentioned earlier seems to refer to 'social solidarity' (see chapter "Rebalancing the Rationing Debate: Tackling the Tensions Between Individual and Community Rights"). A basic principle in this context is equity: 'The Committees believe that people should have access to health care on the basis of need' (South Central Ethical Framework 2008:3), with healthcare need usually defined as 'a health problem which can be addressed by a known clinically effective intervention' (NHS Commissioning Board 2013:14; see http://www.england.nhs.uk/wp-content/uploads/2013/04/cp-01.pdf/10.02.2015). And equal need is to be met equally: 'In any public health system committed to social solidarity, the presumption of equality is axiomatic' (see chapter "Rebalancing the Rationing Debate").

However, the South Central and related Frameworks also make the following statement: 'There may also be times when some categories of care are given priority in order to address health inequalities in the community'. The beneficiaries of this concession are not the clinically worst off but those population subgroups that are under the highest health risks, have poor access to healthcare and are poorer than average outcomes due to precarious life circumstances. A strong focus of this type of solidarity is on health promotion, primordial and primary prevention.

According to Newdick (see chapter "Rebalancing the Rationing Debate"), the 'commitment to social solidarity has a redistributive element which is no part of the 'individual rights' approach'. It may, however, interfere with maximising the 'health of the population' dependent on the size and the capacity to efficiently confer benefit on the disadvantaged group(s). This was clearly seen by the Citizens Council of the English National Institute for Care Excellence and Health (2014:13; see https://www.nice.org.uk/Media/Default/Get-involved/Citizens-Council/Reports/cc-report17-equity-efficiency.pdf/10.02.2015): 'Equity: Distributing wealth and resources fairly to everyone but this may mean that less is achieved overall'.

It follows that maximising health (e.g. in terms of Quality Adjusted Life Years/QALYs) is certainly a central and publicly supported (Shah and Devlin 2012; Olsen and Richardson 2013) but not the sole aim of the English healthcare system (cf. Shah et al. 2012) – leading to the impression that the NHS pursues two separate and partly antagonistic goals, namely, 'to improve the health of the whole population and reduce health inequalities' (The NHS Confederation 2010:3; see http://www.nhsconfed.org/resources/2010/03/rising-to-the-challenge-health-priorities-for-government-and-the-nhs/10.02.2015).

Against this background, it comes as no surprise that the severity or gravity of patients' conditions is neither explicitly mentioned in the South Central Ethical Framework and its derivatives nor in a second family of frameworks developed in the West Midlands (NHS West Midlands Commissioning Group 2010; still available via www.eaststaffsccg.nhs.uk/10.02.2015)[1].

A last comment on the English way of priority setting: It may be doubted if the moral essence of clinical solidarity is grasped by the term 'individual rights approach'. Clinical solidarity implies mutual expectations and obligations, i.e. more than one-sided (legal) rights. While § 1 of the German Social Law Book V (SGB V) characterises the national statutory health insurance (GKV) as a solidarity community, it demands co-responsibility; its members 'should contribute to avoiding illness and disability and overcoming their consequences'. An even stricter formulation can be found in § 6 SGB XI: Care-dependent members of GKV 'have to cooperate' in their rehabilitation. Such expectations have a century-long history going back at least to the Rule of Benedict (around 550 AD), chapter 36 'On sick brethren': 'But let the sick on their part consider that they are being served for the honour of God, and let them not annoy their brothers who are serving them by their unnecessary demands'. Modesty and cooperation on the patients' side are still central elements of the sick role and a prerequisite and working principle of mutual solidarity.

In Sweden, on the other hand, solidarity with the severely diseased patients is not and cannot be the sole purpose of its healthcare system. Here the question to consider is, is it economically realistic and ethically defensible to ignore the very high treatment costs arising out of solidary decisions solely focussing on (a group of) individual patients? What about certain newly developed antitumour drugs that add (on average) a few weeks of life at the price of potentially severe side effects and overall cost of more than 100,000 Euros at the expense of a solidarity community?

'Priority setting that considers only the condition (e.g. chronic disease) but not the patient benefit or cost-effectiveness of various interventions does not live up the ethics platform as a whole' (Broquist et al. 2011:15). This cautious formulation suggests that the condition and its severity must not be seen as absolute and overriding all other criteria. Poor cost/benefit ratios and/or total budgetary impact are also to be taken into account.

What else could and should set limit to the clinical solidarity principle, given that resources for healthcare are always and everywhere limited and that we must in

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[1] So far, I found only one source that at least mentioned 'severity' as a commissioning criterion: NHS England's Clinical priorities advisory group (CPAG) draft decision-making framework (May 2013; www.england.nhs.uk/commissioning/cpag/10.2.2015). The 15 'key societal values' that should underpin English public health, social care and healthcare identified at the Citizens Council meeting of the National Institute for Care Excellence and Health (NICE) in May 2014 include 'safeguarding the vulnerable', however, without clear reference to the severity of the patients' conditions. In the 2013 version of NICE's Guide to the Methods of Technology Appraisal, 'severity of the condition' was mentioned only as one of the several 'treatment effect modifiers'. The same is true of NICE's manual for developing NICE guidelines (last updated February 1, 2015).

Table 2 Circumstances which may suspend clinical and social solidarity

Trivial health impairment or risk
Health concerns, risks or impairments not covered by a solidary community
Favourable natural course
Illegitimate or unattainable treatment goals
Generally ineffective or predominantly risky intervention
Marginal or highly questionable indication
Negative evidence or lack of easily attainable evidence
Unbalanced cost/benefit ratio
Overwhelming budget impact
Patient's termination of expected or prescribed cooperation

principle, for equity reasons, adhere to the generalisability law[2]? It states that no funding agency should 'agree to fund treatment for one patient which cannot be afforded for, and openly offered to, all patients with similar clinical circumstances and needs' (i.e. NHS Sandwell and West Birmingham CCG, ethical framework for priority setting and resource allocation 2013; see http://sandwellandwestbhamccg.nhs.uk/10.02.2015).

The following Table 2 offers some suggestions but is neither adequately precise nor exhaustive.

4 Working with the Swedish National Model: Some Remarks

A working group of Germany's Federal Chamber of Physicians (Bundesärztekammer/BÄK) chose the Swedish approach to prioritisation as an exemplary model for its own work. In 2014, at the BÄK's annual conference, 94 % of the delegates voted in favour of continuing the work (Brockow et al. 2014).

The main reasons for the choice were:

- From the beginning, prioritisation in Sweden was organised both as a political *and* professional project.

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[2] What are 'similar clinical circumstances and needs?' We have discussed this in the context of a judgement of the Swiss Federal Court (Schweizerisches Bundesgericht; Raspe 2012). Are all cases 'similar' or 'comparable' (Bundesgericht 9C_334/2010), and who can walk a maximum distance of 150 metres, irrespective of the underlying condition, appropriate therapy, capacity to benefit and 'need' as defined above? Obviously not! A second point: are only known patients be considered or additionally those who can be expected to exist in the community based on epidemiological estimates?

- The first and relevant step of the Parliamentary Commission (1992–1995) was an ethical platform reflecting Sweden's still valid national morality. It emphasises the principle of need and solidarity and rejects simple utilitarianism[3].
- A series of a new type of guidelines (in Swedish, Nationella Riktlinjer) appeared (starting in 2004) as the main tangible product of the developing 'national model for transparent prioritisation in Swedish healthcare' (Broqvist et al. 2011).
- They are meant as a support for the distribution of healthcare resources, organisation of healthcare and therapeutic decisions and to develop regional healthcare programmes and routines[4].
- It must be noted that the normative status and strength of the guidelines is low; they have to rely on acceptance and adherence, which, however, does not seem to be a major problem in Sweden.
- In the development of the guidelines based on the ethical platform, clinical professionals from various disciplines play a dominant role with ethicists and health economists also making their contributions. Prioritisation can be understood as 'professionalism in action'. We see it as an antidote against the steadily increasing economisation and commercialisation of Germany's healthcare system.
- Assessment of all values and criteria follows a deliberative 'qualitative appraisal' and not a technocratic method as, for example, applied in Oregon where ranking is the result of a complex arithmetic procedure including variables differently weighed, added and multiplied.
- The addressees of the guidelines are persons and institutions with system responsibility, i.e. working at levels above the clinical micro-situation (intended as 'stöd för styrning och ledning'/'support for management and guidance' in national and regional healthcare).
- The guidelines accept a gap between prioritisation and binding allocation decisions, i.e. between prioritisation and rationing. The gap can be filled with further deliberations possibly based on further values and criteria.

Choosing a highly attractive model (and dismiss alternatives) is one thing. Working with the Swedish model is different. This model was the basis of a project of ours in which we developed – paradigmatically – the first German guideline on healthcare priorities. It focuses on cardiac rehabilitation after an acute coronary syndrome (CAD) or coronary interventions (PCI, CABG) (Raspe et al. 2014). In Germany, rehabilitation is usually organised as a complex 3-week intervention in specialised rehabilitation clinics at some distance from home, family and workplace.

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[3] In a current German discussion, attention is drawn to a possible conflict between need and solidarity: The need principle can be (mis)understood as supporting an individual's right to 'optimal' healthcare, especially in an era of 'personalised medicine'. A selfish interpretation of this right potentially erodes any solidarity principle. It could bring back the 'decibel method' about which I. Lönning warned us: He who shouts loudest or pays the best lawyer, gains most.

[4] I here follow a PowerPoint presentation to accompany the draft version of the most recent edition of the prioritisation guideline on cardiac care (January 2015; see www.socialstyrelsen.se/riktlinjer/nationellariktlinjer/nationella-riktlinjer-hjartsjukvard/10.04.2015).

Our final list comprises 117 condition-intervention pairs addressing five problem areas:

- Basic care (e.g. psychosocial assessment, anticoagulation)
- Consequences of CAD and their treatment (e.g. heart failure (NYHA I–II – physical training, fear of death – individual psychological counselling/therapy)
- Comorbidities, risk and prognostic factors (e.g. newly diagnosed or uncontrolled diabetes type 2 – patient education programme/individualised drug treatment, mild depressive episode – psychoeducational group)
- Socioeconomic and psychosocial context factors (e.g. social isolation – mediating contact to self help group, imminent work loss – individual counselling)
- Success barriers (e.g. cognitive/learning problems – individualised teaching, low social support at home – inviting/teaching relatives)

Each condition-intervention pair was assigned a rank between 2 and 10. ‘2’ indicates a very high and ‘10’ a very low priority. We did not assign the highest rank ‘1’; it must be reserved for highly effective and efficient cardiac interventions (e.g. defibrillation) in life-threatening situations (e.g. ventricular fibrillation) with acceptable side effects and at low cost. We identified ranks 2 and 3 with ‘must’ (be offered, done), ranks 4–6 with ‘should’ and ranks 7–10 with ‘can’. Ranking occurred in a stepwise deliberative process and was based on four criteria: condition severity (leading), clinical effectiveness, quality of evidence and relative costs[5].

Since the body of evidence for the German system of cardiac rehabilitation is both small and weak, the evidence criterion played only a minor role. Besides empirical evidence from evaluative research, we considered normative (legal and ethical) ‘evidence’, ‘evidence’ from clinical pragmatics (e.g. first assessment, then intervention) and from necessities of sustainable rehabilitation (e.g. organising aftercare following 3 weeks of inpatient treatment). Additionally, we used the results of two surveys, one including more than 200 patients who underwent rehabilitation and the other including eight professional groups from 136 rehabilitation clinics.

During our work, we encountered some challenges:

- Identification, selection and wording of (possible) condition-intervention pairs (CIPs): The main problems here are completeness and level of precision. The first Swedish guideline on cardiac care preferred rather general formulations. The most recent ones are as detailed as any clinical practice guideline. Take, for instance, line D6.01 of the musculoskeletal guideline: The condition here is described as ‘early rheumatoid arthritis with a disease duration of less than 3 years, methotrexate-naïve patients with medium–high to high disease activity’. Is this information truly necessary for ‘styrning och ledning’ of healthcare by decision-makers above the clinical level?

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[5] For details, see Raspe et al. 2014.

- When we first came to Uppsala in 2007, we heard from a highly renowned cardiologist that the ranks 1–3 translate into ‘must’, 4–6 into ‘should’ and 7–10 into ‘can’. A more recent e-mail from Socialstyrelsen (January 7, 2013) offered a quite different interpretation: 1–3 is now to mean ‘should’, 4–9 ‘can’ and 10 ‘can in exceptional cases’. Is it the case that healthcare in general lost some weight and became as a whole less relevant? Or did the medical profession become more self-critical? The question is underscored by the virtual disappearance of the rank ‘1’ from the most recent guidelines and the increase of ‘don’t do/icke göra’ recommendations. The 2012 guideline on musculoskeletal conditions, for instance, includes about 280 CIPs. ‘Icke göra’ was assigned to 79, ‘10’ to further 46 and ‘1’ to none. Nearly half of all pairs seem either nearly irrelevant or should not be realised. We adhered in our work to the old Uppsala school and identified our ‘must’ with what Ross (1930) called a prima facie or conditional duty (here duty of beneficence). Such a duty is binding as long as the ever-complex situation entails no other overriding duty.
- A related but inverse problem arises from the high rank of certain clinical preventive services, such as the short counselling intervention to induce smoking cessation in subjects so far healthy (line A1 of the 2008 cardiac guideline). Smoking definitely implies a relevant but nevertheless remote risk of CHD and other diseases, and counselling, though cheap, is not very effective, and it takes years before smoking cessation can restore health. So why is this assigned to a rank as high as ‘1’ if a ‘1’ signifies, for example, defibrillation in case of malignant ventricular tachyarrhythmia? Giving preventive services/CIPs, a bonus would imply a certain form of horizontal prioritisation within the so-called vertical approach. And it seems to imply a change of philosophy from clinical deontology (clinical solidarity) to public health ethics (social solidarity). As Geoffrey Rose has put it, ‘A preventive measure that brings large benefits to the community offers little to each participating individual’ (‘the prevention paradox’, Rose 1992:12).
- A question still unresolved addresses the rising tide of multimorbid patients. Multimorbidity presents another difficulty to the concept of ‘vertical prioritisation’. Is, for instance, the relevance/rank of a certain diabetological CIP the same within the context of diabetes care as compared to cancer or cardiac care? In other words, does the morbidity context matter?
- We have so far neglected this problem and chose a simple additive approach, presuming independence of concurrent clinical conditions and disorders, which is clinically far from being convincing (think of the metabolic syndrome or hypertension as risk factor for CHD or heart failure as a consequence of CHD). The dilemma may partly be solved by considering fixed disease combinations such as diabetes plus hypertension plus CHD. It is obvious that such an approach leads to a steep increase in the number of CIPs. This is of no great help in addressing the equally unsolved problem of how to systematically prioritise various elements in single patient care.
- While we completely agree with the criteriology of the Swedish model, we would nevertheless like to add one extra item: harm of medical interventions.

> The German population has traditionally a higher risk aversion than benefit affinity. We are habitually doubtful, sceptical and even pathophilic. Hence, risks are more hotly discussed than benefits. This example shows that any wide-ranging prioritisation, particularly in its axiology and criteriology, has to respect national peculiarities.

Imagining that Germany lies between England and Sweden, we have to decide towards which cardinal point we should orient ourselves: west or north? While reflecting on this, we have to take further decisions:

Should we adhere to a hierarchy of ethical principles (and criteria) or use a more flexible approach (as proposed by the Swedish Centre for Priority Setting in Healthcare)?

How do we balance clinical against social solidarity? What weight should the severity criterion be assigned? What should be the role of maximisation of population health? What are acceptable limits to clinical and social solidarity?

How should we decide on ranks – by means of a value- and criteria-based deliberation within a multiprofessional group (Swedish model) or a defined 'neutral' algorithm (Oregon model)?

We hope that the work of the research group including our project helps Germany to initiate two strands of discussion: one societal discussion on the axiology, criteriology and procedures of any national prioritisation project and a second discussion, professionally dominated, on the comparative relevance of sets of CIPs from defined (and often related) healthcare areas.

Compared to Sweden and its more than 20-year-long history of prioritisation, Germany is still in its infancy in relation to both strands. Many attempts to initiate them have been actively silenced by politicians as well as purchasers. At least the medical profession has recently taken this issue seriously (Hoppe 2010; Raspe und Schulze 2013). May this be the beginning of a wider societal and inter-professional discourse!

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Health-Care Priority Setting in Practice: Seven Unresolved Problems

Gustav Tinghög

1 Introduction

Abstract models and theoretical concepts related to health-care priority setting are of little use to us in the absence of a real-world context where they can be applied. Continuing on the work by Heiner Raspe from chapter "Prioritisation – (At Least) Two Normative Cultures", this chapter outlines seven lessons learned from the initiatives of *explicit* or *open* priority setting undertaken in the State of Oregon in the United States and in Sweden. These real-world experiences of explicit priority setting also serve as practical examples of approaches that have, from the outset, emphasized two opposing views on distributive fairness, maximizing health benefit within the population versus giving priority to those with the greatest need.

2 The Case of Oregon

Internationally, the most well-documented initiative to engage in explicit priority setting was undertaken during the early 1990s by the State of Oregon. The intent of the initiative was twofold: to expand eligibility to high-priority services among Oregon's population to cover everyone below the federal poverty level and to use limited resources to provide the most cost-effective services as a means to maximize health benefits among the population (Ham 1998). To achieve these objectives, a ranking list of condition-treatment pairs based on cost-effectiveness ratios was developed. Depending on the state's Medicaid budget constraint, every second year

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_8

Table 1 Examples from the initial priority list in Oregon based on cost-effectiveness analysis (Hadorn 1991)

Treatment	Expected net benefit	Expected duration of benefit	Costs (US $)	Priority ranking
Tooth capping	.08	4	38	371
Surgery for ectopic pregnancy	.71	48	4015	372
Splints for temporomandibular joint disorder	.16	5	99	376
Appendectomy	.97	48	5744	377

the state officials would literally draw a line across the list, ensuring public coverage for all items above the line, but leaving items below the line for individuals to fund out of pocket (Oberlander et al. 2001).

To achieve any substantial savings and create resources to expand coverage, the State of Oregon was required to exclude hundreds of serious condition-treatment pairs from coverage. The initial list revealed several counterintuitive results. For example, tooth capping was ranked above appendectomies for appendicitis (see Table 1), despite the fact that the latter is typically a life-saving intervention. While problems in some of the data led to such results, this is nevertheless an expectable result from cost-effectiveness prioritization – the problem arose because life-saving treatments like appendectomies are typically much more expensive than tooth capping (Oregon estimated that it could cap a tooth in over 100 patients for the cost of a single appendectomy). Hence, a small benefit for a large number of individuals was ranked above a great benefit for *one*.

The initial rankings, which were based on cost-effectiveness ratios, invoked strong negative public reactions. Following massive criticism, public consultations and medical experts were used to provide input on the initial list, which was then adjusted extensively (Hadorn 1991). Individual items were moved up and down the ranking list "by hand," informally guided by factors such as the number of affected patients and societal value placed on the item (e.g., high value was placed on palliative and child care) (Hadorn 1996).

Four years were spent revising the initial list, and the final list was made available in 1994. At that time, list included 696 items, with the cutoff point drawn at 565 (Ham 1998). In the final list, the costs associated with treatments had a negligible influence. Instead the final list was based primarily on the expected benefit associated with treatments. Hence, the final-adjusted list ranked surgery for ectopic pregnancy and appendectomy among the top items, while splints for temporomandibular joint disorder and tooth capping were dropped altogether. Most of the items that ended up below the cutoff point were services where individuals generally were considered to posses the ability to be responsible for their own care, or were conditions for which no effective treatments were available (Ham 1998).

To some extent, the initiative undertaken in Oregon was a success. It succeeded in decreasing the percentage of uninsured from 19.9 % of the working age population to 7.6 %. This was achieved while the percentage of uninsured in the United

States as a whole was on the rise between 1990 and 1996 (Alakeson 2008). Further, the state's ambition to engage in explicit priority setting received strong support among the public, which created a necessary platform for constructive dialogue (Rutledge 1997). It is important to acknowledge, however, that the Oregon initiative affected only the Medicaid system, i.e., the poor population. As Daniels (2008:152) points out, "the plan could not avoid the appearance of the *haves* setting priorities for the *have nots*." This is a distinguishing characteristic compared to similar efforts undertaken in systems with universal health insurance coverage.

2.1 Four Lessons from Oregon

Perhaps the most important lesson from the Oregon experience was that it illuminated some of the implicit value judgments imbedded in cost-effectiveness analysis (CEA), which are likely to conflict with deeply held values among the public. This led to abandoning the idea of using CEA as the sole principle for rationing, since as Hadorn (1991:2219) insightfully points out

> …any plan to distribute healthcare services must take human nature into account if the plan is to be acceptable to society. In this regard there is a fact about the human psyche that will inevitably trump the utilitarian rationality that is implicit in cost-effectiveness analysis: people cannot stand idly by when an identified person's life is visibly threatened if rescue measures are available.

The moral conflicts that arose in Oregon regarding the initial CEA ranking can be characterized in what Daniels (1994) has called four unsolved rationing problems: *the aggregation problem, the priorities problem, the fair chances versus best outcome problem, and the democracy problem.* These are all practical problems in health-care priority setting, but very moral in character. Hence, people are likely to disagree on what constitutes the correct course of action.

The aggregation problem can be framed by the question: When should society allow an aggregation of modest benefits to larger numbers of people to outweigh more significant benefits to fewer people? The approach taken in Oregon was based on the economic rationale of aggregation, i.e., health maximization. This led to some nonintuitive results, e.g., that certain life-saving treatments were ranked below some more trivial condition-treatment pairs. Aggregation clearly goes against the rule of rescue, which prescribes that priority setting should be done through one-to-one comparisons, giving priority to the patient with the most urgent need. The strong reactions that the initial list evoked showed that most people do not want society to have "maximized health benefits across population" as its sole objective for distributing resources. However, this does not mean that individuals are likely to find all forms of aggregation impermissible.

The priorities problem can be framed by the question: How much priority should society give to the sickest or most disabled individuals when allocating resources? If two individuals are competing to receive priority for a treatment that will give them an equal amount of health benefits, most people share the moral intuition that priority should go to helping the worst-off individual. Ranking based on cost-effectiveness analysis (CEA) ignores this common intuition and is neutral between individuals in cases where the benefits are of equal size. The fact that the revised Oregon list ranked palliative and child care at the top of the list indicates that the public did not accept this neutral standpoint, but wanted to give some level of priority to the worst off.[1]

The fair chances versus best outcome problem can be framed by the question: To what extent should society strive toward producing what is considered to be the best outcome, instead of ensuring that all individuals are given equal or proportional chances of receiving treatment? CEA focuses solely on the outcome in terms of maximizing health in the population. It could, however, be argued that it is more important that everyone has a fair chance to receive treatment. For example, imagine Larry and Jeb who are competing for the same treatment, but only one of them can get it. Larry will survive 3 additional years if he receives the treatment, while Jeb will only survive 2 additional years. The example could analogously be framed as patient groups competing for scarce resources. Following the CEA rationale, Larry should receive the treatment. However, Jeb might insist that it is unfair that he has to stand back only because Larry will live longer. Instead, he might argue that it would be more fair to have a weighted lottery where Larry has a 60 % chance of getting the treatment and Jeb has a 40 % chance of getting the treatment. It is unclear if this type of rationale played any significant role in abandoning the initial CEA methodology in Oregon.

Finally the *democracy problem* can be framed by the question: When should society rely on a fair deliberate process as the only way to determine what constitutes a fair priority-setting outcome? The normative relevance of public preferences is a complicated matter. Should *public* preferences be based on the general population or involve only the preferences of those who have experienced the specific health condition or have other forms of expert knowledge? What is evident from the Oregon experience is that one cannot ignore the views of the general public. Nevertheless, it is unclear how much weight one should give to moral reasons compared to expressed public preferences in cases when these differ. A related somewhat disturbing question about human behavior which the experience from Oregon raises is: Could it be that people are only *reasonable or fair minded as* long as they are not directly affected by the outcome themselves?

3 The Case of Sweden

Swedish experience with explicit priority setting represents a different approach compared to that of Oregon. In contrast to Oregon's initial cost-effectiveness approach, the Swedish approach has appealed to individuals' equal value and

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[1] Child and palliative care offer an example of two different interpretations of who is the worst off. Children are worst off in the sense that they have not had their fair share of a full life, and palliative patients are worst off in the sense of severity of illness.

priority setting according to need. Values related to cost-effectiveness and maximizing aggregate health in society have been relegated to a secondary role. Moreover, rather than explicitly listing services that should not be publicly funded, Sweden opted for an approach based on explicit principles to which any priority-setting decision should adhere.

The Swedish initiative to engage in a more open and systematic approach toward health-care priority setting started in 1992. An economic downturn led to recognition, at the national level, of the unavoidable need to set priorities for how to allocate scarce resources. The idea was that openness and transparency would create legitimacy for such politically difficult decisions. This led to the formation of a parliamentary priorities commission assigned to

> consider the responsibilities of health and medical services, their demarcation and role in the welfare state; highlight fundamental ethical principles which can furnish guidance and form a basis of open discussions and of prioritization in health and medical services. (Ministry of Health and Social Affairs 1993:29)

The commission's work resulted in what was labeled an ethical platform for making priority-setting decisions in health care (Government bill 1996/97:60). This platform consisted of three principles intended to guide decision makers at all levels in the health-care system when making priority-setting decisions. The principles were (and still are):

1. *The principle of human dignity*. Meaning that all individuals have equal value and rights regardless of personal characteristics or position in society
2. *The principle of need and solidarity*. Meaning that resources should be used in domains (or patients) where needs are considered to be greatest.
3. *The cost-effectiveness principle*. Meaning that resources should be used in the most effective way without neglecting fundamental duties to improve health and quality of life

The principles are ordered lexically in the sense that the human dignity principle has superiority over the need and solidarity principle, which in turn has superiority over the cost-effectiveness principle. Although these principles are referred to as the ethical platform, which implicates a static state, it was never the intention of the commission that these principles were set in stone. Instead the commission emphasized that the principles should always be subject to reflection and discussion.

Following the commission's work, the legislated goals of the Swedish health-care system were amended. Prior to the commission's report, the Swedish Health and Medical Service Act (1982:763 §2) stated that "the goal of all health care services is good health and health care on equal terms for the entire population." The amendment which was added to the formerly stated goal was: "Provision of health care services must respect the equal value of all human beings, and the dignity of the single human being. The person with the greatest need for health care services should be given priority" (Swedish Health and Medical Service Act 1997:142 2§). This means that the cost-effectiveness principle is not explicitly mentioned in the preamble of Swedish health-care legislation, while the principles of "human dignity" and "need" to some extents are. This further underlines the superiority of these two principles in comparison to the cost-effectiveness principle.

The needs and solidarity principle indicates that resources should be invested in the areas, activities, or individuals where need is the greatest. This means that more of the resources in health and social services should go to those in greatest need, those with the most severe diseases, and those with the poorest quality of life. The idea of solidarity as expressed in the ethical platform suggests that the outcome of care should be as equal as possible, i.e., everyone should achieve the best possible health and quality of life. Moreover, it also means that the needs of the weakest should receive particular attention. For instance, children or people suffering from dementia should have their needs assessed since they have fewer possibilities than others to express or communicate their needs. This special consideration refers, however, only to the assessment of care needs. Subsequent ranking should then be based on the other principles expressed in the platform. Returning to the distinction between clinical solidarity and collective solidarity made by Heiner Raspe in chapter "Prioritisation", it is thus interesting to note that the principle of need and solidarity embodies both types of solidarity: the need part focusing on clinical solidarity and the solidarity part focusing on collective solidarity.

In practice, since the ethical platform gives little or no real guidance on how to set priorities, the principle of "human dignity" has played a minor role in actual priority-setting decisions. It gives some indication on how not to set priorities, i.e., personal characteristics such as age, gender, ethnicity, and socioeconomic status should not influence how priorities are set, unless particular medical relevance is associated with these personal characteristics.[2, 3] Moreover it has never been specified, in association to the human dignity principle, what everyone has an equal right to. Hence, it is unclear what it means to have equal rights, when resources are insufficient to address everyone's health-care needs. Instead, the principles of "need and solidarity" have to become the leading principles when making priority-setting decisions.

Over the years, several national initiatives have aimed at applying the priority-setting principles in explicit priority-setting decisions. Since 2004, the National Board of Health and Welfare has used the priority-setting principles to rank pairs of health condition intervention in process for producing national treatment guidelines on various disease categories (Carlsson 2010). Based on the ethical principles, the Board has used a specially designed model for priority setting. This model is described as a "pragmatic" interpretation of the ethical platform, where severity of

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[2] For example, it makes little sense to screen men for breast cancer. Hence, in that case, gender becomes a medically relevant personal characteristic.

[3] However, when allocating vaccine against swine flu, the rule of human dignity was abandoned, and priority was given to individuals "important to the functioning of society as a whole." This further illustrates that the principle of human dignity tends to be more of a symbolic gesture than anything else.

illness is balanced against cost-effectiveness considerations (Broqvist et al. 2011). In similar fashion, the Dental and Pharmaceutical Benefits Agency has applied the priority-setting principles when making reimbursement decisions on public funding for pharmaceuticals. In their work, cost-effectiveness has become a key determinant when making priority-setting decisions with regard to pharmaceuticals (Erntoft 2010).

At the autonomous regional level, several attempts have also been made to apply the priority-setting principles in practice. The first ambitious attempt to apply such principles was undertaken by the County Council of Östergötland in 2003, which developed a set of explicitly defined limitations on providing health care. Examples of rationing were that treatments at pediatric clinics for some minor childhood conditions (e.g., head lice, obesity) and the second hearing aid would no longer be funded publicly. The process leading to explicit priority setting in Östergötland resulted in a heated debate across the entire country and was heavily criticized from leading politicians. Most likely this discouraged other county councils from following in Östergötland's footsteps. During more recent years, however, a new wave of initiatives to engage in explicit priority setting at the regional level has arisen. A handful of county councils have created lists including hundreds of services and have decided to exclude some of the services with the lowest ranking to create funding space for more important services. These more recent initiatives have met surprisingly little objection and appear to have gained public support (Carlsson 2010; Waldau et al. 2010).

To some extent the initiative undertaken in Sweden has been a success. The principles defined by the commission have been applied in actual priority-setting decisions, which prove that they are applicable at least as a framework for departure in real practice. This has spurred several national and regional initiatives to openly discuss the necessity to set limits on what the public can offer. The National Center for Priority Setting in Health Care has emerged as a venue for interdisciplinary research on health-care priority setting. The activities described above signify a long-term commitment from the national level of the health-care system to openly discuss and explore the matter of explicit priority setting and to develop a systematic approach for conducting priority setting.

3.1 Three Lessons from Sweden

In 2005, the Swedish government assigned the National Board of Health and Welfare to follow up the national guidelines for priority setting in health care and their implementation. Based on this extensive report (National Center for Priority Setting in Health Care 2008), three general problems in the Swedish approach, underpinned with ethical values, can be identified. I will label these *the vagueness problem, the balancing problem, and the leveling problem*.

The vagueness problem can be framed by the question: Should ethical principles be symbolic or guiding? The inherent vagueness of the priority-setting principles has arguably rendered them of little guiding value when making distributive decisions. The Swedish "human dignity principle" has a strong position legally, but how it should be applied in practice, when it comes to distributing scarce resources, is unclear. For example, the principle gives no indication about when age becomes a medically relevant characteristic for priority setting. It is possible that the principle of human dignity may have appeared as less vague if it had been framed as an all-embracing procedural principle, focusing on creating equal or proportional opportunities to health care. The "human dignity principle" does, however, have strong symbolic value that could potentially strengthen legitimacy for the health-care system, both internally and externally. The "need and solidarity principle" also holds strong symbolic value. However, the meaning of need has never been sufficiently specified, limiting its applicability as a guiding principle. For instance, to what extent should individuals' capacity to benefit be taken into account when assessing need?

The *balancing problem* can be framed by the question: Should one ethical principle have superiority, or is it necessary to balance different principles against each other? It could be argued that the strict lexical order of Swedish principles is both inapplicable in practice and highly unlikely to be in accordance with the true preferences of the public. It seems unreasonable that priority-setting decisions should be based solely on individuals' level of need, thereby disregarding other aspects such as costs and capacity to benefit. For example, strict adherence to the lexical order would imply that health-care resources would disappear into a bottomless pit[4] when it comes to treating patients with little or no capacity to benefit. Since this is not what is happening in practice, it indicates that the lexicality of the Swedish principles should be regarded as an ambition in trying to steer the process into giving more weight to individuals' health needs compared to their capacity to benefit. However, the strict lexical order stated is, at the very least, utterly confusing when trying to understand the role of the cost-effectiveness principle.

The final stylized lesson from Sweden is the *leveling problem*. This can be framed by the question: Should ethical principles apply equally when making priority-setting decisions at the individual level and at the population level? The Swedish principles are formulated as if they are supposed to guide priority-setting decisions made by all actors in health care, i.e., the national, regional, and clinical levels. However, ambiguity exists concerning the application of cost-effectiveness, which should be applied only at the population level. One could argue that it is questionable to apply a different value basis depending on whether or not priority setting concerns statistical or identified patients. On the contrary, adherence to the rule of rescue is a strong moral intuition among many, and one could argue that it is an important aspect when trying to foster a compassionate society.

As a concluding remark concerning the Swedish experience, it seems like the ethical principles to some extent have promoted an open dialogue regarding inevitable priority-setting decision. Although one could argue that openness helped to increase awareness of the value base for priority setting, transparency, and actual understanding, regarding the "true" values which underpin priority-setting

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[4] If it is assumed that the needs principle does not incorporate *capacity to benefit*.

decisions could potentially decrease as a result of the *vagueness, balancing*, and *leveling* problems. Openess may sometimes come at a cost of decresed transparency.

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Recent Developments on the Issue of Health-Care Priority Setting in Norway

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In November 2014, the third committee on health priorities in Norway (the committee) delivered its report "Open and fair – priorities in the health service" to the Ministry of Health and Care Services. The committee proposes that the goal of priority setting could be to seek the greatest number of healthy life years for all, fairly distributed (NOU 2014). The report is the third in a row of Official Norwegian Reports (NOUs) describing the need for explicit priority setting in the Norwegian health-care services, stating the goals of and recommending principles and criteria for priority setting in Norwegian health care since NOU 1987:23 (Lønning I) and NOU 1997:18 (Lønning II) (NOU 1987, 1997). The aim of this article is to give a brief introduction to recent developments and discussions with respect to health-care prioritization in Norway. The following presentation is mostly based on NOU 2014:12 and a report published in 2012 by the Norwegian Directorate of Health on health care priority setting in Norway (Helsedirektoratet 2012).

NOU 1997:18 had significant consequences in the field of health-care prioritization. The principles and criteria laid out in this report were included in the Patients' Rights Act of 1999 that regulates access to specialized health care and reimbursement schemes for pharmaceuticals (LOV-1999-07-02-63; FOR-2000-12-01-1208; FOR-2009-12-18-1839). Three criteria for priority setting are included in these regulations: (1) expected outcome, (2) cost-effectiveness of the intervention, and (3) the severity of the condition.

These developments at an overarching level were followed by guidance for hospitals in assessing whether individual patients have the right to specialized health care (Helsedirektoratet 2015). This guidance for 33 clinical areas was finalized 2008–2013 and was developed jointly by the Directorate of Health, clinicians, and leaders from the regional health authorities, user representatives, and experts on the

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_9

issue of health-care priorities. The main purpose of the guidance was to ensure equal access to specialized care for those with equal needs, within, and across clinical specialties. It may be said that the clinical prioritization guidance introduced the issue of explicit priority setting and paved the way for principled thinking around the size of expected outcomes, cost-effectiveness, and severity of disease among broader layers of clinicians across specialties. These guidance documents exist alongside national treatment guidelines for the same clinical areas. However, the latter guidelines, which physicians use in individual-patient treatment decisions, do not explicitly refer to the three criteria for priority setting.

The last couple of decades has seen two other institutional innovations that can be traced back to the recommendations from NOU 1997:18: the National Council for Priority Setting in Health Care giving advice on decisions in health care concerning priority setting and a national system for the evaluation and introduction of new health technologies linked to the Norwegian Knowledge Centre for the Health Services (Ringard et al. 2012; Helse- og omsorgsdepartementet 2012). A decision-making forum (Beslutningsforum) justify their final decisions on the introduction of new interventions by applying the existing criteria from NOU 1997:18, informed by evidence on effectiveness, cost-effectiveness, and severity provided by these national bodies and the Norwegian Medicines Agency.

Although the current framework for priority setting at different levels is well implemented, recent controversies concerning new costly therapies sparked new discussions about the goals of health-care priority setting and the need for revision or specification of the criteria used to set priorities. In 2013 the Ministry of Health and Care Services set up a committee to evaluate the existing principles and criteria for priority setting in health and to assess effective tools for acceptable processes for priority setting. The committee responded by launching a comprehensive report, NOU 2014:12, focusing on four principles for good priority setting in the health sector. Priority setting should (1) seek the greatest number of healthy life years for all, fairly distributed; (2) follow clear criteria; (3) be carried out systematically, openly, and with user participation; and (4) be carried out using a complete set of effective tools.

The committee proposed that progress toward the goal of seeking the greatest number of healthy life years for all, fairly distributed, can be achieved by appropriately balancing three main criteria for health-care priority setting:

- *The health gain criterion*: The priority of an intervention increases with the expected health gain (and other relevant welfare gains) from the intervention.
- *The resource criterion*: The priority of an intervention increases the less resources it requires.
- *The health loss criterion*: The priority of an intervention increases with the expected lifetime health loss of the beneficiary.

These criteria are to be considered together and to apply throughout the health sector.

Compared with the existing criteria, the health loss criterion represents the biggest change. Health loss is defined as the number of healthy life years lost over the entire lifespan due to disease compared with a common norm of 80 healthy life years. The ethical rationale for this recommendation is that patients who are worse off in terms of expected lifetime health deserve extra priority and that improving their situation may help reduce inequalities in expected lifetime health between patient groups with different diseases.

As regards principle three, the report strongly emphasizes the need for fair priority setting processes in line with the accountability for reasonableness framework described by Daniels and Sabin (Daniels and Sabin 2008) (see also chapter "Accountability for Reasonableness and Priority Setting in Health").

In closing, it is worth mentioning three issues that reflect some of the responses that have come up in the consultation and public and academic debates following the launch of the report. First, the consultation reflects the plurality of views different stakeholders have on health-care prioritization (Ministry of Health and Care Services 2015). It is interesting to note that the lifetime perspective advocated by the committee, and especially the health loss criterion, appears to be well understood and accepted among those representing patient groups with protracted chronic diseases, such as addiction, and some neurological and mental conditions, but less so by others. Second, the recommendations open up for priority setting indirectly based on age. (The role of age is also discussed in Part "The role of age and personal responsibility"). For example, the average age of a patient group would be taken as an estimate of the past quantity of health when calculating the health loss for that group. As part of the justification for the recommendations, the report carefully describes the various forms in which age already influences medical decisions. Third, the extent to which the focus on the twin goals of outcome maximization and equality in terms of lifetime health comply with traditional values expressed by equal access for all with the same health-care needs has aroused some debate. Critics, like health economist Nord, argue that need is better expressed by the existing criteria, where severity may be operationalized by using a measure called the proportional shortfall (Nord and Johansen 2014). The proportional shortfall is the fraction of healthy life years lost due to disease compared with a healthy life expectancy for people of the same age. The term is closely related to health loss, but would result in very different rankings of conditions, and therefore different priorities, than the health loss criterion (Lindemark et al. 2014; NICE 2014).

NOU 2014:12 presents convincing normative arguments for a lifetime approach to health-care priorities. Researchers in the field differ in opinion about the degree of support this lifetime view has in preference studies compared to, for example, the strength of preferences for severity alone and call for more evidence about the implications of setting priorities according to the health loss criterion. The proposal will be followed by a White Paper on health-care priorities from the Minister of Health in 2016.

Acknowledgments I am grateful to Ole Frithjof Norheim and Kristine Bærøe for their useful comments on the manuscript.

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Part IV

Legal Basis of Setting Priorities

Prioritization in Health Care: Normative Perspective

Gerhard Dannecker

The following articles are concerned with the Rationing Debate in Germany and the UK. The comparison between Germany and the UK is characterized by the different health-care systems, on the one hand an individualistic system (Germany) and on the other hand a utilitarian system (UK). The German health-care system is especially characterized by the anchoring of Fundamental Rights.[1]

Due to the demographic trends and the medical and technical progress, restrictions in public health will be inevitable in the future to reduce the costs of the public health-care system.[2] Legal regulations, which mean an explicit rationing of medical services as well as implicit regulations[3] can be means of reduction. In Germany, the Rationing Debate is at the beginning. The legislature in Germany has made use of the possibility of explicit rationing cautiously and only in less important areas.[4] Instead, the German legislature issued damping control in order to fight exploding health-care costs.[5]

Rationing may be practiced by different means and according to various criteria. The main criteria can be economic calculations of the costs and benefits or fundamental ethical principles. A focus on purely economic criteria inevitably leads to

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[1] Bundesverfassungsgericht, Bd. 120, 125 (155 f.); Bd. 125, 170 (222 f.); *Isensee* (2005).

[2] *Deutscher Ethikrat* (2011); *Breyer*, Bundesgesundheitsblatt 2012, 652 ff.; *Felder*, in: Schmitz-Luhn/Bohmeier, Priorisierung in der Medizin, S. 61 ff.; *Wasem*, Deutsches Ärzteblatt 105 (2008), A 439 f.

[3] *Marckmann/Strech*, Zeitschrift für medizinische Ethik 55 (2009), 15 (16 f.); *Strech/Börchers/Freyer et al.*, Ethik in der Medizin 2008, 94 ff.

[4] *Kemmler*, NZS 2014, 521 (523); *Nettesheim*, Zeitschrift für medizinische Ethik 48 (2002), 139 (142)

[5] *Bohmeier/Schmitz-Luhn/Streng*, MedR 2011, 704 ff.; *Dannecker/Streng*, MedR 2011, 131 ff.

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discrimination of certain patients.[6] Therefore, the consideration of ethical and legal principles is essential.[7]

In addition to rationing by limiting the compensation, problems of rationing are also faced in areas in which shortages cannot be resolved through financial contribution. This is particularly true in the field of transplantation medicine where a significant shortage of organs is recorded.[8]

It is necessary to identify the fundamental, especially the constitutional admissibility of prioritization and the individual prioritization criteria. It is also necessary to determine the importance of each criterion for individual legal issues and parts of the prioritization discussion and to develop their legal implications on the basis of control models for prioritizing implementation.[9] The boundaries for denial of medical services in the practical context of explicit rationing have to be illuminated in a constitutional, social, civil, and criminal law dimension.[10]

The experience of prioritization in foreign health-care systems should also be analyzed. Distinction can be made between two main concepts: an approach, in which the scope of the offered services is directly determined, and an approach, in which various control pulses act upon the allocation decisions in the system. In the power-determining prioritization, the process of evaluating the criteria of the catalogue of services must be on the focus, while controlling prioritization mostly uses clinical guidelines. The main challenge in implementing prioritizing systems is to assess the opposing effects of the two approaches and to align the desired effect on health care: On the one hand, individual decisions should remain possible but should comply with the ethical principles. On the other hand, the determination of a relatively rigid catalog of services by a power-determining prioritization leads in a uniform and therefore legally compliant implementation and application but leaves little deviations from the anticipated decision and can reduce the leeway for individual treatment decisions and sensitive standard situations in the case of deviation.[11]

It must be ensured that the constitutional requirements of the health-care system and of the prioritization criteria comply with the requirements of a democratic process and can be inserted into the system of the applicable law without causing tensions and unjust decisions.

In Germany, it is important to note the German constitution that contains a list of rights and freedoms. Hereinafter *Schmitz-Luhn* and *Katzenmeier* will discuss several parts of the German constitution (especially Art. 1 I, 2 I, II, 3, 20 I of the

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[6] *Dannecker/Streng*, JZ 2012, 444 ff.

[7] *Schmitz-Luhn/Bohmeier* (2013)

[8] *Dannecker/Streng,* JZ 2012, 444 ff.

[9] *Huster* (2011), S. 13 ff.; *Schmitz-Luhn* (2014)

[10] *Bohmeier/Schmitz-Luhn/Streng*, MedR 2011, 704 ff.; *Schmitz-Luhn*, Priorisierung in der Medizin – Erfahrungen und Perspektiven, S. 147 ff.; *Streng-Baunemann*, Strafrechtliche Grenzen der Rationierung medizinischer Leistungen, Berlin 2015, forthcoming; *Bohmeier/Schmitz-Luhn*, in: Bohmeier/ Schmitz-Luhn, Priorisierung in der Medizin – Kriterien im Dialog, S. 257 ff.

[11] *Schmitz-Luhn*, Priorisierung in der Medizin – Erfahrungen und Perspektiven, S. 97 ff.

German constitution) that are important in the discussion of prioritization, because they contain requirements for the health-care system.

Schmitz-Luhn and *Katzenmeier* will also discuss the implicit rationing on the one hand and the explicit priority setting on the other hand and illuminate severities for physicians who find themselves in a double role: On the one hand, they are trying to help the patient and to deliver a good treatment, and on the other hand, they have to keep in line with administrative rules and benefit catalogues of the statutory health insurance.

There is also the question of the legal requirements and limitations of a prioritization of medical services. At first glance, there is little evidence in criminal law for the legal requirements and limitations of prioritization of such services. However, on closer inspection, it is clear that the law provides a far-reaching protection of life and health with medical procedures: The context of criminal law within the prioritization debate is particularly apparent when the question is asked, if the indiviual physician is responsible for failure to act or if he is punishable because of non-assistance. Omission to effect an easy rescue (§ 323c of the German Criminal Code) serves to protect the minimum solidarity in society. But what is owed as a minimum solidarity and what is even punishable may normally not fall within the scope of what is discussed under the term "priorization".

Furthermore, there is the question of the minimum solidarity in the context of justifying necessity, which allows the physician to use equipment and instruments of the hospital without permission by the hospital administration in cases of emergency to save a human life or the health of a patient, unless the prioritization leads to criminal restrictions. The questions refer initially to emergencies but they also have an impact on other areas of health care, as to the due diligence the physician has to exert. In determining the appropriate care, the criterion of reasonableness is of central importance. This criterion is found both in the spurious omission offenses as well as for negligence. In the practical application of this criterion, the results which will be examined in the context of justification under § 34 of the German Criminal Code (Necessity), have to be included in order to achieve a coherent system.

It must be noted that the welfare state legalization and criminal standard structure are fundamentally different. Criminal law is no longer just the delimitation of spheres of action but also a direct and result-oriented behavior control. Furthermore, criminal law focuses on actions as visible social benefits and on the help and protection against danger. However, the non-criminal provisions have to be considered in principle under the framework of criminal law. At the same time, criminal law can interact with other areas of law. In this regard, the question arises, when and to what extent criminal law obligations or the criteria of justice and justice decisions, on which criminal law is based on, have to be considered in other jurisdictions. Traditionally, this topic is discussed from the viewpoint of the postulate of the unity of the legal system. The aim is to have in place a non-contradictory legal system. This raises the question to what extent the criminal reviews must be considered in other jurisdictions or to what extent only the legislature can make changes to the current legal situation. Therefore, it is not enough to ask the question of culpability in individual cases or case scenarios. Rather, the impact on the overall system must be included in the consideration.

The criminal issues raised by the prioritization have so far been inadequately studied in criminal science. As a result, the legal protection of life and health on the one hand and the principle of efficiency on the other hand are in tension. In criminal law, the protection of life and limb is always guaranteed unlimitedly. Life is regarded as the highest good of protection and may not be included in an assessment process. Health protection is also guaranteed unlimitedly, at least in principle. However, prioritization has the consequence that not everything that is possible is used to cure the patient. This raises the question whether the dogma of the maximum value of human life and the primacy of people before property interests applies and excludes a prioritization in health care.

Prioritization requires that medically meaningful measures are refused because of their cost. The decision on this is primarily an issue of social justice. The key question is on what criteria the distribution has to be made. In this regard it is necessary to primarily discuss priorities regarding general medical supply and to make these concepts transparent. Furthermore, a democratically legitimate institution must specify the limitations of benefits.

Ratio alternating waiver can be practiced by different means and according to various criteria. Economic cost-benefit calculations or fundamental ethical principles can be the main criteria. In the medical ethics and health economics literature[12] but also in the legal literature, a variety of conceivable distribution principles are discussed.[13] In this regard, particular attention should be given to the responsibility of the patient for his health and age limits criteria, which are, however, very criticized in Germany. Less problematic are the criteria of urgency of treatment and the effectiveness of benefits and costs of the measure.[14] With regard to the latter criterion, the problem arises that these criteria may point in different directions: Especially with severe diseases, the benefits of therapy can be very low, whereas the required measures are very expensive. Therefore, the relation of these criteria to each other needs to be clarified. This also has to be decided by a democratically legitimate institution.

With regard to the recognition of the various distribution criteria, there are nationally significant differences. The British National Institute for Health and Clinical Excellence (NICE) has fixed their cost ceilings for profits of lifetime and quality of life. In Switzerland, the obligation of health insurance for a drug has been discussed, which should be used to treat "Morbus Pompe". A treatment of this disease for 18 months means that the distance that the patient can go in 6 min on average improves from about 330 m by 28 m. The cost amounts to about 500,000 Swiss francs per year. The court calls for a cost-benefit assessment and takes this back to

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[12] Just compare with *Gutmann/Schmidt (Hrsg.)* (2002); *Rauprich/Marckmann/Vollmann (Hrsg.)* (2005); *Schöne-Seifert/Buyx/Ach (Hrsg.),* Gerecht behandelt?, 2006; *Fleck* (2009).

[13] *Huster* (2011), S. 34 ff.

[14] Compare with *Zentrale Ethikkommission bei der Bundesärztekammer (ZEKO),* Priorisierung medizinischer Leistungen im System der Gesetzlichen Krankenversicherung (GKV), 2007.

the idea of equality: 2.8 % of the population are limited in their ability to walk from 15 years to less than 2300 m. If one intended to equally increase these people's quality of life to the same amount as the quality of the life of persons with Morbus Pompe, this would mean an expenditure of 90 billion Swiss francs. This would be 17 % of Swiss Gross domestic product (GDP). For reasons of legal equality, this effort cannot be operated. By contrast, in Germany, there is the conviction that life and health cannot be valued in monetary terms. Thus, the *Bundesverfassungsgericht* (Constitutional Court) has clarified in the so-called Nikolaus-decision[15] that exclusions are not permitted in the case of life-threatening disease for which no conventional alternative treatment is available, provided that there is a chance of recovery or at least to appreciable positive action on the course of the disease. Since a disproportionate concentration on purely economic criteria inevitably leads to discrimination of certain groups of patients, a consideration of ethical and legal principles is essential.[16]

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[15] BVerfGE 115, 25 – 1 BvR 347/98 – v. 6.12.2005; *Dannecker/Katzenmeier/Huster/Penner/Schmitz-Luhn/Streng,* in: Wohlgemuth/Freitag (Hrsg.), Priorisierung in der Medizin – Interdisziplinäre Forschungsansätze, Berlin 2009, S. 158 ff.

[16] *Schmitz-Luhn/Bohmeier (Hrsg.),* Priorisierung in der Medizin – Kriterien im Dialog, Berlin/Heidelberg 2013

Rebalancing the Rationing Debate: Tackling the Tensions Between Individual and Community Rights

Christopher Newdick

1 Introduction

Health care is not just about the rights of individuals. It is part of a larger endeavour to secure optimum performance from finite funds for a community of patients and to do so fairly, safely and effectively. At a time of economic austerity, questions arise about affordability. Health economists refer to this as "opportunity cost" because choices to commit finite funds to particular purposes prevent those funds being available for other purposes. Inevitably, choices that favour the needs of individuals (what I call the "individualist" approach) tend to disfavour the needs of communities (what I call the "community" approach). My purpose is to discuss the limitations of the "individualist" approach to rationing and the need for clearer population-based objectives in health care. By itself, the individualist approach is not equipped to respond to the challenges presented by scarce resources, especially in the light of the increase in chronic, "lifestyle" diseases. I do not deny the importance of the individual perspective but argue that we need to rebalance the debate.

Therefore, we should be more explicit about the public dimension of health care. However, the community-based approach presents problems of its own, and there is a risk that it may undermine the legitimate clinical rights of individuals. Unless we get the balance right, the forces acting on health-care costs will make the individualist approach unsustainable. By looking through a telescope, instead of a microscope, we highlight broader concerns and different objectives. This chapter considers examples from the English National Health Service (NHS), but the issues it raises are international in scope. Thus, we consider (1) the individual rights model of substantive and procedural rights, (2) the community dimension of health care,

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_11

(3) community interests and the politics of individualism and (4) population-based objectives and the tyranny of targets.

2 The Individual Rights Model of Substantive and Procedural Rights

In the NHS, two systems emphasise individual rights, i.e. *substantive* rights and *procedural* rights. Substantive rights guarantee access to the treatment itself. In the English NHS, substantive rights have been created by the National Institute for Health and Care Excellence (NICE). NICE is a national authority which makes recommendations to commissioners of health care. NICE exists because about 200 clinical commissioning groups are responsible for commissioning patient care in England.[1] The Secretary of State is subject to a legal duty to "promote a comprehensive health service,"[2] but this duty is delegated by regulations to each of them to perform on his behalf.[3] There is clearly a risk of unacceptable variations in local decision-making which, in a *national* health service, is unattractive. NICE introduces greater consistency between commissioners. Thus, recommendations in its *technology appraisal guidance* (TAG) have mandatory legal effect so that the treatment must be made available by commissioners provided a doctor prescribes it.[4] This substantive duty is confirmed by the NHS Constitution, and the duty upon commissioners to support funding is enforceable by individuals against "health care commissioners" in judicial review. Conscious of opportunity costs, NICE becomes more critical of the clinical evidence of effectiveness for drugs which cost more than £20,000 per quality-adjusted life-year (QALY) and is unlikely to support treatments costing more than £30,000 per QALY.[5] Thus, a number of expensive treatments for cancer have not been recommended because their costs are not justified by their limited therapeutic benefits.

This encourages consistency throughout the NHS, and it can respond to general concerns about particular illness, such as cancer (treatments for which are frequently considered by NICE). However, with the exception of NICE, the NHS does not use a national list of approved treatments. Instead (as we have seen), it delegates to commissioners the duty to promote a "comprehensive" health service subject to their own discretion. One of the benefits of delegating this duty to local health commissioners is their ability to respond to local needs in consultation with their local communities.[6] Clearly, decisions made at national level tend to be detached

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[1] Clinical commissioning groups replaced primary care trusts as the commissioners of NHS care from April 2013. See the Health and Social Care Act 2012. For convenience, the word "commissioner" is used to describe the public function of purchasing health care on behalf of a community..

[2] See the National Health Service Act 2006, s 1.

[3] Under the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002, SI 2002, No 2375.

[4] See Secretary of State's Directions on the National Institute for Clinical Excellence 2003.

[5] See generally Newdick (2005a).

[6] In truth, although it is easy to find single-issue pressure groups, finding genuine representatives of "public" interests is more difficult.

from the concerns of local health commissioners and the stresses on their resources. Each of NICE's mandatory (i.e. substantive) recommendations carries opportunity costs which have consequences for other patients, and there is a balance between consistency at national level and local responsiveness. Put another way, within finite resources, the greater the greater the number of treatments subject to substantive rights, the smaller the discretion that remains to local decision-makers. This brings us to the alternative mechanism for rationing health care: the procedural rights approach.

Procedural rights are promoted at national level by the English *NHS Constitution*. Procedural rights do not guarantee access to treatment. Instead, they guarantee a fair and transparent procedure by which the decision-makers are required to justify decisions. After years of denying that rationing was really necessary, the government promoted the NHS Constitution in the form of a statutory bill of rights for patients in 2010.[7] The ideas promoted by the NHS Constitution reflect over 10 years of principles developed by judicial review cases.[8] Thus (other than the substantive rights supported by NICE), in allocating health resources, local commissioners must adhere to the procedural rights approach promoted by the NHS Constitution. The procedural approach recognises that hard choices are inevitable and accommodate broader, community interests alongside the needs of individuals. Equally, it is heavily accountable to the individual. Actually, the Constitution is not wholly candid about the need for hard choices in health care. It says only: "The NHS is committed to providing best value for taxpayers' money and the most effective use of finite resources".[9] However, documentation which explains the Constitution confirms: "Like all public authorities, [commissioners] are required to operate within finite budgets and, therefore, have to prioritise some treatments over others according to the needs of local communities…[] Disinvestments should be considered along with investments".[10] "Disinvestment" recognises that, as in any system working within fixed financial allocations, choices that favour some may disfavour others. The NHS Constitution describes how decisions should be made according to transparent procedures. Promoting the principle of transparency, it says:

> …each [commissioner] must have in place arrangements for making decisions and adopting policies on whether particular healthcare interventions are to be made available for patients for which the [commissioner] is responsible… Each [commissioner] must compile and publish clear written information outlining the arrangements specified….[11]

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[7] "Each of the [NHS bodies] must, in performing its functions, have regard to the NHS Constitution [and] Each person who provides NHS services under a contract, agreement or arrangements [inc PMS and GMS] must, in doing so, have regard to the NHS Constitution" (Health Act 2009, s2).

[8] For the evolution of case law in this area, see Newdick (2005b).

[9] *NHS Constitution*, Principle 1(6).

[10] *Defining Guiding Principles for Processes Supporting Local Decision Making About Medicines*, 3 and 14.

[11] Direction to PCTs and NHS trusts concerning decisions about drugs and other treatments, 2009.

Promoting accountability to individuals, it says that patients are entitled to know how those arrangements have been applied in their individual case:

> You have the right to expect local decisions on funding of … drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.[12]

This means that: "Where a [commissioner] makes a decision to refuse a request for the funding of a health-care intervention, where the [commissioner's] general policy is not to fund that intervention, the [commissioner] must provide that individual with a written statement of its reasons for that decision".[13] In addition, the right of explanation is supplemented by a further right of appeal because "[commissioners] should establish an appeals process for decisions made on individual funding requests, including clearly defined grounds of appeal, independent of the original process and open to patients and the public".[14]

Therefore, health service commissioners must have fair, reasonable and accountable systems for setting health priorities and be prepared to explain to individual patients the reasons for their decisions. Procedural rights insist that rationing decisions are taken within a fair and consistent framework of values capable of explaining why a particular treatment cannot be funded. Although they are procedural only, they are certainly *enforceable* by individual patients. The legal power of procedural rights enables judicial review courts to "overturn" (but not reverse) a decision and to return it to the commissioner to be reconsidered in the light of the court's criticisms. In legal theory, the decision-maker may come to the same conclusion in respect of a particular case, provided the reasoning is defensible, but political and media pressure often mean that the decision is reversed. However, it stops short of creating substantive rights to particular treatment.

These generic procedural rights are given effect by local commissioners of health care (other than treatments subject to mandatory NICE guidance). Local commissioners may combine in consortia to use *ethical frameworks* to make decisions about treatments consistent with the NHS Constitution. For example, such a framework exists in the South Central region of the English NHS where nine health care commissioners have combined to adopt a single ethical framework which forms the basis of its advice to its commissioners.[15] The ethical framework is applied to

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[12] *NHS Constitution*, Principle 2a.

[13] Direction to PCTs and NHS trusts concerning decisions about drugs and other treatments, 2009.

[14] Defining Guiding Principles for Processes Supporting Local Decision Making About Medicines, 23.

[15] See http://www.berkshire.nhs.uk/ search: priorities, containing the South Central Ethical Framework and the 170 treatment recommendations made within it. The author is a founder member of the committee which commenced work in 1999. This accountability for reasonableness approach is championed in Daniels (2008), chapter 4, and Daniels and Sabin (2008), chapters 3 and 4. See also chapter "Accountability for Reasonableness and Priority Setting in Health".

specific *treatments* to determine which should be recommended to local commissioners and which should be considered "low priority". Low priority means that the treatment will not normally be purchased by the commissioner unless the patient is judged to have exceptional circumstances which merit an exceptional response.[16] To preserve consistency in its approach, it considers the following criteria for decision-making: (a) evidence of clinical and cost-effectiveness of the treatment, (b) equity and the principle of equal access for equal need, (c) the health-care needs of the patient and their capacity to benefit from the treatment, (d) the cost of the treatment and its opportunity costs, (e) the sometimes countervailing needs of the community and (f) guidance from national institutions such as NICE or the government.[17] This "procedural-individual" rights approach puts individual claims into a community context and, with proper procedural safeguards in place, can do so fairly and consistently.

Whether they are procedural, or substantive, decisions about affordability involve judgments which are not uniquely clinical. They involve distributive ethics which also engage a range of other views, including those of the public. Although one can attempt to put numbers against criteria to produce (what is called) a "balanced scorecard" which enables comparisons to be made, in reality, this is often no more than a guide because each numerical assessment requires judgement. Therefore, it is difficult to use a single scoring system to compare, for example, a need for mental health care as opposed to palliative care or orthopaedic care and paediatric care. Different assessors may give different scores to identical situations. It is important that this system is not used as a crude utilitarian calculation which promotes aggregates of health benefit by ignoring individual need. Clinicians must be prominent amongst commissioning decision-makers to represent the patient-centred perspective as a counterbalance to broader, economic and managerial considerations. In this way, individual needs can properly be weighed against those of the community. The transparency of the NHS Constitution and local ethical frameworks recognise that we could spend more on the NHS but choose not to. We prefer to value health care in a way that provides extensive but not infinite access to treatment because we also value other non-health "priorities". These structures promote fairness, consistency and equality in the NHS in the hard choices created by this balance. Although the underlying purpose of making choices is to promote community interests, individual claimants are entitled to proper recognition as an expression of the humanity and compassion inherent in the health-care system.

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[16] Exceptional circumstances are considered below.

[17] The lawfulness of this approach was confirmed by the Court of Appeal in *AC v Berkshire West PCT and the EHRC* [2011] EWCA Civ 247, concerning the interaction of two policies on (a) transgender treatment and (b) cosmetic surgery. The former permitted transgender surgery, but the latter excluded cosmetic surgery. The applicant was a male-to-female transgender patient who wished to have her breasts enhanced. Consistent with the cosmetic policy, the health authority refused the treatment in order to preserve consistency with other female patients with small breasts. The Court of Appeals upheld the lawfulness of the policy.

This brings us to the next question. In assessing the balance between individual and community rights, has English law put the fulcrum in the right place, or do community interests deserve greater weight?

3 The Community Dimension of Health Care

Why is it important to keep the community dimension in health care in mind? Once we acknowledge that demand for care will exceed the resources we make available, the answer is obvious. Unless we engage fair and consistent *systems* for allocating scarce resources, the process is likely to become inconsistent and unfair and respond to patients unequally. The question is more urgent than ever. For the past 20 years, the response of government to increased demand has been additional investment; the funds invested in the NHS in the UK have increased steadily from about £24 billion in 1990 to about £110 billion today.[18] Now all that has changed. Additional investment is no longer available as a solution. Instead of responding to illness after it has arisen, more attention must be given to preventing people becoming ill in the first place. The point is made in the following extracts:

> In the future, we are likely to have more people living in poorer health and this presents a significant challenge for health services and wider society. Firstly, we have an ageing population, which partly reflects the huge progress that has been made in reducing mortality and extending lives. Many health conditions increase markedly with age, which will mean a considerable rise in age-related chronic conditions such as diabetes, dementia, blindness and arthritis. It will also mean a greater concentration of poor health, meaning more people living with multiple chronic conditions. It is expected that the number of people who have three or more long-standing illnesses will rise by 60 % over the next 10 years.
>
> Secondly, several major diseases are expected to become more common in all age groups, reflecting changes in people's lifestyles. For example, higher rates of obesity will result in a higher incidence of chronic conditions such as arthritis and type 2 diabetes. There were an estimated 3 million people with diabetes in England in 2009; estimates suggest that the number of people with diabetes could rise to 4.6 million by 2030. There has also been a rapid rise in gastrointestinal diseases, particularly chronic liver disease where the under-65 mortality rate has increased 5-fold since 1970. Liver disease is strongly linked to the harmful use of alcohol and rising levels of obesity.[19]

Thus, demographic pressures and lifestyle choices will significantly increase the pressure on health-care systems at a time when additional investment is unlikely.

The individual rights approach (whether substantive or procedural) is not designed to respond to this challenge. It is good at articulating the patient's voice, but it is not intended to address community interests or redress social inequalities in health status. Courts are not equipped to perform such a role. Public health certainly promotes sanitation, clean air and water, nutrition and tackling infectious diseases. But it also has an *ethical* dimension. Take heart disease, diabetes, cancer

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[18] See *NHS Expenditure in England* (HC Library, SN/SG/724, 2009): www.nhshistory.net/search: keywords.

[19] *Our Health and Wellbeing Today* (HM Government 2010), paras 3.6–7.

and the other diseases associated with today's more affluent lifestyles. As in many countries, the burden falls disproportionately on the poorest classes. In any public health system committed to social solidarity, the presumption of equality is axiomatic.[20] Whilst inequalities in *private* income are largely acceptable, rights of access to *public* health funds to which we have all contributed are a different matter. Public health policy is committed to ensuring that all those it serves have equal access to health. As WHO recommends in *Closing the Gap in a Generation*, "In any country, economic inequality – including inequity in public financing – needs to be addressed to make progress towards health equity".[21] This commitment to social solidarity has a redistributive element which is no part of the "individual rights" approach.

However, this ethical imperative also provokes difficulty because the poorest members of the community are at most risk of neglecting their health. This group is more likely to eat, drink and smoke to excess and fail to take sufficient exercise.[22] Accordingly, life expectancy in this community is shorter and the years spent of suffering from disability are much longer. The cost of remedying these inequalities is also very high, not only because the response is multidisciplinary and long term (rather than a course of medicines or a stay in hospital). In addition groups in this category are more resistant to change. How should public health ethics respond to these stubborn inequalities? "Libertarians" may respond that this is the product of individual choice: that people are free to choose how they live, including the right to neglect their health. Provided they have equal *access* to health care when they are ill, it does not matter if they are more likely to *become* ill, even if this exacerbates inequalities in health.[23] By contrast, "egalitarians" may say this is not just about unrestricted choice because the poorest members of society are not entirely free with respect to these choices. Circumstances impose pressures on the lives of this group which are different from those that exist elsewhere. Whether it is the product of upbringing, education, housing, employment or the pressures of time or money, it is not a mystery that larger numbers of those living in the most difficult circumstances tend to suffer the poorest levels of health. Exposed to a similar environment, surely we are all subject to the same risks. Egalitarians argue that basic principles of fairness and equality demand that more is invested here to redress these inequalities of health status.[24]

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[20] See *Fair Society*, *Healthy Lives* (The Marmot Review 2010).

[21] *Closing the Gap in a Generation – Health equity through action on the social determinants of health* (WHO 2008) 120.

[22] See *Health Inequalities* (HC 286-1, Third Report, 2008–09) 26. Within each social class, differentials of health status exist between gender (men worse than women), age (old worse than young) and ethnic sub-groups (South Asians worst); see *ibid.* 18 and 59. See also *Tackling Inequalities in Life Expectancy in Areas with the Worst Health Deprivation*, HC 186 Session 2010–11, 26.

[23] The scope of the debate is discussed in Knight and Stemplowska (2010) and Anand et al. (2006).

[24] The debate is clearly discussed by Holland (2007).

In England (and Scotland and Wales, too), the Department of Health has given an "egalitarian" response which seeks to reduce health inequalities. There are number of ways in which it has done so. First, generic policies have been promoted without putting any special emphasis on particular groups. For example, targets have been set for reducing inequalities in infant mortality, smoking, obesity and teenage pregnancy.[25] Generic policies are effective in the sense that *aggregate* levels of health status improve and overall levels of morbidity and mortality fall. However, they are ineffective in reducing health inequalities; indeed, they may make them worse. The reason is that better-off groups respond more readily to public health campaigns. Second, campaigns have been focused on particular groups by providing advice and assistance where it is most needed. For example, "Sure Start" children's centres tackle poverty by providing extended services to local schools, additional health-care clinics or child care services, giving advice on parenting and helping parents back to work.[26] But this may produce only modest improvements in health status relative to better-off groups, and it is expensive in terms of resources. In truth, proportionately greater investment is required in this group to reverse inequalities in health status. The policy choice is between generic intervention for everyone's benefit (without favouring any group) and "group-specific" public health intervention to benefit a particular group. However, the latter presents its own opportunity costs. If policy-makers *disinvest* from the majority to narrow the inequality gap with a minority resistant to change, this could reduce *aggregate* levels of health status in the community as a whole. On the other hand, although there are short-term costs of doing so, group-specific intervention promises considerable longer-term savings:

> If everyone in England had the same death rates as the most advantaged, a total of between 1.3 and 2.5 million extra years of life would be enjoyed by those dying prematurely each year as a result of health inequalities. They would, in addition, have had a further 2.8 million years free from limiting illness or disability. The estimated costs of these illnesses accounts, per year, for productivity losses of £31-33 billion and lost taxes and higher welfare payments in the range of £20-32 billion. The additional NHS healthcare costs in England are well in excess of £5.5 billion.[27]

English health policy understands these questions but has provided far from conclusive answers. Indeed, the Department of Health has been criticised by the House of Commons Health Committee for its lack of progress in this area: "Having set an objective to tackle a complex and intractable problem, the Department did not set about its task with sufficient urgency or focus… was too slow in making health

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[25] See, e.g., *Enabling Effective Delivery of Health and Wellbeing* (DoH, 2010), 21. In *Healthy Lives*, *Healthy People – Update and Way Forward* (2011, HM Government), 5: "The bold changes… are a response to the challenges we face to the public's health. For example, two out of three adults are overweight or obese; and inequalities in health remain widespread, with people in the poorest areas living on average 7 years fewer than those in the richest areas, and spending up to 17 more years living with poor health."

[26] Sure Start schemes are described at www.dcsf.gov.uk/ search: every child matters.

[27] *Fair Society*, *Healthy Lives* (The Marmot Review 2010) 38.

inequalities a priority, and set a performance measure that proved too blunt an instrument to target those in most need effectively".[28] No doubt there is sensitivity about government trespassing into people's private lives and of being labelled the "nanny state".[29] Also, the proportion of the total health budget invested in preventive medicine and health promotion (i.e. policies likely to prevent illnesses in those most likely to suffer from them) is small. The UK spends about 3.6 % of its entire healthcare budget on public health projects of this nature (which is more than many other EU member states).[30] Perhaps we are naturally drawn to prioritise the need to rescue those who are ill today, rather than reducing the burden of illness tomorrow. And, of course, public opinion may be less sympathetic to those who are perceived to be responsible for their own ill health. On the other hand, the NHS will eventually absorb the costs of rapidly increasing rates of, for example, cardiovascular disease and type 2 diabetes caused by obesity. So there are compelling reasons of economics (apart from social justice) to prioritise the challenge of health inequality now.[31]

4 Community Interests and the Politics of Individualism

What challenges confront these community-based objectives? Although the NHS Constitution and the procedural rights approach are designed to balance individual and community needs, the voice of the individual is often more articulate and urgent. Inevitably, the circumstances of individual patients are sensitive and sometimes harrowing. From a personal point of view, many of us in similar circumstances would want access to the treatment. Yet, from a community perspective, "last-chance" treatments may be largely untested, ineffective and expensive and may divert resources from other patients on effective treatments. [32]Logically, by engaging the NHS Constitution, local commissioners might reasonably balance community and individual interests and decide that the cost of the treatment cannot be justified by its limited benefits, but the emotional tug of such a case is naturally immense.

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[28] *Tackling Inequalities in Life Expectancy in Areas with Worst Deprivation* (HC 470, Third Report of Session 2010–11) 5.

[29] Interest is being shown in "libertarian paternalism"; see *Nudge – improving decisions about health*, *wealth and happiness* (Penguin Books 2009). However, this argument is framed firmly within the "libertarian" tradition in which individual choice is dominant. It does not claim to have a "community" perspective. Some will doubt whether lifestyle diseases established over many generations will be amenable to such a policy. See Menard (2010).

[30] *The Government's Response to the Health Committee Report on Health Inequalities* (2009, Cm 7621), para 54 (figures taken from *Prevention and Preventative Spending* Health England Report No 4 (2009), 4). The European average is about 2.9 %.

[31] At present, no one seriously suggests individuals should be coerced into healthy lifestyles, although there is talk of "libertarian paternalism" and "stewardship." As the avoidable costs of ill health escalate and impacts on others, there may be discussion of more forthright paternalism in this area. See, generally, *Public Health*: *Ethical Issues* (Nuffield Council of Bioethics 2007) chapter 1.

[32] For a US perspective on last chance treatments, see N Daniels and J Sabin, (note 15) chapter 5.

Unsurprisingly, political pressure is often placed on commissioners to divert funding from other patients to fund the last-chance treatment and get the story off the front pages.[33] Although the Secretary of State is not normally responsible for commissioning NHS services (because, as we have seen, the job is delegated to local commissioners), he or she is often a favourite target for the media when distressing stories are published about, for example, a patient suffering from a terminal illness who has a last chance for a new and expensive treatment. In one sense, commissioners with duties to promote community interests are less party political than the Secretary of State. Perhaps because they are not elected or directly accountable to the public, they are in a better position to resist pressure of this nature. Nevertheless, the Secretary of State may impose severe pressure to fund treatments whose opportunity costs commissioners consider not to be justified (the ultimate sanction being to dismiss commissioner board members from their posts).[34] Although these matters are not aired publicly, in many cases, the commissioner quietly backs down and funds the treatment and the cost is silently diverted from other patients. This represents the realpolitik of the balance of power between commissioners and the Secretary of State.[35] Often, therefore, the *politics* of rationing gives the rights of individuals priority over community interests.

Although in theory the courts endorse the procedural rights approach to rationing, similar pressure is imposed by litigation. By their nature, rationing cases highlight the rights of individuals. And by *their* nature, lawyers are probably better at comprehending individual rights than more recondite "public" or "community" interests. Indeed, modern legal theory lauds individual and human rights as a bulwark *against* the state. This preconception in favour of individual patients is demonstrated by the principle of "exceptional circumstances".[36] Judicial review requires decision-making to be based on all the relevant considerations, which include the *exceptional* needs of the patient. For example, a last-chance, life-saving treatment for a terminal illness may be refused under the general ethical framework because its cost is not justified by its benefits. However, in response to this general policy, individual patients are entitled to argue that their circumstances are so "exceptional" that they should be given exceptional access to funding. The difficulty is in knowing how readily the court should concede such claims. Too much willingness and *litigants* will tend to get special consideration over others, and this would be unfair. But if there is too little, the sense of compassion for individuals will be undermined.

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[33] See *Incentives for Prevention* (Health England Report No 3, 2009), 3 discussing the "politics" that can stand in the way of public health policies.

[34] Barrett et al. (2006). In one case in which a senior manager was held to have been unfairly treated, the court said: "As a bystander at the execution of Admiral Byng explained to Candide: "Dans ce pays-ci, il est bon de tuer un amiral de temps en temps pour encourager les autres." It seems that the making of a public sacrifice to deflect press and political obloquy, which is what happened to the appellant, remains an accepted expedient of public administration in this country", *Gibb v Maidstone and Tonbridge Wells NHS* [2010] EWCA Civ 678, [42], Sedley LJ.

[35] Although this does not represent the legal position because once statutory powers are delegated from central government to another statutory body, *all* the delegated powers are transferred to the delegee. See *Blackpool Corporation v Locker* [1948] 1 KB 349.

[36] See generally Newdick (2006a) and (2005c).

The strength and weakness of the judicial forum in these cases are that it focuses on the tragedy the individual is facing, but can it also give adequate weight to the interests of others whose interests are unknown to the court?

Take the example of *Otley*. Mrs Otley suffered from lung cancer and had received NHS treatment for it. Unfortunately, it had not halted the disease and her condition became terminal. A new drug, *Avastin*, became available which was unlikely to halt the disease but might slow its progress and extend her life by a number of months. The commissioner considered its costs and benefits and said that it could not afford to purchase the drug as a general policy. The patient argued that she had "exceptional circumstances". An eminent oncologist, Dr Karol Sikora, supported her case and the matter proceeded to judicial review. The court agreed that she was "exceptional" because she

> was relatively fit. She was young by comparison with the cohort of patients suffering from this condition. Her reactions to other treatment, in particular to Irinotecan plus 5FU had been adverse. Her specific clinical history suggested that her reaction to a combination of chemotherapy and Avastin had been of benefit to her. By comparison with other patients, she, unlike many of those the subject of the studies, had suffered no significant side effects from a cocktail which included Avastin. All of those points are fairly made by Professor Sikora…[37]

In one sense, this supports a finding of exceptionality. However, it is highly individualistic. Doctors will naturally support their patients in these cases. But if each case were considered on this very personal basis, it would surely include large numbers of patients and defeat the logic of being "exceptional". If it is insufficiently robust to withstand individual claims, the *raison d'etre* for priority setting is undermined and the principle fails in its objective of promoting fair and equal resource allocation by preferring the articulate and litigious.

Therefore, we need a more consistent approach to exceptional cases. One proposal would be to have a hierarchy of persuasiveness against which new treatments could be assessed as follows: (a) well-conducted meta-analysis of several, similar, large, well-designed randomised controlled trials (RCTs), (b) a large well-designed RCT, (c) meta-analysis of smaller RCTs, (d) case-control and cohort studies, (e) case reports and case series, (f) consensus from expert panels and (g) individual opinion.[38] Commissioners should use this to identify treatments for which there is reliable evidence of clinical and cost-effectiveness. Cases should be considered in a way that does not simply reflect individual circumstances but against a common framework and in a way that assesses whether the clinical merits of one person are so different to those of other patients that they should be regarded as "exceptional". *Otley* was not decided on this basis. As the judge said in Otley: "The one significant respect in which [Dr Sikora's] criticism may not be justified is that it may be the case that Ms Otley's prospects of long term survival may not be enhanced…".[39] Indeed, the drug could prolong Mrs Otley's life for a few additional months only.

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[37] *Otley v Barking and Dagenham PCT* [2007] EWHC Admin 1927; [2007] LS Law 593, para 20.

[38] See, e.g., *Supporting rational local decision-making about medicines* (*and treatments*) (National Prescribing Centre 2008) 42.

[39] *Otley*, at para 20.

The community side of the rationing debate has also been undermined by litigation in the European Court of Justice (ECJ). Applying the principle protecting free movement of services between member states, it has developed a theory of *substantive* rights of access to treatment. Thus, it says if a patient requires “normal” treatment which cannot be provided in the “home” state within a “reasonable time”, the treatment may be obtained from a “host” member state, paid for by the patient and its cost reimbursed by the local health system. This individualistic approach favours those who are robust and wealthy enough to travel but ignores those who are too frail or poor to do so. It also ignores those denied care because younger, fitter and stronger patients who can travel may take priority in respect of funding.[40] The only exception to this principle is when there is a risk of “undermining the balance of a social security system”. But whilst this may focus on *economic* stability, it has little to do with fairness, democracy or equality, i.e. the ethical integrity of the system. Until recently, it appeared that the ECJ had simply not understood the implications for resource allocation of its individualistic approach to patients’ rights.[41] However, in October 2010, in *Commission v France*, the ECJ accepted the argument for balance between individual and community choices. Rejecting the Commission’s claim that free movement principles protected individuals’ right of access to expensive diagnostic testing in another member state, it said:

> If persons insured under the French system could, freely and in any circumstances, obtain at the expense of the competent institution, from service providers established in other Member States, treatment involving the use of major medical equipment corresponding to that listed exhaustively in the Public Health Code [ie Scintillation camara, magnetic resonance imaging, medical scanner, hyperbaric chamber, cyclotron], the planning endeavours of the national authorities and the financial balance of the supply of-up-to-date treatment would as a result be jeopardised. That possibility could lead to under-use of the major medical equipment installed in the Member State of affiliation and subscribed by it or yet a disproportionate burden on the Member State’s social security budget.[42]

This community-sensitive approach has also been endorsed by the European Directive on Cross-border Access to Healthcare which concerns the rights of EU citizens to obtain treatment in a “host” member state and to have the costs reimbursed by the “home” health system. Despite strong opposition from the European Parliament (which argued for individual-substantive rights), the final version of the Directive created *procedural* rights. Thus, Directive 2011/24 of 9 March 2011 on the Application of Patients’ Rights in Cross-border Healthcare confirms that subject to the principles of non-discrimination justified by “planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment”, public health insurers may impose on patients wishing to obtain hospital treatment elsewhere in the EU

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[40] See Case C-372/04 *R*(*Watts*) *v Bedford PCT and the Secretary of State* [2006] ECR I-4325, para 103. For criticism of the shortcomings of the ECJ’s reasoning in these cases, see Newdick (2006b).

[41] See Newdick (2008), discussing the failure of the ECJ to consider these matters.

[42] Case C-512/08 *Commission v France* [2010] ECR I-0000.

> …the same conditions, criteria of eligibility and regulatory and administrative formalities, whether set at a local, regional or national level, as it would impose if this healthcare were provided in its territory. This may include an assessment by a health professional or healthcare administrator providing services for the statutory social security system or national health system of the Member State of affiliation… if this is necessary for determining the individual patient's entitlement to healthcare.[43]

Accordingly, member states "may provide for a system of prior authorisation for reimbursement of the costs of cross- border healthcare".[44]

Thus, procedural rights systems are preferable for providing a fair, consistent and objective mechanism for balancing individual and community interests. Put another way, individual needs cannot be considered in isolation from the wider context of community interests. The precise balance between the two is a matter for effective political participation by all socio-economic groups, assisted by the "procedural" approach discussed above.[45] In truth, the NHS has had limited success in engaging public opinion, and this important subject deserves considerably more attention.[46]

5 Population-Based Objectives and the Tyranny of Targets

Now, we consider challenges that confront population-based objectives. We have noted how priority setting is often understood in terms of particular individuals and treatments but that we should also focus on population-based outcomes. We have also discussed targets for smoking, obesity and teenage pregnancy and health-care inequalities. In addition, in England, hospitals are subject to a regular "Health Check" in which they are assessed against a wide range of "target" standards which are reflected on a league table of comparative performance. These measures include waiting times for (a) hospital admission (18 week maximum), (b) care in accident and emergency departments (maximum of four hours) and (c) cancer treatment (maximum of 2 weeks from referral). The purpose of these objectives is to enhance health-care efficiency.[47] These targets are intended to promote the interests of whole populations of people. In principle, therefore, there is much to be said in support of this approach and, indeed, for extending its focus to particular sub-groups, especially those at most socio-economic disadvantage. The following does not quarrel with the principle. Rather, it considers some of the unintended consequences of

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[43] Art 6(1). Non-hospital treatment may be obtained on a substantive-rights basis.

[44] Art 8(1).

[45] See N Daniels, (note 15) ch 3, asking "When Are Health Inequalities Unjust?" and using Rawls' Difference Principle to assist his analysis.

[46] Regulation of public participation has been subject to rapid and destabilising change in the NHS. See Newdick (2005b). Discussing the recondite nature of the subject, see Fung (2006).

[47] Health Checks are now undertaken by the Care Quality Commission; see generally www.cqc.org.uk/ search: annual health check.

these population-based policies for patients and reminds us again of the need for balance in assessing individual and community needs.

Take the example of waiting time targets. Undoubtedly, prioritising waiting times has been beneficial to NHS patients. But the benefit is not entirely risk-free. The danger is of NHS managers regarding the "target" as the primary objective to be achieved even at the cost of good quality care for patients. The reason for this is that government treats the achievement of targets as a proxy measure of its own success in improving the NHS and hospital managers are subject to "performance management" by reference to, for example, the percentage of patients treated in time. Also, league tables are published and permit patients to compare hospitals and choose where to receive their treatment. Hospitals which achieve targets may be rewarded with additional funding and greater freedom from supervision by government and regulators. Failure, on the other hand, is taken as a sign of poor management and may lead to senior managers being dismissed from their posts. There is a danger that as rationing by *delay* declines, rationing by *dilution* may increase.

A number of examples demonstrate the risks. I do not say they are common; rather, they are not completely exceptional. First, consider the 18-week target for referral for treatment. Compare two patients: Patient A has been on the waiting list for 17 weeks and nearing the target limit. He has been waiting so long because his condition is not serious and is not getting worse and he would not suffer were he have to wait longer than 18 weeks. Patient B has just been referred to hospital. She needs urgent treatment. Unless she is dealt with quickly, she will quickly deteriorate. Who should we treat first? Clinicians will say Patient B. Managers, however, may argue that the decision is not purely clinical because if Patient A misses the target, then the hospital will compare unfavourably in the league table and patients may choose to go elsewhere. Hospital revenue will fall, staff will not be appointed to the unit, or new equipment may not be purchased. Government and the regulator may subject the hospital to closer scrutiny and inspection. Such a case is said to have occurred in the Bristol Eye Hospital when less urgent, long waiters were treated before more urgent, short waiters, in order to achieve the waiting time target. As a result, 25 patients may have lost their sight.[48]

Their difficulty is also highlighted by a report into the Mid Staffordshire Hospital NHS Foundation Trust in respect of the treatment of patients between 2005 and 2009. The hospital was being encouraged to become an NHS foundation trust. This meant that it would be regarded as an example of excellence for the NHS with greater autonomy and less supervision by regulators. However, to qualify for foundation status, it had to demonstrate compliance with waiting time targets and robust financial governance. However, the targets distorted managerial and clinical judgement because the 4-h waiting time target for treatment in the accident and emergency (A&E) department sometimes led to those with less pressing needs being given higher priority than those with most urgent need. As one report said:

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[48] See evidence of Dr Richard Harrad, Clinical Director of the Bristol Eye Hospital, to the House of Commons Public Administration Committee. See *On Target – Government by Measurement* (HC 62-1, 2003) paras 52–53.

> … the care of patients had become secondary to achieving targets and minimising breaches. Doctors considered that the prioritisation of the patients with minor ailments led, on occasions, to a distortion of clinical priorities. Middle grade doctors told us that they were asked to work with patients in the "minor" side to push these patients through, although this was at the expense of more seriously ill or injured patients. They felt pressured to prioritise patients who were close to breaching the [four-hour A&E] target rather than prioritise by clinical need.[49]

Pressure to demonstrate financial stability meant that insufficient clinical staff were engaged to manage the hospital wards. For example, when patients arrived in A&E, "they were usually assessed by reception staff with no clinical training, before waiting in an area out of sight of the staff in reception. There was no regular check by nursing staff of the patients in the waiting room…". To give the appearance of meeting the target: "Patients were moved to the clinical decision unit to 'stop the clock', but were then not properly monitored since this area was not staffed".[50] These are examples from A&E, but inadequate staffing levels also led to harrowing accounts of some elderly patients being neglected in their beds because insufficient nurses were available to respond to their calls for assistance and some were left to soil their beds which led to increased infection and further illness. Thus,

> the trust stabilised its finances and successfully focused on becoming a foundation trust. However, it lost sight of what should have been its main priority: to provide high quality care to all of its patients. It took a decision to significantly reduce staff without properly assessing the consequences. Its strategic focus was on financial and business matters at a time when the quality of care of its patients admitted as emergencies was well below acceptable standards….[51]

Mid Staffordshire is not an isolated example. Comparable institutional pressures played a role in the circumstances surrounding Stoke Mandeville Hospital NHS Trust in 2006 and Maidstone and Tunbridge Wells NHS Trust in 2007. In both cases, hospital reorganisations had been undertaken to improve financial efficiency but at the costs of standards of care. For example, in the Stoke Mandeville Hospital Report, the Healthcare Commission criticised unacceptable infection rates in the hospital. In Stoke Mandeville, "there was a lack of effective leadership, accountability and support for the control of infection. The director of infection prevention and control had not persuaded the board to give sufficient priority to the control of infection in general and to the control of C. difficile in particular. The achievement of the Government's targets was seen as more important than the management of the clinical risk inherent in the outbreaks of C. difficile. This was a significant failing".[52] And, in Maidstone and Tunbridge Wells Hospital, principles of good clinical gover-

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[49] See the *Investigation into Mid Staffordshire NHS Foundation Trust* (Healthcare Commission, March 2009) para 49.

[50] ibid. 129.

[51] ibid. 134–35.

[52] *Investigation into outbreaks of Clostridium difficile at Stoke Mandeville Hospital, Buckinghamshire Hospitals NHS Trust* (Healthcare Commission, July 2006) 6.

nance were overridden by targets relating to finance and access. The report noted that organisations "should not compromise patient safety by making decisions and taking actions that put some patients at risk".[53]

These examples arose from conscious choices to prioritise some objectives over others and to dilute the quality of care to patients. Local hospital managers and clinicians are surely responsible for this failure. But the House of Commons Health Committee considered that government should also bear some responsibility. It said:

> The Government's overwhelming emphasis on hitting targets (particularly waiting-list and A&E waiting), achieving financial balance and attaining Foundation status did not help to improve failing Trusts – rather it compounded their failure. The failing Trusts, like Mid Staffordshire and Maidstone and Tonbridge Wells, clearly thought the Government was telling them that patient safety was a second-order priority.[54]

Naturally, government prefers to hear good news that the NHS is improving. To this extent, there are "institutional" pressures to report good statistical results and, indeed, for government to turn a blind eye to some of the unintended effects of targets. As commentators have remarked:

> … there was no systematic audit of the extent to which the reported successes in English health care performance… were undermined by gaming and measurement problems… The audit hole can be interpreted by those with a suspicious mind (or long memory) as a product of a "Nelson's eye" game in which those at the centre of government do not look for evidence of gaming or measurement problems which might call reported performance successes into question… In the English NHS, "hard looks" to detect gaming in reported performance data were at best limited.[55]

This echoes theories of "regulatory capture" which explain how those subject to regulation may dominate the agenda and decision-making of regulatory agencies. However, in these examples, the "capture" appears to have been by government itself. The problem has been described by Julian Le Grand in his metaphor of good intentions being turned bad in which noble "knights" are turned into selfish "knaves".[56] Put another way, systems created to improve standards and encourage patient choice and transparent competition in the interests of quality may unintentionally encourage staff working under pressure to undermine clinical standards and, consequently, to spread distrust and cynicism amongst those they are intended to serve.[57]

These examples must be seen in context. The general quality of care available to NHS patients is good, and I do not suggest that targets should be abandoned. They

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[53] *Investigation into Outbreaks of Clostridium difficile at Maidstone and Tunbridge Wells NHS Trust* (*Healthcar*e Commission, October 2007) 111, 113.

[54] *Patient Safety*, *Sixth Report of Session 2008–09* (HC 151-I, 2009) para 300.

[55] Bevan and Hood (2006).

[56] See Le Grand (2006).

[57] See also O'Neill (2002).

are valuable for assessing the health-care outcomes of large groups of patients and emphasising the community perspective of *priority* setting. However, they illuminate some of the *risks* of putting too much weight on crude targets of measurement if the net effect is to undermine or distort the proper balance of priority setting.[58] The challenge now is to develop more sensitive and accurate measures of quality which are less prone to gaming and properly represent the experience of the community.

Conclusion

Rationing and priority setting systems may not be popular, but they are not terrible things. Ideally, with public support, they openly recognise that the investment we choose to make in a crucial part of our lives is not infinite. In public health systems, they express fundamental values about community, solidarity, equality and fairness. However, in answering one group of questions about individual rights and the sharing of health-care resources, they also raise others, especially when systems seek to promote population-based objectives. I have emphasised some of the risks and benefits raised by the community end of the *choices* debate and the need to respond to the challenges that confront us. Public investment in health-care systems is unlikely to increase at a time when we are living longer, pharmaceutical and medical technology is becoming more costly and the burden of chronic, “lifestyle” diseases is increasing. The remorseless economic logic of the position argues for a much larger community-based enterprise to reverse upward trends of mortality and morbidity. In this, health-care services are not the only, or even the dominant, actor.[59] In addition, it will need the cooperation of departments of education, housing, employment, town planning, the environment and private enterprise. We have discussed some of the difficulties of integrating public and private objectives in health care and probably raised more questions than answers. The public health logic of diverting finite funds from those currently receiving care to those who are not yet to fall ill raises immense problems of politics and ethics, but the need to do so is inescapable. Unless we rebalance the priority setting agenda towards the community end of the equation, current patterns of investment in health care will become unsustainable.[60]

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[58] “Fear of numbers” has been identified as a sign of “ethical collapse”. See Jennings (2006).

[59] See *Health Inequalities* (HC 286-1, Third Report, 2008–09), 26. It is estimated that 80–85 % of variation in PCTs’ mortality statistics are caused by socio-economic factors outside the control of health care, such as poverty, intelligence and ethnicity.

[60] “Public finances are likely to come under pressure over the longer term, primarily as a result of an ageing population… Government would end up having to spend more as a share of national income on age-related items such as pensions and healthcare. But the same demographic trends would leave government revenues roughly stable as a share of national income. In the absence of offsetting tax increases or spending cuts this would eventually put public sector net debt on an unsustainable upward trajectory…The UK, it should be said, is far from unique in facing such pressures.” See *Fiscal Sustainability Report 2011* (Office for Budget Responsibility) paras 4 and 5.

Acknowledgements Grateful acknowledgement is made to Maklu Publishers, Antwerpen, Apeldoorn and Portland for permission to republish this work which, subject to minor updating, originally appeared in Rationing Health Care: Hard Choices and Unavoidable Trade-offs (2012, edited by André den Exter and Martin Buijsen).

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The Law Behind Priorities: Implementation of Priority Setting in Health Care – The German Example

Bjoern Schmitz-Luhn and Christian Katzenmeier

Priority setting in health care is a promising approach to tackle the challenges of today's society and increasing health-care costs that most statutory health-care systems have been facing over the last decades.

However, no prioritization in health care can exist without instruments of implementation. It's introduction needs mechanisms for the steering and governance of its principles, to ensure that the ideas of how to allocate goods in a better way can be transformed into practice. Naturally, any such substantive change of the ways of allocation can have manifold impacts on the existing health-care system and legal framework it is incorporated into. Sometimes, the existing regulatory framework even poses hindrances to effectively apply prioritizing schemes or at least raises questions of permissibility, effective implementation, and impact on existing regulatory equilibria.

This article points out some of the challenges to introduce a scheme of priority setting in Germany by highlighting specific aspects found on various levels of regulation in the German legal framework and its system of health care.

1 The German System of Public Health Care

The German statutory health insurance is one part of the German social security system which also comprises retirement, worklessness, accident, and geriatric care protection. It was introduced at the end of the nineteenth century, and most of its governing principles have since been in place, modified only in part. The German

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_12

statutory health insurance thus offers, also from an international perspective, widespread coverage of health services as well as an overall high level of care.

Approximately 87 % of the German population are insured in the statutory health-care scheme, i.e. about 70 million citizens.[1] Their health services are offered through 357,200 medical practitioners,[2] 69,236 dentists,[3] and 49,288 pharmacists.[4] Overall, 12 % of the German population work in the health-care sector. [5] 300 billions of euros were spent for health-care services in 2014.[6] The quotient of health-care spending in relation to Germany's gross domestic product has been around 10 % for years.[7] The system is funded by premiums for every citizen which are paid for both by the insuree and his or her employer with equal shares, the amount of the premium being relative to the employee's income (currently ~14.6 %).[8]

One of the governing principles of the statutory health insurance is its mandatory character. Every citizen who falls within the statutory prerequisites is automatically and mandatorily insured; no treaty is needed between the insurer and the insuree. Only citizens who are assumed not to be needing protection are excluded, i.e. basically persons with an income above currently 54,900 euros[9] per year and the self-

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All citations given in this article refer to works in German language of which no English version is currently available, except otherwise noted. Titles of institutions and referenced books have been translated for better understanding; the original German title is, in these cases, indicated in parentheses. Journals are cited by their original German title with their common abbreviation in parentheses.

[1] Numbers from 2013; cf. http://www.vdek.com/presse/daten/b_versicherte.html, source: Association of German Health Insurance Companies (vdek), retrieved Feb. 21, 2015.

[2] http://www.bundesaerztekammer.de/downloads/Stat13AbbTab.pdf, source: German Medical Association (Bundesärztekammer); http://www.bundesaerztekammer.de/page.asp?his=0.3.12002, source: German Medical Association (Bundesärztekammer); http://de.statista.com/statistik/daten/studie/158869/umfrage/anzahl-der-aerzte-in-deutschland-seit-1990/, source: Statista Ltd. (Statista GmbH), retrieved Feb. 21, 2015.

[3] http://www.bzaek.de/fileadmin/PDFs/df/df13/df13_web.pdf, source: National Association of Statutory Health Insurance Dentists (Kassenzahnärztliche Bundesvereinigung), retrieved Feb. 21, 2015.

[4] http://www.abda.de/fileadmin/assets/ZDF/ZDF_2013/ZDF_2013_08-Apotheker.pdf, source: German Association of Pharmacists (ABDA), retrieved Feb. 21, 2015.

[5] http://www.bpb.de/nachschlagen/zahlen-und-fakten/soziale-situation-in-deutschland/61807/beschaeftigte, source: Federal Agency for Civic Education (Bundeszentrale für politische Bildung), retrieved Feb. 21, 2015.

[6] Publ. no. 18/1023 of the German parliament (Bundestagsdrucksache), Jan. 1, 2014.

[7] In 2012, it has been at 11.3 %, with slight increases each year: https://www.destatis.de/ DE/PresseService/Presse/Pressemitteilungen/2014/04/PD14_126_23611.html, source: Federal Statistical Office (Statistisches Bundesamt), retrieved Feb. 21, 2015.

[8] http://bmg.bund.de/themen/krankenversicherung/beitragssatz.html, source: Federal Ministry for Health (Bundesministerium für Gesundheit), retrieved Feb. 21, 2015.

[9] http://www.bundesregierung.de/Content/DE/Artikel/2014/10/2014-10-15-rechengroessen-sozialversicherung.html, source: Federal Government (Bundesregierung); http://www.bafin.de/SharedDocs/FAQs/DE/Verbraucher/Versicherungen/ PrivatKrank/04_beitragsbemessungsgrenze_versicherungspflichtgrenze.html, source: German Federal Financial Supervisory Authority (BAFin), both retrieved Feb. 21, 2015.

employed in certain fields. Other maxims are the principle of mutual insurance, meaning that the acceptance of health care from the system is generally linked to the payment of premiums, as well as the principle of social equivalence, guaranteeing every citizen the same level of care regardless of how much he or she has to pay as a premium. All needed treatments are rendered as such, i.e., the insuree is, apart from very few exceptions, entitled only to receiving the treatment itself but not monetary claims for treatment obtained otherwise or waived.

Hence, every insuree has equal access to all available services and specific treatment methods that fall within the general scope of the statutory health insurance. What specific forms of treatment are covered in this general scope is defined by a catalog of available health services which lists applicable treatments in ambulant care and excluded treatments in all other medical areas, especially stationary care/hospital treatment.[10]

As to the choice of the specific form of treatment for the individual patient, statute prescribes that all administered health services given to patients must be sufficient, appropriate, and economically reasonable and must not exceed what is necessary (§§ 2 and 12 of the German Social Code, Book Five – SGB V). The cost of the treatment is only to be considered if a cheaper alternative treatment is applicable and feasible. The patient is therefore entitled to whatever needs to be done for him or her, regardless of the cost, and without any specific monetary threshold per illness, etc. – as long as the suitable treatment is within the benefit scheme. Neither does the cause of the illness generally play a role, e.g., the lack of the patient's compliance or self-induced causes that may have contributed to the formation of the illness.

What specific treatments are part of the insurance scheme or which are excluded is decided by a Federal committee (Gemeinsamer Bundesausschuss), composed of representatives of both the health insurers (which are privately organized but mostly uniformly regulated by law, e.g. in regard to amounts of premiums and scope of benefits) and physicians and hospitals (as well as patient representatives, however without vote). Explicit priority setting is, until today, largely unknown in the German statutory health-care system. So far, the legislature has rather attempted to contain health-care expenditures more indirectly, by introducing measures of competition improvements, budgeteering, and rationalization.

The discussion about priority setting in health care has not been much noticeable in Germany for a long time,[11] also due to the widespread belief that priority setting

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[10] Cf. the so-called Uniform Assessment Scale (Einheitlicher Bewertungsmaßstab, EBM), accessible at http://www.kbv.de/html/ebm.php, source: National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung, KBV), retrieved Feb. 23, 2015.

[11] Early introductions at Arnold, Solidarity 2000. Health Care and its Financing after the Millennium (Solidarität 2000. Die medizinische Versorgung und ihre Finanzierung nach der Jahrtausendwende), 1993, p. 167; Uhlenbruck, Medizinrecht (MedR) 1995, p. 433. Newer overviews at Preusker, GGW 2004 (2), 16; Kliemt, in Marckmann/Brock (eds.), Health Care in Older Age (Gesundheitsversorgung im Alter), 2003, p. 59 with further reference; Katzenmeier, ZEFQ 2010, p. 364; id., in Schmitz-Luhn/Bohmeier (eds.), Priority Setting in Medicine – Criteria under Discussion (Priorisierung in der Medizin – Kriterien im Dialog), 2013, p. 1. Comprehensive over-

is but a means to rationing of necessary health-care measures. This remains true for most of the political level. Slowly, however, a new understanding about prioritization seems to form in the societal discussion. In spite of the containment measures of the recent decades, scarcity in health care has become more and more noticeable: Especially physicians and clinicians have started to call for the discussion about priorities, emphasizing its effect of avoiding implicit rationing, cases of which are currently increasing due to the effects of the "soft" steering mechanisms like budgeteering and strengthening of competition.[12] In fact, physicians claim to face more and more situations in their daily professional life forcing them to allocate resources on an individual level due to budgeteering as well as economic constraints and impulses while lacking any upper-level guidelines or regulations on how to trade off these multilevel, indirect influences of an economic nature.[13]

Priority setting yields at a more efficient, fair, and need-related application of resources and the avoidance of phenomena of implicit rationing. It has thus been increasingly discussed in the German context.

In Germany, like in most other countries, the existing regulatory framework can be divided into two levels: On the primary level, main principles of state activity and regulation are set forth, mostly in constitutional or comparable basic rules, or settled and accepted ethical principles. On the secondary level, laws and statutes specify the particulars of the functioning of the system as well as individual and procedural rights and thus describe what exactly the health-care system offers to its insurees and how this is administered.

2 The Primary Level: Basic Principles of State

The current discussion on priority setting in health care both in Germany and in many other countries mostly focuses on the applicable normative bases. Naturally, finding solutions on determining the fairest possible way to allocate means is primary and essential. Many aspects of finding fair principles for allocation are mirrored by the basic principles of state which set forth a number of rights. In Germany,

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view of priority setting in different countries, and priority setting in the German context at Schmitz-Luhn, Priority Setting in Medicine – Experiences and Perspectives (Priorisierung in der Medizin – Erfahrungen und Perspektiven), 2014, § 10, p. 119 et seq.

[12] Cf., inter alia, Central Ethics Commission of the German Medical Association (Zentrale Ethikkommission bei der Bundesärztekammer), Priorities in Health Care within the System of Statutory Health Insurance (Prioritäten in der medizinischen Versorgung im System der Gesetzlichen Krankenversicherung), 2000, p. 7 et seq.; see also Opinion of the German Ethics Council (Stellungnahme des Deutschen Ethikrats), Utility and Cost in Health Care – Regarding the Normative Function of their Assessment (Nutzen und Kosten im Gesundheitswesen – Zur normativen Funktion ihrer Bewertung), 2011, esp. p. 13 et seq.; later update: Raspe/Schulze, Dtsch Arztebl 2013, 110(22): A-1091.

[13] Cf. German Medical Association (Bundesärztekammer), Health Strategy Principles of the Medical Profession (Gesundheitspolitische Leitsätze der Ärzteschaft, "Ulmer Papier"), 2008, esp. on p. 12 et seq. and 20 et seq.

for example, the constitutionality test is one of the main aspects for the permissibility of allocation criteria. This is widely due to the country's past – Germany's constitution has a specifically enumerative list of rights and freedoms and has incorporated many ethical rules. Therefore, some criteria openly discussed in other countries would be inadmissible in Germany for this reason.

2.1 General Requirements

The German Constitution (the *Grundgesetz – GG*, i.e., the German Basic Law[14]) requires that the government shall offer a functioning scheme of health care which is accessible to all its citizens (Art. 2 (2) and 20 (1) GG).[15] The original constitutional guarantee of protective rights of an individual against the state from unlawful interference has thus been extended into a positive duty of the state to become active in order to protect the individuals' right of physical integrity.[16]

However, the state is left with a relatively wide regulatory leeway. Only a total inactivity or taking solely inappropriate or unsuitable measures would be constitutionally impermissible.[17] In the perspective of rationing, a true duty to offer a benefit of health care to its citizens can therefore only be assumed for cases in which a total exclusion of certain health-care measures results in a drastic loss of chances for specific groups of patients.[18] On the other hand, this also means that at least for certain specific cases of priority setting leading to rationing, the German constitution can set limits to the governmental scope for restrictions in the extent of its health-care system.

2.2 Minimum of Subsistence

The idea whether the German constitution calls for the state to offer a "minimum of subsistence" to its citizens in terms of an absolute minimum of health services, has first tangibly become relevant in light of a decision of the German Constitutional

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[14] The text of the German Civil Code is available in English at http://www.gesetze-im-internet.de/englisch_gg/index.html, retrieved Feb. 21, 2015.

[15] Schultze-Fielitz, in Dreier, Commentary of the German Basic Law (Grundgesetz-Kommentar), 3rd ed., Art. 2, note 96; Kunig, in v. Münch/Kunig, Commentary of the German Basic Law (Grundgesetz-Kommentar), 6th ed. 2012, Art. 2, note 60.

[16] Zippelius/Würtenberger, German Constitutional Law (Deutsches Staatsrecht), 32nd ed. 2008, p. 227; Kunig, in v. Münch/Kunig, Commentary of the German Basic Law (Grundgesetz-Kommentar), 6th ed. 2012, Art. 2, note 55.

[17] Cf. the early decisions of the constitutional court regarding this matter: German Constitutional Court (BVerfG), Neue Juristische Wochenschrift (NJW) 1988, p. 1651 at 1653 and NJW 2001, p. 1779 at 1780; cf. also Schultze-Fielitz, in Dreier, Commentary of the German Basic Law (Grundgesetz-Kommentar), 3rd ed., Art. 2, notes 86 and 89.

[18] Cf. Nettesheim, Verwaltungsarchiv (VerwArch) 2002, p. 315 at 327 et seq.

Court from 6 December 2005[19] which has caused intense discussions throughout the German legal profession and jurisprudence.[20] It is still unclear whether the decision actually stipulates an individual right of every citizen to a minimum of health-care services as an immediate constitutional claim. Indeed, the court's decision calls for the reimbursement of treatment costs for members of the statutory health-care system even for treatments that do not conform with the "generally recognized state of medical knowledge." However, such a right was only granted for the quite limited scope of diseases that are, cumulatively, (1) life-threatening or which usually are lethal, (2) for which no standard treatment exists, and (3) in which the intended nonstandard treatment does at least promise a prospect of cure or significant positive effect on disease progression that is not "totally distant."

Thus, a constitutional subsistence level of medical care is indeed hinted at, at least as far as this provision for the treatment of life-threatening or fatal disease is considered part of the "core" of the required minimum supply according to Art. 2 (2) (1) GG under the specified conditions[21]: Within these narrow limits, the constitutional court has therefore effectively widened the service of German statutory health insurance even beyond its statutory scope for cases in which a nonstandard treatment for a life-threatening or regularly fatal disease shows a not totally distant prospect of cure or significant positive effect on disease progression. Accordingly, the assumption of the state's duty to provide at least this level of medical subsistence seems dominant by now in pertinent legal literature.[22]

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[19] Decision Reporter of the German Constitutional Court (BVerfGE) 115, p. 25. The decision was made regarding the constitutional complaint of a plaintiff born in July 1987 who suffered from Duchenne muscular dystrophy, a disease caused by a genetic mutation, which leads to a progressive breakdown of muscle tissue and, consequently, the loss of ambulation, increasing respiratory failure, and other symptoms which greatly limit life expectancy. Therapy is only available for symptomatic treatment. The plaintiff had been in treatment since 1992, receiving, inter alia, high-frequency oscillations ("bio-resonance therapy") for which his parents applied an amount of 10,000 German Marks. The statutory health insurance refused reimbursement due to the fact that "bio-resonance therapy" was not a recognized standard treatment and had not been shown to have any medical effect.

[20] Cf., inter alia, Francke/Hart, Medizinrecht (MedR) 24 (2006), p. 131; Huster, Juristenzeitung (JZ) 2006, p. 466; Wasem, Gesundheit und Gesellschaft Wissenschaft (GGW) 2006 (4), p. 15; Dettling, Gesundheitsrecht (GesR) 2006, p. 97; Hauck, Neue Juristische Wochenschrift (NJW) 2007, p. 1320; Padé, Neue Zeitschrift für Sozialrecht (NZS) 2007, p. 352.

[21] Decision Reporter of the German Constitutional Court (BVerfGE) 115, p. 25 at para. 66, citing Wiedemann, in Umbach/Clemens (eds.), Commentary of the German Basic Law (Grundgesetz), vol. I, 2002, Art. 2, note 376; Di Fabio, in Maunz/Dürig, Commentary of the German Basic Law (Grundgesetz), 72nd ed. 2014, Art. 2 para. 2, note 94; Schmidt-Aßmann, Neue Juristische Wochenschrift (NJW) 2004, p. 1689 at 1691.

[22] Kunig, in v. Münch/Kunig, Commentary of the German Basic Law (Grundgesetz-Kommentar), 6th ed. 2012, Art. 2, note 60; Starck, in v. Mangoldt/Klein/Starck, Commentary of the German Basic Law (Kommentar zum Grundgesetz), 6th ed., Art. 1, note 36; Schulze-Fielitz, in Dreier, Commentary of the German Basic Law (Grundgesetz-Kommentar), 3rd ed., Art. 2, note 96; cf. also Central Ethics Commission of the German Medical Association (Zentrale Ethikkommission bei der Bundesärztekammer), Priorities in Health Care within the System of Statutory Health

Naturally, this is a rather technical issue as long as the practical extent of such a right is not clarified. And beyond the prerequisites of the case just described, there is little agreement on how far this principle will effectively extend patients' individual rights for treatment in general.

In this context, the expression of "naked existence" as the indispensable level of protection of life is often quoted, which, given the narrow wording of Art. 2 (2) (1) GG and seeing its liberal-defense origin, only protects life and physical integrity as such rather than granting a comprehensive health guarantee,[23] meaning that medical subsistence consisted only of the ban to deny medical services to treat situations which would otherwise lead directly to death.[24]

However, even beyond such a "core" of a medical subsistence, further considerations arise from the perspective of the principle of social welfare and of human dignity, both of which are part of the provisions in the German Basic Law (Arts. 19 (4), 20 (1), and 1 (1) GG, respectively).[25] Health is a basic need and a prerequisite for the achievement of any life and personal lifestyle and therefore of exposed meaning for the discussion of social issues. Cuts in health care tend to be, more than in other areas of life, considered socially unjust.[26] This factor is underlined by the principle of solidarity in statutory health care which does not differentiate between rich and poor or old and young and which does not determine premiums based on risk but exclusively on personal income.[27] Based on these thoughts, an obligation of the state might even be conceivable to provide for a comprehensive health care in a way that no person, no matter his or her income, can be identified as "poor" in social interaction, e.g., by showing missing or bad teeth.[28] Of course, such an argument would probably confuse social justice and measurable health needs. It shows how

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Insurance – long version – (Prioritäten in der medizinischen Versorgung im System der Gesetzlichen Krankenversicherung – Langfassung –), 2007, p. 16.

[23] Kunig, in v. Münch/Kunig, Commentary of the German Basic Law (Grundgesetz-Kommentar), 6th ed. 2012, Art. 2, note 62; Gröschner, in Dreier, Commentary of the German Basic Law (Grundgesetz-Kommentar), 3rd ed., Art. 20, note 27; Murswiek, in Sachs, Commentary of the German Basic Law (Grundgesetz: GG), 7th ed. 2014, Art. 2, note 150.

[24] Kunig, in v. Münch/Kunig, Commentary of the German Basic Law (Grundgesetz-Kommentar), 6th ed. 2012, Art. 2, note 60; Taupitz, in Wolter/Riedel (eds.), The Influence of Fundamental Rights on Civil, Public and Criminal Law (Einwirkungen der Grundrechte auf das Zivilrecht, Öffentliche Recht und Strafrecht), 1998, p. 113 and 119.

[25] Accordingly, another decision of the German Constitutional Court does assume a constitutionally guaranteed level of subsistence in the form of an individual "right to a life of human dignity." However, it is clarified that constitutional rights of guarantee are subject to "specification and constant updating by the national legislature – whose duty it is to adjust benefits to the current level of social development and conditions of living in the German society" [translation by author]: Decision Reporter of the German Constitutional Court (BVerfGE) 125, p. 175.

[26] Huster, in Schöne-Seifert/Buyx/Ach (eds.), Treated Fairly? (Gerecht behandelt?), 2006, p. 121 at 132; Gethmann et al., Health – Made-to-Measure? (Gesundheit nach Maß?), 2004, p. 201.

[27] Huster, in Schöne-Seifert/Buyx/Ach (eds.), Treated Fairly? (Gerecht behandelt?), 2006, p. 121 at 126 et seq.

[28] Cf. Ebsen, Nachrichtendienst des Deutschen Vereins für öffentliche und private Fürsorge e.V. (NDV) 1997, p. 71 at 78.

difficult it can be to differentiate between the level of health as such and other core values of society that are, in the end, dependent on the health of its individuals. In the given example, the social integration of individuals by "health empowerment" does not necessarily have to be constructed as an individual right to medical subsistence as part of the statutory health insurance[29] but can much better be taken care of in other systems of social transfer, most especially when health-related issues are concerned that are not, in their principal effect, *specifically* health related but more of a social nature.[30]

In addition, there are other considerations to be made when considering an especially wide application of the German principle of social welfare: First, this principle lacks any legal measure for the extent to which social differences are to be accepted.[31] On the contrary, the principle of social welfare rather calls for a distribution of funds that concentrates on the most elementary areas of public welfare rather than individual social similarity. Addressing social inequalities by way of constructing the statutory health insurance accordingly will become, in any case, impermissible once specific health needs cannot be addressed because resources are used for primarily social purposes.[32] Second, the fundamental rights of the German constitution are, traditionally and prevalently, defensive rights and thus also imply a certain subservience of state-funded social assistance versus the principle of self-responsibility of citizens.[33]

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[29] Therefore, reimbursement by statutory health insurance of merely socially stigmatizing impairments which are externally visible but, for the affected person who cannot afford their remedy, not absolutely pathological can scarcely be justified on the grounds of a minimum level of subsistence. General social welfare benefits can address them more appropriately, since they are not, in their effect, primarily health related; cf. also Schmidt-Aßmann, Neue Juristische Wochenschrift (NJW), 2004, p. 1689 at 1690.

[30] Huster, Social Security for Designing and Mastering the Future (Soziale Sicherung als Zukunftsbewältigung und –gestaltung), 2007, p. 25; Gethmann et al., Health – Made-to-Measure? (Gesundheit nach Maß?), 2004, p. 201.

[31] Antoni, in Hömig (ed.), Basic Law for the Federal Republic of Germany, Commentary, (Grundgesetz für die Bundesrepublik Deutschland), 10th ed. 2013, Art. 20, note 4.

[32] Cf. the decision of the German Constitutional Court (BVerfG), Neue Juristische Wochenschrift (NJW) 2001, p. 1779 at 1780; Sodan, Neue Zeitschrift für Sozialrecht (NZS) 2003, p. 393 at 396 with further references.

[33] Cf. Jarass, in Jarass/Pieroth (eds.), Basic Law for the Federal Republic of Germany, Commentary (Grundgesetz für die Bundesrepublik Deutschland: GG), 13th ed. 2014, Art. 20, note 117. Schmidt-Aßmann, Neue Juristische Wochenschrift (NJW) 2004, p. 1690, rules out a "total welfare" ("Rundum-Fürsorge") by the state; cf. also Central Ethics Commission of the German Medical Association (Zentrale Ethikkommission bei der Bundesärztekammer), Priorities in Health Care within the System of Statutory Health Insurance (Prioritäten in der medizinischen Versorgung im System der Gesetzlichen Krankenversicherung), 2000, p. 16.

2.3 Mandatory Insurance and Premiums

Another constitutional right of individuals, equally originally formed as a defensive right against authoritative arbitrariness, is the right to self-determination and freedom of action. In a system of mandatory membership in a statutory health system, this is of some importance as citizens are obliged by law to become members of such a system and to pay premiums that they might otherwise choose to use for purposes other than health care.[34] The law prescribing this mandatory membership therefore requires a constitutional justification – which, in turn, is only plausible as far as the system of health care into which the citizen is obliged to enter at least covers the essential social risks associated with possible illness.[35] In particular, it requires an adequacy of compulsory contributions and the potential benefits of the solidarity system.[36] While cutting benefits that have only a small impact on risks therefore seem less problematic, it is the more expensive treatments for drastic, life-threatening diseases whose non-compensation by statutory health insurance is the hardest to justify.[37] By imposing compulsory contributions, the state binds a substantial part of the income of the citizen and withdraws it from any private use – quite realizing that, generally, he or she will have no significant funds left for additional private procurement of services or insurance.[38] Thus, cutting expensive and life-saving treatments which a citizen can otherwise not afford would therefore, de facto, result in an almost complete denial of health care.[39]

At the same time, the state is constitutionally obliged to maintain premiums for the statutory health insurance within limits that can be afforded by its citizens in order to provide an efficient health-care system for all compulsory members.[40] This is due to the fact that the justification of the compulsory insurance by an equilibrium of premium and potential individual benefit is, on both ends of the scale, limited by nature. Justification of the compulsory nature of the system becomes increasingly

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[34] Decision Reporter of the German Constitutional Court (BVerfGE) 115, p. 25 at 30; see also the earlier decision at BVerfGE 109, p. 96 at 109 concerning the statutory pension scheme. In regard to the relationship of self-determination and self-subsistence versus solidarity health care, see Central Ethics Commission of the German Medical Association (Zentrale Ethikkommission bei der Bundesärztekammer), Priorities in Health Care within the System of Statutory Health Insurance (Prioritäten in der medizinischen Versorgung im System der Gesetzlichen Krankenversicherung), 2000, p. 16.

[35] Decision Reporter of the German Constitutional Court (BVerfGE) 115, p. 25 at 26; Ebsen, Nachrichtendienst des Deutschen Vereins für öffentliche und private Fürsorge e.V. (NDV) 1997, p. 71 at 73.

[36] Jachertz/Rieser, Dtsch Arztebl. 2007; (104)1-2: A-21, A-24; Schmidt-Aßmann, Neue Juristische Wochenschrift (NJW) 2004, p. 1689 at 1692.

[37] Vosteen, Rationing in Health Care and Patient Protection (Rationierung im Gesundheitswesen und Patientenschutz), 2001, p. 310.

[38] Vosteen, ibid. at p. 298, who understands this as a violation of Art. 2 (2) GG in its function as a liberal-defensive right.

[39] Decision Reporter of the German Constitutional Court (BVerfGE) 115, p. 25 at 26 et seq.; commented by Schimmelpfeng-Schütte, Zeitschrift für Rechtspolitik (ZRP) 2006, p. 180 at 183.

[40] Cf. Huster, Juristenzeitung (JZ) 2006, p. 466 at 468 with further reference.

difficult when premiums are raised above an affordable level.[41] While demographic change and increasing medico-technical progress steadily increase the overall expenditure, the equilibrium of justifiable compulsory health insurance premiums and benefits needs to be maintained. After all, in order to maintain an affordable and effective health-care system covering the fundamental health risks in life, cost-oriented aspects need to be included in the determination of the benefit package, and lower-priority benefits must be excluded where this is required in accordance with the foregoing principles – this is, just as well as providing for elementary health care – a duty of state.

2.4 The Principle of Equality

The provision in Art. 3 (1) GG is the central constitutional norm on equitable distribution. It basically stipulates that same persons and conditions shall be treated equally and different ones, according to their peculiarities, differently.[42] In the light of the rights of patients to the allocation of health-related goods, and in connection with the libertarian and individual rights of patients as described above,[43] this means that, in effect, every member of the statutory health insurance has the right to *equal access* to the given capacities of statutory health care.[44] More specifically, every allocation of health-care goods resulting in a differentiation of patients or patient groups needs to withstand a test of proportionality taking into account an overall view of all affected libertarian and individual constitutional rights.[45] While, in general, the aim of maintaining the financial stability, the functioning, and the efficiency of the statutory health-care system is permissible as a justification for the allocation decision,[46] the specific means and its proportionality must be justified as well. In the end, the point of reference is whether every member of the statutory health-care system is effectively equipped with the same chance to benefit from health-care treatments that are generally available.[47] Equality, in this context, means

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[41] Sodan, Neue Zeitschrift für Sozialrecht (NZS) 2003, p. 393 at 398; Huster, Juristenzeitung (JZ) 2006, p. 466 at 467.

[42] Gubelt, in v. Münch/Kunig, Commentary of the German Basic Law (Grundgesetz-Kommentar), 6th ed. 2012, Art. 3, note 11.

[43] Osterloh, in Sachs, Commentary of the German Basic Law (Grundgesetz: GG), 7th ed. 2014, Art. 3, note 5; Badura, in Commemorative Volume for Friauf (FS-Friauf), 1996, p. 529 at 543.

[44] Gutmann, in Gutmann/Schmidt (eds.), Rationing and Allocation in Health Care (Rationierung und Allokation im Gesundheitswesen), 2002, p. 179 at 181.

[45] Also cf. Schmidt-Aßmann, Constitutional Positions and Questions of Legitimacy (Grundrechtspositionen und Legitimationsfragen), 2001, p. 21; Neumann, Neue Zeitschrift für Sozialrecht (NZS) 2005, p. 617 at 623.

[46] Neumann, Neue Zeitschrift für Sozialrecht (NZS) 2005, p. 617 at 623; Pieroth/Schlink/Kingreen/Poscher, Constitutional Rights (Grundrechte), 30th ed. 2014, § 11, notes 440 et seq.

[47] Decisions of the German Constitutional Court (BVerfG), Neue Juristische Wochenschrift (NJW) 1977, p. 569 at 570; and NJW 1972, p. 1561 at 1567.

a specific *equality of chances*, taking into account the affected constitutional rights of the members of compulsory statutory health insurance.[48]

Furthermore, the basic law stipulates *absolute prohibitions* of differentiation by the state, including unequal treatment on the grounds of sex, race, language, origin, belief, or disability. Finally, closely connected with these principles, the guarantee of human dignity in Art. 1 (1) GG draws another line to the permissibility of allocation decisions, since it comprises a principle of "life value indifference"[49]: Every human life has the same value; a selection of patients according to their social worth, responsibility, or societal position is absolutely impermissible.[50]

2.5 Constitutional Permissibility of Specific Allocation Criteria

The interdisciplinary debate of priority setting and rationing as well as the experience with prioritizing allocation systems abroad has brought forward a whole number of possible criteria on which a possible decision on the allocation of health-care goods can be based upon. Beyond their societal acceptability, ethical justifiability, and economic efficiency, all of these criteria must meet the prerequisites of constitutional permissibility. This encompasses both the principle of equal chances in light of all other fundamental and individual constitutional rights of a member of the statutory health-care scheme and the avoidance of differentiations that are explicitly precluded, both of these aspects having been described above. They seem to be the most substantial requirements of the German constitution as far as the modeling of a statutory health-care system including priority setting or rationing is concerned – and they seem to be largely comparable to the ethical principles which have been discussed in many a historical surrounding of plans to introduce priority setting into existing health-care systems worldwide.[51]

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[48] Vgl. Sommermann, in v. Mangoldt/Klein/Starck, Commentary of the German Basic Law (Kommentar zum Grundgesetz), 6th ed., Art. 20, note 105.

[49] Decision of the German Constitutional Court (BVerfG), Neue Juristische Wochenschrift (NJW) 1975, p. 573 at 580; Künschner, Forgoing Treatments due to Economic Aspects and Selection of Patients (Wirtschaftlicher Behandlungsverzicht und Patientenauswahl), 1992, p. 29.

[50] Vgl. Gutmann, in Gutmann/Schmidt (eds.), Rationing and Allocation in Health Care (Rationierung und Allokation im Gesundheitswesen), 2002, p. 179 at 202. A common example in the German discussion includes that a murderer has to have the same rights to a treatment as a mother or a physician who frequently saves other lives.

[51] In Sweden, for example, the principle of human dignity has been seen as one of the leading and most fundamental ethical requirements in a scheme of priority setting. Also, the historic debate has explicitly included the principle of equality of chances: cf. Federation of County Councils of Sweden, Nationellt stöd för kunskaps- och verksamhetsutveckling i hälso- och sjukvarden, 4 May 1999 (in Swedish) and National Centre for Priority Setting in Health Care, Resolving Health Care's Difficult Choices. Survey of Priority Setting in Sweden and an Analysis of Principles and Guidelines on Priorities in Health Care. 2008. However, not every country with an experience of priority setting has always chosen this approach: In Oregon, for example, a much more economic and utilitarian approach has been chosen – nevertheless, the principles of equal access and human

The legal examination of a number of potential criteria for priority setting and allocation in light of the German constitution, including urgency, chances of success and prognosis, waiting time, patient behavior and compliance, cost-benefit considerations, and even chronological age, has found that the use of all of these criteria is generally permissible, as far as the specific configuration of the allocation or the individual situation of a patient does not impose otherwise by resulting in an unfair or unjustified differentiation of patients.[52] Only those criteria which rely on evaluating the social worth or value of lives, or which violate explicit prohibitions of differentiation as mentioned above,[53] are impermissible a priori.

The exact configuration of any system of allocation as well as the criteria to be applied to allocation decisions depends, in the end, not only on considerations of equity but also on value preferences of the affected citizens and on the ideals and conceptions of a good and successful life.[54] Their determination and the necessary societal decisions require a democratic, open, and fundamental societal discussion.

2.6 Procedural Requirements

An essential condition for a successful composition and implementation of any system of priority setting pertains to the entire process of decision-making on all levels of health care, including the shaping of the system on a macrolevel up to the designation of specific or specifiable criteria for individual allocation on a microlevel. All of these levels of decision-making require adherence to the legal and ethical rules of democracy but also a public discussion on what society holds as most important values and aspects of health care. This democratic, public *deliberation* is, in fact, the most significant reason to prefer explicit priority setting to implicit rationing. In any case, deliberative aspects can greatly increase the public's acceptance of necessary containments in the health sector and bring many

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dignity have been often cited, if only as an underlying argument for the prioritization debate as such; cf. Hrinda, The Oregon Health Plan, 2007, p. 2 et seq., with further reference.

[52] Cf., for an overview, Schmitz-Luhn, Priority Setting in Medicine – Experiences and Perspectives (Priorisierung in der Medizin – Erfahrungen und Perspektiven), 2014, § 10, p. 119 et seq., with further reference for each criterion and, for an interdisciplinary view, Schmitz-Luhn/Bohmeier (eds.), Priority Setting in Medicine – Criteria under Discussion (Priorisierung in der Medizin – Kriterien im Dialog), 2013.

[53] E.g., an allocation that results in the differentiation of disabled persons; cf. supra II.1.c.

[54] Marckmann, in Wiesing (ed.), Ethics in Medicine (Ethik in der Medizin), 4th ed. 2012, p. 282 at 291; Emanuel, in Marckmann/Liening/Wiesing (eds.) Fair Health Care (Gerechte Gesundheitsversorgung), 2003, p. 128. In the end, no system relying on criterial decisions will, in addition, work without a scheme to balance out different criteria and their respective scales: see Ahlert/Kliemt, in Schmitz-Luhn/Bohmeier (eds.), Priority Setting in Medicine – Criteria under Discussion (Priorisierung in der Medizin – Kriterien im Dialog), 2013, p. 231; with comment by Bohmeier/Schmitz-Luhn, ibid., p. 265.

other advantages. As much as this is generally agreed upon, [55] recommendations of how this discussion should specifically take place are rare, and manifold are the possible ways of setting up this process. They range from a stronger participation of patient representatives in the process of determination of benefits, the holding of citizens' conferences,[56] to the active survey of preferences, values, and opinions within society.[57]

Deliberation can be as far reaching as a people's public vote on fundamental matters pertaining to their future health system but can as well be much less intense, e.g., when public representatives are given the right to attend meetings of health boards and introduce arguments but not the right to vote. In general, possible forms of deliberation can vary greatly on two scales: firstly, in regard to the extent of participants and, secondly, on the scale of participatory intensity. Interestingly, a look at nine countries with experience in priority setting has shown that even fundamental decisions are mostly made rather representatively, i.e., without large participatory effects of the public's declared opinion.[58] This even applies to countries where a long history of rather strong deliberative rights and direct democracy prevails.[59]

The specific design of the decision-making bodies and their occupation by experts and other stakeholders is, in itself, already a question of political

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[55] Cf., inter alia, National Ethics Council (Nationaler Ethikrat), Health for Everyone – How Much Longer? Rationing and Fairness in Health Care (Gesundheit für alle – wie lange noch? Rationierung und Gerechtigkeit im Gesundheitswesen), 2006; Central Ethics Commission of the German Medical Association (Zentrale Ethikkommission bei der Bundesärztekammer), Priorities in Health Care within the System of Statutory Health Insurance (Prioritäten in der medizinischen Versorgung im System der Gesetzlichen Krankenversicherung), 2000; id., Priorities in Health Care within the System of Statutory Health Insurance (Prioritäten in der medizinischen Versorgung im System der Gesetzlichen Krankenversicherung), 2007; Schöne-Seifert/Buyx/Ach (eds.), Treated Fairly? (Gerecht behandelt?), 2006; Huster, Social Fairness in Health Care. Economizing, Redistributing, Provisioning (Soziale Gesundheitsgerechtigkeit. Sparen, umverteilen, vorsorgen), 2011; Article Series in Dtsch Arztebl 2009 (106); Focus Edition ZEFQ 2009 (103:2); summarization of the position of the medical profession in Fuchs, Bundesgesundheitsbl. 2010, p. 435; Raspe/Schulze, Dtsch Arztebl 2013, 110(22): A-1091; Schmitz-Luhn/Bohmeier (eds.), Priority Setting in Medicine – Criteria under Discussion (Priorisierung in der Medizin – Kriterien im Dialog), 2013.

[56] Essentially Schicktanz/Naumann, in id. (eds.), Citizens' Council: The Issue of Genetic Diagnostics (Bürgerkonferenz: Streitfall Gendiagnostik), 2003, p. 57 et seq.; in the field of priority setting in health care: Stumpf/Raspe, Dtsch Arztebl. 2011, 108(7): A-316.

[57] For first quantitative findings on the values and preferences in the German society, see, inter alia: Diederich/Schreier, in Schmitz-Luhn/Bohmeier (eds.), Priority Setting in Medicine – Criteria under Discussion (Priorisierung in der Medizin – Kriterien im Dialog), 2013, p. 265; Ahlert/Kliemt, ibid., p. 231 at 232 et seq.; with critical comment by Lübbe, ibid., p. 245; Bohmeier/Schmitz-Luhn, ibid., p. 257 at 259 et seq. and 264.

[58] Schmitz-Luhn, Priority Setting in Medicine – Experiences and Perspectives (Priorisierung in der Medizin – Erfahrungen und Perspektiven), 2014, §§ 3 to 8 (United Kingdom, Sweden, Norway, Oregon, the Netherlands, Denmark, Finland, New Zealand, and Israel), with further reference for each country.

[59] Concerning Sweden, for example, see Bäckman/Andersson/Carlsson, Transparent Priorities in Östergötland. Part I, 2004, p. 32 et seq.; de Fine Licht, Transparency and Perceived Legitimacy, 2010, p. 15 et seq. (both in English).

decision-making. In any case, the developed conclusions and decisions on the organization of the health-care system must meet the requirements of truly democratic decision-making. One of the most interesting, however somewhat neglected, theoretical questions that need to be addressed is what role direct democracy, deliberation, and participation can effectively take in traditional representative democracies. New models for increased deliberation in today's media-rich, informed, and instantaneous society must be located within the proven concept of traditional representative democracy.

3 The Secondary Level

The constitutional principles and norms as showed above prescribe but the fundamental, i.e., wider, basic framework of state's actions (and thus for equitable allocation and health care). The specific functioning and technical implementation of the health-care system are, however, regulated in a number of laws and statutes concerning the substantive, individual, and procedural rights in terms of the individual access to health-care services and its equitability – in other words, what individual patient can, based on his or her disease or situation, ask for what specific treatment. The rules and regulations on benefits and premiums can mostly be summarized into parts of the social law,[60] while other aspects on this regulatory level, e.g., the regulation of liability, or the cost for treatments that are to be paid for privately, form a part of the civil law.[61]

Parliament's decision to introduce and incorporate a scheme of prioritization would, therefore, necessitate changes mainly and most directly in the area of social law, which has to be reshaped as far as a new allocation scheme is to be implemented. More specifically, since this is the branch of the law which directly governs the extent of coverage of the health insurance, these rules of coverage would need to be changed to reflect the new criteria on which medical need to serve first and which to serve last. The societal and political decisions as well as criterial and systematic choices need to be implemented by regulations, and normative rules for the allocation of means according to these criteria must naturally be developed or adapted. The incorporation of abstract criteria of prioritization would thus be transformed into substantive, procedural and administrative rights of individuals by statute of social law.

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[60] The central and most important of the statutes governing social law is the German Social Code, with its Fifth Book comprising the statutory health insurance scheme (Sozialgesetzbuch, Fünftes Buch – SGB V). It encompasses almost all of the rules regarding membership, premiums, benefits, and scope of reimbursed treatments: text available at http://www.gesetze-im-internet.de/sgb_5/index.html (no English version available, retrieved Feb. 21, 2015).

[61] The main codex of German civil law including treatment contracts and the norms on liability can be found in the German Civil Code (Bürgerliches Gesetzbuch – BGB), sections (§§) 630a et seq. dealing with the foundations of the treatment contract, 276 with the necessary standard of care, and 823 et seq. with the fundamental elements and legal consequence of liability: text of the German Civil Code available in English at http://www.gesetze-im-internet.de/englisch_bgb/index.html, retrieved Feb. 21, 2015.

Civil law, on the other hand, stands in a somewhat more subtle relation with the potential introduction of priority setting into an existing legal system. This does not mean, however, that there are no interdependencies. In fact, the effects of priority setting on civil law have seldom been mentioned in the scientific discussion. Since this field of the law governs medical liability and the standard of care which applies to medical treatments, a closer look is needed into what treatments are expected by the physician when administering a medical treatment: on the one hand, with regard to the social law, governing the extent of coverage and benefits, and on the other, in regard to medical standards of care – which may well differ.[62]

In civil law, the standard of due care describes what can be expected from a duly acting physician in a specific situation when he or she applies medical treatment to a patient.[63] If the physician fails to administer this standard of care, he or she might be subject to liability to the patient who can demand his or her damage to be reimbursed for.[64] As part of this concept, the law expects the physician to administer all *specific actions* that can be expected from a duly acting physician in this situation, including diagnosis and the kinds of treatment that should be applied.[65] This first legal requirement, while it sounds natural and easy, can already become problematic. This is due to the fact that whether a specific treatment is necessary is not determined by the law itself. Rather, the law only requires that the physician does what can be reasonably expected from him or her. What can reasonably be expected is, in turn, something that only the medical profession itself can decide. Only physicians can answer the question whether a duly acting physician can be expected to administer a certain treatment in a specific situation. Therefore, in medical liability proceedings before court, the expert opinion of a medical specialist is usually necessary in order to determine whether the medical treatment in question conformed to the standard of due care.[66]

On the other hand, the scope of benefits as set forth in social law can eventually become more limited by way of priority setting, e.g., by waiting times or other treatments to be administered first, or even explicit rationing, e.g., if treatments have

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[62] More specific interdependencies and changes to the social and liability laws by introducing different kinds of prioritizing models are described at Schmitz-Luhn, Priority Setting in Medicine – Experiences and Perspectives (Priorisierung in der Medizin – Erfahrungen und Perspektiven), 2014, § 12 III, p. 181 et seq.

[63] § 630a (3) BGB and the established line of court decisions, e.g., at Federal Court of Justice Reporter (BGHZ) 144, p. 296 at 305; decision of the Federal Court of Justice (BGH), Versicherungsrecht (VersR) 1999, p. 716; further elaborated on by Laufs, in Laufs/Kern, Handbook of Medical Law (Handbuch des Arztrechts), 4th ed. 2010, § 97, note 3; Dressler, in Brandner/Hagen/Stürner (eds.), Commemorative Volume for Geiß (Festschrift für Geiß), 2000, p. 380 et seq.

[64] Katzenmeier, in Laufs/Katzenmeier/Lipp (eds.), Arztrecht, 7th ed. 2015, chap. X, notes 6 et seq.; Laufs/Kern, in id. (eds.), Handbook of Medical Law (Handbuch des Arztrechts), 4th ed. 2010, § 97, note 3.

[65] Federal Court of Justice Reporter (BGHZ) 144, p. 296 at 305; decision of the Federal Court of Justice (BGH), Versicherungsrecht (VersR) 1999, p. 716.

[66] Buchborn, Medizinrecht (MedR) 1993, p. 328 et seq.; Steffen, MedR 1995, p. 190; Hart, MedR 1998, p. 8 at 9 et seq.; Kern, MedR 2004, p. 300 at 301; Katzenmeier, Physician Liability (Arzthaftung), 2002, p. 279.

been ruled out from the scope of the statutory health insurance. Such a treatments, however, may not always be considered "useless" only because of its exclusion from the scope of benefits.[67] By professional standards, the majority of physicians might well still find such a treatment medically necessary in a given case or at least consider it to be part of a sensible and good treatment in a specific case, *even though* it has been ruled out from the statutory health insurance. This would bring forward the awkward situation in which the physician is required by the standard of due care to administer that treatment, while, on the other hand, it is impossible for him to be reimbursed for this due to the exclusion of this treatment according to social law.

These examples show that there is a tension between social law and civil law or, more precisely put, between coverage laws and liability laws. It can arise because the standard of care is a nonlegal, medical one, based on the convictions of the medical profession on what is a sensible treatment, while the extent of coverage in the state health insurance must be prescribed by law. In Germany, this effect is increased by the fact that cases regarding social law are dealt with before a special jurisdiction in "social courts," while cases regarding medical liability go before the regular civil courts. The latter have consistently refused to take economic aspects – including the scope of benefits of the statutory health insurance – into account when establishing the standard of care.[68] This can lead to situations in which physicians would have to decide whether to administer a treatment outside of the coverage laws and not be reimbursed by the state or to risk a liability claim.

The simplest and most intuitive approach for a physician to deal with such a situation would be to inform the patient about the fact that the intended treatment is not covered by the statutory health insurance, and that it is up to him or her to decide whether to pay for it privately or to refuse the specific treatment.[69] While a termination of the treatment contract due to these reasons is generally possible by both the physician and the patient, there are legal limitations to changing or alleviating this contract once treatment has commenced. The main problem, however, is not one of dealing with the binding contract in the individual case, but of the destructive impact these situations can collectively and ultimately have on the trust between patient and

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[67] Possible examples for these situations at Katzenmeier, in Nehm/Greiner/Groß/Spickhoff (eds.), Commemorative Volume for G. Müller (Festschrift für G. Müller), 2009, p. 237 et seq.; and Voigt, "Individual Health Care Services" [i.e. services excluded from the benefit scheme and paid for by the patient himself] (Individuelle Gesundheitsleistungen), 2013, p. 84 et seq. and notes 214 and 216.

[68] Cf., inter alia, the decisions of the Federal Court of Justice (BGH) Neue Juristische Wochenschrift (NJW) 1954, p. 290; NJW 1983, p. 2081; and Versicherungsrecht (VersR) 1975, p. 43; as well as the decision of the Appellate Court Cologne (OLG Köln) Versicherungsrecht (VersR) 1991, p. 186. The problem has also be specifically elaborated on by Arnade, Economic Pressure and Standard of Care (Kostendruck und Standard), 2010, p. 193 et seq.; and G. Müller, Gesundheitsrecht (GesR) 2004, p. 257 at 264.

[69] Also cf. Voigt, Individual Health Care Services (Individuelle Gesundheitsleistungen), 2013, p. 199 et seq., with further reference; Kreße, Medizinrecht (MedR) 2007, p. 393 at 400. Regarding the shopping of treatment in urgent cases, see Katzenmeier, in Laufs/Katzenmeier/Lipp (eds.), Medical Law (Arztrecht), 7th ed. 2013, chap. III, note 33.

physician – which remains one of the leading and most important principles of any treatment and of the relationship between doctor and patient.

These longer-term effects can therefore easily lead to a change in the professional image of physicians prevalent in society. Physicians increasingly find themselves in a "double role" – on the one hand, empathically trying to help the patient and delivering a good treatment that conforms with the applicable medical standards and, on the other hand, knowing and informing about the wide array of administrative rules and benefit catalog of the statutory health insurance. In some cases, it might not be too easy even for the physician to know whether coverage by the state insurance can be expected. Should we leave the risk of non-reimbursability with the physician or with the patient? How intensely do we want our doctors to be responsible for administrative tasks of the statutory health insurance and to assess questions of social law? And, finally, how do we safeguard that information given to the patient is correct, and what consequences shall incorrect information have?

This eventually also raises the question whether we want physicians to become more and more active in fields that are excluded from state insurance coverage but need to be paid for by the patients themselves. The more benefits are cut and left to the private provision of citizens, these increasingly become consumers of medical services in lieu of the traditional patient in a one-stop system of health care.[70] How can a patient decide whether a treatment that he or she is supposed to pay for is necessary? Might it be tempting for a physician to take advantage of this situation and offer treatments that are not, in the narrowest meaning of the term, necessary? How do we ensure that treatments which are useful but non-reimbursable do not become confused with "useless" but costly ones, being offered "alongside"? Certainly, these aspects may not be new to countries which have traditionally relied on privately funded health insurance. It is, however, a new aspect for patients who have not learned to ask questions about necessity or cost of treatments because their universal insurance has always come up with the funding. They are used to a comprehensive, "all-inclusive" medical system. In the end, these phenomena will need to be assessed and means of protective consumer regulation contemplated, to be applied alongside the primary laws governing allocation.

4 Conclusion: Regulation in Complex Systems

When implementing a scheme of priority setting in health care, various legal and societal aspects must be considered and anticipated rather than, although being the most important and primary necessity, "only" the question of whether the allocation is fair and socially just. In addition, the existing legal and organizational structure of the health-care system must be assessed, constitutional and ethical prerequisites must be analyzed, and the multitudinous methods of control, allocation, and governance which have, over the decades, already been incorporated into existing systems, are to be taken into consideration when introducing a scheme of priority setting. Much

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[70] Voigt, Individual Health Care Services (Individuelle Gesundheitsleistungen), 2013.

diligence should furthermore be given to the process of finding socially desired or acceptable criteria and to the design of democratic decision-making.

The specific challenges of implementation certainly differ from country to country. In all countries where experience with priority setting has been made, it has proven challenging to balance the multilevel outcomes and various effects of priority setting and its necessary means of implementation, control and procedure into the complex surroundings of an existing statutory health insurance scheme, and to reach suitable, useable, and practical procedural structures to effectively apply and transform basic allocation criteria to specific and individual allocation decisions.

The international experience with introducing priority setting into existing regulatory health-care schemes shows that the multitudinous effects that need to be blended with basic ideas, principles, and governance within an existing scheme, also depend on what basic concept of priority setting and which methods of governance to implement allocation criteria are chosen.[71] Basic concepts for the implementation of criteria-based systems of priority setting into health-care schemes can basically be divided into two approaches[72]: They can be more precisely defined as either focusing on the governance of allocation, attempting to ensure that all decisions made in the system are based on the grounds of the predefined allocation criteria ("governance approach"), or as more directly defining the catalog of benefits, i.e., of all health services that are covered by statutory health insurance ("benefit regulation approach").[73] Countries' historical, legal, ethical, and systematic background seems to affect the chosen approach. Naturally, the reciprocal effects of existing system governance and the mechanisms to implement priority setting are influenced by the approach chosen, albeit the overall effectiveness of priority setting also fundamentally relies on what mechanisms of governance are chosen and how well they are embedded into the existing system.[74]

In Germany, the two main challenges are to blend democratic allocation criteria into the complex framework of constitutional law and to solve the interdependencies between social law and liability law. While in most countries with health-care systems incorporating elements of priority setting, medical liability is mainly replaced by statutory insurance schemes against malpractice or adverse treatment outcome or by no-fault, need-based compensation schemes,[75] this question remains unsolved in Germany. Courts of social and civil law will have to overcome the divide of assessing the treatment duties of physicians and the scope of benefits in

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[71] Schmitz-Luhn, Priority Setting in Medicine – Experiences and Perspectives (Priorisierung in der Medizin – Erfahrungen und Perspektiven), 2014, § 9 at p. 95 et seq., analyzing the motives for introducing schemes of priority setting, its historical development, structures of health steering before and after the introduction of prioritization, outcomes, corrections in the original scheme of prioritization, and the current overall effects of the health system as a whole.

[72] Also cf. the first synopsis of priority setting in different countries by Sabik/Lie, IntlJEquityHealth 2008 (7:4), p. 1-13 (in English).

[73] Schmitz-Luhn, Priority Setting in Medicine – Experiences and Perspectives (Priorisierung in der Medizin – Erfahrungen und Perspektiven), 2014, § 9 II at p. 97 et seq.

[74] Id., § 9 III at p. 107 et seq.

[75] Id., § 9 III at p. 113 et seq.

statutory health care differently, and the alternative way of replacing the traditional regime of liability needs to be assessed – however considering that the protective and quality-ensuring effect of liability rules would be lost. Furthermore, the role of physicians must be integrated into the changing conditions of which treatments are reimbursed by statutory health care and under which circumstances. Solutions must be found for how to deal with a necessarily expanding "market" of privately purchased medical care in a society of traditionally comprehensive health care.

The discussion on priority setting is a helpful and necessary process for tackling the economic challenges most statutory health-care systems are facing. In order to effectively maintain their proven and reliable function of social safety, equality, and nation-wide assurance, expenditures cannot indefinitely grow until premiums become affordable only for few. On the other hand, benefits must be sensibly adjusted to the needs and allocated to where they are needed most. Priority setting explicates the process of allocation and thus promises transparent, socially accepted yet flexible allocation. Nevertheless, the systematic impact of health-care allocation schemes is far reaching and should be considered from the beginning. Individual and procedural rights need to be newly arranged in a consistent way, the methods of governance must be analyzed and carefully chosen, and they must be sensibly embedded into the existing complex system, in order to avoid unforeseen systematic effects.

Part V

The Role of Age and Personal Responsibility

Priority Setting and Age

Greg Bognar

1 Introduction

The role of age in priority setting is one of the most controversial issues in health policy. It has also been a contentious topic for many years in medical ethics and philosophy, and any discussion of age as a criterion for setting priorities in health care is likely to stir up intense public debate. Age is an easily observable characteristic; hence it is tempting to use it when priorities must be set between different resource uses or patient groups. Indeed, age considerations pervade health systems worldwide. Consequently, there is an urgent need to clarify the role that age can play in health care resource allocation.

Against this background, there have been surprisingly few systematic studies of the justifications for using age as a criterion in priority setting. In this chapter, I provide a broad outline of the range of ideas that have been used to defend the relevance of age. At the end of the chapter, I also reflect on a recent public debate on the role of age in priority setting.

Priority setting is a highly sensitive issue in every country where it comes onto the agenda. Suggestions for using age as a priority-setting criterion are particularly controversial. Part of the reason is that the issue is relatively easy to communicate to the public and to discuss in the media without the use of technical language. As a result, the discussions tend to be rather black and white. The problem of age is usually presented as the narrow question whether age has any legitimate role in priority setting at all. This obscures the fact that few people seem to be opposed to age-based priority setting categorically in every possible setting. Most people are willing to use age as a criterion at least in *some* circumstances and at least in *some* ways. This is shown by empirical studies of public views on priority setting: while

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_13

the survey questions and methodologies vary considerably, most studies suggest that a majority accepts that age can have some role in priority setting.[1]

At the same time, a few countries have issued national policy documents with explicit guidance for priority setting in the health sector. Among these countries are Norway, Sweden, and the UK.[2] For the most part, these kinds of guidelines deal with age in an ambiguous manner. For example, while they generally warn against age discrimination and letting age influence priorities, they also recommend criteria that are closely associated with age and discuss circumstances in which age may be a legitimate consideration.[3]

In addition, age is frequently used as an indicator in actual clinical practice.[4] This is partly because chronological age is an objective, easily observable measure, and it is correlated—or at least it is perceived to be correlated—with many factors that are deemed relevant for decision making in the health care sector. For instance, age can be an indicator for the risk of contracting a disease, for the expected severity of the natural course of a disease, for the risk of adverse events from treatment, for the probability of successful treatment, for the duration of benefit if treatment is successful, and so on. Decisions based on such factors can have a profound impact on particular patients or patient groups, yet the role of age in these decisions is seldom explicit. Indeed, even clinicians expressing disagreement with age-based priority setting may themselves use age inadvertently in practice!

Age enters priority setting in numerous other ways. For instance, it influences cost-effectiveness studies as well as disease burden estimates. At the end of the day, considerations of age can pervasively shape policy and practice, having a profound impact on who gets what, when, and how in health care. It is, therefore, a necessary and urgent task to clarify the role of age from an ethical point of view.

At the most fundamental level, age can play two kinds of role in priority setting in health care. On the one hand, it can have a *direct* role in a particular proposal, policy, or set of guidelines for setting priorities. It can be used as an independent criterion. In order to justify its direct role, it must be shown that age in itself is a morally relevant consideration, and hence it is one of the factors that must be taken into account in the deliberation about the use of available resources. Still, it may not

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[1] See, for instance, Cropper et al. (1994), Nord et al. (1996), Johannesson and Johansson (1997), Tsuchiya (1999), Eisenberg et al. (2011), Olsen (2013), and Petrou et al. (2013). Among the empirical studies on the views of health personnel, some find support for age-based priority setting and others not (see, e.g., Neuberger et al. (1998), Ryynänen et al. (1999), and Werntoft and Edberg (2009)). At the same time, there is considerable, and ongoing, controversy regarding the question of just how the results of these studies should be interpreted (see Dey and Fraser (2000), Tsuchiya (2000), Tsuchiya et al. (2003), Bognar (2008), and Whitty et al. (2014)). The issue is complex, and the very opposite of black and white!

[2] See Sabik and Lie (2008).

[3] See, for instance, SOU (1995:5) and NOU (1997:18). Moreover, explicit age limits abound in both international and national clinical guidelines. For example, this is the case for the guidelines issued by the European Society of Cardiology (2015) and many guidelines for cancer care and screening (e.g., American Cancer Society (2015)).

[4] See Kapp (1998).

be—and it usually isn't—the only relevant factor, and it may not provide the decisive consideration. But it cannot be ignored.

This implies that when a set of guidelines for priority setting recommend age as an independent criterion, then if two patients are equal on every other criterion, a difference in their age will result in priority being assigned to one over the other.

On the other hand, age can have an *indirect* role in priority setting. Rather than serving as an independent priority-setting criterion, it can be used as an indicator or proxy for some other, morally relevant factor. In this case, it enters the deliberation on setting priorities indirectly, representing some other factor that is not measurable or tractable in any better way. For instance, age may be a rough indicator of expected health benefit: other things being equal, a younger patient may benefit more from some intervention. Thus, it might be argued that she should be given priority for some scarce resource. But this isn't because she is younger; it is because this is the way to maximize expected benefit. Even though age is used here as a criterion of *decision making*, it is not used as a criterion for the *moral justification* of the decision. The moral justification of the decision is provided by considerations of benefit maximization.

Introducing these distinctions has the advantage of getting to the crux of the moral issue right away. Any proposal to use age as a criterion for priority setting must explain whether it considers age a morally relevant consideration in itself, or it regards it only as an appropriate indicator for some other morally relevant factor. Priority setting is the application of moral theories and moral principles for resource allocation in health care. So it must be based on defensible ethical arguments. Since age-based considerations already permeate decision making in the health care sector, we cannot avoid addressing this issue.

2 Indirect Views

Suppose you are the only surgeon in the emergency room when two patients are brought in. They both need immediate life-saving surgery, but you can only operate on one of them. There is no relevant difference between the two patients (or at least you are unaware of any), except that one is 30 years old and the other is 70 years old. The surgery can restore both of them to full health and would not decrease their life expectancy. In the rest of their lives, their quality of life would be equally high. Which of these two patients should you save?

Most people agree that the younger patient should be saved.[5] There are different ways to justify this choice. For instance, you might argue simply that saving the younger person is more likely to maximize benefits: since the 30 year old person can expect to survive longer into the future than the 70 year old, saving her life does more good. This is a consequentialist justification: it appeals to the value of the outcomes. The best-known consequentialist moral view is *utilitarianism*. Assuming that the 30

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[5] See, for instance, Cropper et al. (1994), Nord et al. (1996), and Johannesson and Johansson (1997), for studies in the USA, Australia, and Sweden, respectively.

years old would survive for many more years, and the 70 years old would survive for only a few, utilitarians would agree that the younger patient should be saved.

This sort of consequentialist justification has been called *utilitarian ageism*.[6] But utilitarianism is not really concerned with age. In utilitarian ageism, both the "utilitarianism" and the "ageism" bits are slightly misleading. For one thing, what matters in this example for utilitarianism is not age, but life expectancy. The younger patient should get priority because she can expect to live longer. In utilitarian ageism, age is primarily an indicator for period life expectancy. (Period life expectancy is life expectancy at different ages.) Since life expectancy typically decreases as people grow older, age can be a rough indicator of the magnitude of benefit from treatment.

But ultimately what utilitarianism is concerned with isn't life expectancy either. Rather, it is well-being. The fact that the younger person has a greater life expectancy is relevant only insofar as life expectancy itself can be taken as an indicator—in this case, a rough indicator of expected well-being. Therefore, utilitarian ageism gives a double role to age: it is an indicator of life expectancy, which is itself an indicator of well-being. But in both, the role of age is indirect. It provides no independent consideration. In itself, it is morally irrelevant that one patient is 30 and the other is 70.

I will refer as *indirect views* to justifications that seek to establish an indirect role for age in priority setting. Utilitarian ageism is one example.

Although utilitarian ageism can justify the choice of saving the younger person in the example, many philosophers find it problematic. They point out that utilitarian ageism inherits the problems of utilitarianism in general. One of these problems is that utilitarianism is insensitive to the distribution of benefits. If you can provide the same improvement in well-being to a person who is badly off or to another person who is well off, then utilitarianism does not imply that you should benefit the worse off person. Since the size of the benefit is the same, benefiting the well off person is just as good as benefiting the badly off person. But many people would agree that you should benefit the worse off person. You ought to be concerned with the inequality between the two people.

The problem for utilitarian ageism can be illustrated by slightly modifying our example. Suppose that the two patients who are brought into the emergency room would be able to survive for 10 years only. That is, the 30 year old patient will die at 40 if you save her life, and the 70 year old patient will die at 80 if you save her life. Suppose also that in the remaining 10 years their lives would be equally good. Thus, the size of the benefit for these two patients is the same.

Utilitarian ageism implies that saving the life of the 30 year old patient is just as good as saving the life of the 70 year old patient. But for many, this is not the right implication. They would insist that even in this case the 30 year old patient should be given priority. It would be *unfair* not to choose the 30 year old patient.

Obviously, those who take this view need to explain why not saving the younger patient straightaway is unfair. They can choose from competing theories of fairness. One explanation may be that the unfairness is due to the *inequality* between the lives

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[6] See Nord et al. (1996).

of the two people: it is unfair to the 30 year old patient, who is worse off in terms of lifetime well-being, if the 70 year old, who is already better off, is saved. It is unfair to increase the inequality between the two patients.

The sort of moral justification that appeals to inequality has been influential in health economics and health policy in the form of the "fair innings" argument.[7] It is a well-known fact that life expectancy at birth varies with social position: the better off you are, the greater your life expectancy. This remains true when the quality of life is also taken into account. That is, the better off have greater *quality-adjusted life expectancies* (QALEs), both at birth and later, than the worse off, poorer members of society. According to the fair innings argument, these inequalities must be addressed.

One way to address these inequalities is to try to increase the QALEs of the worse off. For instance, the mean quality-adjusted life expectancy at birth may be considered as a sort of threshold—commonly called the *fair innings threshold*. Health policy can then be designed around this threshold in order to reduce the discrepancy in QALEs between the better off and the worse off socioeconomic classes or groups. The intuitive idea is that everyone, regardless of their initial position in society, should have an equal chance to live a long and healthy life. It is unfair if people's QALEs differ merely because of the circumstances of their birth.

Since the better off have greater QALEs, health disparities can be reduced by selecting policies which equalize QALEs by sacrificing some of the overall health (or longevity) of the population. Quality-adjusted life expectancy can be used as a measure for the overall health of the population and for the inequality in health within the population. Additional years of life can be given different weights according to how well off people are: additional years to the better off have smaller weights than additional years to the worse off. Thus, this view can help quantify the equity-efficiency trade-offs between population health and equality in health—or between benefit maximization and fairness.

It should be clear that the role of age in the fair innings argument is indirect. It is merely an indicator that can help design policies to reduce unfair inequalities. In itself, age is not a morally relevant consideration.[8]

The fair innings argument focuses on inequality between full lives. It takes a whole-life perspective. Many philosophers accept that this is the right perspective to take when it comes to fairness. A person may be badly off now, but she may become better off later on. Perhaps she is badly off now only because she has sacrificed some of her current well-being for greater well-being later in her life. This is the *argument from compensation*: a person who is badly off at some time can be compensated by advantages at some other time in her life. In such circumstances, the inequality that obtains between her and others at some particular time is not necessarily unfair. Because of this, you need to take a whole-life perspective for assessing the inequality. Inequality is a concern between full lives.[9]

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[7] See Williams (1997).

[8] Views that are similar in important respects are proposed by Ottersen (2013) and NOU (2014:12).

[9] For the argument, see Nagel (1979).

This argument, however, implies that you need not be concerned about inequalities that obtain between people at particular times, at least as far as their lives are equally good overall. In this case, it is not unfair that some of them right now live in poverty and poor health while others are healthy and affluent. But this implication is troubling. For instance, it suggests that it should not be a matter of concern if the elderly now live in poor conditions with inadequate health care as long as they used to be sufficiently well off earlier in their lives such that there is no overall inequality between them and others. Or it should not be a matter of concern if the children alive today get a bad start in life as long as their lives get better later on to make up for their current deprivation in terms of equality between full lives. The whole-life perspective ignores inequalities between people at different ages, or stages, of their lives. This seems wrong.

There are different strategies that try to avoid this implication. One is to give up the whole-life perspective or at least amend it with some other principle for the allocation of resources that applies to particular times or time periods. So you might accept, say, one moral principle that aims for equality between full lives and another moral principle that applies to particular times. One proposed candidate for the latter is the *time-specific priority view*.[10] The priority view, or *prioritarianism*, holds that the right course of action or policy is that which maximizes weighted well-being, where the weights are given by a function that increases with higher levels of well-being at a decreasing rate. In practice, this means that a given benefit will have greater value if it goes to a person who is worse off, and the worse off a person is, the greater the value of the same benefit.[11] Time-specific prioritarianism differs from the "standard" version in that it considers the well-being of a person at a particular time or stage of life, whereas the latter considers overall lifetime well-being. Thus, time-specific prioritarianism takes a *sub-lifetime*, rather than a whole-life, perspective. Hence on this proposal, sub-lifetime shortfalls in well-being are not ignored: the time-specific priority view directs you to make people who are worse off at a particular time better off.

On the time-specific priority view, it becomes unfair if the elderly live in poor conditions, even if they are just as well off as others in terms of their lifetime well-being. And it is unfair if children get a bad start in life even if their lives get better later on to make up for their deprivation.

However, it is worth noting that prioritarianism is concerned with shortfalls in well-being in absolute terms; strictly speaking, it is not concerned with how people fare compared to one another. Therefore, inequalities are unfair on prioritarianism because the badly off are badly off in absolute terms, not merely because they are worse off than others. Prioritarianism is an egalitarian view only in this broader sense. It differs from "standard" egalitarianism in that it is not comparative.

There are many questions that proposals that separate the whole-life and sub-lifetime perspectives have to answer. What is the relation between the principles for the allocation of resources between full lives and the principles that apply to specific

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[10] It is proposed by McKerlie (2013).

[11] See Parfit (1995).

times? What happens if their recommendations are in conflict? Can theories that combine the whole-life and the sub-lifetime perspectives remain coherent?

Here I have to set these questions aside, but I do want to make a couple of points. First, note that there is no entailment between the whole-life and sub-lifetime perspectives on the one hand and particular principles of resource allocation on the other. No principle seems to fit better one or the other perspective, and vice versa. The proposal I have examined is to take an egalitarian view when it comes to full lives and a prioritarian view when it comes to particular times. But other combinations are equally possible: you can accept egalitarianism, prioritarianism, or indeed utilitarianism, on both levels, or any combination of two of these (or other) views on the whole-life and sub-lifetime levels. To be sure, not all of these combinations will be equally plausible. But the distinction between the two perspectives and the differences between the moral principles are independent of one another.

The other remark I want to make is to highlight that none of the views discussed so far takes age into account directly. Principles that are proposed for the sub-lifetime perspective, including the time-specific priority view, apply to inequalities or disadvantages at particular times. They are not concerned with age unless age can be taken as an indicator of disadvantage or shortfall in well-being. The sub-lifetime perspective does not make age in itself relevant, even if inequalities at particular times often take the form of inequalities between people from different age groups. Plainly, inequalities at particular times occur between people from the same age groups just as well. The issues between the whole-life and the sub-lifetime perspectives are orthogonal to the problem of the role of age as a criterion for priority setting.

Naturally, this will leave those who believe that age in itself is morally relevant unsatisfied. They argue that the moral issue between saving the 30 year old and the 70 year old does not turn merely on who has had more or less well-being throughout their life or at particular times. They hold that even if the 30 year old has already had an overall better life, it might still be unfair not to save her. According to this view, age is not merely an indicator for some other factor. It is morally relevant in itself.

3 Direct Views

I will refer as *direct views* to justifications that seek to establish a direct role for age in priority setting. When age has a direct role, it provides an independent moral consideration, to be taken into account with others, in health care resource allocation. On these views, an additional unit of time can have different values depending on the age of the person who receives it.

I have argued that the whole-life perspective has the implication that inequalities between people or shortfalls in well-being at particular times are ignored. If inequalities at particular times are ignored, then inequalities between people in different age groups will be ignored. Thus, for instance, if there is persistent inequality between the old and the young or children and the middle-aged, then they will be revealed as inequalities at particular times. The whole-life perspective will ignore them just as it ignores inequalities at particular times.

One strategy to avoid these implications was to introduce principles of resource allocation for the sub-lifetime perspective in addition to principles that apply to full lives. But, as I pointed out in the last section, there is a worry that such views just lead to inconsistencies. Another strategy is to think of the difference between the whole-life and the sub-lifetime perspectives in a different way. The proposal is that the problem of resource allocation between different people at different stages of their lives can be analyzed in terms of resource allocation within the life of a single person. You can consider how a person would prudently allocate resources for her full life and derive principles of fairness that apply to parts of life. This is the strategy followed by the *prudential lifespan account*.[12]

The strategy is inspired by the following thought. In real life, we all make trade-offs between different times in our lives—we all make *intrapersonal* trade-offs. (The most common example is saving: sacrificing some amount of present well-being in order to promote well-being in the future.) These trade-offs should be prudent: rational and without bias toward the near future. So we can use the idea of prudential *intrapersonal* trade-offs to guide our views about permissible *interpersonal* trade-offs. By prudently allocating resources over your life, you maximize your well-being over your lifetime. By allocating resources over different life stages of different people in a similar manner, you maximize the well-being of all the people involved. That is, if interpersonal resource allocation is designed analogously to intrapersonal resource allocation, it will make everyone as well off as possible over their full lives. And when interpersonal trade-offs are designed analogously to intrapersonal trade-offs, everyone is treated equally over their full lives.

Thus, for example, if it is prudent to give more weight to flourishing in your middle years as opposed to your old age, then it is justified to give priority to benefiting people in their middle years rather than in their old age. The old cannot complain, since they had priority when they were in their middle years. There is no unfairness. If people would rationally prefer to have access to life-saving resources when they are 30 years old rather than when they are 70, then it is not unfair to use life-saving resources to save a 30 year old rather than a 70 year old. In sum, if it is *prudent* to allocate resources in a particular way within one life, then it becomes, on this view, *fair* to allocate resources in the corresponding way between different people.

This is a different way of thinking about fairness. In the prudential lifespan account, fairness is not a matter of inequality or disadvantage. It is a matter, instead, of prudential (or rational) justifiability to each person.

To be sure, the prudential lifespan account needs to be formulated on an abstract level to yield useful conclusions. A thought experiment can help here. You can imagine that a rational person tries to determine how she should allocate a fixed amount of resources over her full life. To do this, she must ignore her present age, and she must assume that she will live through all life stages. So the person should be placed behind a "veil of ignorance."[13] Otherwise, the solution to the allocation problem could not be generalized.

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[12] This account is introduced by Daniels (1988, 2008).

[13] The thought experiment is borrowed from Rawls (1971).

The trade-offs that rational people would accept behind the veil of ignorance can be expected to maximize their lifetime well-being. They can be only *expected to* do so, since the lives of different people will in fact go differently. Some people, for instance, will die prematurely. So once the veil is lifted, people will end up in different positions. Nevertheless, the idea is that it is not unfair to set priorities this way, because no person, if placed in an impartial situation behind the veil of ignorance, could object to the principles that determine the trade-offs between different age groups. The principles can be justified to each person.

What sort of trade-offs would people agree to behind the veil of ignorance? They might agree, for instance, that it would be better if fewer resources are spent on the very old when those resources can be spent on benefiting the young. Thus, they might agree that different age groups should be entitled to different amounts of resources. In this way, age becomes directly relevant. The prudential lifespan account provides one kind of justification to use age as an independent criterion in priority setting.

Should we accept the prudential lifespan account? Some considerations suggest that it is less useful for providing guidance in priority setting than it might initially seem. One criticism of the account is that it would leave too little for the elderly and especially for the very old. This might be in conflict with our moral intuitions. People behind the veil might give less priority to benefits at extreme old age, since they have to distribute a fixed amount of resources and it makes sense to make sure you have enough at earlier life stages.[14]

Perhaps that is so—but it is hard to say. In my view, the main problem is that it is difficult to come to definite conclusions from the thought experiment involved in the prudential lifespan account. How would you distribute resources over your life? How much would you leave for extreme old age? Well, the only answer, it seems to me, is that *it depends*—it depends, for instance, on how much you are supposed to be able to distribute. If the resources are sufficient, you might want to allocate the same amount to every life stage. If there are fewer resources, perhaps you would consider good health to be more important at particular life stages: in young adulthood, for example, when most people are responsible for young children, or maybe in early childhood, in order to have a good start in life. So perhaps you would be willing to make trade-offs between life stages.

The answers crucially depend on the assumptions that the prudential lifespan account makes. Behind the veil of ignorance, you must assume that you will live through every life stage. You must assume there is no premature mortality. But if you knew that there was some probability of dying at each life stage, you would likely be willing to make different trade-offs. You may be willing to accept more risk at some life stages in exchange for higher well-being at others. The assumption that there is no premature mortality drastically limits the usefulness of the prudential lifespan account. But if the assumption is dropped, it's impossible to draw any specific conclusions from the thought experiment.

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[14] This objection is made by McKerlie (2013), among others.

Another, related assumption is that you must allocate a fixed amount of resources behind the veil. Your share of resources is determined independently of the allocation problem. But it's hard to see what justifies this assumption. If you know that there is premature mortality, you will recognize that some people will die before they have used up their full share of resources. Why should those resources not be redistributed and added to the shares of those who survive? (After all, this would be better than wasting those resources.) Once again, the assumption drastically limits the usefulness of the account, but it seems impossible to draw any specific conclusions from the thought experiment in its absence.

At this stage, it is tempting to return to a less complex account of the role of age in priority setting. Recall the example of the 30 year old and the 70 year old patients in the emergency room. Many people agree that it is unfair if you do not choose to save the life of the 30 year old. We have been looking at different attempts to explain the unfairness. One idea was that the unfairness is due to inequality: it is unfair if the younger patient ends up with a much shorter life than the older person. This conception of fairness is comparative. Another conception tied fairness to justifiability to each person. Putting limits on resources is not unfair, on this view, just in case rational individuals taking an impartial perspective would agree to do so. This conception of fairness is not comparative. However, it was difficult to derive any specific conclusions from it.

The less complex account that I am about to introduce is based on yet another conception of fairness. In the example of the 30 years old and the 70 years old, it would be unfair not to save the 30 years old, not because she would end up living less than the 70 years old, but because 30 years is not enough to have a *complete life*. It would be equally unfair not to save the 30 year old patient even if there was no 70 year old patient that she has to compete with for a scarce resource. This sort of unfairness is not comparative.

This view has also been called the *fair innings argument*.[15] (It is not the same view, however, as the one I discussed in the previous section. They are different views that, confusingly, go by the same name. It is also confusing that they are both called *arguments*, rather than specific views on how resources should be distributed, even though that's what they are.) It is based on the idea that there is a length of life that should be considered a full or complete or reasonable lifespan. A complete life lasts long enough to contain all the most important experiences of life: growing up, finishing your education, falling in love, building a career, starting a family, and see your children grow up and start families on their own. Suppose that for such a complete life, 70 years are necessary. It is a tragedy to die younger than this (and the younger one dies, the more tragic the death is), but it is not a tragedy to die once you have reached this threshold. Therefore, when scarce resources must be allocated, you should make sure that people reach this age: it is their *fair innings threshold*. Over this age, their claims on society's resources diminish.

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[15] It is introduced, although not unequivocally accepted, by Harris (1985). For a view that is similar in many respects, see Callahan (1987).

This view is able to explain the common moral judgment in the examples about the 30 years old and the 70 years old. It is unfair to save the older patient because she has already had her "fair innings." She has reached the threshold. If you cannot save both of the patients, you should save the patient who otherwise would not have a complete life. This is true even in the variant of the example where the two patients can only survive for another 10 years. Since the older patient has reached the threshold, the younger patient should be saved, even if she cannot herself reach the threshold.

To be sure, it would be unfair, according to this view, to give priority to one patient over another when neither has reached the fair innings threshold; and it would be unfair to prefer one patient over another when both patients have reached the fair innings threshold. The fair innings argument applies to conditions of resource scarcity between the young and the old who have reached the threshold.

In practice, the view would imply, for instance, that people over the fair innings threshold become ineligible for costly life-extending treatment. In their case, medical care should focus on palliative care and the maintenance of quality of life. Costly curative and life-extending treatments should be provided only to those who have not reached the threshold. (Perhaps they could be provided to those over the threshold when all other claims have been satisfied, but this is usually unlikely to be the case, given the facts about resource scarcity.)

Of all the views discussed so far, the fair innings argument gives the most central role to age. On this view, age is not merely an indicator for a complete life; rather, the notion of a complete life is defined in terms of age. (This is so even if, as defenders of the view might point out, the fair innings threshold need not be a particular age—the threshold could be left somewhat vague or defined as a range to allow for some individual variation.) Having a complete life takes a certain amount of time. No 30 year old can have all the experiences that normally make up a complete life. The fair innings argument is not about having enough lifetime well-being, but about having enough time for a complete life.

Nevertheless, the fair innings argument is not without problems. One immediate question is why there should be a fair innings threshold at all. Why not hold, instead, that those who have lived longer should have relatively less priority across all ages?[16] If age can make a difference to what is fair when resources must be allocated between the young and the old, why shouldn't it be relevant each time when people from different age groups compete for resources? If you have to choose between saving the life of a 30 years old and a 40 years old, why should the younger patient not have priority?

The fair innings threshold has been defended by an analogy.[17] Suppose two people are given the chance to run a mile, which most people can do in 7 minutes. One of these people is given only 3 minutes and the other is given only 4. In this case, it is not true that the second person is given a fairer running time than the first person:

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[16] This sort of view is proposed, for instance, by Lockwood (1988).

[17] See Harris (1985: 92–93).

it is just as impossible to run a mile in 4 minutes as it is in 3 minutes. The unfairness is the same to both of these people.[18]

It is not hard to see how the analogy is meant to work. According to the fair innings argument, if your choice is between saving a 30 years old and a 40 years old, it is unfair to give priority to the younger patient. Just like in the case of the runners, it is equally unfair if they cannot reach their fair innings. Therefore, there is no justification for saving the 30 years old straightaway (as opposed to, for instance, giving them equal chances by tossing a coin to decide whom to save).

The problem with this defense is that it provides no independent argument for the fair innings threshold. Even though neither of the runners can hope to finish the whole mile in their time, they might value the ground they can cover in their allotted time. They might prefer to have as long as possible. So the first person does have, it seems, a stronger complaint in comparison to the other. Similarly, if what is valuable is to have the most important experiences that a complete life can offer, then the 30 years old has undeniably had less of a chance for a complete life. It is not implausible to argue that she should have priority.

The fair innings argument cannot account for this judgment. In order to do that, we can reintroduce prioritarianism, albeit in a formulation that differs from that which I gave above. Recall that prioritarianism is the view that the right course of action or policy is that which maximizes weighted well-being, where the weights are determined by a function that increases with higher levels of well-being at a decreasing rate. As I explained, this means that a given benefit has greater value if it goes to a person who is worse off, and the worse off a person is, the greater the value of the same benefit. Now instead of well-being, prioritarianism can be applied to life-years. In this application, an additional year has greater value if it goes to a person who is worse off in terms of years of life—that is, younger—and the younger the person is, the greater the value of the additional year of life.[19]

This view can justify the judgments that many people have in the cases that we have discussed. It implies that when you have to choose between saving a 30 years old or a 70 years old, you should save the 30 years old, even when each of them can survive for only 10 more years. And when you have to choose between saving a 30 years old or a 40 years old, the view also implies that you should save the 30 years old. By attributing different values to additional years of life, prioritarianism applied to life-years gives a central role to age. This view might provide the best basis for such a role.

4 Priority Setting and Age in Practice

The recent experience of Norway provides an illustration of the controversy over the use of age in health policy[20]. In November 2014, the third Official Committee on Priority Setting in the Health Sector presented its report, laying out a new,

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[18] In fact, some people can run a mile within four minutes. I will follow Harris in ignoring this complication here.

[19] This view is defended in Bognar (2015). See also Bognar and Hirose (2014).

[20] See also chapter "Recent Developments on the Issue of Health-Care Priority Setting in Norway".

comprehensive framework for setting priorities in Norway.[21] As part of this framework, three new criteria were proposed: first, a health-benefit criterion, according to which the priority of an intervention increases when the expected health benefits (and other relevant welfare benefits from the intervention) are greater; second, a resource criterion, according to which the fewer resources an intervention requires, the greater its priority; and, third, a health-loss criterion, according to which the priority of an intervention increases when the expected lifetime health loss of the beneficiary is greater. The committee emphasized that these criteria must be considered together and recommended that they are applied throughout the health sector.

In its mandate, the committee was specifically asked to consider whether age should have "intrinsic value" in priority setting: that is, whether it is morally relevant in itself and could be used as an explicit, independent criterion. The committee concluded that age should not serve as an independent criterion. To support its conclusion, the committee argued that the relevant concerns indicated by age are already taken into account by the three proposed criteria. In other words, the committee denied that age in itself is morally relevant. At the same time, the committee agreed that age can legitimately influence priorities through its proposed criteria. It agreed that it may influence priorities through the health-benefit criterion, for example, due to the correlation between age and the risk of contracting disease, the risk of increased severity of disease, the risk of adverse events from treatment, and so on. The committee also agreed that age may correlate with decreased health loss, although it emphasized that the correlation may often be weak, since many other factors can determine the magnitude of health loss.

The report attracted considerable attention in the national media and generated a lively debate. The question of age was central from the outset. The day the report was released, Norway's largest newspaper featured a 23 year old patient with multiple sclerosis on the front page and declared that the committee recommended that "young people should be prioritized over the elderly in the health queue." In the same issue, a 72 year old man was reported to find the recommendations "unfair" and "discriminatory."[22] Age has continued to be in the limelight in the debate over the report. It has frequently been claimed that age should never influence priorities, often accompanied by the erroneous claim that age has not played any role in priority setting before. More nuanced positions have also been put forward. For example, it has been argued that age can be relevant to priority setting at the macro level and for preventive measures, while it should be irrelevant at the clinical level and for curative services. Similarly, it has been argued that children should have priority over adults, while age should not influence priority among adults, or at least not when the difference in age is small. It has also been argued that the three proposed criteria, put together, allow age to have too much influence.

The debate in Norway has demonstrated once again how controversial the issue of age can be—even in a country with a long tradition of systematic priority setting

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[21] NOU (2014:12).

[22] Dommerud and Olsen (2014).

and robust public debate. People sharply disagree on how age should influence priority setting. Their sharp disagreements are reflected in the philosophical debate on the justification of the use of age in resource allocation. As I have tried to show in this chapter, there is a wide range of ideas and proposals in this area. The issues raised by age are likely to remain for a long time on both the philosophical and the public agenda.

Acknowledgments Financial support from the Swedish Research Council and from the Swedish Research Council for Health, Working Life and Welfare is gratefully acknowledged (2014–4024). I would also like to thank an audience at the KTH Royal Institute of Technology (Stockholm) for valuable comments.

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Fair Innings as a Basis for Prioritization: An Empirical Perspective

Sarah M. Watters

1 The Equity-Efficiency Trade-Off and the QALY

The equity-efficiency trade-off in health care has received increasing attention in recent decades – the 'equity' component referring to the distribution of health care and incorporation of social value and the 'efficiency' component concerned with obtaining the 'greatest health gain per amount spent'. Which dimensions of equity should be incorporated remains unresolved, while factors such as age, social class, and time lived with the condition have all been cited as possible criteria (Dolan et al. 2008).[1] In terms of efficiency, economic evaluation has emerged as a useful means to guide policy decisions as to which health-care interventions should be available to the public (Simoens 2010). The quality-adjusted life-year (QALY) is a composite measure of health benefit that incorporates both quantity (life-years gained) and quality (health-related quality of life) from treatment and enables comparisons of health-care programs with different types of outcomes from various domains (McKie et al. 1996; Ubel et al. 2000). It is widely used as a measure of health benefit in economic evaluation alongside intervention cost.

1.1 QALY Maximization

> … they presume to compare apples, oranges and pears on the grounds that they are all fruit.
> Light and Hughes (2001)

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[1] Norheim et al. (2014) recently summarized priority-setting criteria that might be considered alongside cost-effectiveness results.

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_14

While the current modus operandi in many countries is to maximize health outcomes (e.g. in the form of QALY maximization), whether or not this is the most suitable form of distributing resources is widely debated. An underlying condition of QALY maximization – that 'a QALY is a QALY is a QALY' irrespective to whom it is being allocated – has been actively questioned as many argue that distributional concerns and considerations for equity have been overlooked in efforts to achieve efficiency.

A particular concern relates to the disadvantages incurred by those who have already experienced a misfortune (e.g. poor health) and thus are anticipated to accrue fewer posttreatment QALYs than an otherwise healthy individual. Suppose, for example, there are two individuals equal in all other aspects except that one individual is in relatively good health and the other individual is partially deaf. Consider the circumstance where both require a health intervention (unrelated to the latter individual's deafness) and only one may receive treatment. Under QALY maximization, the individual who is partially deaf is less likely to be allocated scarce resources since their condition will preclude them from generating as many posttreatment QALYs as the individual in good health. This notion of 'double injustice' or 'double jeopardy' stipulates that 'those who have already experienced significant misfortune should not have further tribulation imposed upon them because they are not good candidates (within the efficiency calculus) for the receipt of health care' (Harris 1985; Williams 1997).

In response to the issue of double jeopardy and as an alternative to QALY maximization insofar as incorporating distributional concerns, Alan Williams derived his fair innings argument, which is founded in the notion that everyone is entitled to a particular quality-adjusted life expectancy. Williams' (1997) argument built upon a proposal advanced by Harris (1985) that each individual was entitled to a particular life expectancy 'a fair innings' and that as one fulfills this 'fair inning', they receive relatively lower priority for available resources.

2 The Fair Innings Argument Defined: Two Versions

2.1 Harris' Version

Harris' (1985) version of the fair innings argument is grounded in an aversion to inequality in age of death, positing that everyone is entitled to some 'normal' span of years that constitutes a 'fair inning'. An individual who has reached their fair innings, defined by Harris as a biblical 'three score years and ten, seventy years', might be considered to be living '*a sort of bonus beyond* that which could reasonably be hoped for' (emphasis added) (Harris 1970). This means priority should be given to those that have not yet reached their fair innings since, as Harris (1985) comments, 'it is sometimes said that it is a misfortune to grow old, but it is not nearly so great a misfortune as not to grow old'. He refers to the 'greater injustice' experienced in a younger person dying 'too soon' versus the individual who has lived a reasonable amount of years.

2.2 Williams' Version

Treating Harris' version as a first approximation, Williams (1997, 1999) sought to bypass prioritization based on age alone by merging concerns of health experiences with those of length of life. He commented that failing to include considerations of health experiences meant that those who have lived longer lives (and who possess 'normal' life expectancies) in poor health might not be prescribed appropriate consideration. Thus, Williams extended the fair innings argument to propose that *lifetime health* is the overarching concern and that in order for fairness to be achieved, we must consider two things: first, the amount of life-years and health an individual can expect to have over the course of their lifetime (quality-adjusted life expectancy, QALE) and, second, what constitutes a fair innings QALE. Each individual's QALE is composed of the QALYs they have accrued up to now *in addition* to their (future) QALE (Williams defines the sum of past QALYs and future QALE as the individual's expected lifetime experience of health). The individual's expected lifetime experience of health (hereon referred to simply as their QALE, noting that both past and future health are included) is subsequently compared to the fair innings QALE that serves as a reference point from which equity weights can be calculated.[2] *Ceteris paribus*, individuals who can expect a QALE lower than the fair innings QALE are given priority over individuals who are expected to reach their fair innings. The priority setting calculus is such that QALY gains in individuals with lower QALEs should be weighted more heavily than those of individuals who are expected to reach their fair innings.

Williams (1997) provided a detailed example of the implications of varying QALEs according to social class. He estimated that, at birth, a fair QALE for males in the UK was 61. In separating social classes 1 and 2 ('higher' social classes) from social classes 4 and 5 ('lower' social classes), he noted that the former group had a QALE of 66 whereas the latter group a QALE of 57. Thus, in order for an equitable redistribution to occur among all social classes, QALYs would need to be allocated in such a manner that those in lower social classes would receive more weight.

Although Williams illustrated his argument in the context of social classes, the fair innings argument has been widely discussed in the context of age-based rationing. Williams (1999) explained that the fair innings argument does not discriminate based on age per se, but since achieving one's fair innings (expected lifetime health) is inherently associated with age, priority will often be 'in favour of the young'.[3] It follows that given the young are further away from reaching their fair innings (they have thus far accumulated fewer QALYs than the relatively old), they should therefore be prioritized over older individuals and their QALYs weighted more heavily.

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[2] By definition, the ratio of expected QALE/fair innings QALE should be adjusted by an index of aversion to inequality r (which indicates the strength of aversion to inequality) such that (fair innings QALE/expected QALE)$^{(1+r)}$ (Williams 1997; Oliver 2009).

[3] To highlight an exception where the young would not be prioritized, Williams (1999) gives the example of an older individual with poor lifetime health and a somewhat younger individual with very good lifetime health.

3 Public Preferences

While the fair innings argument has featured prominently in philosophical debate, determining whether its propositions align with public preference is desirable if the argument is to be practically applied and supported in a policy setting. In attempts to incorporate considerations for fairness into value judgments, gauging the public's support for various methods of prioritization has become an increasingly frequent exercise (Cooper et al. 1995; Hadorn 1996).[4] Batifoulier et al. (2013) comment that in the absence of a 'definitive conception of equity, a significant empirical literature has developed which assumes that the answer to this theoretical impasse lies with the general public'. In the UK, for example, it is proposed that 'advice from NICE to the NHS should embody values that are generally held by the population of the NHS' (Rawlins and Culyer 2004).

Public preferences have been shown *not* to align with QALY maximization (or health benefit maximization) across a variety of contexts (Ubel and Loewenstein 1995) and considerations affecting these preferences often extend well beyond strict utilitarian concerns (McKie et al. 1996). In line with both Harris' and Williams' versions of the fair innings argument that both suggest that priority would be allocated to the young over the old, age has been shown to be among the most frequently cited variables affecting the public's prioritization decisions (see Nord et al. (1999) and Dolan et al. (2005) for references).

3.1 Public Preferences: Harris' Argument

A number of studies suggest that public preferences often align with Harris' version[5] of the argument whereby younger individuals are prioritized over older individuals on the basis of having lived fewer years (see Tsuchiya (1999) and Dolan et al. (2005) for comprehensive reviews), although there are some exceptions (Zweibel et al. 1993; Kuder and Roeder 1995; Mossialos and King 1999; Anand and Wailoo 2000). Olsen (2013), for example, provides a convincing test of Harris' argument, showing that it fares better than the end-of-life argument (i.e. that QALYs should be given greater weight where individuals have short life expectancies in instances where capacity to benefit is deemed sufficient).

It should be noted that in some of these studies, however, it is difficult to disentangle whether respondents prioritize younger individuals due to the fair innings

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[4] There are several qualitative (e.g. discussion groups) and/or quantitative (e.g. person trade-off tasks, discrete choice experiments, or contingent analysis) means through which empirical studies can gauge whether public preferences align with particular ethical principles (Green and Gerard 2009). For a detailed discussion, see Hasman (2003).

[5] I have specified these studies as following Harris' argument since they largely do not mention past health (and in some cases – such as life-saving scenarios – any descriptions of health at all).

argument, other forms of 'ageism' – namely, reasons of productivity[6] ('productivity ageism') – or 'utilitarian ageism' (QALY maximization) (Nord et al. 1996; Tsuchiya 1999; Dolan et al. 2005). An exception is a study by Tsuchiya et al. (2003) who sought to separate productivity ageism considerations from those stipulated by the fair innings argument. They found that respondents prioritized on the basis of the fair innings argument (the young received priority) when patients were given the possibility of living out their normal life expectancy; however when the benefit was fixed to 5 years, the respondents prioritized more closely in line with reasons of productivity, ranking middle-age higher.

3.2 Public Preferences: Williams' Argument

Relatively fewer studies of public preferences have evaluated the relevance of Williams' version of the fair innings argument. Although there is some empirical evidence that respondent priorities are influenced by information about past health (e.g. Dolan et al. 2008[7]), Stolk et al. (2005) comment that the literature has tended to focus on *future* gains in life expectancy and/or health. In order to *truly* assess if Williams' arguments are relevant in an empirical setting, the respondent should be asked to set priorities when they are presented with lifetime health profiles – i.e. the individual's pretreatment, present, and posttreatment health states. Implementing lifetime health profiles as well as using a mixed method approach enables the researcher to gain better insight as to if (and to what degree) respondents balanced pretreatment considerations with posttreatment considerations, the two main tenets of the fair innings argument.[8]

I focus here on a study by Oliver (2009) who conducted a mixed-methods investigation into whether the fair innings argument factored into public preferences for prioritization. A brief review of studies by Dolan and Tsuchiya (2005) and Stolk et al. (2005) follows. These studies also aimed at assessing Williams' account of the fair innings argument although they adopted slightly different methodologies to that of Oliver (2009).

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[6] Reasons of productivity refer to the individual's ability to contribute to society and care for others in middle age, widely referenced in the context of 'disability-adjusted life-year' (DALY) age-weights; see Murray and Lopez (1997).

[7] It is worthwhile noting that some recent studies have, in contrast, suggested that past health is not considered to be an adequate criterion on which prioritization can be based (Franken et al. 2015; Nord and Johansen 2014).

[8] The importance of the methodological approach in assessing support for various distributional arguments is highlighted by Tsuchiya et al. (2003) who remarked that, in their review of empirical evidence on age as a characteristic for priority setting, there was a dearth of studies that have incorporated qualitative components that would aid in clarifying respondents' rationales for their decisions.

3.3 A Specific Test of the Fair Innings Argument

To date, the only study to have examined Williams' version of the fair innings argument using equity-weighted lifetime health profiles is Oliver (2009) in his article 'A Fair Test of the Fair Innings?' in *Medical Decision Making*. Oliver developed a number of priority-setting questions whereby selecting one of the patients would attenuate differences in lifetime QALYs between the two patients (possibly consistent with the fair innings argument) and selecting the other patient would correspond to QALY maximization.

Before completing the prioritization questions, a convenience sample of 50 respondents were asked to value each health state using the time trade-off (TTO). The TTO is a commonly used choice-based method for eliciting health state values for implementation into QALY calculations. In its standard form, the TTO asks respondents to state the number of years they would be willing to give up from a certain fixed time period in a deteriorated health state in order to live in full health. In Oliver's study, respondents were asked how many years they would be willing to forgo to live in full health as opposed to living in health state x for 50 years. The aim of carrying out the TTO task was to elicit QALY values (when TTO values are combined with life-years) that could be age-weighted.[9] Since the fair innings argument prescribes that QALYs accrued by relatively young respondents should receive greater weight since they are farther from achieving their fair innings, respondents' raw QALY values were adjusted using age-weights from Williams' (1997) estimations of fair QALE at birth in the UK for social classes 1 and 2.[10]

In the prioritization questions (following the same structure as that presented in Fig. 1), respondents were asked to serve as the decision-maker, and given that resources were limited, they were only able to treat one patient. The lifetime health profiles involved patients of different ages and different lifetime experiences of health. Three questions featured *intra*generational trade-offs (i.e. untreated and treated life expectancies, respectively, were similar between patients), and two questions involved *inter*generational trade-offs (i.e. the patients differed in their untreated and treated life expectancies).

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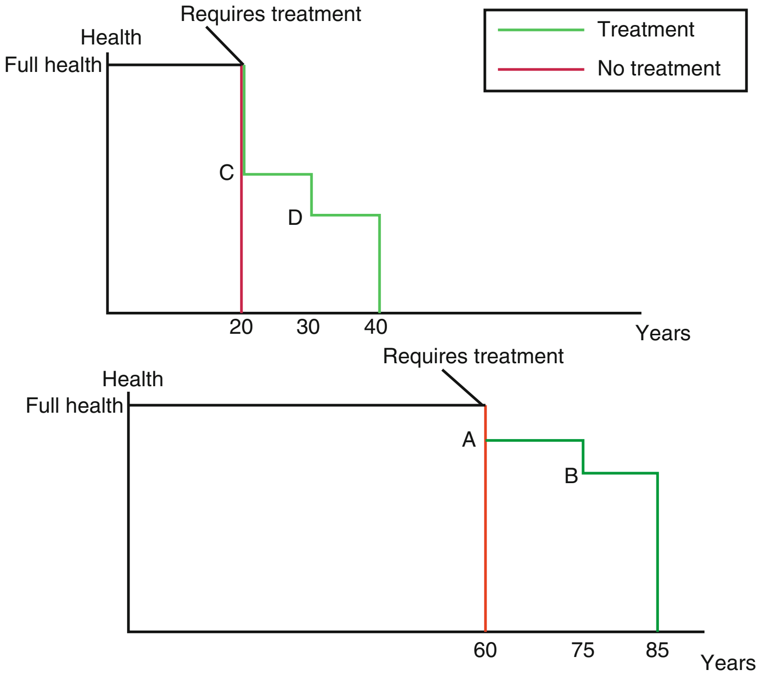
[9] Borrowing an example from Oliver and Sorenson (2009), suppose two individuals, P and Q, require treatment and that without this treatment they will both live for 5 more years during which P will be in full health (a health state-TTO-value of 1) and Q will be in a health state valued at 0.5 using the TTO. Together, they have an average of 3.75 expected QALYs $(([5\times1]+[5\times0.5])/2=3.75)$. In this instance, P will have a QALY weight of $3.75/5=0.75$, and Q will have a weight of $3.75/2.5=1.5$. Consider that either P or Q takes a treatment that provides them with 5 additional years of life (in the same health state: P in 1 and Q in 0.5), the weighted QALY gains for both P and Q will be the same ($5\times1\times0.75=3.75$ for P and $5\times0.5\times1.5=3.75$ for Q).

[10] Based on a fair innings QALE of 61 for UK males, Williams provided expected lifetime QALYs at ages 0, 20, 40, 60, and 80 of 65.8, 66.0, 66.5, 67.6, and 73.9, respectively. It follows, for example, that the age weight for a 40-year-old individual is $61/66.5=0.917$. Thus, if the respondent provides a TTO value of 0.8 for a given health state, then the resulting weighted QALY value will be equal to $0.8\times0.917\times$the number of years spent in the health state.



A:	No problems with mobility No problems with self care No problems with usual activities No pain/discomfort Some anxiety/depression	B:	No problems with mobility No problems with self care No problems with usual activities Some pain/discomfort Some anxiety/depression
C:	Some problems with mobility No problems with self care Some problems with usual activities Some pain/discomfort Some anxiety/depression	D:	Some problems with mobility No problems with self care Some problems with usual activities Some pain/discomfort Severe anxiety/depression

Fig. 1 An illustration of an *inter*generational priority-setting questions in Oliver (2009) (Reprinted by permission of SAGE Publications)

Looking at the quantitative data, Oliver found that there was no discernable pattern in terms of respondents minimizing the difference in QALYs between patients or maximizing QALYs. This suggests that even when those with lower QALEs were compensated, respondents did not always elect to prioritize on the basis of the fair innings argument. Referring to the qualitative data, in three of the five priority-setting questions, some respondents (less than half the sample in each task) seemed to have made their selection on the basis of the fair innings argument. Overall, however, a wide range of context-dependent 'decision rules' emerged across the decision tasks that appeared to be dependent on the scenario presented. Respondents referenced reasons including maximizing QALYs,[11] maximizing life-years or post-treatment quality of life,[12] providing equal access to health care, maximizing health based on perceptions of adaptation, maximizing societal productivity (including familial roles, i.e. 'productivity ageism'), minimizing suffering, minimizing costs, and distributing available resources equitably. As an illustration of its variability, he noted that 46 of the 50 respondents were inconsistent in their reasoning across the questions. Oliver commented that *underlying values* influence the respondents' decisions, but if these values are context dependent, it becomes a challenge – if not impossible – to identify a preferred, overarching rule by which to distribute resources.

3.4 Other Studies of the Fair Innings Argument

Few other studies have implemented lifetime health profiles (including both longevity and health dimensions) in order to test whether the fair innings argument is relevant in empirical settings. Broadly, many of these studies support the results of Oliver (2009) in that the fair innings argument is but one of a host of different decision rules that are called upon.

Stolk et al. (2005) sought to evaluate whether public preferences aligned more closely with any of three equity concepts: severity of illness, fair innings, and proportional shortfall. The latter concept – proportional shortfall – refers to the ratio between the number of QALYs lost due to illness or disability and the number of QALYs expected based on age- and gender-specific norms (I return to this concept later). Respondents were provided with information about each patient's age (ranging from 40 to 70 years old), time spent without disability, their time with health complaints, average quality of life loss, and life-years lost. It should be noted that although information in regard to past health was included, in order to simplify their analysis, all of the patients were described as having been in good health up to the point of intervention. Respondents were asked to prioritize between a series of paired lifetime health profiles and their rankings were then compared to the ranking predicted by the respective equity arguments (they assumed a fair innings QALE of 70 from which they could establish a ranking based on 'fair innings foregone'). They found greatest support for fair innings, followed by proportional shortfall and then severity.

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[11] It is worthwhile noting that in some instances where respondents prioritize on the basis of QALY maximization, they may in fact have referred to the fair innings argument during their deliberative process since the fair innings argument encompasses concerns for both pre-intervention QALYS and post-intervention QALE (Oliver and Mossialos 2004; Oliver 2009). Whether or not the respondent maximizes QALYs when having considered the fair innings argument in their deliberation will depend on the degree to which they are averse to inequality.

[12] Oliver described this reason as the respondent 'maximizing health after adjudicating for the possibility that different respondents may differentially "appreciate" a particular health state depending on the health state to which they are accustomed'.

Dolan and Tsuchiya (2005) had respondents rank a number of health profiles that forced them to consider trade-offs between patients with short life expectancies and severe conditions across different ages. In the first set of questions respondents were asked to rank patients either of 40 or 60 years of age based on past health and future life expectancy without treatment. In the second set of questions, respondents were given the same information about past health and information about future health status without treatment over a fixed 10-year period across all respondents was provided (instead of information about future life expectancy). They found that respondents allocated priority based on past years (i.e. age) in favour of younger patients in both questions. The results were less clear in terms of past health. In the case where a health improvement was at stake (question 2), it was unclear whether the individuals' past health influenced respondents' prioritizations. On the other hand, past health *did* seem to have an influence on who was allocated the life-extending treatment (question 1).

3.5 Summary of Observations

While a relatively large body of literature provides support for Harris' account of the fair innings argument through preferences for prioritizing the young over the old, a smaller number of investigations have assessed whether public preferences are consistent with Williams' version of the argument. In these latter tests – that are focused on concerns of *lifetime health* – it appears that Williams' argument does carry weight in respondents' prioritizations and is a basis for their decisions in *some* circumstances. These findings support a similar 'pluralistic position' observed in some purely qualitative studies (Cookson and Dolan 1999; Wilmot and Ratcliffe 2002).

Although Williams set out with the intention of quantifying equity considerations by attaching fair innings-based weights to QALYs accrued by those with lower lifetime QALEs, empirical evidence – such as that presented above – suggests that these weights may be insufficient in accounting for context-dependent distributional concerns. A number of alternatives exist by which concerns for equity can be included in health-care decision-making, some of which may involve, for example, adopting components or variations on the fair innings argument.

4 Moving Forward: Empirical Findings, Priority Setting, and Potential Policy Implications

Given the empirical observations that respondents do not seem to rely upon a consistent decision rule that is *independent* of the prioritization context, some have suggested that deliberative judgments be used to incorporate equity considerations (e.g. Daniels 2008; Oliver 2009). This means that decision makers may call upon a host of different 'rules' to set priorities depending on the context.

When the patients are of similar ages, prioritization by severity may offer a morally justifiable solution, for example. In contrast, as the age discrepancy becomes greater between the two patients, there may be a point at which 'the priority view' (i.e. those who in the most dire conditions take precedence) no longer holds (Parfit 1997). Wilmot and Ratcliffe (2002) and Lewis and Charny (1989), for example, found that preferences for the young over the old are not constant in that prioritization by severity was more common when age differences were small and, on the other hand, consistent with fair innings arguments when the differences were greater.

In other instances, intragenerational debates could be informed by consideration of the ability to benefit, as implied by some empirical findings (e.g. if Oliver's findings could be replicated insofar as respondents opting to 'maximize' QALYs in choosing between patients of similar ages and 'minimizing' QALY differences when an intergenerational choice is at hand) (e.g. QALY maximization). Whether this 'decision rule' is relevant, however, may be contingent on the severity of the condition of the patients involved.

Case by case deliberations might also be based on various *interpretations* of the fair innings argument. As presented in its original formulation by Harris, it might be desirable in some instances to establish thresholds (based on what Nord (2005) termed 'sufficient innings') rather than allocate priority weighting based on the degree to which one has fulfilled their fair innings. As a result, only in the case where the patient had surpassed a given threshold are they allocated relatively less priority. This is a somewhat more docile reflection of the cutoff age of 80 years Callahan (1987) proposed should be applied to life extending interventions.

In regard to possible practical implementations of such thresholds, perhaps it is helpful to ask ourselves – in what instances do we *not* want to prioritize someone who has 'lived less'? There is some evidence that indicates that public preferences do not support giving priority in instances where the intervention has a poor prognosis (e.g. leaves the patient in poor health). Recently, Brazier et al. (2013) found that in attitudinal questions about end-of-life care, respondents provided preferences that indicated that the support for prioritization of end-of-life care was dependent on the level of posttreatment health the patient was able to achieve (see also Roberts et al. 1999). If older patients have poorer health outcomes as a result of certain interventions, this latter finding might imply that in these instances, they should receive lower priority or not be eligible for certain care. Importantly, Nord (2005) comments that it is one thing to restrict life-extending treatment to those who have reach a fair inning although a separate issue arises when considering the relief of suffering or pain (to a similar extent, Bowling (1996), Evans (1997), and Williams et al. (2011) propose that palliative care be exempt from prioritization and available equally to individuals of all ages regardless of QALY gains[13]). Therefore it may be that this 'threshold' interpretation of an individual's fair innings is most suited for applications to only certain areas of high-cost intervention.

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[13] Johri et al. (2005) provide empirical support for this proposition.

Developing a framework for deliberative judgement aligns with recent attempts in a number of countries to better involve the public in priority setting. For instance, in Canada and the USA, juries and panels have been used to help inform which criteria and ethical considerations are relevant for health technology assessment and cancer interventions (Menon and Stafinski 2008; Abelson et al. 2012). Similarly, NICE's Citizens Council was initiated in order to provide insight from the public's perspective on a number of issues to *complement* economic evaluation (Bognar and Hirose 2014).[14]

Another option is the 'complete lives' system (or a version thereof) proposed by Persad et al. (2009), a framework that integrates several ethical principles into a single system. The complete lives system incorporates distributional principles (specifically youngest-first, prognosis, save the most lives, lottery, and instrumental value) so as to consider the individuals' 'entire lives rather than events or episodes' on the basis that we are assigning value to human *lives* instead of *experiences* (Lockwood 1988; Rawls 1999). Notably, at its core, it is congruent with the fair innings argument insofar as prioritizing the young who have the greatest amount of 'innings' remaining and without intervention may fail to reach their fair innings. Further, although nascent in its development in terms of its applications to priority setting in health care, an additional alternative would be to look towards multicriteria decision analysis as a tool for concurrently balancing considerations of both equity and efficiency (Baltussen and Niessen 2006).

Alongside these attempts directed towards attaining distributive justice (determining one or a set of allocation 'rules' deemed justifiable as a whole), a more concentrated focus on 'procedural justice' and how existing methods of resource allocation are implemented has emerged. NICE specifically addresses this issue through their 'accountability for reasonableness' (AFR) process that encompasses the following criteria: publicity, relevance, challenge and revision, and regulation (see Daniels and Sabin 1997; NICE 2009; see chapter "Accountability for Reasonableness and Priority Setting in Health"). Publicity and relevance refer to the decision and decision process insofar as they must be publicly available (publicity) and align with those of a reasonable, 'fair-minded' individual (relevance). The challenge and revision criteria refer to the consideration of new evidence or further arguments in decisions and existing policy. Lastly, public or voluntary regulation should be in place to ensure the above criteria are met. Setting out policy guidelines a priori offers many advantages and will help in adherence to procedural justice while we learn more about how to appropriately incorporate social value judgments into prioritization decisions.

4.1 Existing Applications of the Fair Innings Argument

Two examples of where the fair innings argument has been translated into policy measures are in a protocol for allocating influenza vaccines in the event of a

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[14] See Abelson et al. (2007) for additional examples of citizen engagement in **policy** decisions.

pandemic and in proposed organ allocation schemes. In the context of emergency medicine and disaster preparedness, the USA has elected to allocate greater priority to younger children than adults or older people in the instance of an influenza pandemic (Dept. of Health and Human Services 2007). Emanuel and Wertheimer (2006) comment that this sort of prioritization is consistent with a 'life-cycle allocation principle' that aligns with the value attached to enabling an individual to pass through 'each life stage'.

In the context of organ allocation, the concept of survival matching under a scheme termed '20/80', as explained in Hoffmaster and Hooker (2013), allocates the '20 percent of kidneys with the longest expected length of functioning to the 20 percent of candidates who have the longest expected length of life' (KTC 2012). The remaining 80 % of kidneys are allocated to age-matched recipients on the basis of time spent on dialysis, a measure similar to wait time. Ross et al. (2012) proposed an alternative method of allocating kidneys termed Equal Opportunity Supplemented by Fair Innings (EOFI). The EOFI strategy operationalizes the fair innings argument by allocating the higher-quality kidneys to younger patients since they are deemed to be 'worse off' since they developed renal disease at a relatively earlier age and 'consequently have had fewer years of healthy life'.

4.2 QALY Shortfall

Recent discussion across several countries has centred around how the notion of QALY shortfall – a 'hybrid' concept drawing on the fair innings argument and concerns for severity – might be incorporated into policy debates. QALY shortfall is manifested in two versions: absolute shortfall and proportional shortfall. Absolute shortfall relates to the *total* amount of QALYs lost due to a disease or condition. For example, ceteris paribus, there are two individuals: one who is perfectly healthy and can expect a future gain of 30 more QALYs and one who suffers from a condition and can expect a future QALY gain of 20 QALYs. The latter individual's absolute shortfall is 10 QALYs (30–20). Alternatively, proportional shortfall is concerned with the ratio of QALYs lost over QALYs remaining assuming a normal life expectancy and health. Referring to the previous example, the individual in worse health has a proportional shortfall of 33 % ($[(30-20)/30] \times 100 = 0.33$) (UK Department of Health 2011). Equalizing QALY shortfall from birth, as opposed to the time of treatment, could be interpreted as a version of the fair innings argument (Towse and Barnsley 2013).

Proportional shortfall has received support as a means of incorporating equity-based considerations in small-scale studies in the Netherlands (Stolk et al. 2005) where it seems likely to be used as a basis for equity weights in the near future (van de Wetering et al. 2013). In the UK, it has been suggested that either proportional or absolute shortfall be used to quantify burden of disease (Towse and Barnsley 2013).

Bognar and Hirose (2014) remark that the case for QALY shortfall is more intuitive compared to that for the fair innings argument given that standard cost-effectiveness is forward looking, in line with the *future* QALY losses considered in

QALY shortfall. To this extent, it offers a simpler solution to incorporating equity claims than would the fair innings argument that would require the incorporation of past health into calculations and incur greater associated uncertainties with regard to disease trajectory, for example (Lindemark et al. 2014). This follows an earlier comment by Nord (2005) that *current* suffering is likely to induce a stronger reaction than *past* suffering, where the former may evoke strong feelings of the obligation to 'rescue' (see McKie and Richardson 2003) as well as align with Norwegian guidelines that recognize that helping the worst off should be a priority in the provision of health care[15] (Dolan et al 2005; Cookson et al. 2008).

An important contrasting perspective, however, is proposed by Lindemark et al. (2014) who posit that 'the length and quality of life lived before time of intervention may be relevant in judgements about who are worse off', referencing instances of early-onset conditions. Proportional shortfall does not encapsulate these types of considerations, and thus in some instances, it may be best to attempt to operationalize arguments that are more consistent with the fair innings argument.

4.3 Public Preferences: Important Considerations

Important decisions are to be made insofar as *how* we want to incorporate public preferences and to what degree. In addition, it is essential to ensure that these preferences are robust and are not artefacts of the conditions through which they are elicited (Shickle 1997; Lloyd 2003; Owen-Smith et al. 2009). It has been shown, for example, that decisions may change with better understanding or knowledge of trade-offs (e.g. of the patients' health conditions or personal circumstances) (Ham 1993; McIver 1995), through deliberation (Dolan et al. 1999), and the decision frame (e.g. 'lives saved' versus 'lives lost' in Li et al. 2010). Schwappach (2002) comments that public preferences in support of age-based prioritization vary depending on whether the elicitation has been through public opinion surveys (limited support) or hypothetical decision or ranking tasks (where preferences have been observed to be stronger).

Congruent with the principle of 'empirical ethics' advanced by Richardson (2000), the evaluation of ethical principles should be undertaken through both quantitative and qualitative researches, whereby an understanding of the respondents' perspectives is clarified and deliberated upon 'until acceptable, stable (reliable and deliberative) ethical principles are identified (albeit unique to a particular context)'.

Whether there is a divide between the prioritization strategies that are evoked in empirical studies using patient scenarios and profiles and public support of their explicit use and the larger-scale implications of these strategies is deserving of greater attention. Cuadras-Morató et al. (2001) found that while respondents thought

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[15] It is worthwhile to note that the Norwegian Commission has combined their concern for severity with that of prognosis in order to form a multiprinciple system that more adequately controls for costs and intervention effectiveness (see Carlsson et al. 2007; Sabik and Lie 2008).

one method of prioritization was 'theoretically' superior given the circumstances presented in the questions, they prioritized on a different basis. Suppose, for example, preferences for prioritization were decided in the context of approval of political candidates' platforms – would this different context increase our moral friction with these ideas when compared to person trade-off exercises? Kuder and Roeder (1995) demonstrated that the change in perspective affects preferences, reporting that in trade-off situations, respondents were willing to prioritize based on age, but when asked in qualitative terms about using age as a means to ration health-care resources, many disapproved (also see Zweibel et al. 1993).

It is important to determine the extent to which the 'should' component of prioritizing by age counterbalances society's 'comfort' with the current utilitarian strategy of QALY maximization. That is, while greater distributional equity seems desirable in both empirical settings and common parlance, whether or not we can come to terms with the broader consequences of a 'redistribution' to the young and to the sick is another matter in itself.

5 Conclusions

While a wide range of prioritization schemes have been discussed within philosophical boundaries, a greater understanding of the degree to which they (and, more importantly, their implications) align with public preferences is necessary to move beyond philosophical arguments and towards measurable (i.e. quantifiable) policy frameworks. A substantial body of evidence indicates that the utilitarian approach of QALY maximization fails to adequately capture public preferences for a greater degree of equity into health-care distribution; however, how to go about incorporating these concerns remains unresolved.

Eliciting public preferences for various methods of distribution is one strategy that decision-makers can use to guide how equity is incorporated into policy; however, it remains open for debate as to *how* and the degree to which these preferences should inform priority setting (Robinson et al. 2012). The brief review of empirical evidence included in this chapter suggests that support for intergenerational equity through the fair innings principle is mixed and seems to be context dependent. Nonetheless, there are several methods by which the fair innings argument in its entirety or parts can start and have started to be implemented.

The extent to which the fair innings argument or similar principles that advocate for age-based prioritization can be translated into policy contexts will become an increasingly relevant debate as populations age, and new technologies enable health improvements and, importantly, potentially allow for increased longevity (van de Wetering et al. 2013). If this discussion is to be informed by public preferences and opinions, much work is to be done before we can assume that these preferences are robust and sustainable across empirical contexts and thus suitable for translation into policy.

Acknowledgements I would like to thank Dr. Adam Oliver for his guidance and insightful comments.

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Just Caring: Fair Innings and Priority Setting

Does a 90-Year-Old Have a Just Claim to an Artificial Heart?

Leonard M. Fleck

Let us start with a scene that I ask the reader to imagine. I am fishing in a boat with a 90-year-old acquaintance. He stands up in the boat, is a bit unsteady, and falls into the water. He used to be a very good swimmer, but he is afflicted with arthritis, which makes it impossible to swim to save his life. I have a lifesaver at hand. Am I morally obligated to throw it to him? Or is it his time to die? I have to imagine that anyone reading this essay would instantly assert that I had a moral obligation to throw that lifesaver to him. Now imagine a 90-year-old with late-stage heart failure in our clinic or in our health plan. Apart from the heart failure, he is in reasonably good health. He loves life; he is not ready to die. He is aware of the fact that we now have a totally implantable artificial heart [TIAH]. These devices cost $300,000 with the surgery and hospitalization (SynCardia 2015). He asks his cardiologist to get access to this device for himself through his health plan. He can reasonably expect five extra years of life of good enough quality from this device. This would be a lifesaver for him. Is his health plan morally obligated to provide the TIAH to him? Or is it his time to die because he has had his "fair innings"? How is his situation ethically like or unlike the situation of our 90-year-old at risk of drowning? We are not talking about a scarce resource; no one else is competing for this resource with him (as would be the case if we were talking about absolutely scarce natural hearts for transplantation). What would justify his health plan not providing this lifesaving TIAH to him?

One initial answer to our question might be that the TIAH cost too much. But this is not quite accurate. Granted, $300,000 is a substantial sum of money. In the context of a typical health plan with expenditures of hundreds of millions of dollars, this would be a drop in the bucket. However, the real problem is not simply the cost of this TIAH for *this individual*; it is the cost of the TIAH for all other individuals

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_15

faced with heart failure and the prospect of death in the next 2 years. If we were willing to spend $300,000 to give this individual five extra years of life, then what would justify our denying the TIAH to other individuals faced with impending death from a cardiac condition (and no alternative way of gaining those extra years of life other than from a TIAH)? Many, of course, will call attention to the fact that this individual is 90 years old. He has lived a very long life. Why should he have a claim to social resources to gain another 5 years of life? Again, a short answer would be that he has no such claim because he has had his "fair innings." But that response just raises a host of other questions. Who determines when one has attained his "fair innings"? If this individual had been 85 years old, would we be less ethically justified in denying him a TIAH? What about if he were 80, or 75, or 65 years old? Or is the real ethical issue that the language of "fair innings" is just perniciously pleasing rhetoric for what in reality is age-based discrimination, i.e., health care rationing that is essentially a devaluing of older individuals whose social productivity is largely exhausted?

I will answer this last question in the negative because I will argue that some form of age-based rationing, justified in part by "fair innings" considerations, is ethically justifiable, i.e., not unjust. To be more specific, the language of "fair innings" suggests some fixed number of years beyond which an individual would have no just claim to life-prolonging health care at social expense. This construal of "fair innings" will have only very limited applicability in the real world, i.e., when there is an absolute limit on needed life-prolonging resources, as during a pandemic. More ethically relevant in the real world of health care today, I will argue, is a more flexible contextual construal of "fair innings" in a range of health care circumstances for determining the just claims to needed health care for the elderly. To my mind, the best account of the just claims to needed health care for the elderly is Norman Daniels' Prudential Lifespan Account (1988). But that account has been subjected to a number of serious criticisms which I will rebut in this essay. Still, Daniels' account will be inadequate in some critical respects. It will require, I will argue, a complex theory of rational democratic deliberation and corresponding political practices in order to address fairly the complexities of medical practice today in relation to identifying the just claims of the elderly to needed health care. I take on that task in the last portion of this essay. To begin to understand these claims, we need to consider the broader background in which this issue is set.

1 The Age-Based Rationing Problem: Background

I have written extensively about what I refer to as the "just caring" problem (Fleck 2009, 2011, 2012, 2013, 2014a, b). What does it mean to be a "just" and "caring" society when we have only limited resources to meet virtually unlimited health care needs? The "limited resources" refers to the money individual taxpayers or insurance premium payers are willing to provide to meet health care needs. Needs are "unlimited" because, as Daniel Callahan has argued (1990), advancing medical technologies create new medical needs (in the morally valenced sense of that term).

The TIAH is a perfect example of that phenomenon. The point of the "just caring" problem is that the need for health care rationing and priority setting is inescapable. There would be no problem of health care justice if resources were always adequate to meet health care needs. The primary reason why financial resources have become scarce is the torrent of new medical technologies over the past 50 years. This is reflected in the increase of the fraction of the gross domestic product [GDP] that is devoted to health care over those 50 years. In the United States, for example, health spending increased from $26 billion in 1960 (5.2 % of GDP) to $3 trillion in 2013 (17.6 % of GDP) (Sisko et al. 2014). Projections to 2023 put that figure at $5.16 trillion (19.3 % of GDP) (Sisko et al. 2014).

The statistics that are most relevant for our purposes, however, are that roughly 35 % of the $3 trillion in health expenditures were spent on the 13 % of our population over the age of 65. A similar statistic holds true for the European Union as well (Rechel et al. 2013). At present about 17 % of the European Union population is over age 65. That figure is expected to rise to 30 % by the year 2060. In the shorter term, the care costs of that aging population are expected to rise by 30–55 % by 2025. In the United States, Medicare expenditures on the elderly in 2014 were about $640 billion. Over the 10-year period to 2023, aggregate Medicare expenditures are projected to be $8.3 trillion. This figure includes virtually nothing for long-term care. These cost figures reflect the fact that the elderly, on average, have many more health needs than the non-elderly. In the United States, 23 % of the elderly have five or more chronic health problems, some life-threatening, some quality-of-life diminishing (Thorpe et al. 2010). Despite this statistic, the majority of the elderly in any given year is quite healthy and makes minimal use of the health care system. Health needs tend to be concentrated. The sickest 5 % of the Medicare population consume 39 % of total Medicare expenditures, and the sickest 10 % consume 58 % of Medicare expenditures (Schoenman 2012). From an economic point of view, if there is an imperative to control health care costs precipitated by the elderly, then those elderly requiring the most health care resources would be the prime target of those efforts. From an ethical point of view, however, the imperative is to meet the health care needs of this fraction of the elderly population because they are the "least well off" (and have the most to lose if their health needs are not met).

If we were to ask why we are spending so much to meet the health care needs of the elderly, we might be tempted to simply call attention to the fact that their bodies are wearing out and, hence, are more vulnerable to all manner of biological and environmental assaults. However, that explanation accounts for only a small fraction of those growing health costs. The more adequate explanation calls attention, as Callahan (1990) does, to all the costly life-prolonging technologies that are now available to the elderly that were not available 40 years ago. In the United States, for example, we have reduced by 50 % since the mid-1980s the number of people who die of heart disease. This is because we have made available numerous medications that correct for biological deficiencies related to heart disease, as well as surgical interventions (bypass surgery, angioplasty) that repair occluded coronary blood vessels, as well as mechanical interventions that correct for various sorts of cardiac dysfunction (pacemakers, implantable cardiac defibrillators, left ventricular assist devices, and the TIAH). None of these interventions cure heart disease. They primarily prolong the length of time that individuals can live with gradually progressing heart disease, often long enough so that individuals will die of something else, i.e., a cancer, or COPD, or diabetes, or renal failure or dementia, though these too have all had their downhill courses substantially prolonged as a result of contemporary medicine.

As a consequence of the successes of contemporary medicine, we are today faced with this ethical challenge: Are we really morally obligated as a matter of justice to meet al*l* the health care needs of the elderly? If we are inclined to provide a negative answer to this question, then there are at least two ethically relevant follow-up questions we must answer. First, which health care needs of the elderly may be regarded as being ethically optional, i.e., regarded as needs that it would be morally permissible for society to overlook by not funding access to the health care that could otherwise address those needs? Second, what would be the morally relevant considerations that would justify a society overlooking meeting those needs, especially if a consequence of overlooking those needs might be the premature death of an elderly individual? It needs to be noted that these various life-prolonging technologies which we might wish to deny to the elderly are technologies that would be amply available to the non-elderly (at least as things are now). This is what creates the appearance of unjust discrimination against the elderly.

One line of response to these questions might go like this: If our society were committed to meeting *all* the health care needs of the elderly, then we would not have enough money to meet all the health care needs of the non-elderly, some of which might be more urgent and more consequential than some of the needs of the elderly that we were committed to meeting. To be more specific, some of the non-elderly might die prematurely because their health needs were not met. This seems intuitively unfair. What would justify facilitating the elderly to have even more years of life at the expense of years of life that the non-elderly could otherwise enjoy? If we have only limited resources for meeting unlimited health care needs, then we ought to use those resources to maximize the likelihood that all in our society would have the opportunity to achieve a normal life expectancy before we use any of those resources to provide already elderly individuals with life-years beyond or far beyond that normal life expectancy. That, in a nutshell, is one version of the *fair innings* argument.

2 Assessing the Fair Innings Argument

Prima facie the fair innings argument has considerable persuasive power. But it has been subjected to considerable criticism as well. The most common criticism is that the argument is fundamentally ageist. That is, the elderly are being discriminated against simply because they are old, a feature of themselves about which they can do nothing, as would be true with regard to their racial or gender characteristics. Hence, they are being denied their equal rights, their equal right to the health care that they need and that they regard as beneficial. If we had to spell out a bit more fully the implied argument here, it might go like this: If the need for health care rationing is inescapable, then it would be fairer if all in the same medical circumstances (same disease process, same prognosis, high cost, and low likelihood of benefit) were all denied access to that medical intervention no matter what their age. If a 40-year-old and an 80-year-old were both faced with imminent death unless they were provided with a $100,000 drug that would give them three extra months of life, then the critic of the fair innings argument would say (mindful of the need for difficult rationing decisions) that both ought to be denied that drug. Both equally want that three extra months of life; neither is quite ready to accept their "premature" death. Though we might be tempted to say that the 40-year-old is losing 30 extra years of life, that claim is factually false and ethically misleading. Both individuals are at risk of losing three extra months of life. Both individuals are deserving of equal moral respect. Consequently, both should be treated the same. There is no compelling moral reason why the 40-year-old should receive the drug while the 80-year-old is denied it.

John Harris is credited with introducing the fair innings argument into the literature (1985, at 91–95). It is noteworthy that he did provide some very specific limitations on the applicability of the argument. Specifically, he imagined a medical situation in which the medical intervention to be allocated (the last ICU bed, a heart transplant) was absolutely scarce. In *that* situation, the good to be allocated should, as a matter of justice, go the 40-year-old rather than the 80-year-old because the 80-year-old has had his fair innings. The gain in either case would be extra years of life (not a few months). Those are years the 80-year-old would already have enjoyed, and then some. The 40-year-old would be lucky to reach age 50. Fairness requires that the 40-year-old at least have the opportunity to get as close to a normal life expectancy as is medically possible. This does not look like an ethically objectionable form of ageism. However, if we have to do something serious about the problem of escalating health care costs, and if that means some form of health care rationing and priority setting are inescapable, and if the elderly are greatly disproportionate generators of health care costs, then endorsing Harris' fair innings argument in the very limited circumstances he envisions would have only a minuscule effect on controlling health care costs. Callahan (1985) and Daniels (1988) both took this conclusion seriously and published books defending a much broader approach to age-based rationing that generated the controversy one would expect.

Callahan deserves credit for at least three critical insights relative to the age-based rationing problem. Many philosophers prior to 1987 who were addressing issues of health care justice and health care cost control saw "need" as a natural moral limit to what society owed its members in terms of access to health care. Needs could make a moral claim on social resources but wants could not. Callahan's first insight was that health needs are not limited by nature but that they are unlimited and defined by emerging medical technologies. Second, there is the problem of "ragged edges," arbitrary limits with regard to the use of new medical technologies. If an artificial heart can save the life of a 50-year-old from premature death, then it can also save the lives of the 70-year-old, the 80-year-old, and the 90-year-old from premature death. We are forced to this cost-escalating conclusion if we assign considerable moral weight to urgent health care needs and if we are committed to equal concern and respect for all when it comes to meeting health care needs. Third, if "ragged edges" are to be replaced with bright lines that establish limits and priorities in meeting health care needs, then explicit social policies and practices will be needed to accomplish that. Nature offers few bright lines. There is a practical sense in which we cannot say that someone was terminally ill until they are dead (given what medical technology makes possible today).

For Callahan (1985), the goals of medicine should include relieving suffering and preventing premature death, i.e., death prior to achieving a natural lifespan. A natural lifespan is defined by Callahan in relation to a "tolerable death." A death is tolerable if "one's life possibilities on the whole have been accomplished" and "one's death will not seem to others an offense to sense or sensibility" (at 66). Callahan contends that a natural lifespan should not be thought of as exceeding age 80. That would be an individual's fair innings. He does not expect that an individual would "just die" at age 80, but he does expect that individuals would voluntarily forego expensive, aggressive life-prolonging care beyond age 80. He is not an advocate for public policies that would deny individuals such care. Instead, he imagines a cultural sea change occurring that would result in individuals making this choice voluntarily in the light of widely endorsed social expectations. This will strike many as a reasonably genteel view respectful of individual rights of autonomy. But critics will see some serious flaws.

On the one hand, some will argue that Callahan's view is too feeble and too ineffective if serious and just cost containment regarding elderly health expenditures must be accomplished. It would only take a small percentage of elderly cultural deviants to undermine Callahan's cultural expectations. To wit, why should I deny myself at age 84 an artificial heart and five extra years of life when my neighbor Sam demanded one at age 86 and is again enjoying life to the hilt? On the other hand, if Sam is essentially reasonably healthy, except for his heart failure, and an artificial heart can correct that deficiency, it would seem to be both unjust and unkind to expect that he would just choose to die. Further, it would seem to be ethically obnoxious to create such a strong cultural pressure that individuals like Sam would be shamed into choosing to accept their deaths. Further still, the injustice would be compounded if some strong-willed rebellious senior citizens secured artificial hearts for themselves in the face of those pressures while more compliant senior citizens meekly acquiesced to these expectations.

Norman Daniels (1988) has offered another version of the fair innings argument, which he refers to as the prudential lifespan account. His argument employs a Rawlsian veil of ignorance device. Daniels asks us to imagine ourselves behind a veil of ignorance, where we do not know our age, our gender, our health vulnerabilities, how long we will live, our life plans, our conception of a good life, and so on. But we do know statistically all the medical problems with which we might be afflicted as well as the various medical interventions that might address those problems, along with the cost of those interventions and the likelihood of their effectiveness in various medical circumstances. We are each given a societally determined fair share of health care resources for our lifetime which we must then allocate across all the stages of our life. That sum of resources is limited, that is, it would not be sufficient to meet all the health care needs that we might have over the course of a life. As a prudent individual I would want to maximize the likelihood that I would achieve my fair innings, that is, I would get to a reasonable old age if that is medically possible. The practical implication of that commitment is that I would take resources from my future possible hyper-elderly self and redeploy them to earlier stages of my life.

I would certainly want access to an artificial heart at age 60 if that device would provide me with a reasonable quality of life up to age 75 or beyond. But if I were afflicted with moderate (but advancing) Alzheimer's disease, or worse, condemned to some very marginal state of consciousness, then I would not want any sort of medical intervention that would prolong my life in such a debilitated state. That would include something as simple as feeding tubes (relatively cheap) that would sustain me potentially for years in a long-term care facility (very expensive). I would also reject these $100,000 cancer drugs for my future possible elderly self that would only yield gains in life expectancy measurable in weeks or months. I would instead want those resources made available to some earlier stage in my life where I might need a very costly medical intervention that would likely be very effective in saving my life and restoring my life to a reasonable quality. The moral virtue of this approach is that I am autonomously making age-based rationing decisions for my future possible elderly self. No institution is imposing these choices on me. No social policy is legitimating some form of discrimination against older citizens. Rather, I recognize that resources for meeting health care needs are limited (because I do not wish to spend more of my own money to purchase very marginal health benefits for my future possible elderly self). It is not that I disvalue that future possible version of my elderly self. What I disvalue is the very high cost of some life-prolonging interventions that will yield only small gains in life expectancy along with a greatly diminished quality of life. To be clear, though I used the first-person form to articulate the sorts of health care interventions I would forego for my future possible elderly self, neither I nor Daniels imagine that this process would be accomplished by individuals as individuals. Rather, a public democratic deliberative process would be the mechanism through which broad social agreement would be achieved regarding rationing protocols that we would apply to our future possible elderly selves. That is, we would be constructing a social insurance scheme aimed at maximizing the likelihood that as many members of our society as medically possible would achieve a socially agreed upon "old age," and we would facilitate achieving that goal by shifting health care resources to younger individuals at medically avoidable premature death or medically avoidable significantly diminished quality of life. The characteristics of that process are discussed further below.

Daniels' ultimate claim is that this approach to health care rationing is both prudent *and just*. The rationing that is imposed is both freely self-imposed and fairly imposed. The transfer of resources is from my future possible elderly self to younger possible versions of myself. That is, the transfer is intrapersonal rather than interpersonal. I am not unjustly seeking life-prolonging gains for my future possible self at the expense of the just claims of other younger selves. The deep moral underpinnings for this view are egalitarian, not utilitarian. That is, the goal of this approach is to maximize the likelihood that *each and every* individual will have an opportunity to achieve a normal lifespan. Again, what we must be mindful of is that Daniels is an advocate for a social policy regarding the allocation of health care resources across a lifetime, as opposed to a practice that allowed each individual as an individual to make these trade-offs. In a later essay (2008), he makes clear that the notion of prudence he invokes is one that is constrained by the need to choose an allocation scheme that will allow "a life as a whole [to go] as well as possible" (at 485). He then explains, "A life as a whole does not go as well as possible if certain important needs are not met at some stage or other of a life, or if certain all-purpose means are inadequately provided at some stage or other of the life" (at 485–86).

What Daniels wants to foreclose is the option of squandering health care resources at an earlier stage in life (having multiple costly MRI scans that are unlikely to yield much medical benefit) with the consequence that the most basic kinds of health care would not be available to my future elderly self. Each stage of life must be prudently provided for. The virtue of this approach is that it protects the dignity of the elderly by protecting their access to costworthy health care that effectively meets their basic health care needs. Also, it requires that the non-elderly deny themselves all sorts of costly, marginally beneficial health care interventions so that those resources are available for meeting effectively more important health needs of their future possible elderly selves. In this respect, the "pain" of rationing is fairly spread across the age spectrum, as opposed to being concentrated unfairly on the elderly. This last point addresses a concern expressed by Carina Fourie (2012). Her concern is that a strict construal of the fair innings argument would result in younger individuals having priority access to mental health care or pain relief over older individuals. This seems patently unkind and unjust. And it is. Neither Daniels nor I would endorse such a version of the fair innings argument because neither fairness nor prudence would warrant denying the elderly those basic health care services. That brings into stark relief our ultimate question: What sorts of health care under what clinical circumstances may be justly denied to individuals who have had their fair innings?

3 A Fair Application of Fair Innings

One answer that might be given to this last question is that the terminally ill elderly should certainly be denied what thoughtful, caring physicians would describe as "futile" medical care. This is a relatively common phenomenon in many hospital intensive care units. The family of a patient is unwilling to accept the fact that their loved one is dying, and consequently, they demand enormous amounts of costly medical care that only prolong the process of dying and make it more burdensome than it needed to be. Physicians feel all sorts of social pressure to acquiesce to these demands, though they see such demands as being neither just nor caring. However, this is not a relevant application of the fair innings argument because *both the* *elderly and non-elderly* in such circumstances ought to be denied care that thoughtful physicians regard as "futile," i.e., not altering an inevitable death.

The fair innings argument is correctly applied when medical care in similar clinical circumstances would be justly provided to the non-elderly but denied to the elderly. For example, if a 45-year-old has his knee badly damaged in a car accident, we might judge that justice would require providing access to a very expensive and complicated surgery that would restore that knee very close to normal functioning, as opposed to a less extensive and expensive surgical procedure that would only restore a level of functioning diminished by 30 % (no running, no sports). But if an 80-year-old had experienced a comparable loss of knee function, either because of normal aging or an accident of some sort, then it might well be "just enough" if only that less expensive surgical procedure would be made available to him. He might well have enjoyed tennis up to that point in time. That option would now be denied him. This would be a clear and justified (I contend) application of the fair innings argument.

Daniels offers the following moral justification for what is in fact my example. He appeals to what he calls the "age-relative normal opportunity range." Decline in functional capacities is part of the normal aging process (though we recognize there is considerable variation among individuals). Some individuals may enjoy playing tennis in their 70s and 80s. But restoring the knees of such individuals through expensive surgery so that they can continue to play tennis seems ethically supererogatory, given that we have only limited resources to meet virtually unlimited health care needs. It seems that it would be "just enough" if the less expensive knee surgery were provided to elderly individuals so that they would have the capacity to walk rather than being confined to a wheelchair. This is a point that would be endorsed by individuals taking the prudent lifespan point of view. I can readily imagine my prudent self being willing to sacrifice my capacity to play tennis at age 80 so that those resources could be applied to potentially more important health needs at an earlier stage in my life while at the same time providing some resources for a simpler less expensive knee surgery at age 80.

The point made in this last paragraph can be generalized. If an elderly individual's ability to see is threatened by cataracts or macular degeneration, and if we have an effective medical intervention for correcting those conditions, then that certainly ought to be made available to these individuals as a matter of justice. Losing most of the ability to see is surely more of a threat to well-being, as well as an age-relative opportunity range, than losing the ability to walk. A similar point can be made with regard to threats to our ability to hear when we have the medical capacity to correct such deficits. Having said that, we are then faced with the problem of where to draw the line with regard to a very large range of health deficiencies associated with advanced age.

It used to be the case in the 1970s that neither dialysis nor kidney transplantation were offered as an option to patients in end-stage kidney failure who were beyond age 65 because it was believed they were not medically suitable. That is, both procedures were judged to be too burdensome for individuals who already had diminished health status (O'Hare 2012; Grams et al. 2012). But some centers started dialyzing older patients with good results, and consequently, the fastest growing segment of the dialysis population today (2015) is over age 75. This phenomenon has now been generalized across many areas of surgery and medicine. To be specific, it is increasingly common to do coronary bypass surgery for individuals in their 80s and 90s (Koutouzis et al. 2010; Speciale et al. 2010). The same is true with regard to the implantation of left ventricular assist devices [LVAD] for patients otherwise faced with death from end-stage heart failure (Vitale et al. 2012; Matlock 2012). And the same is true with regard to the repair of abdominal aortic aneurysms (Prenner et al. 2010). Yet another area is prolonged mechanical ventilation for severe sepsis and respiratory failure (Ehlenbach 2014). This is just a very short list of real-world practical concerns raised by these interventions that require ethical analysis in the context of the fair innings problem.

What all these procedures have in common is that they are very expensive: $70,000 for coronary bypass surgery (though usually much more costly due to complication rates among the hyper-elderly); $200,000 for the LVAD; $100,000+ per month for prolonged mechanical ventilation. In addition, the quality of the results for patients ranges from marginal to reasonable gains in life expectancy and quality of life. The average older recipient of an LVAD will gain one to two extra years of life, better than with end-stage heart failure but far from normal. None of these interventions cure the underlying chronic degenerative disease process; they largely prolong a diminished quality of life before death. The following passage is repeated with slight variation in many of the articles I have cited: “Although the rate of postoperative complications remains high, cardiac surgery in nonagenarians can achieve functional improvement at the price of considerable operative and follow-up mortality rates” (Speciale et al. 2010, at 208). Noteworthy is that the subtitle of this article is “A Bridge Toward Routine Practice,” which is somewhat ethically disturbing in the light of the quoted conclusion. Finally, though these procedures are expensive at the unit level, the real ethical problem is generated by the actual or potential annual volume of these procedures. To take the LVAD as an example, there are now (2015) about 5.5 million Americans in various stages of heart failure and 550,000 new cases annually. Versions of the LVAD are still being improved, but the potential is that 200,000 of these devices could be implanted annually in the United States. That would add at least $40 billion per year to the cost of the Medicare program. The other interventions listed would also add billions annually to the cost of Medicare.

These examples are nicely illustrative of the problem that introduced this essay. But for the introduction of these new medical technologies, the fraction of societal resources devoted to meeting the health care needs of the elderly would be quite modest, and hence, it is unlikely that there would be this issue of intergenerational justice. But these new technologies are here. They were not created specifically to meet the health care needs of the elderly. On the contrary, as the story of dialysis illustrates, many of these technologies were introduced to save the lives of much younger individuals otherwise faced with premature death. But once they are part of the medical armamentarium, it would be very difficult to justifiably deny them to either the elderly or hyper-elderly as long as there is some chance they will benefit from having such access. This is what we mentioned earlier as the "ragged edge" problem; there is no bright line that separates justice-mandated from justice-optional uses of these technologies to meet health care needs. But if we do nothing to identify just limits on access to needed health care for the elderly, their growing and disproportional needs would threaten adequate access to needed health care for at least some of the non-elderly (because in the United States only the elderly have politically assured access to needed health care through the Medicare program). Does Daniels' prudential lifespan account help to address these issues?

4 In Defense of the Prudential Lifespan Account

One of the assumptions Daniels makes in articulating his Prudential Lifespan Account is that everyone will live a complete life of equal length. Hugh Lazenby (2011) sees this as a fatal deficiency in Daniels' account. Lazenby calls attention to the obvious fact that some significant numbers of people die very prematurely and others live to advanced old age. This could be viewed as a matter of misfortune or good fortune. However, Lazenby claims there is an injustice here that is obscured by Daniels' choice of his simplifying assumption. Lazenby notes correctly that Daniels situates his Prudential Account within a larger theory of justice, specifically, a Rawlsian account (1971). What we have to imagine then is that a society decides what it is reasonable to spend on meeting health care needs, given a certain level of technical medical advancement and societal wealth. Since Rawls is a moderate egalitarian, we have to imagine that amount of money being divided equally behind that health care veil of ignorance among members of that society. This is precisely what Daniels assumes is just. Lazenby then imagines someone dying at age 40. They might have died suddenly or they might know 3 years in advance that they have a terminal illness that is incurable. In either case, they may have used only a small share of their health care monetary allotment. Lazenby asks what becomes of the rest of their health care monetary allotment. He suspects it is used to fund the health care needs of those who survive to very advanced old age, which means that they receive in reality more than their fair share of that original health care allotment. This, Lazenby contends, is really an *interpersonal* transfer of health care resources rather than the *intrapersonal* transfer of resources that represented Daniels' distinctive response to the age-based rationing problem. His conclusion is that Daniels' account has no relevance to the real world.

Lazenby, however, has made several unfair assumptions regarding Daniels' account. His criticism only works if we imagine that the societal allotment of health care dollars for each individual is kept in a lifetime account for that individual. This is a mistake. That societal allotment would be used to purchase a societal insurance scheme, perhaps adjusted a bit each year. That is indeed the prudent and just choice to make with those health care dollars. Behind the veil of ignorance (whether the imaginative variety or the real world), we have no idea how long we might live or what our health care needs might be. There is enormous uncertainty in both regards. We do know how heterogeneous health needs are in any population, and we also know there is considerable complexity and uncertainty associated with medical interventions aimed at addressing those needs. This is why the purchase of health insurance is rational and prudent. Given these understandings, there is nothing intrinsically unfair about the fact that some individuals will die prematurely, not having used up their "fair share" of lifetime health care resources. But that is wrongheaded; there is no such "fair share" that was denied them. It is also worth noting that some individuals will die very prematurely, having used up more than their "fair share" of health care resources because of extensive medical efforts to save their life. But that too is a wrongheaded perspective. They will have had (presuming efficient use of resources) their fair share and no more. There is nothing ethically strange or unfair about this situation. In the United States, taxes taken from wages support our Social Security and Medicare programs. If an individual is diagnosed at age 40 with a terminal illness and has 3 years to live, and if he continues to work, he will continue to be legally obligated to pay taxes to support Social Security and Medicare though he will never benefit from either program. This is correctly described as being unfortunate but not unfair. This is the social bargain we implicitly agreed to when we were in good health and ignorant of our future health needs as well as the length of our life. Hence, Daniels Prudential Lifespan Account remains a fair and reasonable approach to addressing the problem of age-based rationing.

Dennis McKerlie (2013) is another critic of Daniels' account. He writes: "There are real conflicts between the claims of the young and the old, and the conflicts are neither transcended nor plausibly resolved by considering a single life and invoking prudential rationality" (at 16). He then adds by way of explanation: "People can possess a claim of justice for a certain temporal stage of their lives, a claim that is independent of how they fare in terms of their lifetime as a whole" (at 17). To illustrate McKerlie's point, imagine lives divided into five health-related temporal segments. Consider Alice and Betty. Alice's health-welfare statistics for those five temporal segments are 100, 110, 100, 100, and 80. Alice has enjoyed good health for most of her life. Betty has enjoyed excellent health for the first four segments of her life (130, 150, 160, 140) but was faced with multiple health crises during the last segment of her life, which is rated 20. Betty's lifetime health welfare is 600, whereas Alice's was only 490. From a lifetime egalitarian welfare perspective, it would seem that something should be done to improve the health welfare of Alice, not Betty. But that is precisely the conclusion McKerlie rejects.

McKerlie will contend that Betty is the one deserving more in the way of health resources for that last segment of her life because she would be at that point in time among the medically least well off (and justice would require that her needs be addressed by whatever medical technology is available and effective in meeting those needs). If we take that last life segment to cover age 75 to 95, and if Betty begins to experience heart failure at age 80, then she would be entitled to bypass surgery at age 83 and an LVAD at age 90 that might give her an extra year of life for $200,000. Note that this would still only raise her health-welfare score for this last segment of her life to 60 (by hypothesis). Note also that for McKerlie, it is not justice-relevant that Betty could be said to already have had her fair innings. It is also justice-irrelevant that Betty may have enjoyed excellent health for the vast majority of her life because she was genetically blessed with a superior immune system which effectively protected her from a number of health threats that would otherwise have diminished the quality of her life. By way of contrast, Alice may have had a very average immune system. It would also be justice-irrelevant for McKerlie if Betty had been faced with some potentially serious health problems early in life but received superior health care that quickly restored her to excellent health status because she had excellent health insurance. All that is justice-relevant is the urgency and seriousness of the present health need, not the quantity or quality of health or health care that one might have benefitted from in an earlier life segment. In brief, that is why McKerlie finds Daniels' prudential lifespan account inadequate as a perspective for addressing the problem of just health care between the young and the old.

My judgment is that in some respects McKerlie's intuitions are fundamentally correct. We would find it ethically objectionable to deny lifesaving surgery to an 85-year-old in reasonably good health, but with an aortic abdominal aneurysm near rupturing. The same would be true if this patient needed coronary bypass surgery. In part, this judgment is explained socially by the fact that most Americans and Europeans resist the idea of picking an age beyond which individuals would be denied expensive life-prolonging health care. However, McKerlie sees as the justice-relevant justification for this judgment that these patients are among the medically least well off (for whom we have the medical capacity to provide some benefit). For him this is the dominant justice-relevant consideration, not the length of their life. In this respect, McKerlie would be characterized as being a prioritarian.

However, the reader will recall that the age-based rationing debate arose because of the societal need to control health care costs (fairly), along with the fact that the elderly are greatly disproportionate users of high-cost life-prolonging medical technology. If "being among the medically least well off" should be the dominant justice-relevant criterion for allocating health care resources, then the 10 % of Medicare beneficiaries who currently consume 58 % of all Medicare dollars would be given an open checkbook that would allow them access to every form of life-prolonging medical care, no matter how marginal the benefit. This would predictably unjustly skew the society-wide distribution of health care resources.

In an earlier essay (Fleck 2011), I argued that the category of the "medically least well off" is quite heterogeneous and that a range of judgments of health care justice are appropriate for that heterogeneity. Thus, a 25-year-old in an accident that results in his becoming a vent-dependent quadriplegic will require $1.8 million in lifetime rehabilitation costs. A society as wealthy and technologically advanced as our own will be required as a matter of justice to provide those resources that will give him access to the opportunity range of our society that would otherwise be denied him without those resources. Rehabilitation in this case can be highly effective. A 75-year-old might be in late-stage heart failure but otherwise be reasonably healthy. He might be able to gain two or three extra years of life of reasonable quality from an LVAD. Perhaps we ought to think of this individual as having a presumptive just claim to this device. Another 75-year-old might have the same degree of heart failure with multiple comorbidities such that he would not be expected to gain more than an extra year of life of somewhat diminished quality. Perhaps this individual should be thought of as not having a just claim to an LVAD. Then there might be a 60-year-old whose medical circumstances are very similar to the second of our 75-year-olds. We might think of him as having a presumptive just claim to an LVAD, even though it is unlikely he will survive more than a year.

The reader will note that I have deliberately used language hedging my judgments of what justice required in the case of this last cluster of examples. This is because, as I have argued elsewhere (Fleck 2009, chapter 4), none of the standard theories of health care justice can provide a compelling rationale for concluding that providing the LVAD in these circumstances is warranted or not for any of these patients. This will also be true of Daniels' Prudential Lifespan Account. This is because there are multiple, reasonable considerations of health care justice that tug in different directions. To illustrate, one might say with regard to our cluster of examples, fair innings considerations must be determinative. That is, the 60-year-old ought to get the LVAD but all the others should be denied it, given limited resources. Alternatively, cost-effectiveness ought to be determinative. If someone can gain 3 years from the LVAD, that is cost-effective (and just, given limited resources). The others should be denied the LVAD. Again, utilitarian considerations matter. We could do three coronary bypasses on three 75-year-olds (perhaps saving more life-years) for the price of one LVAD. Or strong egalitarian considerations might be invoked (all lives are of equal value from the perspective of individuals who wish to live the rest of their lives, whatever the length might be). Consequently, if our society must put limits on certain very expensive life-prolonging interventions, then a lottery (or other randomizing procedure) ought to be used to make an allocation without consideration of age. In the real world, very fine-grained judgments of health care justice must be made and must have a sufficient degree of social legitimacy. Philosophic theories of justice are too blunt to yield these fine-grained judgments. What is needed instead is a fair social process whose outcomes are justified by reason, not relative political or economic power.

5 Fair Innings and Rational Democratic Deliberation

Daniels himself is an advocate for some form of democratic deliberation, what he refers to as "accountability for reasonableness" (2008) (see also chapter "Accountability for Reasonableness and Priority Setting in Health"). His account has the virtue of simplicity, essentially four steps. However, as I have argued elsewhere (Fleck 2009, chapter 5), resolution of the problems identified above should come through a process of rational democratic deliberation that is inclusive and fairly structured. This will be a more complex deliberative process, but I believe that is what is required by these age-based rationing issues. Rawls (1993) would say that what we should seek is an "overlapping consensus." That is, we should seek as much practical agreement as possible with regard to very concrete rationing proposals, even though the reasons individuals would give for their agreement might considerably diverge. In a liberal pluralistic society, this is the best that can reasonably be hoped for. The basic virtue of a well-structured deliberative process is that hard choices will be autonomously endorsed and imposed. Further, those choices will be a product of reasoned agreement (as Daniels emphasizes), not the relative political power of competing interest groups. The primary moral virtue of the deliberative process is reciprocity. If I say that I am unwilling to pay for an LVAD for an 80-year-old patient who is likely to gain less than a year in life expectancy, perhaps because of the damage to his heart, then I am saying at the same time (assuming I have a functioning basic sense of justice) that I would have no right to expect that others ought to pay for an LVAD for a future possible version of myself that is 80 years old with heart failure unlikely to benefit for more than a year from an LVAD.

A reasonable question to ask at this point is whether this conclusion is based upon fair innings considerations or something else, such as cost-effectiveness. The short answer to that question is that both sorts of considerations might be thought of as part of the justification for that conclusion. The fair innings argument is often presented in terms of some very specific age threshold, such as 70. But there is no compelling moral reason why that same number must be used across the entire spectrum of life-prolonging medical interventions where the issue of limits and health care rationing might be considered. Actually, we can go a step beyond that and suggest that applications of the fair innings argument need not invoke any specific age at all. Instead of using biographical age for making such judgments, the notion of physiological age might be invoked legitimately in some range of clinical circumstances. The language used might be “frailty,” or “significantly diminished lung capacity,” or “significantly diminished cardiac capacity,” or some other combination of physiological metrics that can be objectively measured. These are metrics most often associated with advanced age and diminished physiological reserve, and so in that respect “fair innings like” considerations are being given ethical relevance.

We might distinguish a “pure” fair innings argument from a “mixed” fair innings argument. If we imagine a very severe pandemic and a severe shortage of ICU beds and ventilators, then denying access to an ICU bed for any pandemic patient over the age of 70 would be an example of a “pure” fair innings argument. That age threshold alone determines denial of access. There might be a 75-year-old who was judged medically to have a very good chance of recovery from the pandemic infection, but he would nevertheless justifiably be denied an ICU bed on the basis of his age alone because he had had his fair innings of life, and some much younger person with good prospects for recovery would have to be denied that opportunity. By way of contrast, when we are faced with the issue of implanting LVADs in octogenarians or nonagenarians or doing open heart surgery in those same individuals, there is no absolute shortage of LVADs or surgeons to do these procedures. The only real limit is the amount of money a society (taxpayers and payers of insurance premiums) is willing to spend to provide these interventions. In these circumstances, there is a mix of considerations that could justify limits on access to LVADs or bypass surgery or other very expensive life-prolonging interventions for individuals who are octogenarians or nonagenarians and beyond. Some of those considerations might be of the fair innings/egalitarian variety. Others might be related to cost-effectiveness and the purchase of marginal benefits. If tens of billions of dollars were needed to provide LVADs for hyper-elderly individuals in end-stage heart failure, yielding on average only an extra year of life of diminished quality, it would be morally obligatory to ask about the justice-relevant opportunity costs of such a decision. In other words, could those same dollars be used to meet higher priority health needs of the non-elderly that would result in saving more life-years of higher quality? Likewise, could at least some of the dollars be used to meet other health care needs of the less-aged elderly for medical interventions that would yield at least improved quality of life if not also some degree of improved length of life? From behind a health care veil of ignorance would not such choices be judged both more prudent and more just?

In order to answer these questions thoughtfully and fairly, we would have to imagine a prioritization project that took into account everything that might be reasonably identified as a health care need along with medical responses to those needs and the costs of those medical responses. This project would have to occur within the context of a hard budget that would force deliberators to make difficult trade-offs. There is nothing utopian or unrealistic about asking prudent deliberators to consider creating health care priorities by making difficult trade-offs, most especially with regard to the future health needs of their future possible elderly selves. This is because the vast majority of us at any point in time are behind a health care veil of ignorance. Even if we know that there is above average heart disease or cancer in our family history, we are still vulnerable to an enormous range of health care problems, some potentially prematurely deadly, others associated with significant diminishment of quality of life. We are also emotionally connected to many other individuals in our lives whose health and well-being and vulnerability to various health problems would be as much a concern as our own health vulnerabilities. Hence, if a reasonable goal for any reasonable person is to maximize the likelihood of reaching average life expectancy in my society, and if we know that enormous sums are now being spent on current elderly individuals that often only yield very marginal benefits at very high cost, then we will want to deny our future possible elderly selves such benefits so that those resources can be used to fund effective medical interventions that, if unavailable, would result in either premature death or significantly diminished quality of life for younger versions of ourselves or others about whom we care.

As noted earlier, we will also be motivated not to squander health care resources likely to yield only very marginal benefits on younger versions of ourselves, thereby leaving less in the way of resources for the basic health needs of our future elderly selves. These perspectives are quite reasonable and realistic; they do not represent what Rawls refers to as “strains of commitment.” Nor would we expect that the results of a deliberative process that adopted this perspective would result in a devaluing of the lives of elderly individuals. We would be those elderly individuals. We would have made these choices collectively and autonomously through reasoned deliberation. What gives this perspective moral legitimacy is the reciprocity and impartiality that is built into the process itself. The outcome that we can reasonably expect will represent “rough justice” or nonideal justice. That is, if we were to focus moral attention on isolated outcomes of the deliberative process, we might be inclined to judge those outcomes “unjust” from the perspective of some reasonable norm of justice. But that would be the wrong perspective. We have to look at the results of the whole process, the complex balancing judgments made during the deliberative process. If that process is “just enough,” if that complex mix of outcomes is not reasonably rejectable by our rational deliberators, then that is the best that can be hoped for.

We should emphasize that health care justice concerns social health care resources. Hence, if we have a rationing protocol that would deny an LVAD to individuals over age 70 whose physiological status is such that confident medical prediction would conclude they would survive less than a year with that device, those individuals, if wealthy enough, could still purchase that LVAD with their own money. From a social point of view, this does not represent a cost-effective or “just enough” use of limited health care resources. But no one is made worse off, nor is anyone’s rights violated, if we allow individuals to purchase this LVAD. Hence, there is nothing intrinsically unjust about allowing this option. This is not an absolutely scarce resource. By way of contrast, if someone were to propose that there should be a 50 % social subsidy for anyone who wished to purchase an LVAD with their own resources, this subsidy would be unjust. This is because this subsidy would be paid for by somewhat less wealthy individuals who would have no opportunity themselves to purchase this benefit, were they in end-stage heart failure with a predicted gain in life expectancy of less than a year.

In conclusion, I want to return to the beginning of this essay and the artificial heart. I need to assume that at some point in the future this device will be widely disseminated, a not unreasonable assumption. What makes this technology especially challenging from a health care justice perspective and the problem of ‘fair innings’ is that appropriate implantation in the relatively vigorous elderly are predicted to yield on average five extra years of life. That makes it different from the current LVAD issue in several critical respects. First, it seems it would be easy enough to deny the TIAH to individuals whose predicted life expectancy was a year or so with the TIAH, especially if a comparable deliberative judgment had been made regarding the LVAD. But what if the predicted life expectancy for patients in end-stage heart failure implanted with a TIAH were 2–3 years and of reasonable quality? It would be difficult for a compassionate society to deny those extra years to someone in their 70s or early 80s. But if someone were in their 60s or early 70s and needed a TIAH for two or three extra years of life, a compelling *justice* argument could be made supported primarily by “fair innings” considerations. That brings us to our second point.

What should a just and caring society with limited resources and unlimited health needs do if relatively vigorous individuals in their late 80s or 90s with end-stage heart failure could benefit with a predicted gain in life expectancy of five extra years? Could we justly allow them to die “prematurely” with such a significant loss of life-years? They might have gotten to that point because of good luck in the genetic lottery or because of diligent attentiveness to excellent health habits. In either case, it does not seem that a morally persuasive argument could be made for saying such individuals *deserved or merited* those five extra years. Likewise, it does not seem any egalitarian, utilitarian, prioritarian, or sufficientarian arguments would yield the conclusion that these individuals had a just claim to those five extra years and the social resources necessary to buy those years. To be sure, we could imagine our society providing these individuals with excellent palliative care for "allowing them to die" rather than providing the extra years of life through the TIAH. But there would remain something morally unsettling and tragic about such a practice.

Calabresi and Bobbitt (1978) have argued at this point that there should be no such social *decisions*, but that such tragic choices should be hidden from public view by allowing evolving social customs and random ability to pay to yield this outcome so that these outcomes appeared to be mere natural misfortune, not the result of a deliberate social decision. I have argued elsewhere (Fleck 2009, chapter 3) that such a social practice would be socially dishonest and unjust. As Rawls (1971) has noted, just social practices do not require hiding those practices from critical assessment. Thus, one possible response to our artificial heart problem might look like this: (1) Individuals below age 70 face with a minimum predicted life expectancy of 3 years with an artificial heart would have this fully paid for by society. This would be a socially agreed upon understanding of "fair innings" in this context. (2) Individuals at earlier stages of their lives could choose to buy private insurance supplements for access to artificial hearts (and other comparably expensive life-prolonging medical resources) beyond age 75. Insurance companies would be free to deny individuals such insurance if they attempted to purchase it "too late," that is, with pre-existing cardiac conditions likely to require the artificial heart after age 75. A reasonable expectation would be that if individuals were anxious enough about maximizing their life expectancy beyond age 75, then as younger individuals with no evidence of emerging life-threatening disease they would take advantage of the option of purchasing such insurance.

What is described above might appear to be something Calabresi and Bobbitt would endorse. But it is not. What I am advocating is that something like this proposal could be explicitly legitimated through this rational democratic deliberative process, which means bringing about a painful self-conscious social recognition of the tragic circumstances we have created for ourselves as a result of the evolution of medical technology. Such a mutually respectful deliberative process best reflects what a just, honest, liberal society ought to be. If there is something morally tragic about some aspects of the "fair innings" problem, then that tragic dimension ought to be explicitly acknowledged, not disingenuously disguised.

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Personal Responsibility as a Criterion for Prioritization in Resource Allocation

Harald Schmidt

1 Introduction

Priority setting takes place in two spheres with distinct features.[1] Cases of absolute scarcity arise where supply cannot meet the demand and rationing becomes necessary. A central question in these contexts is which individuals should be prioritized on what grounds in accessing interventions or services. Distributing organs, vaccines in a pandemic, or ICU beds are typical casesof rationing. Resource allocation, by contrast, is concerned with relative scarcity. The central questions here are how to achieve value for money within healthcare budgets that generally do not have fixed ceilings and how to control overall expenditure. Typical issues are which of several available interventions should be covered by payers of healthcare—given their benefits, risks, costs, and opportunity costs—or whether any form of cost-sharing should be used to prevent excessive use of resources. In both rationing and resource allocation, a number of criteria can be engaged in justifying priorities, including personal responsibility.

The relevance of personal responsibility is largely self-evident. If people were healthier, there would be less competition for scarce organs or limited ICU beds. Equally, if fewer people were overweight, obese, or smokers, there would be reduced need for providing (and funding) interventions for conditions such as diabetes, heart disease, stroke, some cancers, or hip or knee replacements. In the USA, around 40

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[1] Gorin et al. (2015).

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_16

% of premature mortality is attributed to behavioral patterns,[2] and it is estimate that around $1.3 trillion annually—around a third of the total health budget—is spent on preventable diseases.[3] Resources that would not be needed for these conditions could be freed for mostly inevitable healthcare needs such as pregnancy or birth-related care, accidents, and a range of other conditions in which people have extremely limited opportunity to avoid needing care. So what role should personal responsibility play? What normative issues are raised by policies that appeal to personal responsibility in some way?

These questions can usefully be approached in a top-down and a bottom-up way. In a top-down fashion, one begins with the normative grounds on which one might give personal responsibility a role. The bottom-up approach starts from an analysis of the way personal responsibility is implemented in law, policy, and practice. It extrapolates which underlying explicit and implicit justifications are at work and to what extent these align or conflict with relevant normative frameworks or values that are inherent to a country's health system. I suggest that both approaches are necessary for real progress.

The first part of this paper provides a brief outline of how one might usefully think about the normative bases for policies that refer to personal responsibility, and a closer look at four major rationales that commonly drive them. The second part is concerned with a discussion of several central dimensions of different types of incentive policies—the most commonly used approach to implement personal responsibility in resource allocation in ways that go beyond mere appeals (such as those included in the NHS Constitution[4]). The relevance is that incentives are increasingly widespread, yet their basic rationales are not always clear, nor is the complexity of design options—and the ethical issues these give rise to—fully appreciated.

2 Policy Context and Major Rationales

Countries such as Germany explicitly emphasize in health law the link between individual behavior and the efficient operation of a healthcare system. Book V of the German Social Security Code (Sozialgesetzbuch, SGB) governs the provision of publicly funded healthcare. Its overarching Article 1 is entitled "Solidarity and personal responsibility" and reads as follows:

> In the spirit of a mutually supportive solidaristic community, the task of providers of statutory health insurance is to maintain, restore or improve health of the insured. The insured have co-responsibility for their health; through a health-conscious way of living, taking part in age-appropriate preventative measures [and] playing an active role in treatment and rehabilitation, they should contribute to avoiding illness and disability, and overcoming the

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[2] Schroeder (2007).

[3] Chatterjee et al. (2014).

[4] National Health Service (2013).

> respective consequences. The insurers are to assist the insured persons through the provision of information, advice and services, and should encourage a health-conscious way of living [translation HS].

The intertwined characterization of personal responsibility and solidarity entails two normative assumptions. First, the community has a certain degree of responsibility for the health of each individual. In this sense, individuals are entitled to claims against the community for assistance. Second, the community has certain claims against individuals. The appeal to stay healthy is made in the expectation that this will help control overall expenditure and opportunity costs and lessen resource allocation dilemmas. Not using services unnecessarily may also help avoid that another person in need of resources or of medical attention is deprived thereof, which may attenuate rationing dilemmas.[5] SGB's Article 2 on "necessity, efficiency, and personal responsibility" is unequivocal in stressing that providers of care need to ensure value for money and that people have an obligation to use services only when they are needed, with particular emphasis on individual behavior:

> Services … are to be provided by insurers with due respect to the principle of efficiency… and insofar as the need for services is not attributable to the personal responsibility of the insured person. […] Payers, providers and insured persons must seek to ensure the clinically effective and efficient utilization of services, which are only to be used insofar as necessary [translation HS].

The Code then sets out a number of more specific rules that follow from these general provisions. These include lower dental care copays for regular checkups (annually for adults, biannually for minors), the so-called healthy lifestyle bonus: insurance rebates or in-kind benefits such as sports goods for participation in primary and secondary prevention checkups, for an active gym membership, or for other forms of evidence deemed to indicate healthy behavior; "no-claim bonuses" for people who, over a year, do not require hospitalization and do not see their primary care physician for a prescription; and an obligation to repay part or all of the treatment cost for care that is required due to having engaged in criminal actions or due to nontherapeutic cosmetic surgery, tattoos, or piercing.[6] What should we make of such policies? Are they reasonable implementations of more general principles of personal responsibility?

3 The Ethics of Personal Responsibility: Two Problems with Current Approaches

In one sense, the cleanest way forward would be to decide on the right set of principles or theoretical framework that can provide an independent moral yardstick to determine which policies are called for and which should be resisted. Within

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[5] Schmidt (2008).

[6] Ibid.

political philosophy, personal responsibility features prominently in egalitarian,[7,8,9,10] communitarian,[11] and libertarian[12] traditions of thought. However, there are two principal problems with this approach.

First, in value pluralistic societies, agreement about what constitutes the right framework remains generally elusive. This fact has considerable relevance for priority setting in healthcare, where fundamental questions—such as how much priority to give to the worst off or when minor benefits to a large number of people should outweigh larger benefits to small numbers of people—will be answered quite differently depending on what normative basis one starts out from. In view of this situation, Norman Daniels and Jim Sabin developed the approach of Accountability for Reasonableness (A4R) outlined in this volume (see chapter "Accountability for Reasonableness and Priority Setting in Health"). They argue that questions such as the two just mentioned will remain unresolved in principle, because of the unbridgeable differences between theories. Rather than persuade one side (or several, for that matter) to concede that they were wrong all along and declare one position the victor—or, perhaps, develop one substantive master theory that will be acceptable to all—they propose to shift from focusing on agreement on substantive principles of justice to agreement on fair procedures.

The case of what role—if any—should be given to personal responsibility is directly analogous to what Sabin and Daniels see as unsolvable priority setting dilemmas more generally. While commentators from the above-cited perspectives have all argued for more emphasis on personal responsibility, albeit with different accentuations, other influential voices suggested that "personal responsibility for health might be wrong-headed, arbitrary, disingenuous, and even dangerous," deserving "but a peripheral role in health policy."[13,14] Below I will outline how A4R can be operationalized for the context of personal responsibility. Before that, the second problem with drawing on established theoretical frameworks or sets of principles needs to be unfolded, which is centered around the lack of specificity and applicability in practice.

Even if we suppose that we are able to find a country in which all residents (or just citizens) can agree on a normative reference point, such frameworks are typically of a very general nature. For example, seeking to attenuate some the harshness that can be entailed by certain versions of egalitarianism, Alena Buxy proposed the hybrid approach of "liberal egalitarianism-cum solidarity," understanding solidarity

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[7] Arneson (1997).

[8] Dworkin (2000).

[9] Roemer (1995).

[10] Roemer (1994).

[11] Callahan (1998).

[12] Engelhardt (1981).

[13] Wikler (1978).

[14] Wikler (2004).

not as "a one-sided principle, but a dual principle that entails elements of reciprocity: of receiving, but also of giving and contributing."[15]

This characterization aligns very closely with the de facto German policy approach outlined above. There is little question that—in legal terms—the specific policy provisions noted above can be viewed as consistent with the general overarching considerations on personal responsibility and solidarity set out in SGB's Articles 1 and 2. But it is far less obvious that normatively, all of the specific policies that follow in the law are justified. And although it is helpful to point out that solidarity can cut two ways, by itself, this provides no criterion for when the individual owes the community, nor for separating better from worse policies. Would Buyx' approach indeed view an insurance rebate for someone who has always been going to the gym as acceptable as one for people who changed their behavior and lost weight, or a surcharge for people requiring medical care because of a botched cosmetic procedure? And how high should rebates (or penalties) be?

Buyx, along with Shlomi Segall, who explored a similar position in this theoretical space, offers no further guidance, and it is equally scant in the field more broadly. An exception can be found in John Roemer's work. Roemer made a noteworthy contribution to the question of how to determine what individuals might owe a collective, given the problem of considerable variation of social and epidemiological factors that has subsequently been explored more broadly by the social determinants of health literature.[16] According to Roemer, responsibility assessments should be linked to the degree to which a person's risk behavior departs from standards that are typical for the kind of group a person might be assigned to in view of their health risk propensity.[17] While fairly complex—especially where people engage not just in one, but several behaviors that pose health risks—in principle, it would be possible to generate individual-level risk profiles, just as cruder versions of such assessments are made by actuaries in private health insurance on a daily basis. The approach goes some way toward addressing one of the crucial details that matter in implementing fair responsibility policies, but Roemer nonetheless offers no guidance on what to make of the multitude of design options in which policies can then be implemented in practice, as set out below.

Others with luck-egalitarian leanings have focused more on the policy side, although typically in a narrow way that excludes many of the personal responsibility policies that that are found in practice. For example, in the broader public health context, Alexander Cappelen and Ole Norheim[18] directly echoed earlier arguments by Julian Le Grand[19] that tobacco taxation is justified on the basis that it is a penalty for taking a health risk, even if no demonstration is required as to the extent to which individuals' actions de facto led to cancer. More directly centered on the

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[15] Buyx (2008).

[16] Wilkinson and Marmot (2003).

[17] Roemer (1995).

[18] Cappelen and Norheim (2005).

[19] Le Grand (1991).

context of priority setting in healthcare, Eli Feiring suggested that it is reasonable to ask obese patients or smokers to sign a contract to commit to behavior change and frequent medical follow-up, with the option of imposing lower priority in access to treatment for those refusing compliance.[20] And there are related narrowly focused proposals from quarters beyond luck egalitarianism, too. Dan Callahan proposed coercive public health measures, childhood prevention programs, and social pressure on the overweight.[21] In the broader field of health policy, Kelly Brownell and colleagues sought to provide a constructive proposal on personal responsibility and obesity and stressed five policy responses comprising protecting children, improving labeling, curbing marketing, regulating food ingredients, and increasing taxes on less health option—rightly stressing the importance of public health measures but seeing no role for policies focused on individual action. At the other end of the spectrum, David Asch, Ralph Muller, and Kevin Volpp argued that not hiring smokers is a controversial and difficult but ultimately justifiable decision in policy.[22]

4 The Ethics of Personal Responsibility: A Proposal for a Way Forward

In view of this situation, what is needed is, first, an approach that is compatible with the fact of pluralism that characterizes modern liberal societies.[23] Second, this approach needs to offer a framework that can facilitate dialogue in the *realpolitik* of health policy between policy makers, philosophers, healthcare professionals, the public, and other stakeholders. Third, the approach should specify as clearly as possible the areas in which justification is owed. A4R can provide a helpful basis, even if further specification is needed.

A4R requires that policies meet four conditions concerning relevance, publicity, revision and appeals, and regulation. While the latter three are straightforward process conditions, the relevance condition is less obvious and specified in its briefest form as follows[24]:

> The rationales for limit-setting decisions should aim to provide a reasonable explanation of how the organization seeks to provide "value for money" in meeting the varied health needs of a defined population under reasonable resource constraints. Specifically, a rationale will be 'reasonable' if it appeals to evidence, reasons and principles that are accepted as relevant by ('fair minded') people who are disposed to finding mutually justifiable terms of cooperation.

The point of A4R is to hold those limiting access to services accountable for the reasonableness of their decision.[25] To adapt the approach for the context here and to

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[20] Feiring (2008).

[21] Callahan (2013).

[22] Asch et al. (2013).

[23] Rawls (1989).

[24] Daniels (2007).

[25] Daniels and Sabin (1999).

Evidence, rationale, and feasibility

What are the policy's principal rationales and goals? Have they been justified in an open and transparent manner, with opportunity for comment by all those affected by the policy? How sure can we be that the policy will achieve its aim, in principle and in practice? Are the required efforts and cost proportionate in view of the goals?

Intrusiveness and coerciveness

Are there ways in which the goal of the policy could be achieved in less intrusive ways? If not, is the extent of intrusiveness justifiable in view of the expected benefits?

Equity

Are there some groups (such as particular socio-economic, ethnic, or regional subgroups) who are likely to experience disproportionate benefits or burdens as a result of the policy? At what point would it be reasonable to reject a policy because of inequitable impact?

Solidarity/risk-pooling

Insofar as the healthcare system has an implicit or explicit principle of solidarity or risk-pooling: how does the policy affect it? If it should undermine solidarity or risk-pooling: are all affected clear about this, and can the effect be justified?

Attributability/opportunity of choice

To what extent are penalties or rewards based on actions that can be attributed to people's free and voluntary choices? Where peoples' opportunity of choice is limited: can waivers or alternative standards be implemented? Should rewards be given, even if people have not changed their behavior, but just happen to satisfy the policy's criteria?

Affected third parties

Does the policy have an effect on the relationship people have with, for example, their physicians or employer? Insofar as physicians are involved in assessing whether or not someone has complied with their responsibilities: is their involvement justifiable and accepted by them and their patients? What information should employers have (or not) about people's compliance with responsibilities?

Coherence

How does the policy compare with standards of responsibility, attributability, and blame in other areas of social policy and the law? Since tensions can be resolved in more than one way: in which way should they be addressed?

Fig. 1 Seven central relevant dimensions regarding evidence, reasons, and principles requiring justification in designing and evaluating personal responsibility policies

assist with broader scrutiny of policies that goes beyond those imposing responsibility-related limits by limiting the scope of coverage, varying cost, or other means, Fig. 1 summarizes seven central relevant dimensions regarding evidence, reasons, and principles that come into play when justifying or evaluating personal responsibility policies, set out in more detail elsewhere.[26]

I contend that the framework meets the requirements above and—by mapping the ground in which justification is owed—has the further advantage of providing a

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[26] Schmidt (2008).

complementary structure for proponents of particular normative frameworks. A particularly attractive approach would be to use the framework within a contractualist theory, as presented, for example, by Thomas Scanlon. In this sense, the framework can be used for identifying those principles or policies that, provided people have appropriate choice option sets, "no-one could reasonably reject"[27] and hence have particular robustness and in fact special moral value.

5 Four Rationales for Promoting Personal Responsibility in Resource Allocation[28]

Appeals to personal responsibility are made in both rationing and resource allocation contexts. Responsibility plays a less complex role—and is typically addressed more explicitly—in rationing compared to resource allocation. For example, the American Thoracic Society's *Fair Allocation of Intensive Care Unit Resources* guidelines stipulate unambiguously that when demand exceeds supply, "medically appropriate patients should be admitted on a first-come, first-served basis… [as] every individual's life is equally valuable." Expressly, the guidelines note that "relative benefit, … relative medical need" [29] are unfair criteria and, by implication, that personal responsibility should play no role whatsoever: first-come, first-served trumps all other values. A somewhat different accentuation is found in relation to transplant policy. Alcoholics are frequently required to abstain from alcohol for 6 months before they are eligible for transplantation. Generally, this is based on the assumption that some patients may no longer require a transplant as a consequence and that the effectiveness of the procedure can be increased by an extended period of abstinence.[30] Research has shown that this approach exacts a heavy toll on some patients with severe alcoholic hepatitis: they have a threefold higher 6-month survival rate when the 6-month abstention rule is not enforced.[31] In the following, the focus is, however, not on cases of rationing, but on resource allocation. This is not to diminish the need for robust justification for personal responsibility policies in rationing—where the above framework can be applied just the same—but to concentrate on the area where there is more need for clarity and transparency due to a plethora of policy design options.

A major complication of assessing the justification of responsibility policies in resource allocation is that there are often several different rationales at work, whether declared or undeclared. These center around genuine efforts to support people's health agency, controlling cost, securing advantages in healthcare markets, and promoting social values.

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[27] Scanlon (1998).

[28] The following section draws, in part directly, on a shorter version published as Schmidt (2014).

[29] American Thoracic Society (1997).

[30] Weinrieb et al. (2000).

[31] Mathurin et al. (2011).

5.1 Helping People Overcome Decision Errors and Unfavorable Social Pressure

In a way, using incentives to appeal to people's responsibility to engage in health promotion is perplexing. Typically, people want to be healthy. So why should they need further encouragement? Anyone who recalls their failed new years' resolutions quickly appreciates why. We often have the best of intentions to exercise more, eat less, and consume alcohol in moderation. But we also often fail to act on our goals. Standard accounts in both classical economics and bioethics rely on strong concepts of autonomous rational agents: but they fail to capture such flaws in human agency and limits to intrinsic motivation. By contrast, the relatively recent field of behavioral economics has set out to map and understand the science of decision errors in detail.

For example, the concept of present-preference bias has been coined for a range of cases that show that powerful cognitive constraints often make a short-term and certain benefit appear much larger than a longer-term, less certain benefit: Faced with the choice of a slice of delicious velvety chocolate cake that is placed right in front of me and the alternative of a slimmer waistline in years to come, the pleasure in the here and now has considerable pull.[32] In other research that examined the role of choice architecture given in settings at home, work, and play, the powerful grip that defaults have on our behavior has been firmly established.[33] We are often content with the path of least resistance, for example, by not using stairs when a lift is easier to reach or choosing a less healthy option from a buffet if the more healthy one is placed in such a way that it requires more effort to reach it. A series of observational and experimental studies also showed that when it comes to motivating people, losses loom larger than gains and have superior traction in policy.[34]

In addition to the principal rationale of enabling and supporting intrinsic motivation, more recently, it has also been suggested that incentives can help people who already have sufficient motivation but face social pressure that counteracts behavior change. For example, a pregnant woman may wish not to smoke. But her social environment may be such that she constantly has to justify herself for not smoking. In addition, her quitting may be experienced by the group as implicit criticism of the dominant behavior. In such cases, incentives may offer "argumentative cover," or a form of rationalization, by providing others with a reason for changing one's behavior.[35]

Much of this research can have direct applications in healthcare policy and practice. A proper understanding of decision errors that thwart healthy behavior can be used to turn around the very mechanisms that underlie them, enabling healthy behavior. To use the examples above, in buffets, items can be arranged in such a way

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[32] Frederick et al. (2002).

[33] Sunstein and Thaler (2008).

[34] Loewenstein et al. (2007).

[35] Wolff (2015).

that healthier options are easier to reach. Rewards such as cash premiums can be used to help people quit smoking. Insurance premiums might be increased for people who do not comply with evidence-based preventive exams. Of course, some people do not require any such assistance. But for many, changes in default situations, or ways of using incentives in the here and now to make those choices most attractive that offer the greatest benefits to their future selves, can offer help where intrinsic motivation to act responsibly is just not strong enough. Given that much of the literature on personal responsibility is—on the whole, quite rightly—concerned with the negative consequences of policies seeking to promote it, it is important to recognize that, in principle, policies can have an effect of empowering agency and responsibility and counter senses of resignation or fatalism that may occur in view of the difficulties of behavior change.[36]

It is far from straightforward to say which types of incentives actually work. However, the proof of principle has certainly been established in a number of relevant policy areas, including smoking cessation, weight loss, medication adherence, and substance abuse management.[37,38,39,40] While it is difficult to generalize, incentivizing so-called "simple" or one-off behaviors, such as getting vaccinations, can be highly effective.[41] But for "complex" behaviors, such as chronic conditions, the evidence is generally less clear, even though there are some robust examples. Clearly, pointing to effective incentives and to the fact that these can help overcome behavioral economics constraints or adverse social pressure, cannot, by itself, justify their use. What complicates both the actual justification and real or perceived acceptability by users is that in addition to the benevolent behavioral economics-based justifications, there are often other sometimes less patient-centered motivations that drive their use.

5.2 Reducing Expenditure for Payers of Healthcare

It was noted above that the German health law assumes increased personal responsibility for better health will curb healthcare spending, if not lead to net savings. The assumption is not merely implicit, but, in fact, reflected in the financing arrangements for the healthy lifestyle bonus program that rest on the principle of gain sharing. Article 65a SGB specifies that insurance rebates and other incentives may not be funded through higher insurance contributions for all, but may only be covered as a portion of the savings that result from peoples' participation in preventive programs. Health plans offering this type of program are required to report in 3-yearly intervals on the operation of bonus programs to the relevant authority: if no savings can be demonstrated for the groups participating in the programs, no bonuses may be paid.

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[36] Schmidt (2009).

[37] Volpp et al. (2009).

[38] Volpp et al. (2008).

[39] Higgins et al. (2010).

[40] Jeffery et al. (1978).

[41] Oliver and Brown (2012).

Data from a large sickness fund in Germany and a review of 36 studies in the USA appear to suggest a return-on-investment ratio for using incentives of around 3:1.[42,43] However, aside from methodological limitations that are rightly acknowledged by the authors (most studies used large employers >1,000 workers, self-selection bias was likely, as not all executed programs are evaluated or submitted for publication, and publication bias was likely, as studies showing positive effects are usually more successful in being accepted), there are fundamental questions about whether, in fact, better health leads to lower cost. Among other things, cost reductions are highly dependent on the period of time that one considers. What services are covered by a health system, and how its financing is managed, also matters. Regarding the relative lifetime cost of smokers, obese, and healthy people (never smokers, normal body mass index [BMI]) in the Netherlands, it has been suggested that the latter, and not the former two groups, are most costly—chiefly due to longer life and higher cost of care at the end of life.[44] Other research suggests that incentivizing disease management programs rather than broader prevention programs is far more effective.[45] Cost savings can therefore not be taken for granted but require consideration of the condition being incentivized, the organizational specifics of the health system, and, in particular, the time horizon over which possible savings are assessed.

A focus on positive cost impacts can also influence the choice of incentive mechanism. Financial incentives are particularly prominent. As described further below, there are many different ways of framing incentives, but in essence, they function either as "carrots" or as "sticks." Carrots may consist in a cash lump-sum payment or in an insurance premium reduction. This type confers a net benefit of monetary value in relation to someone's insurance contributions. Sticks are surcharges or penalties that enable shifting part (or all) of the cost associated with unhealthy behavior back to the user: they result in a net loss. It is therefore clear that for insurance companies interested in seeing a positive effect on cost as quickly as possible, stick approaches are likely to be most attractive. For in the case of carrot framings, the cost for the incentive needs to be recouped through later savings, be absorbed by the health system, or be carried by insurance contributions of other users.

It is noteworthy that the US approach differs significantly from the German one that is focused on gain sharing. Within group insurance—typically provided through employers, and covering more than half of the population—it is explicitly permitted to shift cost from the insurance provider to participants who do not satisfy standards required for programs, or from participants who satisfy standards to those who do not, or some combination of these. [46] Legally permissible standards include risk factor targets such as body mass index, blood pressure, or cholesterol thresholds. The

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[42] Baicker et al. (2010), Bödeker et al. (2008).

[43] Bödeker et al. (2008).

[44] van Baal et al. (2008).

[45] Caloyeras et al. (2014).

[46] Department of the Treasury, Department of Labor, and Department of Health and Human Services (2006).

levels by which healthcare cost for individuals can be varied are considerably higher than in the German context. In general, decreases as well as increases up to 30 % of the total cost of coverage are permissible (around $1,500 for single coverage) and 50 % including the special case of tobacco use (around $2500 for single coverage).[47] Moreover, it is legally permissible not to hire smokers in around half of US states. Insofar as data that suggest incrementally higher healthcare cost for smokers of around $2,000 are applicable (and $3,000 arising from lower productivity and higher rates of absenteeism),[48] this form of "lemon dropping" can have a direct impact on payers' health budgets.

5.3 Conferring a Competitive Advantage on Payers of Healthcare

In many countries, health plans compete for what economists call "good risk" clients: People with high rates of insurance premium contributions but low levels of morbidity and associated healthcare use. Publicly funded European and other health systems that are based on solidarity typically prohibit overt risk selection, such as higher premiums for sicker people. The thought is that fairness requires that good risk users support bad risk ones: young vs. old, healthy vs. sick, or employed vs. unemployed.[49] But incentive programs of the carrot type typically evade the radar of overt risk selection detection and can be used for "cherry picking," i.e., for attracting and retaining good risk insurees. For example, it has been shown that adding free gym membership to Medicare Advantage plans leads to a 6 % relative increase in enrollees reporting a health status of "excellent" or "very good."[50] A similar effect on the structure of payers' risk pool may be given where a large employer seeks to incentivize healthy behavior by imposing surcharges for higher BMIs or not employing smokers.[51] Such approaches may deter prospective employees from seeking employment (or insurance coverage, where such initiatives are part of a health plan). The policies are likely to have a direct positive impact on the payer's risk pool—despite and because of their negative impact on solidarity or other principles that underlie risk sharing.

5.4 Promoting Moral Values

The somewhat pejorative moniker of "lifestyle diseases" is commonly used for the kinds of conditions sought to be averted through personal responsibility programs. Oftentimes, the implication is that being a smoker, alcoholic, or overweight person

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[47] Madison et al. (2013).

[48] Berman et al. (2014).

[49] Prainsack and Buyx (2012).

[50] Cooper and Trivedi (2012).

[51] Asch et al. (2013).

is as much a personal choice as one might choose playing golf, tennis, or lacrosse as a hobby. Clearly, however, opportunity of choice and associated degrees of freedom and voluntariness differ immensely. Social and other determinants of health can make it extremely challenging for people not to smoke, drink excessively, or be obese.[52] Yet, sympathy by both policy makers and the population can be limited in societies with a cultural history in which the deadly sins of gluttony, sloth, and lust still cast long shadows.[53] For example, researchers established that a carrot-type incentive program amounting to $750 was effective in helping people quit smoking. A large American company at which the research had been carried out planned to offer the program to all of its more than 150,000 employees. But the companies' nonsmoking employees objected vehemently to smokers being offered what amounts to lower health insurance premiums for doing something they had been doing all along. Instead of making the case that all insured employees stand to benefit from lower healthcare cost associated with fewer people being smokers, to appease the backlash, the company turned the carrot into a stick and charged smokers $625 more.[54] Notions of deservingness and responsibility come into play in practically all incentive programs, and it can be far from straightforward to ascertain what is really driving a certain program "under the hood."

5.5 Aligning Interests, Reducing Goal Conflicts

Clarity about declared and possibly undeclared rationales underlying personal responsibility policies is central element in their justification. Much progress with the fairness of programs seeking to promote personal responsibility can therefore be made if in planning, implementing, and evaluating programs, policy makers and payers of healthcare are clear about which rationales play which roles, set these out unambiguously to the target population, and evaluate systematically the extent to which programs accomplish the intended goals, especially in terms of health promotion. Particular attention should be paid to ascertaining the winners and losers of incentive programs, as it cannot be assumed that all who are offered them will have an equal chance at reaping the associated benefits[55]—whether these come in the form of a net gain or the opportunity to avoid a net loss.

Moreover, given that several goals may be pursued simultaneously, the possibility of goal conflicts needs to be considered. For example, it may be that programs reduce cost (through cost shifting) or give a payer a competitive advantage (through changes in the risk pool) without improvements in health. It would seem that in such cases, health incentives have missed their mark and that, more generally, health improvement should always trump other goals. But at least in practice, health improvement is not universally seen as paramount. For example, in Germany, the

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[52] Wilkinson and Marmot (2003).

[53] Ubel et al. (1999).

[54] Volpp and Galvin (2014).

[55] Schmidt (2012).

government recently reviewed the range of incentive programs offered in the public insurance system and concluded that it was not uncommon for incentives to be offered for interventions that had no or at best an indirect impact on health promotion, demanding that in the future, incentives should only be offered for programs with quality assurance.[56]

Conversely, in setting out new rules for wellness incentives in the US, relevant government departments expressly specified that programs were "not required to be accredited or based on particular evidence-based clinical standards."[57] This can be puzzling, given that the same document also highlights that "insufficient broad-based evidence makes it difficult to definitely assess the impact of workplace wellness programs on health outcome and cost," echoing similar concerns expressed in a major prior report to the US Congress.[58] Instead, the report noted that "overall, employers largely report that workplace wellness programs are delivering on their intended objectives of improving health and reducing costs."[59] And indeed, an estimated 80 % of all US employers providing healthcare used incentives in 2012, according to major surveys.[60,61,62]

The discrepancy between the evidence base regarding the effectiveness of health incentives and their widespread use can be puzzling. One possible explanation is the belief that the dictum of "an ounce of prevention saves a pound in cure" is held to be self-evident. This could explain why programs are rolled out on a large scale, but only a fraction is evaluated. Another may be that the option of cost shifting does not require improved health to confer an economic advantage to employers or health plans: By implementing surcharges for smokers or the overweight, a net gain can be achieved instantly. A third explanation for the widespread use could be that the moralistic and political undercurrents of personal responsibility for health have traction with payers of healthcare and are more influential in implementing policies than economic expectations, or those pertaining to health improvement.[63]

6 The Complex Anatomy of Incentives for Promoting Personal Responsibility

While clarity about the underlying evidence and motivations of responsibility-promoting programs are necessary conditions for determining their ethical acceptability, they are not sufficient. In addition to the further considerations in Fig. 1, it is crucially important to be aware of the highly complex design options of incentive

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[56] Bundesministerium für Gesundheit (2012).

[57] Department of the Treasury, Department of Labor, and Department of Health and Human Services (2013).

[58] Mattke et al. (2013).

[59] Department of the Treasury, Department of Labor, and Department of Health and Human Services (2013).

[60] AON Hewitt (2012).

[61] Kaiser Family Foundation and Health Research & Educational Trust (2012).

[62] National Business Group on Health and Towers Watson (2012).

[63] Volpp and Galvin (2014).

programs. The following overview delineates nine of the most central parameters that need to be considered in planning, implementing, and evaluating programs: the type of incentivized behavior; the incentivized unit and target population; the nature of the conditionality-triggering target; the incentives' currency; mode and framing; levels; certainty; time horizon, or frequency; and the extent to which alternatives are provided to users who are unable to meet targets.

6.1 Type of Incentivized Behavior

Incentives can be used for a wide range of behaviors that differ, among other things, in how challenging it is to achieve the target behavior. As noted, at one end of the spectrum are "simple" or one-off behaviors. These can comprise using vaccinations, completing a health risk assessment, or undergoing biometric screenings for BMI, cholesterol, or blood pressure values. At the other end, there are "complex" behaviors relating to chronic conditions: These may require repeated behavior change and take the form of exercise, weight loss, smoking cessation, substance abuse, or medication adherence programs. Since the baseline difficulty of achieving the target behaviors differs, and since incentives can, at best, support people's motivation, it would generally be wrong to expect that incentives for complex behaviors are as effective as the ones for simple ones.

6.2 Incentivized Unit and Target Population

Incentives are typically viewed as an individual-level intervention. But they can also be provided to groups of people. Group incentives seek to draw on many peoples' interest in competitions or seek to capitalize on constructive forms of social pressure. Group incentives may add an element of playfulness, for example, where teams of people strive to lose the most weight collectively, and a prize is shared among all members of the winning team. In alternative approaches that incorporate a more individualized form of loss aversion, each member of a team receives a certain incentive amount for sticking to a weight loss trajectory, but if one member fails, their reward is shared by all others.

While the form of such and similar competitions is easy to grasp, it cannot be assumed that everyone will respond equally well to group incentives. People differ in their personality types, and while highly competitive types may welcome such programs, others may find the regular pressure resulting from their work sufficient to cope with and may not respond positively to additional challenges. This constraint can be equally effective in standard individual-level incentives. Possible variation underlines, again, the need to assess winners and losers among program users.[64] Ideally, programs are tailored or patient centered as much as possible under logistical and funding constraints that typically apply.

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[64] Schmidt (2012).

6.3 Nature of the Conditionality-Triggering Target

Many regulatory policies differentiate between incentives for behaviors that practically anyone could accomplish, such as attending a lecture on healthy eating, on the one hand, and, on the other, incentives for meeting specified hard targets that are regarded as indicators of good health, such as BMI, cholesterol, or blood pressure thresholds. The former are sometimes called participatory and the latter health-contingent incentives.[65] The distinction is of central relevance for the fairness of incentives,[66] as not everyone starts from a level playing field. Health-contingent incentives may be disproportionately more challenging for some groups of people. Largely for this reason, incentive levels are capped in the USA for health-contingent incentives but not for participatory ones. A further normatively relevant variation that acknowledges that people differ in their baseline health is to provide incentives not for meeting rigid target threshold levels, but for making improvements (e.g., with regard to certain BMI or blood pressure levels), which can be more accommodating of given variations.

Most preventive interventions offer nothing but benefits. But some, such as cancer screenings, also entail risks. This feature renders screenings sensitive in the sense that users need to decide how they weigh the balance of benefits (in the case of, e.g., breast cancer screening: potential early detection of disease) and risks (false positives, worry, overdiagnosis, overtreatment in the form of possible needless hormone-radiation and chemotherapy, surgery).[67] Incentivizing different forms of cancer screening use becomes ethically troubling where it interferes unduly with the decision-making process. An alternative would be to incentivize not the uptake of screenings, but active choice, e.g., by providing the incentive for reviewing evidence-based information and subsequently making a decision for or against a screening test.[68] While incentives for preventive care and the option of averting cost for later treatment can be particularly attractive in view of their potential to reduce resource allocation dilemmas, the cost of screening also needs to be considered, as well as the possibility that needless follow-up testing and care may exacerbate rather than alleviate dilemmas.[69]

6.4 Incentive Currency

Incentives can take different forms. One general distinction is between those with monetary value (such as cash) and those without (such as honors or achievement

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[65] Department of the Treasury, Department of Labor, and Department of Health and Human Services (2013).

[66] Schmidt et al. (2012).

[67] Marmot et al. (2013).

[68] Schmidt (2013b).

[69] McCartney (2013).

badges used by initiatives such as Weight Watchers). Among those with monetary value, there are financial incentives and nonfinancial ones. The former consist centrally of fixed cash amounts and insurance premium variations. Some employers also tie access to a higher tier benefit package or the entire employer-sponsored insurance package to the completion of health risk assessments or biometric screening.[70] Nonmonetary incentives may take the form of in-kind benefits, such as sports goods, wellness holidays, concert vouchers, or other items. And policies such as not hiring smokers fall somewhere in between, as the value of employment in no small part rests on the associated financial benefits, even though the form of implementation differs from that of other financial incentives. Different incentive currencies can have different traction in terms of their effectiveness and are also likely to be experienced differently by users in terms of where they fall on the spectrum of being entirely voluntary or outright coercive—amplified by the level of value of the incentive.

6.5 Incentive Level

The value of incentives with monetary value can be small, and mainly symbolic, such as a T-shirt or mug with a message promoting healthy behavior. Larger ones, as noted above, can come in the form of insurance surcharges up to $1,500 for failing to meet biometric targets such as BMI, blood pressure, or cholesterol values and up to $2,500 for smoking. In cases where activities presumed to be health conducive such as biometric screenings are tied to accessing insurance in the first place, the monetary value might be calculated as being the cost of coverage altogether and accordingly be higher still—likewise in the case of making employment conditional on no smoking. High incentive levels may again have more traction but also raise fairness issues, where there are limits to the extent to which the target is under control of an individual.

6.6 Incentive Mode and Framing

As noted, the basic distinction between types of incentives is between carrots, which confer a net benefit, and sticks, which result in a surcharge. Sticks, however, can also be framed as carrots: A health plan could increase premiums for all at the beginning of the year and then offer a rebate as an incentive for insurees who achieve a health-conducive behavior. The effect for those who fail to accomplish the behavior is the same as in the standard stick scenario: a net increase in cost. Yet, the health plan might advertise it, and users might perceive it, as a carrot.[71] Such framing may be welcome by some users but antagonize others. Despite the same economic

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[70] Kaiser Family Foundation and Health Research & Educational Trust (2012).

[71] Wikler (1978).

consequence, it should not be assumed that the stick and “false carrot” approach will be equally effective or acceptable to all groups who are exposed to the incentive.[72]

A further difference in mode goes beyond simply offering cost reductions or threatening surcharges, by trying to get users to have skin in the game in a more direct way. One way of accomplishing this is through deposit or commitment contracts that exploit the behavioral economics principle of loss aversion. Here, users put their own money on the line, at amounts that they specify. For example, an employee might set herself a goal of losing one pound a week over 3 months. At the beginning, she hands over $300 to an administrator. If she achieves her goal, she gets back the $300 after 3 months. But for every week that she fails to meet the target, $50 are deducted and wired to a charity of her choice.[73] A variation of this approach is for the employer to match the employees’ stakes at specified rate. In a further variation, lost amounts can be pooled and distributed among all those who are on target. Deposit contracts may engage employees more than stick or false carrot formats but may also appeal disproportionately to those who already have strong baseline confidence that they will accomplish their goals.[74]

6.7 Certainty of the Incentive

Most incentives, such as cash rewards, insurance premium increases, or deposit contracts, have guaranteed outcomes—in fact, one might say that the hard-wired conditionality of “if you do (or don’t) do X, then Y will occur” is at their heart. Yet there is worry that such forms of (at least partially) extrinsic motivation may replace or “crowd-out” intrinsic motivation and will not lead to sustainable behavior change[75]—even though empirical evidence shows that this is not universally the case.[76,77] An alternative approach that can go some way toward addressing crowding-out concerns is to make the gain less certain, by using a lottery format. Here, by complying with the behavior that is deemed desirable, users may be entered into a lottery or sweepstake. Since, by definition, not everyone will receive a prize, wins can be made larger, which can render participation more attractive. At the same time, participants will also consider—at least briefly—the possibility that they might not win. The option of winning is then likely to be viewed more as a windfall: nice, if it happens, but if not, nothing is lost either. One implication is that the merits of engaging in the incentivized behavior may loom larger than the prospect of

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[72] Schmidt (2013a).

[73] See, for example, http://www.stickk.com/ for a more individualized approach.

[74] Halpern et al. (2015).

[75] Frey and Jegen (2001).

[76] Sen et al. (2014).

[77] Promberger and Marteau (2013).

reaping an associated net benefit of some value, reducing the possibility of "mercenary" motives.

6.8 Time Horizon

As noted, one principal way in which incentives may be active is by providing a benefit in the here and now for engaging in a behavior that, by itself, at best yields a benefit in the more distant future. This can raise the question of what the optimal timing for an incentive is. In part, this will depend on the type of behavior: for example, an obvious way of creating incentives for regular dental checkups would be through a waived copayment every time one sees one's dentist every 6 months. To increase the use of flu shots, a cash incentive could be offered annually during flu season.

But the timing of incentives for more complex behaviors, such as smoking cessation or weight loss, is less straightforward from a behavior change perspective. Moreover, the timing may be influenced by other rationales that underlie a program, and designs may be driven more by what is convenient from a policy perspective, rather than by what is most effective. For example, one way of providing an incentive for weight loss would be to impose an annual penalty on all those whose BMI exceeds the normal range. For this, insurees would need to be weighed once a year, perhaps during a physician visit, and a premium adjustment would subsequently be made where the target has been missed. In some sense, such a policy would provide clear incentives to control ones weight. And it is relatively easy to administer and would certainly accomplish the rational of expressing that overweight is undesirable.

But it is not likely to be a particularly effective intervention, given the behavioral economics mechanisms that are at work. First, people who wanted to avoid the target might simply "binge diet" by losing weight in time for the weigh-in—but be putting it back on shortly afterward. Second, even though sticks are generally a stronger motivator than the carrot format, they can be highly problematic for weight gain from an ethical perspective. For while it is reasonable for anyone to see their dentist twice a year, body weight can be far more depended on factors outside of one's personal control, such as upbringing, availability of affordable and healthy food, opportunity to exercise safely, and so on. Third, a year can be a long time to reap a benefit for a behavior that entails daily choices. Much shorter intervals, such as monthly, weekly, or even daily options of benefitting if one is on track on a reasonable weight loss (or control) trajectory, are likely to be more effective, as has been shown in studies using the carrot format.[78] The timing of incentives is therefore not merely something that needs to work within the policy makers' pragmatic framework, but—from a behavior change perspective—also, and foremost, something that requires close consideration of the features of the target behavior.

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[78] Kullgren et al. (2013).

6.9 Alternatives Standards

For some users, it may be impossible or unreasonably challenging to achieve the target behavior. For example, pregnant women will not meet normal BMI thresholds, and certain genetic mutations can put weight control entirely outside of the reach of individual action. And there may be other difficulties arising from medical or nonmedical factors that render incentives irrelevant.[79] In such cases, fairness demands that an alternative standard be provided, especially in the case of penalizing stick incentives, to avoid that people are held responsible for factors that are beyond their control. Planning for alternative standards invites a close consideration of the possible difficulties that the target population faces, and analyzing the actual use of alternative standards can be one way of ascertaining their acceptability and appropriateness.[80]

Conclusion

Policies seeking to promote personal responsibility for health can be structured in a very wide variety of ways, with a range of different consequences. In the best case, the stars are aligned and programs empower people's health literacy and agency, reduce overall healthcare spending, alleviate resource allocation dilemmas, and lead to healthier and more productive workforces. But the devil is often in the detail: A focus on controlling or reducing cost can also lead to an inequitable distribution of benefits from incentive programs and penalize people for health risk factors that are beyond their control.

I argued that appeals to general moral theories are insufficient to make progress in practice with deciding which policies should be acceptable. Firstly, consensus is set to remain elusive regarding which approach should be guiding. Secondly, there is lack of sufficiently fine-grained specificity with regard to criteria for judging key structural elements of incentive programs, such as acceptable mode, levels, or target behavior. The most promising approach is to focus on reasonable rejectability within Contractualism or, more pragmatically, Accountability for Reasonableness. Seven central dimensions in which justification is owed were identified to facilitate focused and constructive discussion. The outline of the complex anatomy of incentive programs showed that of these, opportunity of choice has particular—albeit not singular—importance. In practical terms, the importance of evaluations by regulators cannot be overstated.[81]

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[79] Schmidt (2009).

[80] Department of the Treasury, Department of Labor, and Department of Health and Human Services (2013).

[81] Madison et al. (2014).

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Age and Personal Responsibility as Prioritization Criteria? The View of the Public and of Physicians

Adele Diederich

Health systems worldwide are struggling with the need to control costs to maintain system viability. With the combination of new expensive health technologies, an aging population and changing epidemiology on one hand, and worsening economic conditions and reductions in tax revenues on the other hand, the pressure to make structural changes is expected to continue growing. An efficient but also fair allocation of limited medical resources is needed (Cappelen and Norheim 2006). Priority setting in health-care services according to some predefined criteria is proposed as one possibility to handle the problem of limited resources (Sabik and Lie 2008 for a review). Various criteria have been offered, from purely medical ones to personal and social ones (Cappelen and Norheim 2006). One of the most controversially discussed criteria is the age of the patient. Should elderly patients be preferred to younger patients or younger to older ones? Is the biological age of a patient more important than the chronological age? Or should age play no role whatsoever when allocating health-care resources? And how is a decision made (morally) justifiable? By utilitarian ageism? Fair innings? Time-specific prioritarianism? Or by prudential lifespan account? (See chapters "Priority Setting and Age", "Fair Innings as a Basis for Prioritization: An Empirical Perspective", and "Just Caring: Fair Innings and Priority Setting".) Personal responsibility is another debated criterion. Should a healthy lifestyle be rewarded? Should a person with an unhealthy lifestyle share some treatment cost? Or should lifestyle be no factor when deciding on health-care provision? But is it fair that some patients seem to free ride on a system built on solidarity? And again, how can a decision be justified? By distributive justice norms like equity or equality or by need after all? And who should make the decision? (See chapters "Hellish Decisions in Healthcare" and "Personal Responsibility as a Criterion for Prioritization in Resource Allocation").

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_17

This article is completely ignorant of philosophical debates but rather aims at reporting the views on some of these questions from a representative sample of the German population. As Bruni et al. (2008) pointed out, there are at least four reasons why the public should be engaged when setting health-care priorities. One of them is that the public is the most important stakeholder in the health-care system. It finances it (by taxes and premiums) and predominately uses it. Another reason is that public involvement in the priority setting decision-making process provides not only their perspective on decisions that affect their lives but also encourages support for those decisions, which in turn improves the public's trust and confidence in the health-care system (ibid, p. 15). See also ZEKO (2007) for a strong support of public engagement.

The request for public involvement is not without opposition. One argument against it is that citizens are not objective and only pursue their own interest. However, this argument holds also for other stakeholder groups such as representatives from the pharmaceutical industry, health insurances, medical associations, and more. To modify the concerns, a sample of physicians was asked for their opinion on health-care allocations as well.

The population survey was conducted by TNS Healthcare between July and September 2009, involving people aged 18 and over in Germany, living in private households. Data were collected with computer-assisted personal interviews (CAPI). The number of selected addresses was 3729 with a response rate of 56.8 % (2031 respondents). The sample included 1131 (55.6 %) female and 900 male respondents. Mean, median, and standard deviation of their age were 52, 52, and 18 years, respectively.

The physician survey was conducted via an online platform (www.unipark.de) between December 2013 and June 2015. The link to the questionnaire was sent through e-mail to 1515 members of the Deutsche Ärztinnenbund (German Medical Women's Association), and 1057 link clicks were registered (multiple clicks per person were allowed). The return rate was 66 % (702), i.e., at least one answer to a question, and 44 % (464) of the physicians completed the questionnaire. Included in the subsequent analyses are those who have less than 15 % missing values (either by not responding to a question or by aborting the questionnaire early). This results in a sample size of 445 participants. Of the respondents, 11 % were resident, 44 % consultant, 14 % senior physician, 6 % head physician, and 23 % work in other positions. Mean, median, and standard deviation of their age was 53, 52, and 12 years, respectively.

Unless indicated otherwise, the percentage of responses are based on $n = 2013$ for the citizens and $n = 445$. For the citizens, "Don't know" and "Answer refused" response options are included. They are reported when the percentage of both responses taken together exceeds 10 %. For the physicians, no such options were offered. They could simply omit to answer the question.

1 Age

Age as a criterion for priority setting in health-care services has previously been approached from both theoretical and empirical perspectives. Economic and ethical research predominantly focuses on efficiency and equity and investigates how and what type of age-weight functions (e.g., single-peaked functions for relative weights; flat for equity weights) can be incorporated in the quality-adjusted life-year (QALY) measure used in economic evaluations of health-care programs (e.g., Murray and Lopez 1994; Tsuchiya 1999; Tsuchiya et al. 2003; Williams 1997). The results of most of those studies suggest that lower weight is given to older people (e.g., Busschbach et al. 1993; Dolan et al. 2005; Johannesson and Johansson 1996; Rodríguez and Pinto 2000). That is, elderly are given a lower priority when distributing health-care services.

Results from opinion surveys, which mainly focus on age-related preferences and attitudes and on the acceptance of age as a criterion for prioritizing patients, are often inconsistent and seem to depend on the design of the study, the framing of the questions, the response format (e.g., binary responses, ranking), and nationality (Tsuchiya 1999; Dolan et al. 2005; Sassi et al. 2001; Schwappach 2002). While prioritizing health services has been discussed for many years in several industrial countries, in Germany, it received little attention so far. In particular, German politicians and most lawyers adamantly refuse age as a criterion for allocating health-care resources. Some lawyers and philosophers, however, consider age as a rather fair allocation criterion. They argue that it is fairer to ration by age than by, for instance, therapeutic benefit or severity of disease, since it affects all persons equally: Everybody is getting old. Furthermore, chronological age is a transparent and objectively measurable criterion (Huster 2010). Empirical studies show that German physicians already practice age-based rationing (Brockmann 2002; Strech et al. 2008).

In the following, I present the views on age as a criterion for priority setting in health care of the random sample from the German population and from German physicians described above. In order to receive a broad perspective on preferences and attitudes of the German public and the professionals toward age and to clarify some of the inconsistencies observed across the various studies reported above, questions on age are included that varied with respect to both complexity and form. Some questions were embedded in a health-care scenario, while others were rather abstract. The interviewee's own age was included as explanatory variable to account for differences in preference.

When asking for attitudes to age per se as prioritization criterion, the majority of citizens agreed to prefer children to be treated prior to all others (73 %). At the same time, half of the respondents (50 %) agreed to a preferential treatment for elderly, and only 14 % of the respondents agreed to one for people of working age. For the physicians, the results are quite different in numbers but with a similar in tendency. The agreement rate to preferential treatment for children, elderly, and people of working age was 80 %, 27 %, and 15 % of the respondents, respectively. If we, however, count only those cases in which the respondent had a clear opinion on age, that is, giving a positive answer to only one age group and a negative to the two remaining age groups, the preference for a certain age group diminishes. Of all citizens, 32 % indicated a preference for one age group; for the physicians, 44 % clearly preferred one age group. The detailed results are shown in Fig. 1. A true preference for preferential treatment – to a certain degree – seems only to hold for children. Elderly and people of working age should not be prioritized.

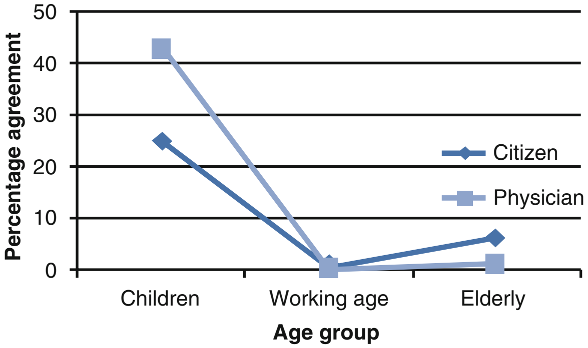

Fig. 1 Hypothetical preference functions of citizens and physicians for age as prioritization criterion. The curves represent the proportion of agreement of those respondents who accepted preferential treatment of patients in one age category and rejected preferential treatment of patients in the two remaining age categories. They are believed to have a "true" preference for a particular age category

If we assume that the amount of agreement with any of the three questions somehow reflects the respondents' preference *strength* for specific age categories when setting priorities in health-care services, then the function shown in Fig. 1 deviates from what is proposed in the literature. It is neither flat nor decreasing as a function of age nor single-peaked with the peak somewhere in the middle as described, for instance, by Murray (1996), Tsuchiya et al. (2003), or Williams (1997).

Note, however, that those studies required a comparison and ranking of age groups from the interviewees.

The questionnaires included several scenarios in which age was also considered a criterion for prioritizing a patient. One scenario described a situation with two life-threateningly ill patients, but only one treatment could be offered at the moment. Of the citizens, 27 % of the sample was in favor of treating the younger patient first and 19 % of them of treating the 30-year-old patient first, and 21 % of the participants preferred to let a lottery decide. For the "Don't know" response, 22 % of the sample opted and 12 % refused to answer this question. For the sample of physicians, 50 % preferred the younger patient being treated first, 4 % of them favored the 30-year-older patient being treated first and 38 % opted for the lottery to decide, and 10 % did not answer this question.

"Younger" was not specified in the previous questions, and therefore, the 30 years older patient's age is relative to what the participant imagined as being younger. Thus, a 40- or 50-year-old patient could have easily been classified as an older patient.

Therefore, respondents who did not prefer the younger patient to be treated first were asked to imagine that the older patient was very old. For this scenario, 17 % of the remaining citizens ($n = 1493$) now preferred the younger patient to be treated first, 22 % of them still preferred the older patient first, and 27 % decided that even if the older patient is very old, a lottery should decide about the order of treatment.

The proportion of non-informative responders ("Don't know" and response refused) was, as before, relatively high (21 % and 13 %, respectively). A detailed analysis of preference reversals is found in Diederich et al. (2011). A similar analysis for the physicians' responses revealed that of those who opted for the older patient in the first scenario, about half of them preferred the younger and half of them the very old patient to be treated first in the second scenario. Of those who preferred the lottery solution in the first scenario, half of them preferred the younger patient to be treated first and half of them still preferred the lottery. None of them decided for a preferential treatment of the very old patient. Figure 2 shows the proportion of informative responses combined for both scenarios for citizens and physicians (based on $n=1525$ and $n=395$ responses, respectively).

The previous scenario raises the question what participants considered as "very old." That is, from what age on should it play a role for a preferential treatment of a patient?

For the citizens, the mean (median, mode) of the specified age was 82.5 (80, 80) years with a standard deviation of 8.6 years; values ranged from 50 to 110 years. Similarly, the majority of the physicians considered a person as very old beyond the ages of 80 years. The mean (median, mode) of the indicated age was 84.1 (85, 80) years with a standard deviation of 5.6 years, and values ranged from 60 to 100 years.

Chronological versus biological age of the patient may play a role when deciding to prioritize health-care services. The next scenario intended to find out whether in the interviewees' view age per se might be crucial for allocating medical services or whether additional factors, such as the general health status of the patient, should also be taken into account. The fictive scenario described a situation which reports that in England, a kidney dialysis is not paid for by the national health insurance if the patient is 65 years and older, regardless of his or her general health status. The respondents were asked to imagine that Germany would have a similar statutory age limit in Germany. In the population survey, 61 % agreed that patients above the age limit but with a good general health status should be exempted from this regulation and the treatment should be paid for. About a fifth of the respondents (19 %) agreed that patients above the age limit should not be exempted from the regulation regardless of their general health status. Note that the proportion of nonresponders is relatively high (20 %). In the physician survey, 84 % opted for an exception, and 11 % did not.

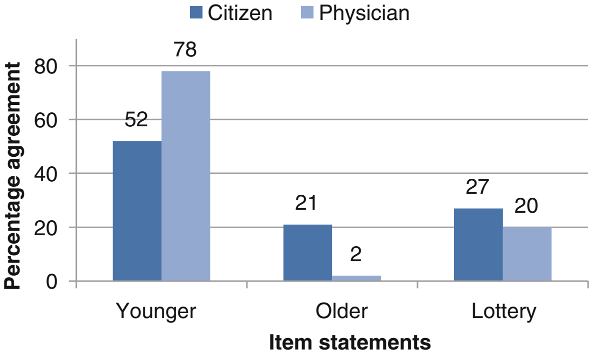

Fig. 2 Agreement of citizens and physicians to statements for preferential treatments in the Life-Threatening Illness scenario

There are a few areas of the medical services in Germany in which an open priority setting already exists. One example is the so-called triage procedure applied in disaster medicine to determine treatment priorities for mass casualty incidents. The third scenario described this situation exemplified as a fire break out in an apartment house. The participants were asked to imagine being the responsible doctor on scene and to decide who should be treated in preference to the other. Besides the criteria such as survival rate, degree of injury, and level of pain, the age of the patient was one critical variable.

In the population survey, 28 % of the participants would treat the younger casualties first. The majority (54 %) would not treat the younger in preference to the older casualties; 18 % of the respondents did not provide information to it. In the physician survey, the respondents' opinion was split: 47 % of them would grant the younger casualties preferential treatment, and 46 % of them would not.

The final scenario had to do with patients in need of organ transplantation. The allocation problem becomes obvious as the number of patients waiting for an organ exceeds the number of donors. Since the set of existing criteria for allocating an organ is modified from time to time, it is interesting to know which of the criteria would be accepted. Among four statements, one was concerned with the age of the patient as a criterion to allocate the organ (the remaining dealt with survival rate, waiting time, mismatch probability).

Of the population survey participants, 50 % disagreed with the statement that younger patients should be preferred to older patients in the allocation of donor kidneys (26 % rather not agreed, 24 % not agreed at all); 39 % agreed to it (16 % completely agreed, 23 % rather agreed). The remaining 10 % did not give an informative answer. The results are in contrast to what the physicians agreed to: 66 % agreed with the statement that younger patients should be preferred to older patients (20 % completely agreed, 46 % rather agreed), whereas 29 % disagreed (22 % rather not agreed, 7 % not agreed at all). Figure 3 shows the opposite choice patterns of both participation groups.

In the population survey, two more scenarios were offered in which age played a role. Both scenarios were designed as discrete-choice experiments. In one of the experiments, hypothetical patients were characterized by six factors or attributes:

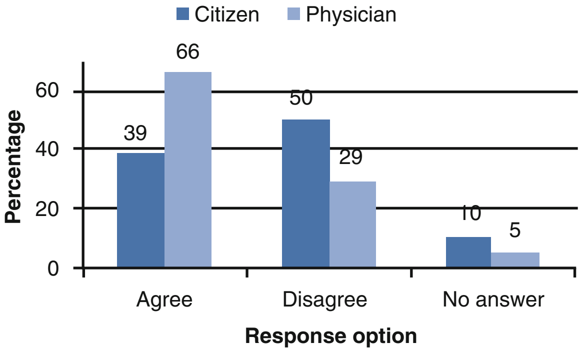

Fig. 3 Response frequencies of citizens and physicians to the statement whether younger patients should be preferred to older patients in the allocation of donor kidneys

health status with levels severe and light disease, quality of life (no restrictions, restricted, and severely restricted), unhealthy lifestyle (yes/no), family status (single with/without dependents (children, relatives to care for), couple with/without dependents (children, relatives to care for)), occupational status (high, medium, and low), and age with levels 25, 43, 68, and 87 years. The attribute levels were combined to hypothetical patient profiles. Three of these hypothetical patients were shown simultaneously, and the participant had to decide in which sequence they should be treated.

The advantage of the discrete-choice method is that the participants need to trade off several characteristics of a patient when deciding who should be treated first without going into any technical details; therefore the relative importance of each attribute can be determined as well as the part-worth utilities for each level of an attribute (Louviere et al. 2000).

On a normalized scale from 0 to 100, age received a relative importance weight of 12 (for comparison, "health status" received the highest weight, 50, followed by "quality of life," 25; "family status," 8; "occupational status," 5; and "lifestyle," 1). The part-worth utilities of the four age values are presented in Fig. 4. They provide a quantitative measure of the preference for each attribute level, with larger values corresponding to greater preference.

When varying the age levels and keeping the levels of the remaining attributes fixed, a 43-year-old patient should be treated first, a 25-year-old patient second, a 68-year-old patient third, and an 85-year-old patient should be treated last. That is, the most preferred age here was 43 years – people of working age. This group, however, is the group least preferred when the respondents answered abstract age-related questions (see above). Although the age categories in the discrete-choice scenario are not exactly the same as in Fig. 1, it becomes obvious that the preferences for age groups are reversed.

In the second discrete-choice experiments, hypothetical treatments were characterized by the following attributes: frequency of disease (low, medium, high), life expectancy without treatment (no effect, 4 weeks, 6 months, 2, 5 years), life prolongation with treatment (no effect, 2 months, 1, 2 years, at least 5 years), effect on quality of life (high-low, medium-low, low-low, low-medium, low-high), target

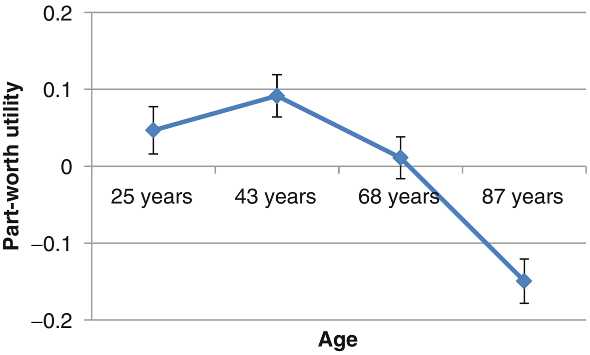

Fig. 4 Citizens' part-worth utilities and their 95 % confidence interval for factor "age" obtained in a discrete-choice experiment

group (infants/children, adolescents/adults, senior citizens), and treatment costs (low, medium, high). The attribute levels were combined to hypothetical treatment profiles. Two of these hypothetical treatments were shown simultaneously, and the participant had to decide which of the newly developed treatments should be added to the public health-care service and which one should not be (or both not). Several different discrete-choice models were applied which resulted in different absolute weights. The ranging of the different attributes, however, was the same regardless of the underlying model. Utilizing the standard model target group (the age-related attribute) obtained a relative importance weight of 21 (on a scale between 0 and 100). The relative weights for the remaining attributes were 27, 18, 17, 12, and 5, for life prolongation with treatment, life prolongation without treatment, effect on quality of life, frequency of disease, and cost. The part-worth utilities of the three target group categories – infants/children, adolescents/adults, and senior citizens – were 0.37, 0.12, and −0.50, respectively. Clearly, treatments for infants/children receive the highest priority to be added to the public health-care service, while treatments for senior citizens receive the lowest.

Finally, to test the often brought up argument that citizens are not objective and only pursue their own interest and, therefore, their preferences should not be taken seriously into account when deciding about health-care allocation (see Bruni et al. 2008, for references and a discussion), the participants' own age served as covariate in several statistical analyses. Multinomial logistic regressions showed no clear relation between the participants own age and a preference for a fictive person's age in the various scenarios (for details and contingency analyses, see Diederich et al. 2011). Furthermore, in both discrete-choice scenarios, no significant differences between the respondents' age groups for the part-worth utility estimates were observed. For the physicians, a preference for older patients was observed only in the abstract question: The older the participant was, the more she was in favor for a preferential treatment of the elderly.

To summarize, when asked whether patients of a specific age group should receive preferential treatment to all others, the highest proportion of agreement was observed for children, the lowest for people of working age, and those for the elderly somewhere in between. This is true for both, the general public and the physicians. Since these three age groups were not mutually exclusive, it turned out that the vast majority agreed to prioritize children to all others, but, at the same time, a slight majority – at least for the citizens – also agreed to prioritize the elderly to all others. While the first result is not surprising, the latter is in the first instance. The results of the other studies (see above and also chapters "Fair Innings as a Basis for Prioritization" and "Just Caring") showed that if a certain age (group) was accepted for prioritizing health-care services, then it was for the younger patients, never for the elderly. A more detailed analysis revealed that only a minority of the citizens had a clear preference for a specific age group. Still, the agreement was at its lowest level for treating people of working age preferentially. The pattern of the physicians' responses is similar to the one of the citizens'. However, they have a clearer preference for treating children first.

The results of the citizens on the four health service scenarios showed little evidence that age may serve as criterion for prioritizing health services in Germany. Considering the results of the physicians, the rejection of age as a prioritization criterion is less obvious. The tendency to prefer younger patients over older patients can be inferred by at least half of the physicians.

The proportion of “no answer” (i.e., “Don’t know” and “Answer refused”) in the population survey was relatively high in most of the scenarios, up to about 34 % in the Life-Threatening Illness scenario. For comparison, the proportion of a “no answer” for the abstract questions was between 2 and 4 %. This may be interpreted as a way out for the interviewees when a decision had to be made between two patients, one described as young and one as old, rather than between two anonymous subpopulations, one described as an age group and one as “all others.” For the physicians, the proportion of nonresponders was similar to the other questions.

In the Life-Threatening Illness scenario where only one treatment could be offered at the moment, the proportion of those favoring a lottery for medical treatments seemed relatively high compared to related studies (Gallego et al. 2007; Shmueli 2000). Again, this may be interpreted as kind of avoidance behavior since a decision for one person means a decision against the other. Nord et al. (1995) offered three options in their life-threatening scenario indicates the scenario in the current study, the younger, against/ for the older, and equal priority. Overall, the equal priority option received the largest acceptance, its strength depending on the concrete context. In the Life-Threatening Illness context, we also investigated what “older” and “old age” meant to the interviewees. To call a person “very old,” the mean was 82.5 and 84.1 years, for the citizens and physicians, respectively, which is little above the life expectancy in Germany which is about 80 for men and woman taken together.

The Fixed-Age scenario asked for acceptance or rejection of an exemption for treating people with general good health beyond a certain age. Although the majority favored an exemption, 19 % of the citizens and 11 % of the physicians opted for no exemptions. Obviously, such a strict rule is not even applied in countries where a similar regulation exists for many years.

For the citizens, the Triage scenario showed generally no evidence for accepting age as a prioritization criterion. More than half rejected a preferential treatment for younger casualties and about fifth of them gave no answer to this question. The physicians’ opinions were split: About half of them were in favor of treating the younger casualties first and the other half were not in favor of it.

The Organ Transplantation scenario showed in the population data no evidence for accepting age as a prioritization criterion. Half of them disagreed with allocating an organ to younger patients prior to older patients. This was different for the physicians. They clearly preferred younger patients to be transplanted before older patients. The latter result is in accordance with Ratcliffe’s study (2000) who found that 66 % of participants agreed that younger people should be prioritized over older ones in organ allocation.

Finally, the discrete-choice sets enabled us to estimate the importance weight for the factor “age” and the preference strength of its levels. A major advantage of this approach is that participants consider several attributes jointly, compare them, and make trade-offs to reach a decision. Opting for preferential treatment of the elderly over all others and of children over all others at the same time, as it was done for the abstract questions, is logically impossible. Furthermore, specific prioritization criteria are less obvious, like for the abstract questions and the health-care scenarios.

When asking participants directly, social desirability may affect the response (e.g., children yes, but people of working age no). On a scale from 0 to 100, age received a relative weight of about 12, while "health status" and "quality of life" obtained weights of about 25 and 50. On the other hand, age is more important than the remaining three attributes. Indeed, it is as important as taking social responsibility (family status), socioeconomic status, and the patient's own responsibility for the illness together. Schwappach (2003) found related results in a conjoint-analysis-like approach with budget allocation, conducted with 150 students from medical and economic faculties. Age received the lowest relative weight (9), while quality of life after treatment received the highest weight of about 33 (the remaining attributes with relative important weight were healthy lifestyle (25), socioeconomic status (23), life expectancy after treatment (13), prior receiver of costly treatments (16)). Age has some weight but there are other more important criteria when allocating health-care resources.

The part-worth function (Fig. 4) resembles in shape the so-called productivity ageism function, proposed by Tsuchiya et al. (2003) which gives priority to young adults because they are more productive. The ordinate units are relative values of life-years rather than utilities for age values. The productivity ageism function in turn is related to the age-weight function proposed by Murray and Lopez (1994) to weigh disability-adjusted life-years (DALYs). The rationale of the so-called efficiency-based age-weighting functions is that health gain at different ages is valued differently according to the expected level of productivity at each age. Productivity is defined in a broad sense including home and society (Tsuchiya et al. 2003, p. 688). This, however, is in stark contrast to the response pattern observed here for the age per se questions where the most productive group received the lowest rates of agreement. We cannot settle this issue from the survey data. Focus groups – which were carried out in the context of the current research group – may shed some light into the controversy. The results are not presented here due to limited space (see Schreier et al. (2014) for details). Note, however, that those techniques can only be applied to a very limited number of participants and results may not be representative at all.

2 Personal Responsibility

Personal responsibility for maintaining good health is another potential criterion for prioritizing health-care services which is often debated in different context. In Germany, taking responsibilities for one's own health is bound by law, including an obligation for co-payments of treatment costs for self-inflicted injuries (see chapter "Personal Responsibility as a Criterion", for the text (verbatim translation) of the law). There is considerable evidence that people's lifestyles may impact health and, consequently, their present and future need for medical treatment. Cappelen and Norheim (2005) cite World Health Organization (WHO) studies showing that among the ten leading risk factors contributing to the burden of disease in high-income countries, seven can be directly attributed to unhealthy lifestyles. The most prominent risk factors are tobacco (first), alcohol (third), overweight (fifth), low fruit and vegetable intake (sixth), and physical inactivity (seventh). These lifestyle factors may influence risk factors such as blood pressure (second leading risk factor) and cholesterol (fourth), which may be indirectly attributed to unhealthy lifestyles.

Private health insurance takes such factors into account when calculating premiums for health insurances (Olsen 2009). In contrast, publicly funded health-care systems are mainly based on the so-called solidarity principle, which generally excludes risk-based premiums. However, in some countries, several incentive schemes such as "fat taxes" (Alemanno and Carreno 2011), bonuses, or reductions of premiums (Schmidt 2007, 2008) have recently been implemented in order to incorporate aspects of personal responsibility in public health-care systems. Schmidt (2013) found in a population survey that the acceptable size of penalizing overweight and obese people is quite small (around $50); a reward-based incentive for people with a normal BMI was four times higher. But not only health-care insurers are in favor of those measures. According to Cappelen and Norheim (2005) and Olsen (2009), liberal egalitarians support the idea that society should carry only those health-care expenditures that result from factors outside one's personal control, such as genetic dispositions, whereas costs that arise from the individual's choices should be partly or fully carried by the individuals via taxes, co-payments, or additional insurances to guarantee a fair allocation of scarce medical resources.

Several of the aforementioned risk factors were included in the surveys for eliciting the participants' opinion on prioritizing patients who avoid these factors and on posteriotizing patients who lead a risky lifestyle. Prioritization was measured in terms of agreement to partial refunds of the health insurance premiums and posteriotization in terms of co-payments. The population survey included only the posteriotization version, the one for the physicians both.

Figure 5 shows the percentage of agreement to co-payments for the following patient behaviors: unhealthy diet, high alcohol consumption, smoking, extreme

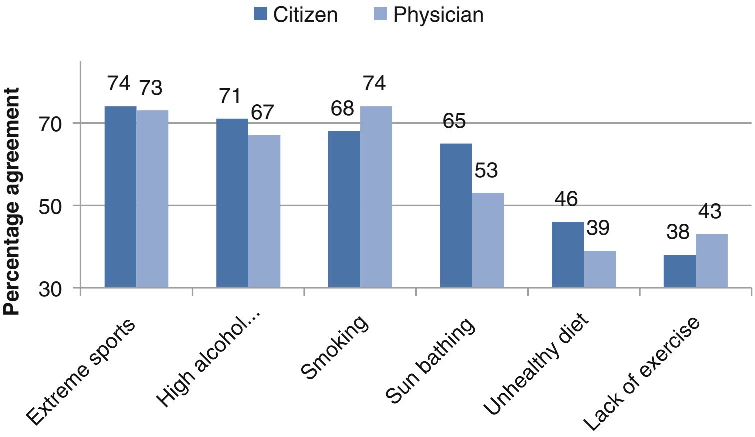

Fig. 5 Agreement to co-payment of citizens and physicians for the following health-related behaviors (as presented in the questionnaire): unhealthy diet, high alcohol consumption, smoking, extreme sports (e.g., free climbing, cliff diving), sunbathing/solarium, drug consumption (e.g., heroin), and the lack of exercise

sports (e.g., free climbing, cliff diving), sunbathing/solarium, and the lack of exercise, for both survey groups. The consensus is remarkable for most criteria. If extreme sports such as free climbing or cliff diving lead to health problems, the patients should contribute to the cost according to more than 70 % of the responders. Patients with high alcohol consumption and smokers should also contribute to the health cost according to the majority of the participants. Unhealthy diet and the lack of exercise, however, are for the majority of responders no reason for co-payments of treatment costs.

The population survey included another criterion for posteriotizing: drug consumption like heroin to which 76 % of the citizens agreed to have the patients share in the health-care costs. The physician survey included the criterion adiposity (BMI >30) as possible criterion for posteriotizing patients; 55 % of them agreed to it.

Notice that the majority of health-related behaviors described here reflect an "active" role of the individuals in harming their health: taking drugs, smoking, drinking, etc. For those behaviors, citizens and physicians alike favored a co-payment. The lack of exercise and unhealthy diet, however, reflect a "passive" role of the individuals in harming their health. For those two behaviors, the majority of citizens and of physicians did not agree to a co-payment, i.e., a posteriorization. This observation can be related to the so-called omission bias (Ritov and Baron 1990) which is defined as "the tendency to judge acts that are harmful (relative to the alternative option) as worse than omissions that are equally harmful (relative to the alternative)" (Baron 1994, p. 446) and has been confirmed in several (psychological) experiments: People feel more responsible for what they do than what they omit to do.

Another related question was concerned with therapy compliance. Participants were asked whether they agree that a patient who did not adhere to agreements concerning his/her therapeutic treatment should share the treatment costs out of pocket. Of the citizens, 72 % agreed to a co-payment for therapy noncompliance; of the physicians, 59 % did so.

In this context, passivity, i.e., noncompliance, is negatively evaluated: The majority agrees to co-payments. This seems to be in contrast to the previous reasoning. Note, however, that different from the lack of exercise and unhealthy diet which may or may not lead to harm the person's health, in the case of needing a therapy, the patient's health is already affected. The patient may restore the health by actively following the doctor's advice. This may also partly explain the difference in agreement of citizens and physicians.

The criteria in Fig. 5 are all phrased as negative, unhealthy behavior patterns. The physician survey also included descriptions of positive, beneficial behaviors. Figure 6 shows the list of behaviors including the percentage of agreement and disagreement for partially refunding the insured person. The most accepted behaviors for refunding were vaccination and screening tests, the least accepted ones being health education like courses on stress coping strategies and alcohol abstinence.

Considering the descriptions of unhealthy and beneficial behaviors, four behaviors are related: smokers versus nonsmokers, adiposity (BMI >30) versus normal weight people (BMI 18.5–25), patients with high alcohol consumption versus patients with no alcohol consumption, and patients with a lack of exercise versus patients exercising. If, for instance, someone agrees to a co-payment for smokers, then she should also agree to a refund for nonsmokers. Comparing the results of the physicians in Fig. 5 with those in Fig. 6 shows that this is not necessarily the case, i.e., we observe preference reversals and preference shifts (Fig. 7) as a consequence of framing (Tversky and Kahneman 1981; Levin et al. 1998). The differences in agreement for the two frames are statistically significant ($p < .001$) for all four behaviors. See also Schmidt (2013) for a framing effect (differences in dollar amounts) for penalizing overweight and obese people and rewarding normal weight people.

The population survey included a general statement of preferential treatment for patients with a healthy lifestyle. Only 8 % of the citizens agreed to it, and 89 % did

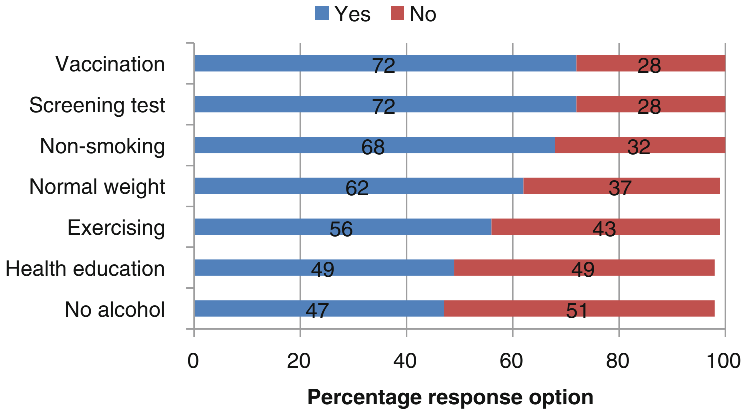

Fig. 6 Agreement to refunds of the physicians for the following health-related behaviors (as presented in the questionnaire): nonsmoking, normal weight (BMI 18.5–25), participation in screening tests, exercising, alcohol abstinence, participation in health education (e.g., classes on stress coping strategies), and vaccination

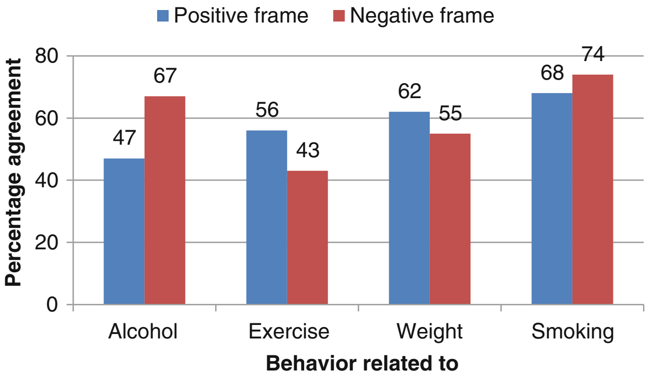

Fig. 7 Physicians' agreement of refunding (positive frame) and co-payment (negative frame) for various health-related behaviors

not. This is in contrast to the results when the lifestyle was specified by concrete behavior and negatively framed. Again a framing effect in terms of positive/negative frames may have occurred, but in addition to it, another effect related to unpacking a hypothesis, here a statement. Unpacking means partitioning a general description into its components, i.e., lifestyle in smoking, drinking, exercising, and so on, which may remind people of possibilities they haven't thought of, and it may increase the salience of an explicitly mentioned possibility which may increase its perceived support (Tversky and Koehler 1994).

The discrete-choice experiment reported earlier included the factor "unhealthy lifestyle" among five factors with levels yes/no to characterize patients on a waiting list. This factor received the lowest value (1) on a relative importance scale between 0 and 100. That is, other criteria are more important than lifestyle. Obviously, the relative importance of lifestyle for prioritizing health-care services depends on the other criteria offered and competed with (trade-offs) and might change if criteria such as life prolongation are not included.

Acceptance and rejection of unhealthy lifestyles may be influenced by self-interest, that is, by the respondent's own health-related behavior. For example, smokers oppose co-payments for smokers, while nonsmokers oppose supporting smokers' health imperiling behavior by paying a higher premium to the statutory health system. Furthermore, a kind of "cross-effect" may appear. For competitive reasons, smokers may opt for co-payments for other behaviors, like the lack of exercise, as this could prevent higher co-payments for smoking. In contrast, they could also display solidarity with other groups and reject co-payments, for example, for alcohol drinkers.

In the population survey four unhealthy behaviors (high alcohol consumption, the lack of exercise, unhealthy diet, and smoking) were related to the following characteristics: alcohol consumption habits; body exercise habits; weight and size to determine the BMI; and smoking habits. For the remaining three items (extreme sports, sunbathing/solarium, drug consumption), no corresponding characteristics of respondents were elicited in the questionnaire.

The self-serving hypothesis (Bruni et al. 2008) could be confirmed for the behaviors smoking and the lack of exercise. The majority of citizens agreed to a co-payment for smokers, among them, however, more nonsmokers agreed to it. Similarly, the majority of citizens refused co-payments for patients not exercising, but among them, those who never exercised were most against it.

For strategic and/or competitive reasons, people with a health-risky behavior may opt for co-payments for behaviors besides their own to prevent higher co-payments for their own behavior. In contrast, they could also display solidarity with other groups and reject co-payments for all specific lifestyle-related behaviors. These effects could be observed for some behaviors and person characteristics. Respondents with little alcohol consumption were more likely to support co-payments for all listed potentially unhealthy behaviors (except for the lack of exercise) compared to those participants who never drank alcohol or were moderate or heavy alcohol consumers. Obese people agreed more often to co-payments for high alcohol consumption, extreme sports, sunbathing/solarium, and drug consumption than normal or underweight individuals did. Individuals who reported exercising very often supported co-payments significantly more often for unhealthy diet, extreme sports, sunbathing/solarium, and the lack of exercise than those who reported exercising often, rarely, or never. Smokers less often agreed to co-payments for unhealthy diet, high alcohol consumption, and smoking compared to nonsmokers (for details, see Diederich et al. 2014).

To Summarize The agreement of co-payments was high for active unhealthy behaviors, i.e., when patients took an active role in harming their health, for both citizens and physicians alike. Several psychological framing and context effects could be observed. Whether a statement is framed positively (reward, here refund) or negatively (penalty, here co-payment) should lead to the same results. This was not the case for the physicians who were offered two different scenarios with the same content but with different frames. For the citizens, data on their own health-related behaviors was collected. Unfortunately, this could not be done for the physicians. The self-serving bias for the former group then could be observed for two criteria: smoking and the lack of exercise. Note, however, that the vast majority, including the smokers, approved for smokers to contribute to their treatment cost. Furthermore, health-related behavior as a criterion for allocating health-care services became less important or unimportant when it competed with other criteria like life prolongation.

3 Final Remarks

The attitudes toward age and personal responsibility as possible criteria for priority settings were elicited from two different stakeholders groups: the general public of Germany and physicians from the German Medical Women's Association. Both criteria are highly debated in the literature, and they are obviously quite different. Age is easy to measure, everybody has it, and some are lucky to have a lot of it (in good health). There is no effect of age on health per se. Personal responsibility for one's own health is difficult to measure, everybody can exercise it or not and thus has a choice, and this has an effect on health. Age and priority setting are mainly discussed in philosophy and economics (and law) (see chapters "Priority Setting", "Fair Innings as a Basis for Prioritization", and "Just Caring") and personal responsibility in research on health-care insurance.

Watters brings together age and QALY (cf. Williams's version of fair innings) and concludes that to move forward to policy making, philosophical views and public preferences need to be aligned. This was exactly the major objective of the research group on "Setting Priorities in Medicine." Fleck discusses fair innings and favors Daniels' prudential lifespan account as "a fair and reasonable approach to addressing the problem of age-based rationing." Ignoring all the criticisms (e.g., intrapersonal versus interpersonal transfer, (deterministic) equal length of life, individual lifetime account) at the moment, which Fleck partly rebuttals, the approach is very appealing because it does not only address prioritizing recourses according to age but enables an individual (eventually groups after a general consensus, health policy) to prioritize *treatments conditioned* on age and possibly *conditioned* on lifestyle. How and what guidelines are to be developed and how this can be implemented is a different question. Schmidt (see chapter "Personal Responsibility as a Criterion") provides some guidelines for the process in designing and evaluating personal responsibility policies. That is a step in the right direction. However, to enhance the process of priority setting in medicine in Germany, different stakeholder groups, in particular the public, need to be involved.

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Part VI

Economic Evaluation

Using Economic Evaluation in Priority Setting: What Do We Know and What Can We Do?

Iestyn Williams and Stirling Bryan

1 Introduction

The aim of this chapter is to examine the use of cost-effectiveness analysis (CEA) in priority setting. It provides a commentary on the evidence base and highlights two categories of barriers. These are *accessibility*, that is, issues of availability and understanding, and *acceptability*, that is, issues to do with the views, preferences and circumstances of decision-makers. The chapter then seeks to address the persistent neglect of *context* in explanations of the use of CEA. For example, a focus on context helps to explain the differential usage levels at national and local decision-making tiers. It is argued that not only is CEA rarely used by local decision-makers but also that the contexts in which such bodies currently operate preclude significant increases in use. By contrast, it can be seen that national bodies are more likely to operate in a political and institutional environment which facilitates and creates the demand for routine use of CEA. The chapter argues that in order for CEA to have more of an impact at local levels, analysts should better recognise and reflect the constraints in which decision-makers operate and that greater clarity is required over specific roles, responsibilities and relationships in the resource allocation process. Finally, the authors make a plea for researchers to resist simple replication of prior studies and instead to direct their energies at devising innovative ways of filling theoretical and empirical gaps in understanding across healthcare systems and contexts.

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_18

2 Priority Setting Terms and Contexts

The primary purpose of economic analysis is to assist decision-makers in addressing problems arising due to resource scarcity. Therefore, such evidence is intended to influence policy priorities:

> By providing estimates of outcomes and costs, Cost Effectiveness Analysis shows the trade-offs involved in choosing among interventions or variants of an intervention. Put another way, it helps define and illuminate the 'opportunity cost' of each choice: the health benefits lost because the next-best alternative was not selected (Russell et al. 1996: 3)

The types of priority setting and decision-making that in theory might be shaped by such analyses are presented in Fig. 1.

As employed here the term priority setting 'describes decisions about the allocation of resources between the competing claims of different services, different patient groups or different elements of care' (Klein 2010: 389). These claims are in competition because of scarcity and the imbalance between demand and supply which is a feature of healthcare systems internationally. Explicit priority setting is merely one possible response to these challenges and not one that has received universal support (see, e.g. Mays 2000; Mullen and Spurgeon 2000). However, the growing recourse to priority setting internationally suggests that evidence-based prescriptions for practice are likely to be of some value. The concern in this chapter is with national bodies (excluding government) and local decision-makers at area and organisational levels. Correspondingly we are concerned with decisions relating to investment and disinvestment in services and interventions (rather than overall budget setting or funding for individual treatments). The compatibility of economic evaluation with the range of these decisions varies. A root-and-branch critique of health economics methodology is however beyond the remit of this chapter.

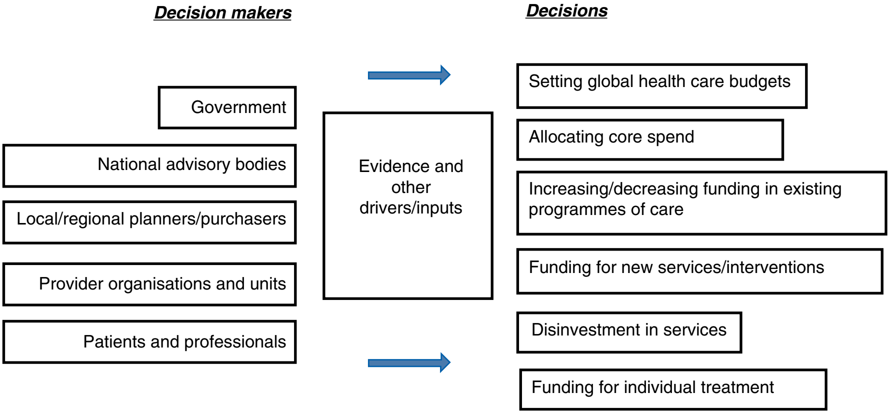

Fig. 1 Decision makers and decision

At national levels, economic evidence is generated through techniques such as model-based analyses supported by systematic reviewing in Health Technology Assessment (HTA) which enables clinical evidence to be presented as specific solutions to policy problems. HTAs typically incorporate information relating to the efficacy, safety, ethics and costs of an intervention and can be seen as 'a means of implementing knowledge-based change within the health care system' (Lehoux et al. 2005: 609). Incorporation within HTA of economic evaluation is now routine (Neumann 2005), and prospective economic evaluations of technologies are a feature of many clinical trials (Gelijns et al. 2005). These methodologies are designed to help technology adoption bodies deal with the uncertainties they face, for example, in determining what the benefits and risks of a new technology are and what the financial implications for their patient population will be. The use of HTA has been a feature of OECD country healthcare systems since the 1990s. In most cases HTA agencies have been set up as advisors to government decision-makers, although variation exists in both their legal standing and their relationship to reimbursement and pricing. Beyond these agencies, responsibility for decisions affecting wider patient populations varies. For example, plurality exists at the national level in decentralised systems such as the USA where public bodies responsible for coverage (and therefore setting of priorities) include Medicare, Medicaid, the Children's Health Insurance Program and the Department of Veterans Affairs and in Canada where health policy is devolved to provincial government. In systems with a strong central planning function such as the UK, there is typically a more prominent role for government agencies as allocators of tax revenues, whether as purchasers or planners of services. In contrast, non-profit insurance agencies carry greater responsibility in countries such as Germany and the Netherlands. Irrespective of these discrepancies, national recommendations rarely cover the full range of new and existing treatments licenced for use, and most healthcare systems therefore require additional local arrangements for managing formularies and spending. Clearly the arenas and tiers in which meso-level technology coverage bodies are set vary in accordance with the wider structure of the healthcare system (Haslé-Pham et al. 2005; Erntoft 2011).

3 Rates of Usage of CEA in Priority Setting

There is a growing international evidence base relating to levels of usage of CEA in priority setting and decision-making, with studies increasingly being reproduced throughout a range of healthcare systems and settings. Despite this, the evidence base is at a fairly early stage of theoretical and methodological development and remains heavily influenced by a study instigated in the late 1990s and aimed at establishing current levels of usage of health economics analysis across European health systems (von der Schulenburg 2000). This Euromet study collected survey data from decision-makers drawn from local (and in some cases national) decision-making levels employing a standard questionnaire which covered the following core questions:

- To what extent are the methods of economic evaluation known amongst the healthcare decision-makers?
- To what extent are results of economic evaluation being used in healthcare decision-making?
- What are regarded as the main barriers in the use of economic evaluation in decision-making?
- What factors might encourage the use of economic evaluations?

In some countries the survey was augmented with data generated using other research techniques such as interviews. In a summary of findings, Hoffman and von der Schulenburg (2000) concluded that knowledge of the methods of economic evaluation, overall, was poor and that actual use of economic evaluation in decision processes was rare, despite most respondents reporting the application of economic evaluation to be a desirable aspiration. The five most telling obstacles to use of economic evaluation were reported to be: difficulty in transferring funds, concerns about bias in industry analyses, other budget constraints, study savings being anticipated rather than real and concerns about the assumptions made in economic studies. The five most important strategies for improving use were reported to be: more practical explanation of study relevance, training in health economics, more comparability of studies, more flexible healthcare budgets and easier access to studies.

At a similar period of time, US studies employing similar research techniques – again dominated by postal or telephone surveys – reported similar results including a widespread willingness to use economic information tempered by low levels of use in practice (Sloan et al. 1997; Motheral et al. 2000; Odedina et al. 2002). Two prior surveys conducted in a UK context both found that at local levels of decision-making, economic information had a limited impact (Drummond et al. 1997; Walley et al. 1997), and these findings were echoed in a study of senior provincial government bureaucrats in Canada (West et al. 2002) and decision-makers at local and national levels in Australia (Ross 1995). Similar studies reveal equally low rates of impact and usage in non-Western and/or developing world settings (Iglesias et al. 2005; Yothasamut et al. 2009; Lafi et al. 2012). A scan of the more recent literature and systematic reviews of the evidence base suggests that not a great deal has changed since these early studies were conducted, and we know a little more than we did 10 years ago about the reasons for this persistent under usage (Drummond 2012; Fischer 2012; Silva et al. 2013).

However, this overall trend masks some significant points of variation. Whereas local-level decision-making has proven stubbornly resistant to the use of economic evaluation evidence (Eddama and Coast 2009), exceptions to these low levels of reported usage can be found in the form of the macro-level guideline-producing bodies mentioned earlier, many of which are now formally mandated to include cost-effectiveness in their calculations (Silva et al. 2013). Overall it seems that national (or macro) bodies find the incorporation of economic evaluation into their activities more achievable than local decision-makers do, albeit with significant country-by-country variation (Williams et al. 2008; Erntoft 2011). The divergent experience of national and local bodies begs questions relating to the transferability of learning between settings and decision-making tiers. In order to address these questions, the following section focusses on what the literature tells us about the 'barriers' to use of cost-effectiveness analysis.

4 From Accessibility to Acceptability

Increasingly, empirical contributions to the literature on this topic adopt the accessibility-acceptability framework devised by Williams and Bryan to understand barriers to use of CEA (Williams and Bryan 2007; Bryan and Williams 2014). In relation to the *accessibility* of CEA, three impediments are typically reported. The first relates to the shortage of relevant analyses and the second relates to uncertainty or ignorance over how and from where existing studies can be obtained. This is compounded by the funding and access difficulties inherent in commissioning new analyses that can be delivered in a timely manner. Finally, and most consistently, studies demonstrate a lack of expertise in the interpretation and critique of CEA. It is clear from studies at local levels that decision-makers struggle to understand health economic analyses including the concepts and language used and the presentational styles adopted (Williams et al. 2008).

The concern for the authors of many such studies has therefore been to increase accessibility, that is, the 'availability of relevant research in a timely manner, the clarity of its presentation and the extent to which it can be understood by the policy makers' (Williams and Bryan 2007: 139). However, more in-depth qualitative studies suggest that problems of accessibility are compounded by barriers relating to the perceived *acceptability* and ease of implementation of CEA. There are multiple elements of acceptability. For example, some studies indicate that perceived methodological flaws have been an impediment to utilisation amongst decision-makers with a grasp of the methodologies involved. More commonly, studies have found that decision-makers do not always consider the source of CEAs to be independent and credible. The pharmaceutical industry has been active in using economic evaluations to promote their products (Bergthold et al. 2002), and studies repeatedly emphasise the distrust this engenders in decision-makers (e.g. Sloan et al. 1997; Anell and Svarvar 2000).

Studies employing qualitative methods (e.g. Ross 1995; McDonald 2002) have uncovered additional acceptability factors relating to the complexity and interactive nature of the decision-making environment and therefore the competing drivers of decisions. Ross (1995) used structured interviews to identify how economic evaluation was being used by decision-makers at state and national levels in Australia and found that use was limited. This was again seen as a result of economic evaluations either not being, or not being seen to be, relevant to the circumstances of policy decision-making. This study found that far from reflecting a linear model, decision-making was subject to multiple influencing factors including: political considerations, administrative arrangements, equity concerns, societal opinion and the values and attitudes of decision-makers.

McDonald's study also uncovered fundamental value conflicts between decision-makers' guiding principles and those underpinning normative health economics. She reinforces the assertion that single objectives are not routinely present in decision-making and details instances of decision-making which could not be said to be following any single maximisation principle. As a participant observer, her attempts to introduce a rational (i.e. maximising) approach to resource allocation resulted in a 'paralysis' caused, in part, by complex funding constraints. Rational approaches to policy formulation were considered by decision-makers to be less satisfactory than standard non-rational practices of muddling through in a context of resource scarcity. A key complicating factor here was the political and ethical unacceptability, within the NHS, of the explicit priority setting encouraged by adherents of normative health economics.

Finally, studies employing a range of methodologies suggest that decision-makers perceive recommendations from CEAs to be difficult to implement. For example, budget holders operating within short-term budgeting cycles may be under pressure to contain cost over and above promoting efficiency (Walley et al. 1997), and others experience difficulties redirecting resources across inflexible financial structures (Hoffman and von der Schulenburg 2000; Eddama and Coast 2009). These barriers feature strongly in a study by Duthie et al. (1999) in which interviewees claimed that savings identified in CEA were frequently unrealisable in practice, and health economists were perceived as being ill informed on issues such as block contracting agreements and the effects of secondary care costs upon planning/commissioning budgets.

Overall, the literature suggests a growing realisation that interventions by health economists in the area of research utilisation have not always addressed the totality of factors which influence policy makers or accounted for the complexity of healthcare decision-making processes. Hoffmann and colleagues (2002) used focus group discussions in an attempt to establish a 'best case scenario' in which respondents would be able to envisage effectively using economic evaluations. This study again found that despite the feeling that these were useful in principle, 'in practice their usefulness may be limited'. This was found to be a result of the lack of generalisability of studies and of the complexity of decision-making situations. Similarly, Duthie et al. (1999) found a high level of stated interest from respondents but concluded that 'current methods of economic evaluation and the communication of the results do not assist pragmatic decision-making'. Spath et al. (2000) interviewed pharmacists from public and private hospitals and clinics in France and concluded that 'economic data appeared to be a minor decision making factor'. Reported barriers varied from budget inflexibility to difficulties in accessing studies and concerns about study bias.

Overall it seems that whilst difficulties in accessing and interpreting economic studies present a barrier for decision-makers, issues of acceptability are more critical and far reaching. These include concerns about bias, assumptions and relevance of studies, political factors and the inflexible and/or limited budgets which often prevent the implementation of study findings. If greater application of health economics to priority setting is our aim, therefore, it seems logical to devise strategies for improvement which address each of these aspects.

5 Beyond Accessibility and Acceptability: Understanding Contextual Factors

Unfortunately this plethora of barriers to usage has yet to be met with a similar scope and range of potential solutions. By and large, prescriptions for improving practice have focussed on the need to standardise and improve methods of CEA and the need to increase the available evidence base for decision-makers both in terms of volume and speed. A strong strain within prescriptions for greater usage focusses on education and training for decision-makers so that CEA can be better accessed, understood and applied. Overall, responses to reported barriers have therefore tended to centre on questions of how research by health economists can be made more *accessible* to policy makers (Ross 1995; Duthie et al. 1999). These prescriptions usually involve a combination of increasing resources, improving the means of communication with decision-makers and providing decision-makers with training in interpreting health economics.

As a result, the more challenging barriers to acceptability have remained relatively unaddressed. This has been compounded by a tendency in the recent literature to narrow the range of acceptability barriers to ethical objections (see, e.g. Airoldi et al. 2014), and therefore it is unclear from this literature how barriers relating to organisational and political context are to be addressed. Certainly there is little, for example, by way of prescriptions for shaping the healthcare system in order to incentivise and facilitate the use of CEA. Indeed, one study author, McDonald (2002), is pessimistic as to the normative and positive case for increasing the use of CEA. As a result of the complex and sometimes perverse structures of healthcare and frequent value conflict with health economics, she concludes that it is inappropriate to prescribe rational frameworks for decision-makers. In this context health economics only serves to highlight to decision-makers the gap between the 'rationalist ideal' and the structural and political reality of the system.

Studies such as these suggest the importance of a sustained and rigorous examination of the congruence between economic evaluation and organisational mission and aims, links to budget flows and compatibility with performance measurement/accountability mechanisms. Despite their relative neglect in the broader literature, such factors are integral to any analysis of CEA usage in priority setting. For example, if decision bodies have little or no jurisdiction over actual resource flows, then to what extent can they be said to be 'using' CEA? There is already a considerable literature demonstrating how context can shape the use of evidence in organisational and policy decision-making (Nutley et al. 2007; Smith et al. 2014). If the extent to which knowledge is used in practice depends at least to some extent on institutional receptiveness, we clearly need to understand the incentives, rewards and penalties that might affect priority setters' inclination to adopt CEA into their decision-making. Brousselle and Lessard (2011: 835) note that these factors vary according to the tier of decision-making which

> … differ in their structures, objectives, informational requirements and budgetary responsibilities, all of which have a significant impact on how decision makers perceive economic evaluation as an aid for decision making.

Whereas barriers to use at the national (or macro) level remain largely a matter of accessibility and ethical acceptability, at local levels they are at least as much due to incompatibilities of context (Erntoft 2011). For example, in a comparison of national and local decision-makers in England, Williams (2013) makes some key distinctions. He notes that at local decision-making levels, the aims and goals of decision-making tend to be poorly specified and/or complex and multidimensional. The relationship of priority setting to actual executive decision-making is often indirect but decision-makers are not divorced from implementation concerns. Furthermore, levels of internal pressure on decision-makers (e.g. from professional groups) are relatively high, whereas external scrutiny levels are comparatively low. These factors combine to disincentivise use of CEA in favour of bargaining approaches supported by impact/affordability information. By contrast, the National Institute for Health and Care Excellence (and in particular the Technology Appraisals Programme) is not characterised by high levels of internal interest group contestation but is subject to extremely high levels of external (including media) scrutiny. It therefore finds CEA to be an invaluable means of legitimating and defending its decision-making. Furthermore, unlike local decision-makers, NICE does not have to consider the implementation of its decisions and can therefore operate in relative insulation from the potential pitfalls that occur when putting decisions into practice.

The implications of this analysis is that more needs to be done if priority setting at the local level, where the challenges and risks of decision implementation are more pronounced, is to routinely incorporate CEA. Research into local bodies suggests that evidence tends to be merely one of a range of factors which influence deliberations and that the process of decision-making can be characterised as: 'a system of equivocation involving a complex set of interactions in which there are a number of obstacles' (Coast 2001: 168). Here even the phrase 'decision-maker' is called into question by evidence of practices designed to postpone, defer or 'pass on' difficult decisions. Jenkings and Barber (2004: 1763) detail how at local levels technology coverage requests were in theory 'either accepted or rejected'.

> … however in practice there were variations including deferring a decision … sometimes the decision was not voiced at the meeting, but was made implicitly and later put into writing by the Chair and Secretary.

This observation hints at some of the weaknesses in the current evidence base relating to the use of economic evaluation in priority setting. At the national level there has begun in recent times to be a sustained analysis of variation between guidance-producing bodies especially with regard to the terms of their delegated responsibilities (Landwehr and Böhm 2011). We believe specific analysis of how these features interact with aspects of wider context to produce varying levels of demand for CEA would be a fruitful line of future enquiry. Much of the existing research also confines its respondent group to those formally involved in the decision-making process. However, it is not difficult to see how responses from a wider range of interested parties – including government, industry, the professions and the public for example – might enrich future understanding of both the normative and positive elements of CEA and its use in priority setting. At the local level, where the decision-making infrastructure is most complex, future studies might also benefit from a systems approach. The tendency to focus on individual decision-making committees, whilst informative, means that important dimensions of the wider environment tend to be left unexamined, thereby restricting the development of theories relating to the full range of determinants of behaviour. Certainly we believe that the duplication of survey or case study methodologies (including those previously employed by the authors!) will yield ever-diminishing insights. At the heart of the challenge for researchers and practitioners alike is to more thoroughly appreciate the complexity of the task in hand. We agree with Checkland et al. (2007: 100) that it is perhaps time to move beyond the rhetoric of removing barriers towards a more sophisticated appreciation of the change process:

> … the essentially linear and simplistic language of 'removing barriers' inhibits understanding of how change happens. In our view, the analytical category 'barriers to change' should be retired from the literature.

6 Summary and Conclusions

This chapter has set out some of the reasons why health economics, or economic evaluation more narrowly, is present in the work of some national priority setters and absent from the work of many local decision-makers. Our analysis is agnostic with regard to the normative claims for and against CEA as a means of making priority setting decisions. Instead we have surveyed the reasons cited for the modest impact to date and the apparent disparity between national guidance-producing bodies and local decision makers. Notwithstanding issues of accessibility we have hoped to show that information of any type is generally only considered important when the broader environment creates the demand for it. This is not to suggest that the quality and reliability of information is unimportant or that health economists do not have a role to play in shifting attitudes of healthcare decision makers. It does imply, however, that those who seek to promote the efficient and equitable distribution of scarce resources must avoid naivety: information is only as influential as politics, institutions and values allow.

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Let's Talk About Health Economic Evaluation: Relevant Contextual Factors for the German "Sonderweg"

Lars Schwettmann

1 Introduction

The starting point of the chapter provided by Williams and Bryan (see chapter "Using Economic Evaluation in Priority Setting: What Do We Know and What Can We Do?") is the observation that the usage of economic evaluation as a criterion for priority setting differs tremendously between countries and between national and local levels of decision making. In the following, I will first briefly comment on some aspects raised by Williams and Bryan's elaborations of what is known about typical barriers to the usage of health economic information (Sect. 2). One of their main observations is that context is often neglected as a central explanation for differences observed. Hence, in Sect. 3, the notably limited role played by economic evaluations in the context of the German statutory health insurance (SHI) system, which serves almost nine out of ten Germans, will be sketched. Also, the special evaluation methods developed by the German "Institute for Quality and Efficiency in Health Care" (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG) will be described. Potential reasons for these German-specific limitations and regulations will be collected in Sect. 4 by summarizing especially findings of some qualitative studies. Section 5 concludes.

"Sonderweg" might be translated as "unique path." See Wahler (2009) for the usage of this term with respect to health economic evaluations in Germany.

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E. Nagel, M. Lauerer (eds.), *Prioritization in Medicine: An International Dialogue*, DOI 10.1007/978-3-319-21112-1_19

2 General Comments

Healthcare systems all over the world face growing financial pressure and higher need for healthcare services, which are caused by rapid medical-technical progress, demographic shifts, and epidemiological changes. Probably not only from a health economist's perspective, this should foster interest of decision makers in the usage of economic evaluations in priority setting. Is economics not *the* discipline that focuses on resource scarcity? And is the primary aim of health economic analysis not to assist decision makers when tackling problems arising from scarcities (Bryan et al. 2007)?

When using the term "priority setting," Williams and Bryan (see chapter "Using Economic Evaluation") adopt the well-established definition summarized by Klein (2010, p. 389) who describes it as "decisions about the allocation of resources between the competing claims of different services, different patient groups or different elements of care." Resource scarcity and the discrepancy between supply and demand lead to this competition of claims. Also according to Klein, the term "rationing" then "describes the effect of those decisions on individual patients, that is, the extent to which patients receive less than the best possible treatment as a result." Consequently, rationing is understood as the actual consequences of priority setting for patient care (see Williams et al. 2012). These authors also point out that alternatives to "explicit priority setting" exist, including rationing by delay or by ability to pay, and implicit ("bedside") rationing, as well as increasing the overall health care budget, eliminating system inefficiencies, or strengthening preventive public health. However, they argue that each of these alternatives is problematic and, whenever applied, has been unable to decisively reduce the gap between demand and supply. In the present paper, this interpretation of the terms "priority setting" and "rationing," and the distinction between them are adopted, as they are helpful to describe the specific characteristics of the discussion about the acquisition and potential usage of health economic information in Germany.

In the literature, various normative arguments are raised for or against the inclusion of cost-effectiveness analysis as one criterion for priority setting. However, instead of providing a further account of the discussion about such normative claims, Williams and Bryan (see chapter "Using Economic Evaluation") draw our attention to the steadily growing number of quantitative and qualitative studies, which aim at identifying reservations raised by decision makers. They are the natural target group for health economic analyses as soon as one agrees with Gaertner and Schokkaert (2012, p. 8) that the "ultimate aim of any normative theory" must be to have an impact on practice (see also Bryan et al. 2007; Bryan and Williams 2014). It should be noted that quantitative studies facilitate investigating the frequency and, thereby, the overall relevance of obstacles of the usage of economic evaluations among the participating groups of individuals. However, qualitative investigations have demonstrated that interview techniques might be better able to identify potential barriers in the first instance. As Strech et al. (2008) point out, this is partly due to complex notions of central terms, methods, and conceptions, which are more difficult to present unambiguously in surveys or closed questions. Hence, in Sect. 4, the main focus will be on qualitative findings.

As a first result, Williams and Bryan (see chapter "Using Economic Evaluation") report different intensities of usage of health economic evaluations along two dimensions: on the one hand, at local level decision makers are rarely found to incorporate health economic information into their processes, while several national priority setters are even mandated to include such evaluations (see Eddama and Coast 2008, for a comprehensive review). On the other hand, at national level, significant variations between countries are also apparent. For example, in the UK, the National Institute for Health and Care Excellence (NICE) has to explicitly include results of health economic evaluations into the decision on coverage of medical interventions by the National Health Service (NHS), while such evaluations have played virtually no role in the German SHI system until now (Gerber-Grote et al. 2014). Williams and Bryan (see chapter "Using Economic Evaluation") provide an overview of various factors, which deter the application of health economic methods and, furthermore, categorize them either as accessibility or as acceptability barriers. They explain that aspects of the latter category are regularly found to be more severe but less often addressed especially by responses of health economists.

In contrast to several earlier contributions, the argument of Williams and Bryan (see chapter "Using Economic Evaluation") does not end at this point by "simply" proposing to reduce accessibility barriers by health economic training of decision makers. Instead, they indicate that in particular contextual factors, including especially the organizational and political environment of decision making, determine the demand for health economic information. Hence, their main point is that context is often neglected although it may help to explain the different extents of usage of economic evaluation in priority setting observed. However, as will be explained in the next sections, also the selection of the specific evaluation methods applied may depend on contextual aspects.

3 Health Economic Evaluation at the National Level in Germany

This section offers a brief sketch of the minor role played by health economic evaluation in the German SHI system up to now (see, e.g., Gerber-Grote et al. 2014, for a more comprehensive overview). Furthermore, the special evaluation methods developed are described. The central body for decision making about the benefit catalog of the SHI is the "Federal Joint Committee" (Gemeinsamer Bundesausschuss, G-BA). Its main committee comprises representatives of both health insurance companies and healthcare providers, while patient advocates only have an advisory function. Hence, although the G-BA is formally independent from the government, it displays less independence from its regulatees (Landwehr and Böhm 2011). In 2004, IQWiG was established as a scientific agency to support the G-BA by conducting health technology assessments and improving evidence-based health policy making. In particular, rising prices of drugs led to a healthcare reform in 2007. A new law explicitly introduced health economic evaluation as the tool to set a reasonable maximum reimbursement for pharmaceuticals, but not to make general reimbursement decisions or to determine funding priorities of society (Gerber-Grote et al. 2014; Sandmann et al. 2013). Accordingly, IQWiG should perform full benefit assessments and health economic evaluations. However, in 2011, a further reform led to a reduction of the relevance of health economic assessments for the decision-making process in the case of drugs with new active ingredients. Now, price negotiations are implemented between the "National Association of Statutory Health Insurance Funds" (GKV-Spitzenverband) and the pharmaceutical manufacturer of the drug. They are based on a dossier provided by the manufacturer, which contains information on patient-based benefits and forecasts of annual drug costs, but no health economic evaluations. This dossier has to be evaluated by IQWiG. Only if added benefit compared to an appropriate existing therapy is acknowledged but price negotiations fail, the G-BA can commission IQWiG to perform a health economic evaluation to provide a (further) evidence-based reimbursement price. Gerber-Grote et al. (2014) review the impact of health economic information on the setting of reimbursement prices for new drugs. They conclude that despite the fact that the legal regulations of the German SHI system have allowed for cost-effectiveness analysis for many years, "the current impact (as of mid-2014) of health economic evaluations for statutory decision making in Germany has been factually non-existent" (p. 5). In contrast, other regulations, including global budgets, efficiency checks, and reference values for prescriptions, are used in Germany, which has led to less explicit rationing mainly delegated to local levels (Breyer 2013).

Furthermore, because the method which IQWiG (2009) is going to apply if a health economic evaluation is commissioned makes the German case so special compared to other healthcare systems; Wahler (2009) has named it the German "Sonderweg." It was updated in 2011 due to legal changes, but the basic procedure has remained unchanged since 2009 and is equally applicable to drug and non-drug interventions (Caro et al. 2010; Gerber-Grote et al. 2014). The so-called Efficiency Frontier describes the efficient interventions currently available within *one* therapeutic area. To determine this frontier, all existing interventions for a therapeutic area are plotted in a diagram with costs per patient to be borne by the community of all citizens insured by SHI on the horizontal axis and clinical benefit per patient on the vertical axis (Caro et al. 2010). The connecting line between the origin of the diagram, which denotes the case without treatment and costs, and those interventions which are not dominated either by a single therapy or a combination of existing interventions ("extended dominance"), form the Efficiency Frontier at increasing levels of benefit. Due to the additional constraint in Germany that a new intervention has to be more effective than the currently best one, two remaining situations have to be distinguished. The case of a more effective and less expensive new intervention compared to the currently most effective therapy is certainly unproblematic. However, for the alternative case of a more effective and more expensive intervention, the last segment of the Efficiency Frontier is extrapolated. Hence, the extension of this line denotes the same ratio of costs and clinical benefits as for the currently most effective therapy relative to the second most effective therapy (Gerber-Grote et al. 2014). It forms an "ad hoc cost-per-effect threshold" (Klingler et al. 2013). New interventions above the extrapolated Efficiency Frontier should then be fully reimbursed, whereas those below the line receive a price cap so that the intervention lies exactly on the (extrapolated) Efficiency Frontier from the perspective of the German SHI.

The approach developed by IQWiG together with external experts and IQWiG's Scientific Advisory Board has proved to be very controversial (see the literature cited by Gerber-Grote et al. 2014; Kifmann 2010; Klingler et al. 2013). Critics have pointed out that prices depend on the efficiency prevailing in the therapeutic area concerned, which regularly differs from other therapeutic areas and, therefore, lead to inconsistencies due to different reimbursements of similar health benefits. Also, Drummond and Rutten (2008) remarked that efficiency standards may differ between therapeutic areas leading to increased inefficiencies due to the extrapolation of the Efficiency Frontier. Furthermore, the current restriction to one-dimensional clinical outcome measures for determining health benefits has been criticized. Quality-adjusted life years (QALYs), which are used, for example, by NICE to quantify the impact of a therapy on survival and health-related quality of life (NICE 2013), are criticized by IQWiG (2009), but alternative multidimensional concepts have not been developed, yet.

Nevertheless, it is often pointed out that both the ignorance of health economic information and the development of the Efficiency Frontier approach have been induced by specific German circumstances (Caro et al. 2010; Gerber-Grote et al. 2014). According to Williams and Bryan (see chapter "Using Economic Evaluation"), these are contextual factors, which may help to explain differences in both health economic evaluation methods and the extent of their usage in decision making at the national level.

4 Contextual Reasons for the German "Sonderweg": Some Insights

Williams and Bryan (see chapter "Using Economic Evaluation") not only claim that acceptability barriers are relatively unaddressed in the health economic literature, but that they are reduced to ethical concerns while organizational and political factors are regularly ignored. For example, in an interview study with key healthcare decision makers in Australia on the usage of economic evaluation, Ross (1995) collected typical barriers but also identified "other factors" which influence allocation decisions in health care. Based on an earlier classification by Sax (1990), these factors included political aspects such as the "philosophy of the Government," "the climate of opinion in society and pressure groups," and values and attitudes held by decision makers (Ross 1995, p. 107).

Several of these factors are also relevant for the German context. Gerber-Grote et al. (2014) summarize major challenges during the implementation of health economic evaluation in Germany. Besides several ethical concerns, experiences during the Nazi regime are often said to influence these discussions, since parts of the population were identified as "life unworthy of life" ("lebensunwertes Leben") in the Third Reich. Furthermore, the authors mention an extraordinary reluctance of many Germans to explicitly determine a concrete and fixed threshold value for reimbursement of costs for medical interventions. In fact, decision makers regularly claim that "the German public" is not prepared to link health to costs (Breyer 2013;

Klingler et al. 2013). However, although this observation might be true as a general and more abstract statement, empirical evidence is less clear-cut. In a series of four representative surveys conducted between 2012 and 2014 among adult Germans, Ahlert et al. (2014) revealed that, at least in their specific settings, Germans displayed no higher willingness to pay for health improvements or life extensions compared to respondents from several other European countries. Also, the ambiguity of public opinion in Germany can be inferred by the results of a representative survey reported by Diederich and Schreier (2010). In one question, about 70 % of respondents were opposed to the statement that (the amount of) costs should play a role if it had to be decided whether a medical treatment should be financed by the SHI. In contrast, only about 31 % of the same sample agreed that the treatment of a cancer patient, which costs €15,000 and extends the patient's life by a short period of time (e.g., 11 days), should be financed by the SHI, whereas 54 % disagreed. Hence, it seems that many participants rejected the consideration of costs for health improvements in general, but were less reluctant when they faced a more concrete case.

It has already been explained that the main decision-making body on the inclusion of new interventions in the benefit package of the SHI system in Germany is the G-BA, which comprises representatives of health insurance funds, health service providers, and patient advocates. Thus, the qualitative studies reported by Schreier et al. (2011) and Klingler et al. (2013) with members of these groups are particularly suitable to shed further light on contextual reasons for the minor role played by health economic evaluations in the German healthcare system and for the development of the Efficiency Frontier as a specific tool. In the first study, 45 members of relevant stakeholder groups including physicians, nursing personnel, and health insurance administrators, as well as healthy individuals, patients, and politicians, participated in semi-standardized interviews on different topic areas concerning prioritizing in health care. Here, I will only focus on one particular question, which is aimed at eliciting the acceptance of a "guideline adopted in the UK according to which the costs of cancer therapy must not exceed 30,000 Euro per life year gained by administering the therapy" (Schreier et al. 2011, p. 3).[1] To start with, 19 participants were in favor of adopting the guideline in the German SHI system, while 22 respondents opposed this proposal (seven individuals were undecided). When asked for reasons for their decision, the former group stated two major aspects: while 67 % thought that the German SHI funds were already under enormous financial pressure, 33 % argued that such a guideline would finally provide a clear regulation. Thus, the second reason also indicates a desire to avoid (further) bedside rationing within the healthcare system, which is a growing matter of concern for many physicians and other healthcare professionals (see, e.g., Strech et al.

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[1] It should be noted that this question somewhat simplifies the method applied by NICE. More specifically, for a new technology with an "incremental cost-effectiveness ratio" (i.e., the ratio of expected additional total cost and expected additional QALYs compared with alternative treatment(s)), above £30,000, the provision by the NHS is not excluded immediately but requires "to identify an increasingly stronger case for supporting the technology as an effective use of NHS resources, with regard to [further] factors" (NICE 2013, p. 74).

2008). However, 12 different reasons have been mentioned by participants who opposed the guideline. Besides more general accessibility and acceptability concerns, context-specific obstacles have been mentioned. Some respondents expected that the German public would be strongly opposed to the implementation of a corresponding limitation, while others mentioned the comfortable financial situation of the German SHI system especially compared to the NHS, which prevents more dramatic measures (see Gerber-Grote et al. 2014, for a similar argument). Furthermore, several interviewees pointed out that financially better-off patients may also be better able to bear incurred treatment costs on their own and, thereby, undermine the principle of solidarity, which is thought to be one of the most fundamental principles of the German SHI system.

The study by Klingler et al. (2013) gives further insights into contextual factors relevant to the adoption of the Efficiency Frontier approach by IQWiG and into differences between the corresponding German and UK "regulatory spaces." Hence, the authors confirm the context hypothesis of Williams and Bryan (see chapter "Using Economic Evaluation") but without referring to their work. To investigate such factors, in summer 2011, Klingler et al. (2013) conducted semi-structured interviews with 11 representatives of institutions including IQWiG and G-BA, which are highly involved in the German discourse on health policy. Again, I will focus only on contextual factors, which reveal the specific situation in Germany.

The authors categorize results into two major groups: first, rejection of a fixed threshold and second, doubts regarding QALYs. With respect to the first category, many respondents pointed out strong reservations toward linking health benefits and costs, which led to the adoption of a less visible tool to set limits, viz., the ad hoc cost-per-effect threshold denoted by the Efficiency Frontier. Furthermore, several individuals argued that there is a German tradition of focusing only on (clinical) benefits, which makes rationing decisions "culturally unacceptable" (p. 275). Other respondents stressed an "all-inclusive mentality" of the German public and the conviction that "everything for everybody will be made available" (p. 276). This is backed by politicians and other decision makers, who have experienced a comfortable financial situation of SHI funds during the last years, despite several reforms of the healthcare system. They regularly assure German citizens that all beneficial therapies will be made available so that cost-effectiveness research is unnecessary (Breyer 2013). However, the results reported by Klingler et al. (2013) also reveal that policy makers are well aware that such statements shift rationing decisions toward the local level where physicians and other care providers are often forced to ration implicitly.

Regarding the second category of results, QALYs as a measure for health-related benefits are generally rejected for two reasons. First, methodological reservations are articulated especially by respondents who can be expected to "really" understand the underlying concept, i.e., members of IQWiG or the G-BA. Second, QALYs are refused because they are commonly associated with healthcare rationing especially in the UK, although QALYs do certainly not imply per se the application of thresholds or rationing decisions (see also the clarification by Klingler et al. 2013, or IQWiG 2009). However, it seems to be particularly this connotation combined with the general objection of healthcare rationing that led to the refusal of QALYs and, more generally, other health economic tools.

5 Concluding Remarks

Williams and Bryan (see chapter "Using Economic Evaluation") have argued that contextual factors are crucial, but often neglected, when it comes to explanations of the use of health economic information in priority setting. In the present contribution, I have related this general statement to the special situation of economic evaluations in the German SHI system. First, it is characterized by an overall absence of an explicit impact of economic evaluation on priority setting decisions at the national level. Second, the development of the Efficiency Frontier approach as a method of health economic evaluations has led to the conclusion that the German SHI system follows a "Sonderweg" ("unique path"). A combination of ethical, historical, and political or cultural factors seems to have created a general refusal of open discussions about healthcare rationing and, particularly, about health economic evaluations. This leads to a shift of responsibility to local decision makers and often results in implicit rationing. Although once in a while decision makers try to put these issues on the political agenda, one probably has to agree with Gerber-Grote et al. (2014) who conclude that the exceptionally comfortable financial situation of German SHI funds has avoided, and still avoids, stronger pressure to attain the "best value for money" and to take health economic information into consideration.

Acknowledgments Helpful comments by Marlies Ahlert are gratefully acknowledged. The usual disclaimer applies.

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