Prioritization in Medicine

An International Dialogue

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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
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Printed on acid-free paper

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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 — Eckhard Nagel
October 2015 — Michael Lauerer

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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.

[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