

Health under austerity in Europe

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Health under Austerity in Europe
– Ethical Considerations

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Health under Austerity in Europe – Ethical Considerations

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Health under Austerity in Europe – Ethical Considerations

Dissertation

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Chapter 1 Introduction

The economic crisis and health – a general introduction

Background

In the aftermath of the 2008 global financial crisis, countries around the world including the European Union have been hit by the consequences to various extents (Thomson et al., 2014; Stuckler et al., 2009; Reeves, McKee & Stuckler, 2015; Karanikolos et al., 2016; Anastasiou et al., 2016). The resulting scarcity of financial resources also affected institutional spending for health systems, leading to adjustments regarding health budgets and restructuring measures of health system arrangements, such as rationing in coverage for health care. Eventually this scarcity also affected health levels of the European population depending on the rigorosity of the measures implemented (Maresso et al., 2015; Labonté & Stuckler, 2016; McKee et al., 2012). European policy-makers proposed – as Stamati & Baeten (2014) term it – “unprecedented levels of social spending cuts”. These spending cuts have been led by the neoliberal ideology of the superiority of austerity measures as proposed by the so-called Troika, which is composed by the International Monetary Fund (IMF), European Commission (EC) and European Central Bank (ECB). The neoliberal stance emphasises the role of free markets and favours less government support in terms of stimulating the economy (Ruckert & Labonté, 2017; Sen, 2015). In contrast to these neoliberal policies another competing ideology can be identified: Keynesian economics stresses the importance of continued or increased government support during economic regressions aiming to sustain high employment rates and to stimulate economic growth (Wapshott, 2011; Sen, 2015). As shown in figure 1.1, health expenditure as percentage of overall GDP has shown reductions since 2009 in the overall level of Member States and selected Member States, indicating a distinct tendency towards neoliberal approaches and policies in these states.

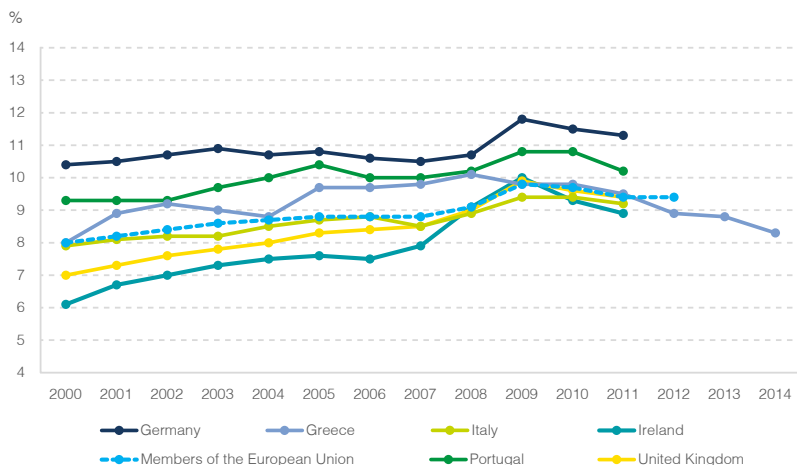


Figure 1.1: Total health expenditure as % of GDP in Member States of the European Union and selected Member State countries, 1970 – 2015. Data derived and graph adapted from WHO Regional Office for Europe.

When looking at the growth rate in health expenditure per capita, the same picture appears, as highlighted in figure 1.2: per capita health expenditure did not show growth but rather reductions immediately after the onset of the economic crisis. The percentage of health expenditure per capita reduced from 2009 – 2010 for nearly all countries compared to the years before. Only Germany and Malta showed a light increase by 0.1 – 0.2%.

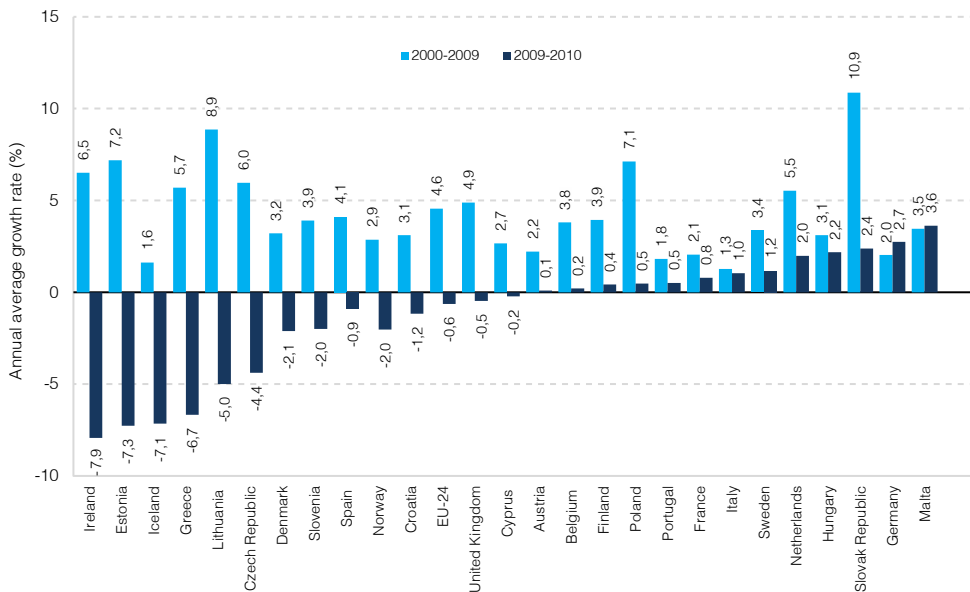


Figure 1.2: Annual average growth rate in health expenditure per capita, selected Member States, 2000 – 2010. Source: OECD, Health at a Glance: Europe 2012 (based on OECD Health Data 2012; Eurostat Statistics Database; WHO Global Expenditure Database).

The impact of reduced budgets on health care provision and hence also on population health could only be quantified in the recent years since 2010, when data became available. Research assessing those impacts therefore only recently emerged and revealed predominantly negative outcomes of the crisis for health and health systems (Simou & Koutsogeorgou, 2014; Labonté & Stuckler, 2016; Branas et al. 2015; Morgan & Astolfi, 2015; Maresso et al., 2015; Stuckler, Basu & McKee, 2010; Stuckler et al., 2011; Rajmil et al., 2014; Borisch, 2014; Reeves, McKee & Stuckler, 2015). Those negative health outcomes are also shown by the increase of self-reported unmet medical needs in four Member States since 2011 (figure 1.3).

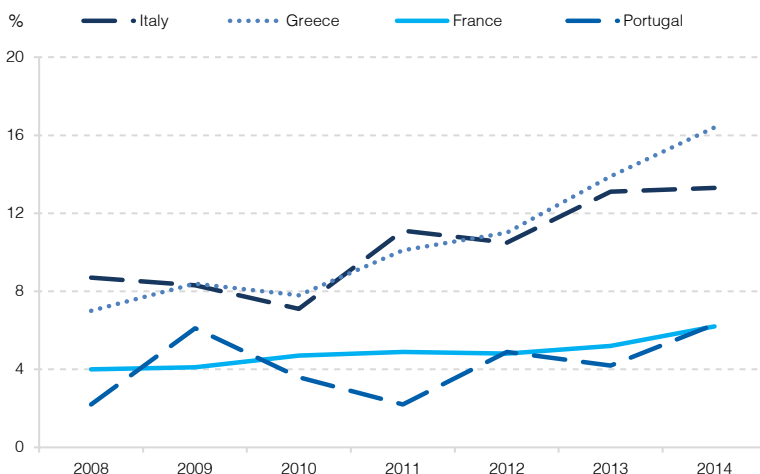


Figure 1.3: Change in unmet medical care needs for financial reasons among the lowest-income group, selected Member States, 2008 – 2014. Source: OECD & European Commission (2016). Health at a Glance: Europe 2016 – State of Health in the EU Cycle.

Reasons for research and ethical assessment

Besides those first endeavours to understand the consequences of the economic crisis for health and health care provision, debates containing moral concerns evolved. They grew both within the academic realm, mainly surrounding the increase of differences in health levels of the EU population as a consequence resulting from the crisis as assessed by Stuckler and colleagues, as well as in public spheres, including newspaper or magazine articles about the deteriorating health care situation in Greece, for example. In general, discussions in the broad public evoked around questions surrounding equality and related aspects, as sparked by the works of scientists and authors such as Thomas Piketty, Michael Sandel or Joseph Stiglitz.

Specifically in the context of public health ethics, various questions emerged as well. These essential public health ethical questions are approached in the course of this thesis. The discipline of public health ethics is here defined as dealing “primarily with the moral foundations and justifications for public health, the various ethical challenges raised by limited resources for promoting health, and real or perceived tensions between collective benefits and individual liberty” (Faden & Shebaya, 2016). Examples of emerging questions in this context of this thesis are whether there are limits to crisis driven budget cuts in health care, what forms of aid ethics can provide to health policy and decision-making, and if severe budget cuts are justifiable as such in the domain of health. However, when the research for this thesis started in 2013, no systematic public health ethical analysis was available in the literature of the public health community (literature searches were done in PubMed/Medline, the standard

database for health sciences and public health). Even some years later, by 2018, only limited normative public health ethical discourses evolved. This is also shown by a combined search of the terms “ethics” and “austerity” in PubMed: Only 28 articles match the search, with only four of them being relevant in terms of fitting the issue under study (Gustafsdottir et al., 2018; Lopez-Valcarcel & Barber, 2017; Kerasidou, Kingori & Legido-Quigley, 2016; Molina-Mula & Pedro-Gómez, 2013; excluding the research published by the author of this dissertation). Relevance was determined as including ethical perspectives towards austerity measures in the health sector, precisely in public health and health systems. The matching studies address questions of access and arising inequities to health care, effects of austerity on the health care system in Spain and Greece, as well as ethical reflections about health care reforms in times of austerity. All articles provide an ethical assessment of health systems under austerity and hence can be regarded as valuable in bringing forward the topic of this thesis in the years between 2013 and 2018. A reason for negligence of the explicit ethical dimension of austerity in the early years after the onset of the economic crisis could be that economic concerns were assumingly given priority over ethical concerns and considerations. In an attempt to understand this gap in the academic public health literature about the consequences of the economic crisis and resulting austerity measures from an ethical perspective, a review of the existing literature is conducted (cf. chapter two).

A public health ethical assessment of the implications of the crisis and austerity on population health is of utmost importance, as it uncovers what is socially at stake and provides justifications for policy choices. Public health ethics – and ethics in general – deals with decision-making and quite often with decisions which have to be made due to scarcity of resources, as for instance allocation of the limited number of donated organs for numerous transplantations. The discipline of ethics “develops ethical principles, rules, and ideals that spell out standards of good and bad, right and wrong. Normative ethics tries to offer a substantive, albeit general answer to the question, What should I do?” (Jennings, 2003). Answering this question with regard to responses to the economic crisis provides robust justifications of public health policies (Holland, 2007). Potentially, it can inform future policy-making to be more sustainable, just and equitable – values that are also widely acknowledged and incorporated in EU Treaties, as stressed by the EU Charter by referring to the values of, equality, freedom, solidarity, respect to dignity citizens’ rights and justice (European Parliament, 2015). A subsequent issue, which is assessed, is if and how ethics can help to inform decisions in the face of this ‘unfamiliar’ challenge.

Conceptual and methodological approaches

The objective of the research, which follows in the next chapters, is to address the impact of the economic crisis, which started in 2008, on health from a public health ethical perspective. In order to have an encompassing approach for assessing different areas which constitute a public health system, the WHO Health Systems Framework (WHO, 2007) is drawn on to define a spectrum of cases being relevant for such an analysis of health systems and which is more closely explored during the course of this thesis. The WHO Health Systems Framework is widely recognised within public health and describes different sectors – referred to as system building blocks – which are elemental for a functioning health system and their population health outcome. The six building blocks are leadership/governance, health care financing, health workforce, medical products/technologies, information and research, and service delivery, as also shown in figure 1.4. The WHO Health Systems Framework indicates that when all system building blocks function well and access, coverage, quality and safety can be ensured, the outcomes for health systems are improved health levels and equity, a responsive system, better efficiency in general and protection against financial risks.

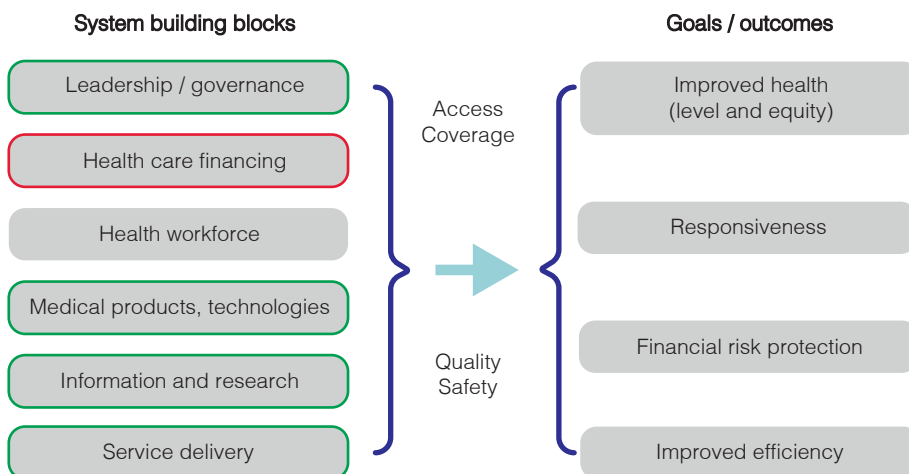


Figure 1.4: WHO Health Systems Framework (WHO, 2007). Own drawing: colours added to building blocks for indication of PhD thesis structure.

In order to analyse the impact of the economic crisis and austerity on diverse levels within the field of health, the system building blocks of the WHO Framework serve as a basis for laying out the distinct areas and examples, which should be assessed in order to attain an overview of how the economic crisis affects health system outcomes, equity and efficiency. While four building blocks serve as a framework for choosing the specific fields within a health care system, which are assessed from an ethical

perspective as outlined in the following, one building block – health care financing – is regarded as the underlying precondition and main influencing factor, affecting all other areas through austerity measures and hence reduced spending and budgets on health. This building block is indicated in red in figure 1.4, while the other areas from the WHO Framework, which are drawn on to as specific examples to be assessed, are highlighted in green.

At the core of the first part of this thesis (chapters two and three) is the assessment of the impact these austerity measures in health financing had on service delivery of health care systems (the sixth block) and health levels as such. Choosing the building block of service delivery (in the course of this thesis referred to as health care provision) is of relevance when aiming to assess the consequences of the economic crisis and austerity measures on health care systems and health, because it is a crucial element for attaining good health and inherently lies at the core of the research. The right to equity in basic health care provision for everyone (as also laid out in the Ottawa Charter) furthermore gives reason and ground for assessing the ethical dimensions of austerity (Gustafsdottir et al., 2017).

In the second part of this thesis, the building blocks of medical products and research are addressed. Here, the focus is specifically on the promising and innovative medical product of personalised medicine (chapter four). Taking into account innovative medicines such as personalised medicine – which strains health spending by extending the scope of treatments offered (OECD, 2015) – offers a perspective how a highly expensive and promising domain of health care is affected by scarce resources and how this can be shaped in ethical terms. Moreover, due to the general attention given to the pharmaceutical sector in public debates within health systems, it is an important sector to focus upon. It is specifically interesting to address the example of personalised medicine therein, as it is not only a highly debated topic in the general public, but also a treatment that is extremely costly. Assessing an example of such an expensive medicine with regard to reduced resources and austerity provides insights into how access to such treatment could nevertheless be provided in a fair way. Building upon this background, the thesis furthermore addresses the area of research within this context of personalised and genomic medicine, given the fact that such an innovative field also brings about novel challenges for research (chapter five).¹

Lastly, perceptions of the group of stakeholders are addressed, who shape policy-making and governance of health systems (the building block of leadership and governance) as such – the policy-makers themselves (chapter six). Addressing the key actor of policy-making is relevant in order to gain empirical insights about their perception and its respective underlying values, also given the fact that policy-makers

¹An additional reason for addressing personalised medicine specifically is that the researcher has worked on this topic before within the context of its governance (see curriculum vitae and Schee genannt Halfmann, Brall & Brand, 2016; Wäscher et al., 2013) and felt that the debate surrounding personalised medicine still holds unaddressed issues and questions. Addressing those issues was hence integrated in the thesis at hand.

have not been involved in research about the economic crisis hitherto (cf. literature review in chapter one).

For the purpose of this research, four building blocks are hence more thoroughly assessed, focusing on health and health care provision (service delivery), pharmaceutical innovation (medical products and technologies), research (information and research) and policy-makers (leadership/governance).² Those examples cover different fields within public health and are stipulated by the WHO Framework as core elements for a functioning health care system, ranging from basic conditions of health care provision, which impact health as such, to the more advanced and high cost area of innovation and research in a pioneering field such as personalised medicine and genomics.

Examples within the health system are chosen, which are differing with regard to their level of care, precisely looking at basic or general health care provision to more advanced (and more expensive) health care provision in the specific example of personalised medicine. Hence the chosen examples in health care provision and pharmaceutical innovation cover different levels of economic weight. Research is furthermore selected in order to address challenges of scarcity in a field, which is not directly associated with health, but nonetheless makes an impact on health on the long term. Lastly, addressing policy-makers, who are influenced by values and norms and shape conditions of health systems, and asking about their perspective with view to the economic crisis and health provides an explorative reality-check for the findings from previous examples.

In order to conceptualise how those examples are seen within the broad context of the issue under study – addressing ethical issues of austerity measures in health – and how they stand in relation to each other, a simplified form of the main research areas and concepts used in the course of the thesis is depicted in figure 1.5. Looking at the dimensions on a broad level, three main concepts are involved. Those concepts are (1) scarcity of resources and austerity, as an influencing factor on (2) health systems at a macro level. How those external circumstances of austerity affect dimensions within the health care system and on health levels is influenced by the (3) ethical norms and values, which guide decision-makers in shaping health policies. Within the health system dimension (2), the distinct and interconnected examples derived from the WHO Health System building blocks are located and influence each other: Firstly, there are decision-makers, who are influenced by values and norms and shape conditions of health systems. A second example is health care provision, having an impact on health levels (public health) on the one hand, and being impacted by pharmaceutical innovation (such as personalised medicine) on the other. Lastly, research is understood as a separate area within health systems throughout this thesis, while it is also influencing the example of pharmaceutical innovation and vice versa.

² Here, a more precise wording is used, referring to the respective building blocks in brackets.

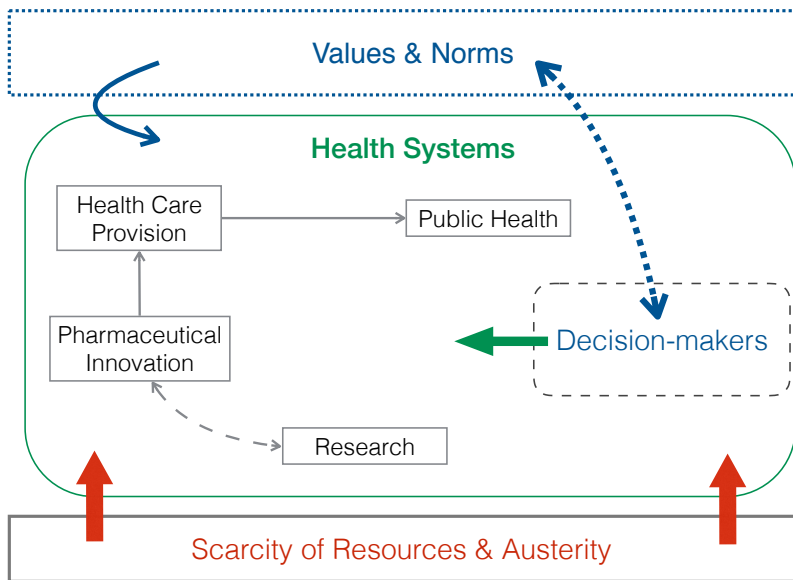


Figure 1.5: Main concepts of the research (own figure).

Ethical assessment

Against this backdrop, an ethical assessment of the four examples within the health system dimension is made, for which two different angles are chosen.

Firstly, and primarily, the capability approach (CA) by Amartya Sen (Sen, 1999) is applied. The CA addresses the question “what people can do and be (their capabilities) and what they are actually achieving in terms of beings and doings (their functionings)” by looking at whether the respective policies, institutions or social arrangements facilitate sufficient opportunities for them to lead a life they value (Robeyns, 2017). It focuses on assessing if people have the same real opportunities (termed as capabilities) or whether “global economic structures, domestic policies or brute bad luck make people’s capabilities unequal” and whether this has to be regarded as unfair (Robeyns, 2017). In order to expand this theoretical domain and to prevent repetition, a more elaborate introduction to the CA is given in the respective chapters, in which the CA is applied (chapters two and four). In general, the CA can be located within the realm of ethical, normative analysis (Robeyns, 2017), aiming to evaluate and prescribe what ought to be done.

Reasons for choosing this theory are not only that the CA recently emerged as a prominent theoretical approach within public health to address inequalities in health (Dabrock, 2012; Ried, 2016), therefore stemming from the branch of theories of health justice – or in the case of the CA rather approaches or frameworks concerning the latter. By serving as a framework to address the core question (of both the CA itself as

well as the guiding question of this thesis) mentioned above whether economic structures or policies affect people's opportunities to lead a life they value, the CA moreover is precisely suitable to analyse and evaluate the ethical challenges the economic crisis brought or still brings about for the health of the European population. Applying the CA emphasises values that are often neglected when assessing economic structures or arrangements and their impact on populations, namely values such as justice, well-being and freedom (Robeyns, 2017, Robeyns, 2006). Here, the CA is not explanatory, but offers a framework to "conceptualise and evaluate" phenomena such as well-being and inequality (Robeyns, 2006).

Another central reason why the CA is chosen as the framework for the ethical assessment is that the CA offers an approach stemming from social ethics. Social ethics and social justice investigate in a normative manner how our social institutions are designed. Hence a social ethics approach can be of value to address ethical issues of health policies arising from the economic crisis and austerity. Testing this theory against one of the biggest challenges posed to public health in the recent years (i.e. the economic crisis) adds new insights to the theoretical foundation and is thus an ancillary aim of this thesis.

Secondly, ethical, normative analyses are applied (chapters three and five). While chapter five addresses questions in research ethics from a general normative stance, chapter three applies a theory stemming from the bio-ethical stance. In essence, the Imperative of the 'founder' of modern bioethics Fritz Jahr (a deontological approach) is applied, in addition to the only proposed ethical recommendation with regard to the crisis, which is 'first do no harm' proposed by Stuckler and Basu (2013). Stuckler is one of the main researchers and opinion leaders examining the consequences of the economic crisis on public health. To combat the threat austerity poses on health, Stuckler and Basu (2013) formulated a bioethical imperative for policy makers: 'first do no harm' – a principle traditionally stemming from the clinical-medicine realm. To the researcher's knowledge, Stuckler and Basu are also the first – and in the first years of the research that lead to the thesis, only ones – to explicitly introduce ethical norms to public health discussions of the economic crisis. This proposed normative guidance is assessed, thereby juxtaposing this rather consequentialist guidance with the deontological theory of Fritz Jahr. Drawing on those theories, an analysis from an individual ethics perspective is applied.

On the overall level, a combination of a social ethics approach (the CA) and an approach of individual ethics (Jahr's Bioethical Imperative and 'first do no harm') offers a framework to grasp the impacts of the economic crisis and austerity on health in a holistic and comprehensive way in line with the outlined definition of public health ethics, which aims to address the tensions between collective benefits and individual liberty. Diverse levels of focus are addressed accordingly, with the result that different perspectives are taken and ethical issues can be addressed from the following relevant angles:

- The framework of the CA taking a social ethics perspective addressing justice and right to well-being concerns on an overall population level and from the perspective of social institutions, issues which are inherently at the core of questions which arise when asking questions about the impact of the economic crisis on health at a population level, such as access to care, health inequalities and justice,
- the principle of ‘first do no harm’ which serves as a minimalist guidance on an individual ethics perspective,
- the deontological theory of Fritz Jahr’s Bioethical Imperative which puts forward to “respect every living being in general as an end in itself and treat it, if possible, as such” (Jahr, 1926, p. 21), implying the importance of dignity of human beings as such.

In the following, the aim of this research will be summarised and corresponding research questions will be presented in an overview.

Aim of the research & research questions

As outlined above, the aim of this thesis is to shed light on the ethical dimensions arising from the economic crisis in the context of health and health systems. The region, which defines the scope of the following research, is Europe, specifically Member States of the European Union.

Arguing from a right to well-being and justice point of view, an ethical assessment is performed, addressing distinct areas or examples within the field of health, namely health and health care provision, pharmaceutical innovation, research and policy-makers.

The main research question to be answered throughout this thesis is:

What ethical issues and dimensions arise in the light of recent austerity for health, public health, health care systems, pharmaceutical innovation and health research in Europe (and the EU context)?

With the aim to answer this overarching research question, each chapter addresses corresponding sub-questions in line with the examples and their rationale outlined previously:

- i. Did the crisis have an impact on health and health care systems and if yes how is it evaluated in ethical terms when applying the capability approach (chapter 2)?
- ii. Which public health issues that are at stake during austerity can ethics bring on the agenda – from a consequential and deontological perspective (chapter 3)?

- iii. Which challenges does scarcity pose on pharmaceutical innovations, precisely personalised medicine, and are there opportunities in terms of access an ethical perspective – specifically the capability approach of justice – can provide? (chapter 4)?
- iv. Which challenges do scarce resources pose to research ethics and integrity (in an innovative field such as genomic research) (chapter 5)?
- v. How do European policy-makers perceive the economic crisis with regard to health, and which values and ethical implications are regarded as essential with regard to policy and priority-setting (chapter 6)?

For answering the underlying questions of this research, different methods are used, involving a conceptual as well as empirical approach. In general, the overall methodological approach is exploratory and inductive. Therefore, no precise overall framework is used, however two main different theories are applied as outlined above (chapters two and three), two succinct normative assessments in the context of personalised medicine and research are made (chapters four and five) and one reality-check by means of a descriptive, exploratory interview study is conducted (chapter six).

Outline of this thesis

The thesis consists of two conceptual parts and one empirical part, each exploring ethical challenges of austerity since 2008 and resulting scarcity of financial resources for different areas within health and health care, precisely for health and health care provision (part 1), pharmaceutical innovation and research (part 2) and perceptions of European decision-makers (part 3). An overview of the chapters is given in figure 1.6.

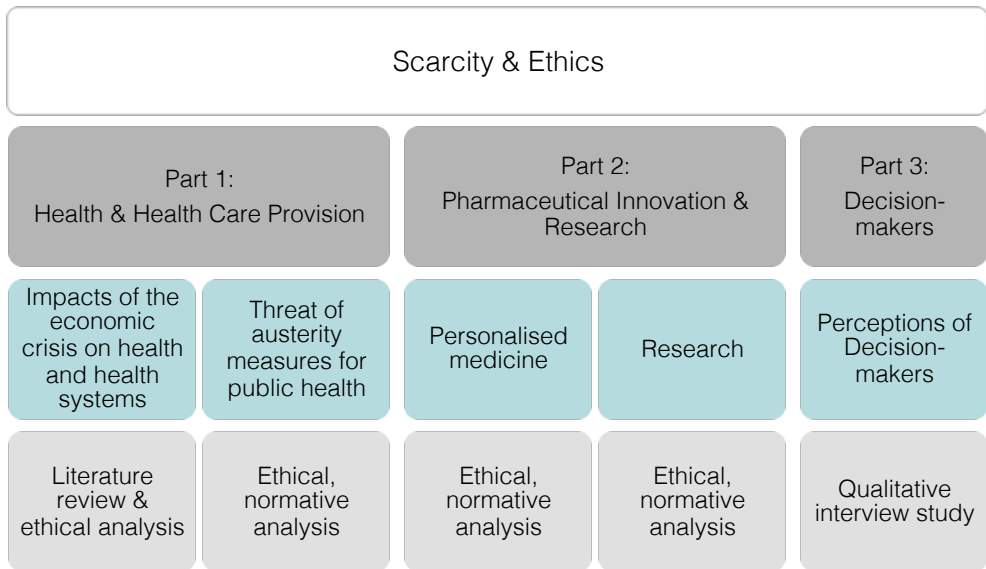


Figure 1.6: Overview of chapters.

Part 1: Health and health care provision

The health impacts of the global financial crisis and the European debt crisis are deemed severe, yet only limited literature exists about the consequences for the population's health and for health care systems in general. In order to gain understanding of the impact of the economic crisis on population health and health systems, a literature review is conducted in **chapter two**. Therein, the ethical dimension of health outcomes caused by the economic and financial crisis and especially the ethical dimensions of austerity measures and other policy responses are explored. The findings are then analysed and discussed using the normative framework of the capability approach (CA) by Amartya Sen (Sen, 1999). Applying Sen's CA theory to the economic crisis facilitates the identification of morally challenging, critical issues for population health and health systems in Europe from a social ethics perspective. An additional question of the article is hence, in how far the CA aids to evaluate policy options and health related outcomes of the current financial and economic crisis.

Like the second chapter, the third chapter is of theoretical nature and applies additional normative-ethical frameworks to the issue of whether and how austerity measures adapted as a response to the economic crisis pose a threat to health. In health policy debates, ethical aspects of the crisis are implicitly discussed by using consequentialist approaches, as done by Stuckler & Basu (2013) who point out the consequentialist principle of 'first do no harm' among others. Yet, in order to fully grasp the ethical dimension of such a threat for health and health systems it is also

helpful to apply deontological theories to use a wider ethical perspective. **Chapter three** therefore assesses the implications of 'first do no harm' in an ethical perspective and furthermore applies Fritz Jahr's view of bioethics – referred to as the founding father of bioethics – as the theoretical lens through which the impact of the current economic crisis on health is analysed (Muzur & Sass, 2012). Discussing the implications and meaning of these norms and values and contextualising them with relevant ethical criteria helps to critically reflect on challenges of the economic crisis in an individual ethics perspective.

Part 2: Pharmaceutical innovation and research

Chapter four subsequently frames ethical aspects of scarce resources in the specific context of highly expensive and innovative personalised medicine and genomics. Priority-setting and rationing of existing resources is also affecting pharmaceutical innovations like personalised medicine. Once again, the CA is applied in order to identify chances and challenges of personalised medicine with regard to ethical considerations in terms of equality of opportunity. A special focus is on how patient's 'real options' are affected to access innovative therapies.

In **chapter five** another topic to date within the field of personalised medicine and genomics is highlighted, namely the ethics of research. The changing scientific landscape and increasing demands and competition in the academic field placed research ethics on the international agenda again. Scarcer resources even exacerbate the competition and pose a challenge to scientific integrity. So far, debates regarding research ethics were concerned with individual integrity and informed consent, which can be termed as research ethics 1.0. A broader approach to research ethics is established in this chapter, evolving to research ethics 2.0 and entailing social scientific integrity within a wider perspective of a research network. Within this research network, every stakeholder involved should jointly act in order to meet the ethical challenges posed to research.

Part 3: Perceptions of European policy-makers

Chapter six entails an empirical study of perceptions of European policy-makers about ethics in relation to the economic crisis and its consequences on health and health care systems in Europe. The aim is to find out how European policy-makers perceived the economic crisis with regard to health policy, which values they perceive as essential to be integrated in policy-making, and how they evaluate the role of ethics in political decision-making. Findings depict to what extent the ones in charge of political decision-making are confronted with the challenges raised by the economic crisis and how they evaluate their decision-making and involved values in this regard.

General discussion

Finally, **chapter seven** summarises and discusses the main findings from this research. It is examined what ethics can provide for public health during times of scarcity by elaborating on the aspects, which are identified in the course of this thesis for improving policy-making from an ethical view, thus interpreting the common findings from the separate chapters on an overall level. The chapter furthermore addresses the added value of the thesis from different angles and outlines its limitations as well as implications for policy, practice and research.

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Part 1: Health and health care provision

Chapter 2 The economic crisis and its ethical relevance for public health in Europe – An analysis in the perspective of the capability approach

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Abstract

Policy responses to the economic crisis have manifest consequences to European population health and health systems. The aim of this article is to assess, by using the capability approach advanced by Sen, the ethical dimension of trade-offs made in health policy due to austerity measures. From a capability approach point of view, austerity measures such as reducing resources for health care, further deregulating the health care market or moving towards privatisation are ethically challenging since they limit opportunities and capabilities for individuals of a population. Public policies should thus aim to guarantee sufficient capabilities (options to access health care and possibilities to make healthy choices) for its populations. Prioritising those in need is a notion the capability approach particularly focuses on in its goal of supporting those with the least capabilities.

Introduction

Recent developments in several European countries have shown that the economic crisis has not only affected governmental budgets and private households but has also had an adverse impact on social arrangements, and in particular, on the health of citizens [1; 2]. Yet only limited literature has been published concerning the consequences of the crisis on health or on health systems, whilst its ethical relevance has been neglected thus far. This article aims to provide a general overview of literature relating to this topic. It seeks to further explore the ethical dimension that the economic crisis and subsequent policy responses, in particular austerity measures, had on population health and health systems in Europe. For an ethical framework with at least heuristic value the capability approach (CA) by Amartya Sen is used [3]. This approach will assess the ethical dimension of the trade-offs made in (health) policy due to the widespread ideology of austerity. An ancillary question of this article asks whether the CA's criteria help in evaluating policy choices, and health related outcomes during the current financial and economic crisis.

The capability approach

Sen's CA can be used as a normative framework to analyse how people's capabilities are affected by individual and population well-being and related social arrangements and policies [3; 4]. Capabilities are all the potential options a person can choose from in order to lead a good life and therefore achieve good quality of life [4]. Thus, capabilities can also be termed real opportunities or (positive) freedoms. Whereas Rawls' theory of justice is focussed on the equal redistribution of so called primary goods (e.g. income), Sen amends it by arguing that it is also morally relevant to see what people can really do with these goods (considering their personal circumstances) [3; 5]. Sen thus takes a broader perspective that also considers potential outcomes (i.e. what an individual can realise with the goods he or she receives): when a certain capability is realized, it is termed an achievement or 'functioning' [3]. A person can thus attain a specific set of functionings chosen on the basis of their own personal values from real options (or capabilities). For Sen, it is essential that people have the choice of whether or not to make use of their capabilities. For example, a person fasting and a person starving might be in a similar physical state with respect to their health, however one can eat but chooses not to whereas the other has no such freedom of choice. According to Sen's CA – and also Nussbaum's version [6] – decisions should be fully informed, deliberate and consciously made. The real freedom (perceived as a real opportunity) to achieve a good life is thus the core value for Sen [7].

Besides the distinction between capabilities (freedoms and options to choose from) and functionings (achieved outcomes), Sen bases the CA on another distinction, namely between means and ends. Whilst means are merely instrumental to attain certain ends, ends are valuable in themselves, and as such are central to the CA in

assessing health related outcomes of the economic crisis. However, in some cases there is no strict demarcation between means and ends, as capabilities can also be ends as well as a means to other capabilities. For example, being healthy is an end as well as a means for being able to work [3]. In our diverse societies means, such as income, enable different people to reach either valuable capabilities (opportunities) or transform them into functionings (achievements). The ability to transform means into functioning, if valued, is described by the term 'conversion factor' [8]. By placing a special focus on the ends and simultaneously assessing the means, it is possible to examine the extent to which people's situations influence their ability to realise pursued ends [8].

Within public health, the CA can be used to assess people's health in general and test whether the resources (or means) to reach good health and well-being exist. For instance, access to fresh water and adequate food supplies, access to medical care, basic understanding and knowledge of health-related matters and/or methods to prevent infectious diseases are all means to good health [4; 9]. Factors influencing these capabilities range from economic and financial resources to social structures, institutions, norms, traditions and political practices [3]. Social and political structures can also have a key influence on inequalities between different social groups. In addition to personal differences in access to resources, institutional arrangements – such as gender disparities – can be a source of inequality [10]. Nussbaum [6] adds in her version of the CA that, from a moral standpoint, the question of how much resources one must have in order to consider these resources 'sufficient' to lead a dignified life depends on the resources and capabilities that exist in society. Thus, the CA' conception of justice inherits a social-relativist perspective [8], which neither requests a total redistribution (as Rawls' difference principle would), nor is it indifferent to 'brute luck'. Rather, it requires a (social-relative) sufficient level of capabilities.

Notably, capabilities also entail a personal responsibility to act reasonably [11; 12]. In terms of health, this personal responsibility denotes a person's capability to influence his/her health status positively. Yet in order to act in a self-responsible manner, one has to be empowered or enabled to do so (e.g. by being offered health education, access to medical care etc.) [12]. The CA thus pronounces clearly that social determinants of health demand ethical appraisal and evaluation. Here, Sen's approach offers a wider perspective than many liberal theories of justice (such as theories inspired by Rawls) which consider only the access and distribution of goods, instead of asking what people can do with these goods and to what extent they can really affect their capabilities. Along these lines, applying the CA allows the identification of certain issues arising in the wake of the economic crisis, which endanger justice in health. In this respect, the CA clarifies which goals should be prioritised for improving health-related functionings [13].

Materials and methods

In order to fully understand the impact of the economic crisis on population health and health systems, and whether the CA has already been used in this regard, a literature review was conducted. The online databases PubMed, SpringerLink, Oxford Journals, Embase, Elsevier, Informa Healthcare, JSTOR, SAGE and Science Direct were searched. Keywords for the meta-search included the terms 'austerity', 'austerity measures', 'economic crisis', 'financial crisis', 'health', 'health care', 'ethics', 'European Public Health' and 'capability approach'. These were used in combination and were searched for in the title and abstract of articles. The sampled literature was filtered by publication period (January 2007 to March 2014) and for publications written in the English language. A title and abstract review was used to assess the relevance of each article to the recent economic crisis in Europe. Citation mapping was then applied to check for additional literature via snowball sampling.

The information collected on the consequences of the economic crisis on health and health systems was then reviewed, synthesised and presented according to an adaptation of the categories identified by Karanikolos et al. [14] and Quaglio et al. [15]: existing policy approaches, consequences for health systems and effects on health. Lastly, the findings were analysed and discussed using the CA [3]. Applying Sen's CA theory to the economic crisis facilitates the identification of morally challenging, critical issues for population health and health systems in Europe. Thus relevant issues can be conceptually constructed and discussed using ethical language derived from normative concepts of the CA.

Results

Twenty-six articles were identified as relevant to health and the economic crisis at a general policy level. None of them explicitly referred to the CA in relation to the health crisis.

Policy responses to the economic crisis and their impact on health care systems

From a macro-economic perspective, governments have mainly engaged in two policy options during the crisis: employing stimuli compatible with the Keynesian framework or implementing austerity measures so as to decrease their debts (framed more in the neoliberal ideology). While Keynesian economics stress the importance of government support during economic recession, neoliberal policies favour less government support and emphasize the role of free markets [16; 17].

Austerity measures

In alignment with neoliberal policies, the implementation of austerity measures has been the most common policy response acted upon by countries such as Portugal, Spain, Greece and Ireland, among others [14]. Due to budgetary pressures, several

EU countries accepted the conditionalities proposed by the International Monetary Fund (IMF), European Commission (EC) and European Central Bank (ECB) (composing the so-called troika), so as to be eligible for financial rescue packages aimed at initiating economic growth [2; 14; 16]. For instance, corresponding reforms in the health care sector implemented by the Greek government resulted in strict austerity measures; restricting access to health care services, introducing privatisation schemes and deregulating private health services [2]. On the other hand Belgium and Denmark, for example, preserved their health budgets and some countries such as the Czech Republic, Lithuania, Estonia, Slovakia and Italy were able to refer to counter-cyclical policies, which were taken before the crisis with the goal to protect health, for instance, retaining financial funds specifically assigned to health [18]. However, most other EU countries reduced their health expenditure [14] by altering the contribution levels, volume, quality, and/or costs of care [18]. Such health expenditure reduction is analysed below.

Contribution levels have already partially decreased due to the rise in unemployment, which has led to a loss of social insurance contributions [18; 19], yet countries with counter-cyclical policies implemented governmental contributions for unemployed people.

Alterations to the volume and quality of health care were not directly implemented, however, some countries introduced policies to lower the demand for health care through raising taxation on alcohol and tobacco [18]. Nevertheless, countries neglected to promote healthy behaviours, e.g. diet, physical exercise and screening measures [18].

Primary targets for cutting costs of health care were found in the reduction or freezing of salaries for health professionals and rises in health service user charges [18; 19; 20]. Uncompetitive salaries can lead to a migration of health professionals to other countries or to private health sectors further worsening an already 'brain-drained', publicly financed, health care system [14]. Raising user charges for health care services decreases access to health services, especially for low-income and frequent users, who are also normally the ones most in need [14; 19]. Thereby health services may not be accessible in time, resulting in decreasing levels of health. This in turn may require emergency care, further reducing savings made in the first place [21]. Additional cost-saving measures introduced by some countries included pay-for-performance systems, lower prices for health services paid to providers and reduced prices for pharmaceutical and medical devices through negotiations with pharmaceutical and medical technology companies [18; 20]. Cuts in other areas, for instance those in higher education, are also seen critically, as they might have a negative impact on pharmaceutical innovation and thus on economic growth [22].

Moreover, cuts in health spending rapidly affect the primary care setting, with medical services increasingly shifting to this 'low-priced' primary care setting [23]. In order to further reduce health care costs, the role of general practitioners should incorporate action to lower health illiteracy by providing health information, preventive behaviour, and self-management techniques for patients. Such action represents 'low hanging

fruit' for cost savings, with health illiterate patients generally being more frequent users of health services and with lower levels of health than literate ones. With regard to patient-centeredness, it is feared that the dehumanisation of care through the growing application of computerised techniques and increasingly market-focused view of health have been fortified by the economic crisis with patients being regarded as costs to the health care system instead of human beings [24]. Indeed, there have been criticisms stating that contemporary health care systems and their adherence to market values and consumerism neglect patient-centred approaches which respect patient dignity and individuality irrespective of his/her "social or economic situation, personal characteristics or the nature of the health problem" [24].

Stimuli

Another possible reaction towards the economic downturn, which was employed by countries such as Sweden, Germany and Iceland, was the implementation of stimuli to strengthen social safety nets. According to the Keynesian approach, stimulus is the opposite of austerity [14; 17]. Unlike countries which were pressured to opt for austerity, countries enacting stimuli do not show an increase in adverse health effects [18; 25; 26]. A prominent example therein is Iceland, which, in relation to its economy, experienced the most severe banking crisis in history, nevertheless, health services quality remained stable. In two referenda, the population voted against austerity measures to favour a gradual pay off. The result was that the economy recovered without any decrease in health coverage or rise in suicides [14].

General policy responses

General health policy responses to the economic crisis have used arguments strongly advocating for health in order to prevent the health care system being adversely affected by cuts in spending or services [1]. Policy responses should aim at controlling costs instead of simply shifting costs or narrowing health coverage [27]. Schröder-Bäck et al. propose the use of ethical guidance in decision-making processes [28]. Apart from basing trade-offs on values such as solidarity, equity and justice, which might not be of sufficient help for particular decision-making, procedural justice should be integrated and emphasized as a tool in policy-making. Indeed, further tools and methods for analysing values and trade-offs ought to be framed and elaborated [29].

Consequences for health of the population

It remains difficult to assess health outcomes since research has been limited, and data is largely unavailable yet. In contrast to financial data, health and mortality records typically suffer a two-year time delay before effects are seen. This means that the full consequences of the (long-lasting) economic crisis are only likely to become measurable in the years to come [14; 15]. Existing findings on health impacts however are described below and where possible linked to attributing factors.

So far, unemployment was found to be a major factor impacting health levels [26; 30]. Even a 1% rise in the unemployment rate (of under the age of 65) correlates to a 0.79% increase in the number of suicides amongst the working age population [30]. In Greece and Ireland suicide rates rose dramatically, showing a 17% and 13% increase, respectively, with the highest rate seen in Greece for 30 years after renewed austerity measures were introduced in 2011 [20; 31; 32]. Moreover, sudden and vast increases in unemployment cause higher numbers of alcohol-related deaths [30]. Among the unemployed, mental health issues are also twice as prevalent as in employed persons (34% vs. 16%) [14; 15; 20]. Such declining health status due to unemployment can be directly linked to lower income levels or lack of health coverage, increasing difficulties faced in accessing health care services or affording a healthy and nutritious diet [2; 14; 30]. Interestingly however, lower levels of income have reduced the use of private vehicles due to increased gas prices, which has led to a reduction of traffic-related deaths [14; 30; 31]. Yet the crisis has seen the number of unmet medical and dental needs increase in tandem with poorer self-reported health levels [33]. In a view of previous research it is expected that countries which suffered fast socio-economic changes will show a decrease in life expectancy in the years to come [14]. Also, HIV infections increased substantially in many countries, e.g. in Greece from 15 to 484 between 2009 and 2012 [19]. Besides HIV, incidence of other infectious diseases was observed, e.g. outbreaks of the West Nile Virus and malaria in Greece during 2010 and 2011 [2]. Portugal also saw mortality rates related to influenza increase; a product of low temperatures and lack of heating capacities [34]. This rise in HIV infections can mainly be attributed to a rise of illicit drug users, spending cuts on street work programmes, and a reduced distribution of condoms and syringes to drug users [19; 20]. Additionally, child health was affected seriously; stillbirths for instance increased by 21% and infant mortality by 43% [15; 19]. This marks a reversal in otherwise stable or decreasing prevalence thereof.

When examining the impact of responses to the economic crisis on health, it was found that for each 100 USD increase in social welfare spending there was seven times greater mortality reduction compared to each 100 USD rise in GDP [1]. This implies that economic growth is not the primary determining factor of positive health outcomes per se. Rather, such outcomes depend on whether resources are distributed equally across the population [26]. Thus, investing in health by means of strengthening social safety nets may reduce the adverse effects of the economic crisis [1; 26; 35-37].

As regards taxation as an attributing factor for health outcomes, increased taxes on certain goods can lower the use of harmful substances, such as alcohol, tobacco, soft drinks, fast food chains, sweets etc. [15]. Conversely, decreasing taxes on health-promoting resources, and thus increasing the affordability of healthy food, can positively affect health [14; 30].

It should be kept in mind that the crisis' effects on health may not be perceived to the same extent by all parts of the population due to differences in socio-economic status [26; 35; 37]. Especially vulnerable populations such as the poor, the destitute, children, elderly, immigrants or those at risk of social exclusion will be affected most by the economic crisis and austerity policies. Such populations are particularly likely to suffer health deterioration when opportunities regarding employment, education, housing or health services are limited [22; 35; 38]. This suggests that health inequalities, both between and within countries, may grow. The widening gap in health inequalities might thus hide existent health consequences of more vulnerable populations which then rather remain hidden in statistics also encompassing the ones which are better off [30]. Also GDP, as the commonly used measurement for economic performance, does not take into account relevant factors for assessing economic instability e.g. inflation or unemployment [16]. In order to enhance the measurement of well-being, it is therefore proposed to include elements such as living standards and life expectancy, following approaches such as the Human Development Index [16; 39].

Discussion

The current literature available on the consequences of the economic crisis for European population health and health systems has shown that health outcomes are adversely affected. While it is a trivial statement to say that this is morally unfavourable, such a view is also supported by the CA. Drawing on the theory of CA in assessing health related outcomes of the economic crisis confirms that health – and in particular the capability for health – is essential for well-being and leading a good life. Health should therefore not be neglected during times of economic crises, and it should constitute a key component of policy-making instead.

The CA also highlights which social determinants of health are worsened by the economic crisis. In this context, the CA concentrates on the 'conversion' of capabilities into functionings. Speaking in terms of the CA, one can see that Keynesian economic stimuli generally open up opportunities which promote freedoms and capabilities to live a healthy life. Conversely, the implementation of austerity measures and cutbacks in health budgets limit opportunities and capabilities (for individuals of a population). From a CA point of view, there is a burden of proof (an obligation to provide verification) that reducing resources for health care, further deregulating the health care market and moving towards privatisation is actually ethically acceptable. Thus, it is not only crucial that sufficient capabilities should be guaranteed to everyone through the help of public policies, but also that the ability to make the right choices – choosing the option which benefits oneself – is ensured. The CA asks if everyone really can make choices which promote health (e.g. by using health care) and whether these choices are available only to those who can afford it or are health literate enough. Thus, one could also state from a CA perspective that everything diminishing health literacy is *prima facie* morally unfavourable, which would also bear the burden

of proof of being ethically acceptable. Since given 'choice' plays such an essential role in Sen's approach, the real opportunity for an informed choice is morally salient.

Austerity measures in the health and social sector affect especially vulnerable groups, depriving them of the opportunities they might have had if the austerity measures were not introduced. Fewer resources (i.e. means) reduce a person's conversion factor. Consequently, they are then less able to translate capabilities into real achievements (functionings). However, prioritising those in need is a notion the CA highlights, demanding support for those with the least capabilities given that these groups overall have the worst chances to achieve valuable functionings.

In contrast to measures of well-being which are solely based on macroeconomic indicators (such as GDP), where inequalities between and within populations remain unknown, Sen's CA helps to identify these inequalities and their underlying factors. Unemployment as a key determinant of health reduces capabilities (e.g. the ability to reach high ages and full life expectancy) through raising the prevalence of suicides, alcohol-related deaths and other diseases. Yet, ill health may also lead to unemployment. Thus, it is essential to provide continued health care access to unemployed patients in order to protect them from diminished income and further financial burden when losing their job due to illness. Moreover, cuts in social welfare spending as a whole were identified as limiting the capabilities of people to live a healthy life.

The lack of health promotion measures is critical from an ethical point of view in terms of the CA. Such lack most often detracts vulnerable groups of the population that would otherwise benefit from welfare and health programmes supporting healthy choices. However, it should be emphasized again that the CA is not inherently paternalistic – wanting everyone to necessarily opt for 'the healthy choice', rather having a real choice is supported. When deciding against the healthy choice, however, one has to live with the consequences. The CA purports that it is essential to be able to understand the consequences beforehand, not making the unhealthy choice simply due to a lack of knowledge or alternatives. In this respect, raising taxes on alcohol, tobacco and unhealthy foods is an ambiguous policy response. On the one hand it limits the opportunity to consume these goods, constraining the freedom to do and be what one values, on the other health-risky behaviour is contained and health is generally promoted. Therefore, an increase in taxation of tobacco could even be criticised from a CA point of view, at least Breton and Sherlaw [11] do so, arguing that persons have less choice to live a good life according to their individual preferences.

The ethical relevance of what has been termed 'dehumanisation of care' becomes clear when we focus again on the special role which self-respect plays within the CA. One may assume that fewer human encounters in the care setting will result from a shift away from (more costly) human interaction. Of course, there are many advantages of more 'automated care', besides saving costs. However, when 'dehumanisation of care' is introduced to save costs, the burden of proof for showing

that this is not undermining people's self-respect and dignity is on those proposing this way of care.

However, it is also possible to identify factors within policy responses which promote opportunities to gain good health and thereby foster freedom. These include investing in social welfare and particularly labour market programmes, for instance, the capability to have a job as a means to improved health may be facilitated with such investment. Furthermore, government contributions for the unemployed in order to support them are crucial, since they help retain the capabilities or functionings which are only achievable with monetary resources. The reduction of pharmaceutical prices is another policy response to the economic crisis which promotes capabilities by reducing the threshold to attain pharmaceuticals.

With regards to the choice of whether to enact austerity measures or not, Iceland can be drawn on as a capability-promoting example. During the crisis Iceland allowed its citizens to vote on austerity measures in two referenda. This political participation, which was exercised by many citizens and translated into a functioning, enabled them to choose a life according to their values. Austerity and deep cuts to the healthcare system were avoided, thus political participation can be identified as a distinct social determinant of health in this regard.

Taking the 'moral point of view' according to the CA reveals inconsistencies in action which are subject to a burden of proof of being morally justifiable. Germany, for example, followed a different policy approach imposed by the troika on other countries. Whilst other countries were forced into less healthy/ethically favourable austerity measures, Germany itself adhered, at least in some aspects, to a more Keynesian approach stimulating its own economy. Against the perspective of persons having equal worth in the European Union, this policy is at the very least ethically challenging, if not questionable. From an ethical point of view, there is, again, a burden of proof on such rationale which constitutes a seemingly inconsistent behaviour preferring (within a supra-national community) one's own population over others.

As is already demanded by others, further research is indispensable. The knowledge gap has to be closed with regard to both strengthening resilience to health threats (resulting from economic downturns), and to which policy responses can result in a reduction of risks [14; 16; 29; 31; 37]. The findings of this article are dependent on the contingent data available. It is obvious however, that action is necessary even if complete data is not available yet. Thus, it is suggested to act tutoristically instead of not acting at all.

Given the fact that austerity measures cannot be avoided in all cases, research is needed to ensure austerity measures in Europe are based on ethical foundations enabling values and norms to guide action and minimizing any negative impact on capabilities (and functionings) [40]. Apart from the identified elements mitigating the

effects of the economic crisis on health and health systems, other criteria should be taken into account for ethical guidance in dealing with shrinking health resources. As Stuckler & Basu [41] argue, the leading principle should be to 'do no harm'. Regarding the clear ethical normative imperative that harm is to be avoided, the CA offers a perspective to specify the broad notion of 'harm' according to more concrete criteria – namely the lack of capabilities spelled out by Sen. These criteria include dimensions of self-esteem and recognition which are rarely considered in debates about the economic crisis and its impact on health.

Conclusion

Existing literature about the effects of the economic crisis suggest that consequences for health and health systems are severe and that there are a myriad of associated problems. Concluding that a decrease in overall population health and health equity is morally unacceptable does not require extensive consideration of ethical theory – as it is a normative judgement widely shared, at least within the public health community. However, the CA, a theory at the interface of normative economic theories and ethics, offers a framework to highlight morally salient aspects in policy responses aiding ethical evaluation of policy options. The CA thus establishes areas for further ethical discussion aiming to increase awareness rather than offering an algorithm for solving health related consequences of the economic crisis. It demonstrates several cases where there is a shift in the burden of proof for justifying policy actions mandating public health and health science experts to go beyond considering the success of policies just in terms of the level and distribution of life expectancy, incidence and mortality rates. Instead the CA draws our attention to several normatively relevant aspects of health and the determinants of health which otherwise would not have been considered. Among these aspects is the major claim that the success of economic, political and health systems cannot be expressed solely in cumulative figures such as GDP. Instead, ethical judgements need to incorporate other information about the wellbeing of human beings at both the population and individual level.

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Chapter 3 Ethical issues in the current health crisis - Fritz
Jahr's Imperative and the current threat of austerity
measures for public health in the European Union

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Abstract

“Respect every living being in general as an end in itself and treat it, if possible, as such” is demanded by Fritz Jahr, who can be regarded as the founder of modern bioethics, coining the term in 1924. But is such respect safeguarded for everyone during times of economic crisis: when austerity measures affect human health and thus human lives profoundly, as recent research shows? Currently, aspects of the economic crisis and its impact on health are hardly discussed in the ethical literature. One exception is a consequentialist approach Stuckler et al. point out. They advocate the principle of ‘first do no harm’ as guiding ethical principle for the context of health and the economic crisis. Given the developing ethical analysis and the discussion of the economic crisis on health, this article is adding the deontological approach of Fritz Jahr’s account of bioethics to the debate. We argue that Jahr’s ethical principle with its emphasis on the intrinsic worth of human beings, compelling their treatment as an end and never as a means, is adding a meaningful dimension to the ethical evaluation of the effects the economic crisis and the troika’s policy response have on health. While ‘first do no harm’ focuses on a minimalist morality, Jahr’s Bioethical Imperative points more towards the positive value of creating benefits and the conditions for self-respect and dignity. Ultimately, Jahr’s concept offers helpful applications in assessing controversial issues on the level of health systems and public health both now and in the future.

Introduction – impacts of the economic and financial crisis on health

“Respect every living being in general as an end in itself and treat it, if possible, as such” is demanded by Fritz Jahr (1926, p. 21), who can be regarded as the founder of modern bioethics, coining the term in 1924. But is such respect safeguarded for everyone during times of economic crisis: when austerity measures affect human lives profoundly? The current economic and financial crisis of 2008 has affected countries worldwide: not only in terms of economic stability but also in terms of social arrangements. Striving for debt reduction and economic recovery, some governments have been required to implement austerity measures by the so-called troika – the International Monetary Fund, the European Central Bank and the European Commission. This approach – which is in line with neoliberal economics – emphasizes the role of free markets and limited government support. The contrary policy option is employing stimuli according to Keynesian economics, where the importance of government support is stressed even on the cost of states making new debts.

The different fiscal and economic policy approaches taken also have impacts upon public health. According to the available research on EU countries it has been shown that austerity measures bring about adverse impacts on the health of populations, diminishing the population’s resources to live a healthy life. Austerity also has direct effects on health care systems, through measures to reduce volume, quality, and costs of health care services (Karanikolos et al., 2013).

Further threats to health, besides the rationing of health care resources, are predominantly affecting population health. The impacts austerity has on the social determinants of health, e.g. (threat of) unemployment, loss of social cohesion, or decreasing incomes, have been shown to negatively affect the public’s health. Recent European research has identified an increase in suicide rates in Greece of 17%, especially among the working age population (Stuckler, Basu, Suhrcke, Coutts & McKee, 2011); higher numbers of alcohol-related deaths (Stuckler, Basu, Suhrcke, Coutts, & McKee, 2009); increases in mental health issues (Quaglio, Karapiperis, Van Woensel, Arnold & Mcdaid, 2013), HIV infections (Kentikelenis, Karanikolos, Reeves, McKee, & Stuckler 2014), and stillbirths and infant mortality (Quaglio et al., 2013). In a nutshell, austerity measures are perceived as a prominent threat to health.

To combat the threat austerity poses on health Stuckler and Basu (2013) formulated a bioethical imperative for policy makers: ‘first do no harm’ – a principle traditionally stemming from the clinical-medicine realm. By using this principle in the evaluation of health policy responses to the economic crisis, they point out three key aspects: firstly knowledge should be generated about the consequences of specific policy responses, with strict evaluation procedures being applied; secondly, trade-off choices should have a better information base; finally re-evaluation mechanisms should be introduced and health should be integrated in all policies. Stuckler is one of the main researchers and opinion leaders examining the consequences of the economic crisis on public health. He is also the first to explicitly introduce ethical

norms to public health discussions of the economic crisis. It is important therefore to assess this proposed normative guidance.

The imperative of 'first do no harm' is well known in medicine and is often conceived as being at the core of the medical ethos. Yet from an ethicist's point of view it remains questionable whether the imperative of 'first do no harm' is adequate as a tool to evaluate and/or guide policy making in public health. In order to fully grasp the ethical dimension of austerity as a threat to health and health systems, it is important to analyse the issue from other normative perspectives, i.e. applying other bioethical approaches and imperatives. By doing so, Jahr's approach to bioethics will be assessed.

In the following article the principle of 'first do no harm' will be contrasted against the bioethical approach proposed by Jahr, providing a theoretical lens through which to explore one of the biggest bioethical challenges in Europe: namely the issue that "austerity kills" (Stuckler & Basu, 2013). By discussing the 'first do no harm' principle and Jahr's Bioethical Imperative, we will juxtapose approaches stemming from the consequentialist realm with the deontological perspective respectively. Thereby, the development of bioethics and practicality of Jahr's account can be discussed. Examining the implications and meanings of these different norms and values, and contextualising them with other relevant ethical criteria, will help to critically reflect the economic crisis in a bioethical perspective.

'First do no harm' as a normative guide

'First do no harm' is a prominent ethical principle in medical ethics, closely related to, but not directly stemming from, the Hippocratic Oath (Jonsen, 1977). In modern bioethics this norm is reflected in the non-maleficence principle (Beauchamp & Childress, 2013). The principle can be understood and used in four different ways.

To begin with, 'first do no harm' forms an absolute principle aiming to improve health states (Jonsen, 1977); deliberately circumventing actions which impede or set back persons' interests (Beauchamp & Childress, 2013). Skills of a medical professional should thus be used solely for benefiting humans, not abusing them or refusing help to those in need.

The second understanding relates to adherence with standards of due care. For instance, truthful information and sharp reasoning generate better outcomes. In this use of the principle, morality becomes connected to conformity with law since non-adherence with standards of due care frequently bring about accusations of malpractice (Jonsen, 1977). Therefore in this respect conformity prevents risks of harm (Beauchamp & Childress, 2013). Yet it remains crucial to reassess the clinical and political reasoning behind standards of care, as research developments constantly evolve best practice. Also, the level of fallibility versus negligence of physicians or public health agents needs to be assessed (Jonsen, 1977). Negligence

can be defined as preventable intentional or unintentional behaviour which pose risks of harm. The distinction between withholding and withdrawing treatment is relevant clinically and with regards to governmental health decisions. On the first glance, withdrawing or stopping treatments seems to violate treatment opportunities and the hopes of patients and their families. However, withholding treatments or procedures has a higher burden of proof due to the uncertainty about outcomes when comparing to a treatment or procedure having been tested in use. According to Beauchamp and Childress (2013), the distinction between these two is blurred since in some cases withdrawing can include withholding, as e.g. in not recharging batteries of a pacemaker, and thus the distinction is also ethically invalid. In addition, they recommend running a trial phase, which means starting treatments with intermittent outcome re-evaluations. The distinction between killing and letting die, which is closely related to the act-omission division, is also of relevance in this regard. Whereas letting die refers to a natural death caused by the non-maleficent act of withdrawing or withholding medical devices (when non-supported normal biological functions bring about death), killing is a maleficent act where a person's actions cause death instead of natural conditions. In evaluating the ethical acceptability of an act of letting die or killing, the patient's consent is fundamental.

The third interpretation of 'first do no harm' is related to the analysis of risks and benefits of a specific medical procedure or policy option. When a treatment or procedure is futile or when the burdens do not outweigh the benefits, there is no prima facie obligation to conduct the treatment. While the health outcomes of such procedures or options are only predictable to a limited extent, and often include the possibility of harm, due care involves safety and risk-benefit analyses. These enable the physician to choose the appropriate treatment decision, as well as for the patient to understand and accept the risks of a certain treatment. The focus of this interpretation again lies within the autonomy of patients, and physicians' respect for that autonomy.

Fourthly the principle can be construed in another sense, similar to analysing risks and benefits, namely assessing the benefits against possible disadvantages or adverse effects. Disadvantages or harms should thus be balanced against the level of benefit generated by a certain procedure. Thereby, the principle denotes that unavoidable harm should only be done when the related benefit is greater. In medical procedures, the patient should maintain the autonomy to choose the treatment he or she prefers. Weighting is more difficult when more parties are involved and the benefits and harms are distributed unequally between the parties, as for instance in the allocation of scarce resources. Here, Jonsen (1977) pronounces that the rule of double effect applies. This rule asks under what conditions an action can be seen as morally good when it also causes harm. The intended and unintended effects of a treatment or policy have to be differentiated in order to carefully assess the moral character of an action. For an action to be justified four conditions have to be fulfilled: 1) the act itself as well as 2) the agent's intention must be good, 3) the good effect must not be

brought about by means of a bad action, 4) according to proportionality, the good consequence has to outweigh any bad effects (Beauchamp & Childress, 2013).

Fritz Jahr's Bioethical Imperative

In order to contrast a deontological perspective with the more consequentialist principle of Stuckler's 'first do no harm', Fritz Jahr's Bioethical Imperative will be introduced.

Fritz Jahr (1895-1953), a German Protestant pastor, used the Categorical Imperative proposed by Kant as the base for ethical risk-benefit evaluation. Jahr extended it in his Bioethical Imperative towards a broader responsibility for humans towards animals, plants and environments. He stated: "Respect every living being in general as an end in itself and treat it, if possible, as such" (Jahr, 1926, p. 21; cf Sass, 2013), implying that all social framework conditions have to be recognised and taken into account. In his 22 Essays, Jahr offers an integrated approach to bioethics by providing explanations of his imperative. In the following discussion, the ones most relevant for assessing health outcomes resulting from the economic crisis will be depicted.

Jahr describes bio-ethics as "the assumption of ethical responsibilities not only towards humans but towards all living beings", including animals and plants (Jahr, 1926, p. 17). Stating that it is immoral to destroy life, he refers to other scholars such as Schleiermacher, Herder or Krause. Yet, he concedes that although animals, plants and humans have equal rights, they do not possess identical rights since they differ in their 'destination' (Jahr, 1926). Therefore, Jahr proposes that every living being should be treated according to its "necessary requirement to reach their destination" (Jahr, 1926, p. 18). Accordingly, humans have higher requirements than animals, which in turn have higher requirements than plants. Jahr adds that the 'principle of struggle for life' is crucial in strengthening the moral responsibilities of human beings. Regarding other animals, Jahr sees their caring and empathetic treatment as a social responsibility equivalent with that of "towards oneself" (Jahr, 1928, p. 37). In order to carry out this moral responsibility, knowledge and understanding of animals and plants, as well as their surroundings, is needed. The necessity of this knowledge emphasizes education as a prerequisite for acting moral.

Central to Jahr's imperative is that every person has the duty to balance egoistic and altruistic behaviours and orientations. He links the duty of care with the ideal of love, an altruistic conduct. Applied in practice, this means supporting financially deprived persons, and engagement for society by means of social commitment (Jahr, 1929), irrespective of whether it will reiterate or not (Jahr, 1929, p. 57). In so doing the protection of social and economic settings is not only an altruistic interest but also an egoistic one.

Jahr furthermore points out the importance of reporting ethical issues in the daily press. Due to the wide-spread dissemination of newspapers and their influence, they serve as a shaper of public opinion. Reading newspapers is a way of 'character

formation' according to Jahr: they help persons to identify social responsibilities, since socially relevant aspects are highlighted.

In his essay about the fifth commandment 'you shall not kill', Jahr once more emphasizes the importance of the duty to behave morally 'good'. However, he indicates that the motive behind 'you shall not kill' is not love in all cases. He juxtaposes the commandment with Kant's Categorical Imperative: "act only according to the maxim whereby you can, at the same time, will that it should become a universal law" (Jahr, 1934, p.77): conceding that the underlying motive might also be egoism rather than love. Therefore, he suggests acting according to Schopenhauer's maxim "don't hurt anyone, but help everyone, as far as you possibly can" (Jahr, 1934, p.77). Therein, the duty of self-preservation and safeguarding other's lives remains emphasized. This moral duty towards oneself is specified by Jahr through: "not weakening one's health by unchastity, excess in eating and drinking, heavy anger, frivolous foolhardiness and daredevilry" (Jahr, 1934, p. 79).

Uncovering ethical issues in the current health crisis

As outlined above, the principle 'first do no harm' and Jahr's bioethical framework show certain parallels on the one hand, but on the other point towards different priorities. The main parallel between the two is that they both emphasize the importance of avoiding harm – as indicated in Jahr's remarks of 'you shall not kill' and 'don't hurt anyone'. A main difference however is that the maxim of 'first do no harm' solely focuses on acting non-maleficent, i.e. on 'don't hurt', whereas Jahr extends this towards a more beneficence-oriented guideline, encompassing the role of dignity of human beings and helping others as much as possible.

What the outlined principles and values above reveal about health in times of austerity will be tentatively analysed in the following subsections. This analysis will complement Stuckler's aspects derived from 'first do no harm' as outlined above, i.e. generating knowledge about consequences of specific policy responses, providing a better information basis for trade-offs and re-evaluating policy choices.

Assessing the economic crisis and health from the perspective of 'first do no harm'

Duty to not adversely affect public health by adhering to standards of due care

Given the broadness of the 'first do no harm' principle, the three specific aspects proposed by Stuckler & Basu (2013) seem rather incomplete. As such the principle may be relevant to several additional aspects of health in austerity. Foremost, policy-makers as moral agents should not endanger the population's health through implementing policies that adversely affect the public health setting, which can also be affected by policy-making in other sectors, as pointed out by the concept 'health in all policies' (Stahl, Wismar, Ollila, Lahtinen & Leppo, 2006). Policy makers should ensure policies benefit all individuals of the population instead of refusing due care to

the ones in need. The definition used here for persons in need are those suffering unemployment, limited access to health care services, and illnesses brought about by stress and unhealthy lifestyles. All of which are increased in times of economic hardship (Karanikolos et al., 2013). Thus, adhering to standards of due care and thereby preventing risks of harm, also proposed by Stuckler & Basu (2013), is central. Moreover, reassessing political reasoning and prominent ideologies, such as austerity, is emphasized. Failing to conduct re-evaluations, as well as blindly adhering to one policy stream can thus be categorized as negligence – a concept defined as immoral.

Assessing policy options according to their risks, adverse effects and benefits

Both Keynesian approaches and austerity measures should also be assessed regarding their risks and benefits. Here however, the concept of individual benefit, which is guiding in the principle of ‘first do no harm’, does not play a role in relation to the economic crisis. This is because social settings are given on the public level where choice on the individual level is limited. Thus policy options should be evaluated with regard to the adverse effects they bring about on a societal level. It is stated that unavoidable harm should only be done when the benefit is greater, which may not be the case in austerity measures. While the benefits of austerity are in the financial realm of reducing debts, the detriments lie on the social side where the health and well-being of individuals is affected. Weighing benefits against harms is even more difficult in assessing public health outcomes since several parties, namely different parts of the population with distinct social determinants, are involved. The benefits and harms are also distributed unequally, as access to resources are dependent on socio-economic status. This has been clearly demonstrated during the economic crisis: with resources for health care being limited in response to austerity measures leading to declining health statuses as outlined previously.

Intended and unintended effects of austerity measures

It is furthermore morally relevant to apply the rule of double effect to the consequences of the economic crisis on health in terms of its intended and unintended effects. The four conditions for the rule of double effect state (as elaborated above): that the act as well as the intention must be good, that there is a good effect without bad action, and that the good consequence outweighs bad effects. These cannot be fulfilled in the case of austerity measures since good effects cannot be achieved there are no good consequences in terms of public health. It has to be noted here, that means i.e. actions, are planned by the agent, whereas side effects are usually not. In relation to the economic crisis, side effects such as unemployment, bad health outcomes due to unaffordable healthy diets, or unhealthy stress-coping techniques (such as higher alcohol consumption or drug use) are unintended or indirectly tolerated, yet have a burden of proof of being morally acceptable.

Deficiency of acting nonmaleficent in times of crisis (and increased need for acting beneficent)

In relation to the economic crisis and health, austerity measures can be seen as being relevant to the principle of not harming others (nonmaleficence) instead of aiding others according to the principle of beneficence. Since welfare is regarded as a principle of beneficence, it remains questionable if Stuckler & Basu chose the right principle here. Especially given the fact that aiding people in attaining good health in times of crisis is morally relevant to a greater extent than solely attempting to not harm them.

Austerity measures as withholding 'treatment' and letting die

In times of economic downturn and austerity, public health needs to be protected by investing in health care systems, where the costs are seen as a potential disadvantage or 'harm' which are outweighed by the benefits. Choosing not to strengthen social safety nets and not introduce welfare programmes can be seen as withholding 'treatment'. This has a higher burden of proof of being morally acceptable as outcomes are uncertain and should have been assessed. A goal within the economic crisis and in future scenarios should be to test a policy option which invests in health first, then re-evaluate it after given periods and in case of unfavourable outcomes withdraw or change towards another policy option.

With regards to the distinction between letting die and killing, austerity measures may be seen as an act of letting die rather than killing. This is because conditions are caused by withholding or withdrawing resources for health and well-being instead of death being caused by a specific act causing death by unnatural conditions. One can conclude here, that Stuckler and Basu are not right when saying that 'austerity kills'.

The principle of 'first do no harm' gives some limited insights in how to respond to the economic crisis in terms of health, which are complemented by Jahr's Bioethical Imperative.

Aspects related to the economic crisis and health brought forward by Jahr's Bioethical Imperative

In Jahr's account of bioethics, additional important aspects relevant to ethics of the economic crisis are revealed.

Protecting the economic and social setting

Jahr explicitly stresses a focus directly on the economic and social setting or environment. According to him protecting social and economic circumstances is a moral duty (Jahr, 1929). He stresses specifically the implementation of "activities in social care, in particular the support of the economically weak, not taking into account

whether or not it will pay back” (Jahr, 1929, p.57). As outlined above two general policy responses to the economic crisis were either (1) to employ stimuli and government support compatible with the Keynesian framework or (2) to implement austerity measures so as to decrease governmental debts (neoliberal). Referring to Jahr, it becomes obvious to strengthen social safety nets in accordance with the Keynesian approach, which can be regarded as having altruistic, as well as egoistic interests (Jahr, 1929). This is also supported by evidence that has shown reductions in mortality due to increases in social welfare spending (Stuckler, Basu & McKee, 2010; Bezruchka, 2009; Marmot & Bell, 2009; Brand, Clemens & Michelsen, 2013). Similarly, health promoting policies such as raising taxes on alcohol, tobacco and fast foods can contribute to a healthy environment.

Public health advocacy, health literacy and self-respect

Jahr points out that newspapers should be obliged to report on the ethical consequences of the economic crisis, thereby shaping the moral character of their readers, enabling easier identification of their social responsibilities (Jahr, 1928). This is also proposed by Stuckler & McKee (2012) who stress that attention should be drawn to the consequences of austerity measures on health. They call for strong advocacy towards health needs so that public health budgets can be preserved and cuts in spending or services can be prevented (Stuckler, Basu, & McKee, 2010).

In line with this, Jahr also emphasises self-education as a prerequisite for acting morally. In times of economic crisis and austerity, health literacy about healthy lifestyles is important so as to avoid unhealthy habits. According to him healthy behaviour is a moral duty and adverse behaviours such as “excess in eating and drinking” or “taking one’s own life” (Jahr, 1934, p.79) – habits which frequently occur during times of economic hardship – are morally wrong. Indeed, self-preservation and self-respect are central values in his Bioethical Imperative, and can be seen as a guiding principle in dealing with the economic crisis. By extending this towards safeguarding others health (“help everyone, as far as you can” Jahr, 1934, p.77), Jahr denotes that caring for others is a responsibility also “towards oneself” (Jahr, 1928, p. 37).

Equality of opportunity and dignity

The request that every living being should be treated according to its “necessary requirement to reach their destination” (Jahr, 1926, p. 18) can be regarded as of key relevance to health in the economic crisis since resources for reaching ‘destinations’ are scarce. Here, the concept of necessities is used, denoting that in times of crisis, vital needs have to be ensured, which is also in line with the capability approach of justice (Robeyns, 2005). An example of vital health needs in times of economic crisis would be ensuring complete access to health care. This is limited in most countries in the European Union due to reductions in care contribution levels, volume and quality of care, and increases in costs of care. Policy responses such as raising user charges for health care services have further decreased access to health services, especially

for low-income and frequent users (which are also normally the ones in most need) (Karanikolos et al, 2013; Kentikelenis et al., 2014). From Jahr's perspective, this is morally invalid.

For some the 'struggle for life' is a suitable description of life during economic downturns. Jahr stresses that this 'struggle for life' also brings about moral responsibilities for other human beings, by stating that it "can be regulated largely in justice and fairness" (Jahr, 1929, p.56). Governing such situations with neoliberal policies of austerity however, does not support just and fair social environments. On the contrary, privatisation and higher user charges limit access to health care services. Austerity also results in reductions in salaries for health professionals which in turn hinders health professionals to act according to their medical ethos; helping anyone in need even when they are not paid.

Similarly supporting financially deprived persons and encouraging the social engagement of society according to the "ideal of love" (Jahr, 1929, p.57) is proposed by Jahr, who stresses the importance of dignity of human beings.

Importance of beneficence in safeguarding health during economic crises

Referring to the identified aspects above, one could see that Jahr's Bioethical Imperative is a more beneficence-oriented guideline, encompassing the role of dignity and maximising help for others. Accordingly, in order to safeguard health during economic crises Jahr's principle of not hurting anyone, but helping everyone, as far as one possibly can is key (Jahr, 1934). Additionally, promoting welfare can be categorized as a principle of beneficence, meaning that in order to act morally 'right' in times of crisis has more to it than to just 'do no harm'. Instead health-promoting policies should be actively encouraged.

Criteria added by Jahr's account of bioethics to the 'first do no harm' principle

Adding deontological approaches such as Fritz Jahr's account of bioethics emphasizes the intrinsic worth of human beings, compelling their treatment as an end and never as a means. This principle can also function as a justification for capabilities, highlighting the importance of equal worth. Relevant criteria brought forward by this are self-respect and the dignity of human beings. These two criteria are also of special relevance for public health, particularly with their erosion during the economic crisis. Thus Jahr brings in a Kantian perspective – also suggested as normative guidance by current analysts of the crises (Brunkhorst, 2014) – that reminds us to not use people for the benefit of others. However, if the troika imposes austerity on some (southern European) states this seems to currently benefit only other (northern European) states. While 'first do no harm' focuses on a minimalist morality (Beauchamp & Childress, 2013), Jahr's Bioethical Imperative points more towards the positive value of creating benefits and the conditions for self-respect and dignity.

Conclusion

The consequentialist norm 'first do no harm', a core value for health scientists, has some normatively relevant impacts when evaluating the fiscal policies employed during the current economic crisis. The principle however gives little specific direction; rather serving as a reminder for acting with humility. However, when juxtaposed with a deontological approach, the evaluation becomes helpful in pointing out further ethical challenges which align with integrative bioethics. Jahr's concept of bioethics helped to identify other relevant ethical criteria – such as dignity, self-respect and respect for others – and detect further dilemmas for public health emerging during an economic crisis where applying a 'first do no harm' approach is insufficient. Ultimately, Jahr's concept offers helpful applications in assessing controversial issues on the level of health systems and public health both now and in the future.

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Part 2: Pharmaceutical innovation and research

Chapter 4 Personalised medicine and scarce resources:
A discussion of ethical chances and challenges from
the perspective of the capability approach

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Abstract

In the aftermath of the economic crisis that started in 2008, resources have become scarcer than ever in some countries, also in health care. Priority setting and rationalisation of existing resources also affect pharmaceutical innovations, including those that would contribute to what is called personalised medicine. In this paper, we will highlight the ethical issues surrounding rationalisation and its impact on personalised medicine through the lens of the capability approach. Thereby, challenges to and opportunities for personalised medicine will be examined, assessing how they affect patients' 'real options' to access innovative therapies. In our focus on the 'first challenge: citizens and patients' of the so-called Strategic Research and Innovation Agenda, the strength of the capability approach becomes particularly apparent in identifying what different values are at stake in this context.

Introduction

In the aftermath of the economic crisis of 2008, resources have become scarcer than ever in some countries, also in health care. Besides the impact of austerity policies in various European countries on general health care service provision (as e.g. in Greece [1]), priority setting and rationalisation of existing resources furthermore affect the development and implementation of pharmaceutical innovations - as, for instance, the promising concept of personalised medicine. Personalised medicine has been hailed as a strategy to achieve the key goal of medicine: to provide the right person with the right care at the right time [2]. However, there is no common definition of personalised medicine yet, and there is a dispute about what should actually be understood by the term 'personalised medicine' [3]. While this already exemplifies an ethically relevant discourse about the promise and reality of personalised medicine and the inclusion of a person's values and ideas in the course of treatment, we refer to the definition by the European Commission's Horizon 2020 Advisory Group [4], which states: 'Personalised Medicine refers to a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention'. Accordingly, improvements in patient care are realised by optimising care for the individual by choosing the most promising therapy and to eliminate futile therapies including side effects on the basis of genetic and molecular knowledge about the patient.

Additionally, it is becoming more and more apparent that the wide field of personalised medicine is increasingly divided into two strands, namely stratified medicine on the one hand and personalised medicine on the other. While stratified medicine labels the approach that defines certain subpopulations at the cohort level according to shared biomarkers, personalised medicine aims to focus on the individual patient 'using omics and related technologies (e.g. imaging) and based on computer models and simulations' [5]. Combining omics and technologies such as imaging is expected to achieve the greatest potential for personalised medicine [5,6].

The innovative concept of personalised medicine is expected to offer several advantages over conventional therapy. Early diagnosis, prevention, and thus safety and quality for the patient are anticipated to be improved [7]. These changes also denote a paradigm shift in medicine [8] from a 'one-size-fits-all', top-down approach towards an 'individualised' bottom-up approach. This approach would also, as some argue, need to include 'big data analytics of personal data in which the effects of a particular treatment protocol and prevention strategies can be assessed based on distinct diagnostic parameters' [5].

It remains questionable in how far such an innovation, which is often deemed to be a costly treatment [9], is affected by the current climate of austerity and scarcity of available resources. Among the questions that arise in this context of scarce

resources and pharmaceutical innovation is the following: under what conditions are new investments justifiable? Especially when investments are high and outcomes are still indeterminate to some extent, there is great uncertainty about what to do and whether it is morally right to invest in these kinds of innovation. This ambiguity is even exacerbated when a therapeutic innovation only benefits few people (i.e. only those with fitting genetic biomarkers or profiles). However, it has been stated that by individualising care, health care systems will be more sustainable, since wasting will be reduced by cutting unnecessary treatment costs via genetic profiling [10]. Beyond its use in cancer therapy - a field in which personalised medicine pioneered [7] - personalised medicine can also be applied to therapies for other diseases. However, a cancer prevalence of 14 million cases worldwide for all types of cancer as well as related costs of treatment of 5% of total expenditure on health in 2012 already show the magnitude of cancer treatment expenses [11,12].

In general, the accomplishment of personalised medicine is hindered by several factors: the fragmentation of efforts on an international scale, differing national regulations, a non-universal definition and evidence base for personalised medicine, and a wide spectrum of stakeholders, just to name a few [5].

In this paper, we will highlight the ethical issues surrounding scarce resources and rationalisation and their impact on personalised medicine by taking three different stances: we will shortly assess the development from a utilitarian point of view, followed by a libertarian perspective - two theories that traditionally span the spectrum of normative-ethical theories - and finally and mainly through the lens of the capability approach (CA) by Sen [13], which holds the potential to cover the normative blind spots of the other theoretical perspectives. In doing so, we will examine the ethical implications of the challenges to and opportunities for personalised medicine, thereby identifying what different values additionally are at stake in this regard.

Ethical chances and challenges resulting from scarce resources: Utilitarian and libertarian perspectives

Various questions expressing ethical concern have emerged in the last years with regard to the fair use and implementation of personalised medicine. McGowan et al. [14] identified four main categories of ethical concern as regards personalised medicine in an extensive interview study with 117 experts from all stakeholder groups in the field of personalised medicine. These categories included the topics of (1) difficulties in reaching informed consent on clinical cancer genomic testing, (2) ensuring privacy and the confidentiality of genomic test results, (3) safeguarding access to genomic testing and therapies, and (4) the costs of rising personalised cancer therapies.

As the latter two issues have not been dealt with to the same extent as the former two, and in view of the as yet unclear consequences of the economic crisis of 2008 on the

development and implementation of personalised medicine, we will in the following specifically assess the issues of access (topic 3) and costs (topic 4). Which chances and challenges did the circumstances of strict austerity in some countries bring to personalised medicine?

As Caplan [15] stated, an ethical infrastructure for implementing personalised medicine is much needed. Therefore, the different aforementioned theoretical perspectives will be applied in order to highlight the ethical issues at stake. The utilitarian approach is often seen as being the most relevant to questions concerning public health, so that Powers and Faden [16] even call it the 'standard view', since it focusses on best outcomes and efficiency. The libertarian approach, on the other hand, represents the conventional free-market view, demanding no regulation from governments - or at least as little as possible - but liberal and competitive markets. With both approaches, a normative spectrum is covered and controversial ethical issues can be identified.

The utilitarian point of view presents the maxim of choosing the action which results in maximal utility for the greatest number of people [17]. With regard to personalised medicine, the utilitarian view holds that large investments in new therapies should be avoided when opportunity costs are incurred and/or when there is uncertainty about the beneficiaries of the investments. Opportunity costs refer to the forgone options to invest in more conservative treatments, treatments that benefit more people in the short run or treatments or care arrangements for other conditions than cancer, such as for instance mental health or elderly care [18]. With regard to the last, the question arises whether it is ethically justifiable to invest in personalised medicine or whether existing resources should rather be allocated to other developments in the health care sector. A utilitarian perspective - prima facie - could support cheaper one-size-fits-all therapies instead of personalised medicine, assuming that (for the time being) this is more efficient, so that the maximum number of individuals can access - and, if possible, also benefit from - those therapies, even if there remain some people who are not or only suboptimally treated. Therefore, the focus of a utilitarian perspective is more on investing in treatments for common diseases and not for 'rare diseases' or cures that require rare genotypes, as those do not yield a benefit for the maximum number of people within a foreseeable time.

In contrast to the utilitarian perspective, libertarianism highlights individual liberty and demands that there be as few constraints to individuals as possible, no matter what the (population health) outcome of this will be. This would also lead to a more radical free market, which again implies freedom for industry to make the investments they deem promising - mostly in the sense of making profits. For libertarians, purchasing goods is an individual matter; the market regulates the price, and access to goods is an individual issue, not a social responsibility. In this context, all regulatory interventions by the state have a high burden of proof of being justifiable, so that a free market with competitive characteristics is ensured. Moreover, the libertarian perspective is critical of government subsidies - which stem from tax money - for

research done by industry, since market-oriented competition should not be interfered with and new developments should be led by industry.

Unlike the two approaches just briefly introduced, the CA embraces the plausible norm of focusing on equality of opportunity, but in this case even from a more special perspective. The question asked is the following: how do new approaches based on personalised medicine affect patients' 'real options' to benefit from innovative therapies?

The capability approach

The CA was termed by Amartya Sen in the 1980s and is seen to be relevant to the moral assessment of social arrangements. It can thus be used as a normative framework for analysing and evaluating individual and population well-being and the respective social developments and policies on the basis of how they affect people's 'capabilities' to achieve a life they have reason to value [13,19,20]. Capabilities are understood as all the potential 'real' options that a person can choose from in order to lead a good life and therefore achieve a good quality of life [19]. Therefore, capabilities are also termed 'real opportunities' or '(positive) freedoms'. The traditional economic metrics for measuring human progress (as e.g. growth in GDP per capita) are thus widened with the CA, which captures progress or development as an increase in real opportunities.

Sen argues that it is morally relevant to assess what people can really do with the goods or options they receive (considering their personal circumstances), placing a special focus on potential outcomes (i.e. what an individual can realise with the goods he or she receives). Realising a certain capability is thus termed an 'achievement' or 'functioning' according to Sen [13]. People can thus attain a specific set of 'functionings' chosen from real options (or capabilities) on the basis of their own personal values.

Noteworthy in this approach is that it is essential that people have the choice of whether or not to make use of their capabilities. The example of a fasting and a starving person elucidates the value of choice in this regard; they might be in a similar physical state with respect to their nutrition and health levels, but one can eat but chooses not to do so, whereas the other has no freedom to make this choice.

In Sen's view, choices must be fully informed, deliberate, and consciously made decisions. The value of real freedom (perceived as a real opportunity) to achieve a good life also becomes particularly important in this approach [21].

Besides the distinction between capabilities (freedoms and options to choose from) and functionings (achieved outcomes), Sen bases the CA on another distinction, namely between 'means' and 'ends'. While means signify the requirements to reach ends and are instrumental in attaining certain ends, ends are valuable in themselves, and as such are central to the CA when assessing pharmaceutical innovation in view of

scarce resources. However, in some cases there are no strict lines of demarcation between means and ends, as capabilities can also be ends as well as means to other capabilities. For example, being healthy is an end as well as a means of being able to work [13]. Given human diversity, means such as income to different degrees enable people to either develop valuable capabilities (opportunities) or transform them into functionings (achievements). The ability to transform means into functionings - if valued - is described by the term 'conversion factor' [22]. By placing a special focus on the ends and simultaneously assessing the means, it is possible to examine the extent to which people's situations influence their ability to realise pursued ends [22].

Within the context of scarce resources and the impact on personalised medicine, the CA can be used to test whether resources (or means) to reach good health exist. In a basic sense, this would imply, for instance, access to fresh water, adequate food supplies and medical care, a basic understanding and knowledge of health-related matters, protection mechanisms from infectious diseases or other illnesses, and preservation of human dignity [19,23]. In terms of personalised medicine, the resources and means would, for instance, be access to personalised therapies through insurance coverage or sufficient income, understanding genomic information, and possessing the decision-making capacity to choose the 'right' therapy.

Factors influencing these capabilities range from economic and financial resources to social structures, institutions and norms, traditions, and political practices [13]. Social and political structures can also be a key influence regarding inequalities between different social groups. In addition, personal dispositions, preferences, and differences in access to resources, institutional arrangements, as well as genomic disparities can be sources of inequality [24]. Nussbaum [25] adds in her extension of the CA that the question of how many resources one has to have in order for these resources to be considered 'sufficient' from a moral point of view depends on the resources and capabilities that exist in society. Thus, the real-world application of this approach subsumes a social relativist perspective [22]. It is important to note that neither does this conception of justice demand total redistribution (as Rawls' request for an equal distribution of goods or the utilitarian position would do), nor is it indifferent to 'brute luck' (as a libertarian position would be). Rather, it requires a sufficient level of capabilities (according to social relativism).

Notably, capabilities also require the personal responsibility to act reasonably [26,27]. In terms of health, this personal responsibility denotes a person's capability to influence his or her health status positively. In order to be able to act in a self-responsible manner, one has to be empowered or enabled to do so (e.g. by being offered health education, access to medical care, etc.) [27]. Here, Sen's approach offers a wider perspective than many liberal theories of justice (such as Rawlsian theories) that consider the distribution of and access to goods instead of asking what people can do with these goods, what they are really enabled to do with them, and to what extent these goods can really affect their capabilities. Along these lines, application of the CA allows the identification of certain issues having arisen in the

wake of scarce resources that influence the application of personalised medicine. In this respect, the CA can help to clarify which goals should be prioritised in improving functionings with regard to personalised medicine [28].

Figure 4.1 aims to visualise the CA in the context of personalised medicine and scarce resources. It draws attention to the individual capability set, which is based on the available goods, services, and conversion factors, which can then be transformed into functionings, namely good health. The context which shapes an individual's capability set is determined by policy making - which, however, has to adapt to the overall social context. Since the economic crisis of 2008, the societal context of scarce resources has challenged even formerly well-resourced social systems of Western states, not only by its severe short-term effects but also by lasting long-term consequences that need to be dealt with, also in health care.

The Capability Approach and Personalised Medicine

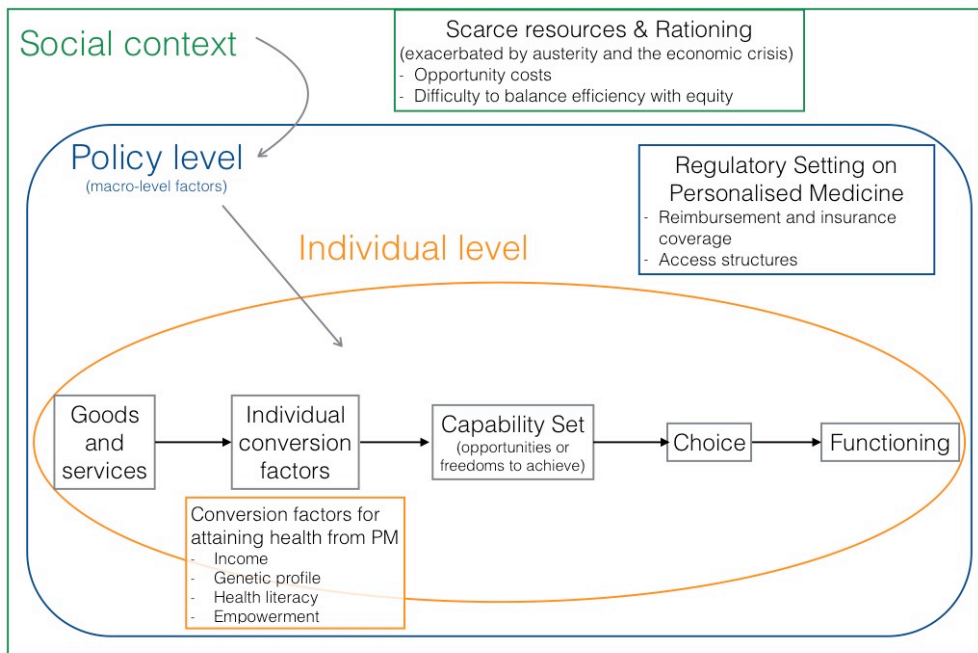


Figure 4.1: The capability approach and personalised medicine. Framework adapted from Robeyns [22] and Arndt and Volkert [36]. PM = Personalised medicine.

Having outlined the main features of the CA, we will now highlight the chances, issues, and challenges regarding personalised medicine from the CA angle.

Chances and challenges regarding personalised medicine from the CA perspective

At first glance, it may seem that in times of scarce resources and rationalisation personalised medicine is facing more challenges than chances when assessing it from the CA perspective, because the opportunity to attain those treatments is reduced due to a lack of resources.

Applying the CA point of view elucidates that financial means are crucial in obtaining personalised treatment, especially when social arrangements are established in such a way that insurances do not cover the costs of personalised medicine - which is the case in many countries in this as yet relatively unregulated field [5,29]. An individual's conversion factor (and hence ability to realise health by undertaking the sought treatment) is thus higher when he or she has more means in terms of money to spend on the treatment. The money to spend on the treatment is accordingly more than a means, but can ultimately be regarded as an end to receive personalised treatment. In other words, money is a prerequisite to realising personalised treatment. When taking into account the means-ends distinction, it furthermore becomes apparent that treatment can also be viewed either as a means to an end - the way by which the goal of better health can be realised - or as an end in itself, when receiving the treatment is already regarded as the end despite unclear health outcomes. Especially those would regard it as an end in itself who wish to pursue personalised medicine even when their genetic biomarkers do not match.

The fact that treatment can be received based on one's financial capability correspondingly leads to the ethical imperative - from the CA perspective - of enabling access to available and auspicious therapies. From the normative point of view, everyone who can benefit from the treatment thus should have the possibility to access and retrieve it, whatever the costs may be. The focus therein should obviously not lie on an individual's financial capability to pay for personalised treatments, but on the social arrangements - the reimbursement schemes - for enabling access.

Related to the costs of treatment is the issue of value-based pricing for personalised or precision pharmaceuticals. As regulations regarding prices and reimbursements have so far been largely uncoordinated [29], pharmaceutical companies mainly determine the prices themselves. In the German context, for instance, the Pharmaceutical Market Restructuring Act (AMNOG) was effected in 2011 with the purpose to control costs. It sets forth that pharmaceutical manufacturers can determine prices solely for 1 year; after that, price negotiations between insurers and manufacturers are possible, which on average yield results of a 10% lowering of prices [30]. However, in many cases the additional benefit from new therapies is not clear, and challenges occur from demonstrating the value of precision therapies [10]. From a moral utilitarian perspective, one can state that asking for higher prices although an additional benefit is not clear has a high burden of proof of being justifiable. The libertarian perspective, however, sees asking for higher prices as being justifiable and solely requests that information about the additional benefit be

elucidated in a transparent manner. From the CA perspective, however, requesting prices which go beyond their value in accordance to the costs of research, development, production, and marketing plus a reasonable profit margin limits individuals' conversion factors to transform capabilities regarding available therapies into the functioning of receiving these treatments due to several factors and initial situations in an unacceptable manner: if reimbursement schemes do not exist - as is the case in several countries - individuals have to pay for the therapies out of their own pocket. In this case, the conversion factor with regard to turning existing therapies into receiving them is limited, since the majority of people cannot pay those high prices themselves; it would again depend on the financial capability of individuals. If treatments are paid by insurances, capabilities are created and individuals can receive the treatment and ultimately attain better health levels. In this case, however, attention has to be paid to the long-term consequences of exorbitant prices for health systems. In times of scarce resources, such high prices are a high burden for social health care systems and might even result in exhaustion of public resources. From the position of the CA, one would argue that everything diminishing the state's capacity to enable opportunities for receiving treatments is morally ambiguous. Hence, pharmaceutical companies asking for prices which are beyond a reasonable profit margin for pharmaceuticals pose a challenge to health care systems in ensuring reimbursement schemes for - and thus opportunities for accessing - personalised medicine. From the moral perspective of the CA, demanding higher prices with no clear indication of an additional benefit is unjustifiable because capabilities are reduced.

The concern of value for money was also identified during a qualitative public deliberation study by Bombard et al. [31]. The study moreover showed that citizens are concerned about whether access to treatment is limited by the application of preliminary genetic tests [31]. They expressed the fear that genetic tests - which check an individual's genetic suitability for a particular personalised therapy - might be used to rationalise care. Their opinion was that all treatments should be made available if patients requested it. From the CA perspective, such genetic tests can indeed be seen as limiting a patient's capability to obtain cure. On the other hand, however, can a capability be limited if a patient - assuming that the genetic test is negative and provides correct results - does not have the conversion factor, namely the genetic biomarkers, to turn the capability (of obtaining the treatment) into a functioning (being cured)? Drawing a conclusion while taking into account the perspective of the CA, it may be stated that a capability cannot be limited if an individual cannot convert it into a functioning. Thus, it is justifiable not to offer a type of targeted therapy if the genetic profile does not match and the drugs do not evoke any response. When the drug responsiveness - or, more fittingly, non-responsiveness - is also clinically proven in a thorough way, it should be socially accepted that only individuals with a fitting profile receive those drugs. This would also be in line with scarce resources and fair allocation, so that only those will receive these drugs who can really benefit from them. In contrast to the utilitarian approach, which tends

towards 'one size fits all', the CA therefore proposes the use of drugs made suitable according to genetic biomarkers and hence the fair allocation of existing medical resources. Fair and reasonable allocation of resources can thus be seen as a chance when unnecessary costs are controlled.

At the research level, this fair allocation of resources moreover needs to be ensured, for instance by appropriate funding of research progress, so that also diseases which have so far not been the focus of research or which are labelled as orphan diseases receive funding, so as to advance drug research and development in these fields as well. Being in line with the CA, advances in orphan diseases should aim to create capabilities - new treatments - for these conditions as well.

Moreover, the CA might offer help in view of the abovementioned challenge of opportunity costs [18]: costs can be saved by providing personalised treatment only to those patients who can obtain a benefit according to their genetic profile. These saved costs can hence be invested wisely in other areas of health care. From the CA point of view, it is primarily important to provide the goods and services from which 'basic' capabilities can be formed. These basic capabilities are defined as the 'freedom to do some basic things that are necessary for survival and to avoid or escape poverty' [32,33]. In the health care context, specific measures in this regard are safeguarding appropriate nutrition and basic health care provision. Secondly, the saved costs should be invested in the best care possible to cure diseases and facilitate survival. According to Nussbaum's version [25], the CA holds a sufficiency account, meaning that distributive justice should be arranged in such a way that everyone has enough instead of adjusting and levelling up inequalities. In terms of personalised medicine, novel therapies can certainly be categorised as the best care possible to cure diseases, but they might even become necessary for survival and obtain their legitimacy of being invested in from this.

With regard to investing resources in other sectors, it is wise to focus on realising a set of capabilities. As Sen proposes, those capabilities should be 'co-realizable' [32]. In terms of personalised medicine, opportunity costs could occur when decisions are made to either invest in (a) more conservative treatments, (b) treatments that benefit more people in the short run, and (c) treatments or care arrangements for other conditions than cancer, for instance mental health or elderly care. The CA could help in investigating which set of co-realizable capabilities yields the best results for people to realise a life according to their goals and achieve a good quality of life. An in-depth analysis in this regard, however, goes beyond this brief outline of issues at stake.

In addition to the ethical issues occurring during the development and implementation of personalised medicine - which were predominantly identified when applying the CA - other challenges to innovations in personalised medicine regarding diagnosis, therapy, prevention, and information communication technology were identified during stakeholder dialogue platforms and meetings and stated in the Strategic Research

and Innovation Agenda (SRIA) [5]. In our focus on the 'first challenge: citizens and patients', more issues at the individual level become evident.

A challenge of key relevance is to develop awareness and empowerment among citizens and patients. According to the SRIA, this should be achieved by increasing public engagement through enabling citizens to get actively involved in research and the development of personalised treatments. This proposal is in line with the CA, since it emphasises one of its core features: empowerment as a main element of choosing the life one values. According to the CA, empowerment can therefore be regarded as a chance to improve the implementation of personalised medicine.

Besides empowering citizens and patients, the SRIA furthermore recommends the empowerment of health care professionals, which is a key element with regard to personalised medicine. Given the fact that new treatments enter the market and treatment outcomes become more complex due to genetic variance and complexity [34], capabilities must also be offered to health care professionals to improve their understanding of these therapies. Moreover, this can improve patients' capability of accessing personalised therapies, since health care professionals can offer better advice and guidance.

Another challenge to be met is the development of more responsibility with regard to health data, not only with patients but also with researchers, industry, and policy makers. Here, the role of the personal responsibility to act reasonably, which is inherent in the CA, is emphasised.

Having outlined the chances and challenges regarding personalised medicine from a CA point of view, we will highlight the added value of the CA in assessing the development of such innovative therapies in the next section.

The added value of the CA in view of personalised medicine

The CA as a concept focussing on equal opportunities can be regarded as a useful method of exploring normative dimensions of patients' access to personalised medicine in times of scarce resources, since the inherent emphasis of the CA on the role of patients is an added value to existing approaches in evaluating innovations in medicine. Utilitarianism, as an outcome-based theory, stresses the importance of achieved functionings and assesses whether the maximum number of people are able to receive personalised treatment - irrespective of an equal distribution of actual health benefits or the value of equality of opportunity, however. In the libertarian concept, as the other dominant ideological moral perspective, the role of 'brute luck' with regard to personalised medicine becomes prevalent: those who can afford personalised medicine and who can benefit from these treatments are lucky - the others, who cannot afford effective personalised treatments or for whom no personalised treatments are developed (because their condition is too rare), are unlucky. Despite

their unluckiness, libertarians would claim that there is no moral demand on social structures to compensate for their situation or invest in their health.

The CA added an important feature to the predominant perspectives of utilitarianism and libertarianism, namely the importance of individual and societal freedoms or opportunities, and especially the significance of the conversion factor of genetic profiles for receiving personalised medicine. It adds to the existing approaches the principle of focussing on equality of opportunity with regard to receiving personalised medicine - a value not addressed by either utilitarianism or libertarianism - and even extends it to how personalised medicine affects patients' 'real options' to benefit from such treatments: when applied to personalised medicine, the CA specifies that only individuals with corresponding genetic biomarkers are able to achieve a 'real benefit' from personalised treatments. In terms of scarcity of resources, it can thus be regarded as efficient to only offer treatment to those who can benefit and thus attain better health from personalised medicine, and to reduce the expenses of futile treatments for persons who do not possess matching genetic biomarkers. Conversely, questions are raised about autonomy on the one hand and real benefit on the other when a person without matching biomarkers cannot receive treatment even if he or she wishes to receive it. From the perspective of the CA, however, 'rationalising' treatments by only offering them to those who can benefit is morally legitimate. Instead of causing inequality or social injustice, introducing the conversion factor as a key prerequisite to benefitting from personalised medicine shows, from an ethical perspective, what aspects could be taken into account when developing equitable structures.

By applying the CA, also issues at stake for an increased use and implementation of personalised medicine become clear and could advise policymakers on which areas to focus upon - and maybe even about investing in personalised medicine. Accordingly, everything that facilitates the conversion of existing personalised medicine therapies into a capability set - the opportunity to make use of these therapies, if wished for - should be furthered. As previously mentioned, practical examples are improving patients' financial opportunities to receive personalised medicine by reimbursement structures that cover the treatments or regulating prices of pharmaceutical companies by means of benefit assessments as shown in Germany. Moreover, engaging in literacy and empowerment is key from a CA point of view, since ensuring knowledge and understanding as a basis for making the right choices promotes the freedom and capability of living a healthy life.

Genetic profiles constitute the only conversion factor that cannot be changed or influenced by social arrangements. Social arrangements in this regard can only help to promote research on personalised medicines and their development, in that a broad spectrum of research foci is covered and treatments for different types of disease may be developed. Here, again, the added value of the CA, as opposed to the ideological perspectives of libertarianism and utilitarianism, is noteworthy.

Conclusions

As outlined above, the chances of personalised medicine become more apparent. One of the advantages of using an approach such as the CA lies in the possibility to delineate chances, since it operationalises relevant theoretically developed variables for use in practice, as has also been proven when it was used in the Human Development Index (as part of such a renowned project as the Human Development Report, which is published annually by the United Nations Development Programme). Another advantage of the CA is that it not only assesses the distribution of goods or population health on an aggregate level but also shifts 'attention from goods to what goods do to human beings' [35].

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Chapter 5 Research Ethics 2.0 – New perspectives on norms, values and integrity in genomic research in times of even scarcer resources

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Abstract

Research ethics anew gained importance due to the changing scientific landscape and increasing demands and competition in the academic field. These changes are further exaggerated because of scarce(r) resources in some countries on the one hand and advances in genomics on the other. In this paper, we will highlight the current challenges thereof to scientific integrity. To mark key developments in research ethics, we will distinguish between what we call research ethics 1.0 and research ethics 2.0. Whereas research ethics 1.0 focuses on individual integrity and informed consent, research ethics 2.0 entails social scientific integrity within a broader perspective of a research network. This research network can be regarded as a network of responsibilities in which every stakeholder involved has to jointly meet the ethical challenges posed to research.

Introduction

Scarce resources and limited funding opportunities resulting from the global economic crisis are recently posing various challenges to research. Ethical conduct was anew in the spotlight, yet existing approaches to research ethics failed to frame these challenges so far. It is widely accepted that researchers have an obligation towards their fellow researchers in providing accurate and reliable research. Fabricating, misrepresenting or falsifying data not only reflects on the individual researcher or research group condoning these practices. It can influence results of other research and in the end infest policy and people's lives. Holding on to norms like knowledge, truth, and avoidance of error are necessary conditions for reliable and trustworthy interpersonal collaboration and reflect the social responsibility inherent in research. Incidents, which highlighted in how far ethics is crucial in research, have been exemplified during events in the 20th century, such as the Tuskegee study or research studies during the Nazi regime. Thereafter, the integrity of scientists was considered to be of key importance. Since then, principles stated in the Belmont Report [1] - respect for persons, beneficence, and justice - have been guiding principles in research ethics ever since. The development of guidelines for research conduct and the evolution of informed consent have also been described by Pelias [2]. Developments until this stage, which have been mainly dealing with the relationship between researcher and research subject, is what we will refer to as research ethics 1.0.

Recently, research ethics newly gained importance due to the changing scientific landscape and increasing demands and competition in the academic field. Specifically in genomic research, a highly complex field both in terms of data complexity and privacy concerns, scientists' integrity is key due to the fact that most sensitive data are involved and can impact the still hidden future of individuals, including the ones of future generations. However, we no longer can focus on the individual researcher or research group. The scientific process is embedded in a complex network with different stakeholders, which need to be more systematically addressed. Meslin and Cho [3] analysed the existing "common set of ethical principles" in research ethics and proposed a reframing of the "social contract" between science and society, highlighting the need to put focus on the broader context of research. With this paper, we will extend the existing body of knowledge assessing the development or evolution of research ethics by highlighting the current challenges to scientific integrity. Thereby, to mark key developments in research ethics, we will distinguish between what we call research ethics 1.0 and research ethics 2.0. Whereas research ethics 1.0 focuses on individual integrity and informed consent, research ethics 2.0 entails social scientific integrity within a broader perspective of a research network, as other actors apart from researcher and research subject increasingly move into the core of research ethics. The aim of this paper is thus to inform in a comprehensive way about recent challenges to research ethics which become evident through our so-called "research network" perspective. In this way, the research network serves as a framework through which changes and complexities in research ethics are modelled and can be systematically conceived.

Research Ethics 1.0: Focussing “informed consent”

A basic moral conflict in research ethics is balancing between the good for the individual and the good for the population. Certain medically oriented research questions that ultimately aim to benefit the population or future generations of patients can only be answered by involving individuals. Depending on the intervention, drug or placebo under research, those individuals however can be part of studies with uncertain outcomes. Two historic medical studies that failed to adhere to ethical standards exemplify the severe consequences. Even though nearly every public health lecture and textbook in the Western world mentions these studies and their misconduct is commonly known, they illustrate what constituted research ethics during the twentieth century. In these examples of scientific misconduct, research subjects were treated not as ends in themselves but were harmed for the benefit of others, while not being adequately (or not at all) informed about the nature of the research or pressured to participate.

The Tuskegee study, which was initiated by the US Public Health Service in 1932 aimed at revealing consequences of untreated syphilis [2]. Four hundred already infected Afro-Americans from Tuskegee, AL, were studied over a period of 4 decades (from 1932 until 1973) through a purely observational study even when effective penicillin treatment became available, yet subjects were not even informed about it. Treatment was only offered to the subjects when the study was publicly exposed in 1973 [4,5].

The other example that influenced the awareness of the rights of human research subjects in research is the study carried out at Willowbrook State School, New York, from 1956 until 1971, which intended to find a cure for infectious hepatitis. The school for “mentally retarded” children admitted new pupils only after their parents consented to place them in the hepatitis unit, where they were actively infected with the virus in order to “determine a prophylactic agent” [2,6].

It was through events like these that ground was given for ethical questions in relation to research and protecting study subjects. Responses to such immoral studies have emerged since the biomedical experiments during the Nazi regime. It turned out that although in Nazi Germany, rules for the protection of human research subjects already existed, they were violated by Nazi doctors in their “research” [7]. In response to the misconduct, the Nuremberg Code was set forth during “The Nazi Doctors Trial” in 1947 and aimed to proclaim 6 norms for protecting research subjects (Box 5.1). The Nuremberg Code can hence be deemed as the “foundation of modern protection of human rights” [[2], p. 74].

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| <ol style="list-style-type: none">(1) Human subjects must give voluntary, informed consent, without coercion or duress.(2) Experiments with humans should be preceded by experiments with animals.(3) Experiments should be justified by the anticipated results.(4) Experiments should be conducted by qualified scientists.(5) Experiments should avoid physical and mental suffering and injury.(6) Experiments should not entail an expectation of death or disabling injury. |
|--|

Box 5.1: The Nuremberg Code 1947 [2]

In 1964, the World Medical Association established the Declaration of Helsinki and regularly updated it ever since. It became the golden standard for research involving human subjects. It was a further elaboration of the Nuremberg Code, paying attention to the distinction between therapeutic and non-therapeutic research and responsibility towards vulnerable groups [8]. The Belmont Report issued by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research in 1979 also served as a basis for several other codes of ethics through its three principles. While respect for persons emphasises absolute autonomy of research subjects, beneficence seeks to safeguard the minimisation of risks. Justice stresses the importance of distributing chances and risks of research fairly and treating subjects in a just way. These principles are also in line with the four principles of biomedical ethics proposed by Beauchamp and Childress [9] in 1977 which have offered an influential normative framework ever since.

Research Ethics 2.0: New perspectives on norms, values and integrity

While research ethics during the 20th century was characterised by questioning behaviour mainly in the relationship between researcher and research subject, the 21st century brought to the forefront further issues at stake that go beyond this bilateral relationship. They encompass multiple levels, and have diverse underlying influencing causes and reasons. Even though these “new” issues might have existed before, they become more and more important due to increased interdependence between the stakeholders. In what follows, we will describe these multiple levels and challenges for various stakeholders, in what we are calling research ethics 2.0. Instead of focusing only on the relationship between researcher and research subject, research ethics 2.0 takes into account the broader social dimension of research that we depict as a research network, which we could also term “network of responsibilities” as different relations of moral responsibilities of the researcher(s) with other stakeholders and actors play a role (figure. 5.1). Identification of the stakeholders was based on a literature review followed by a grouping of the key stakeholders involved in the research realm. Even though we offer a researcher-centrist view of the network, the relationships and mutual responsibilities between other actors also play an influential role.

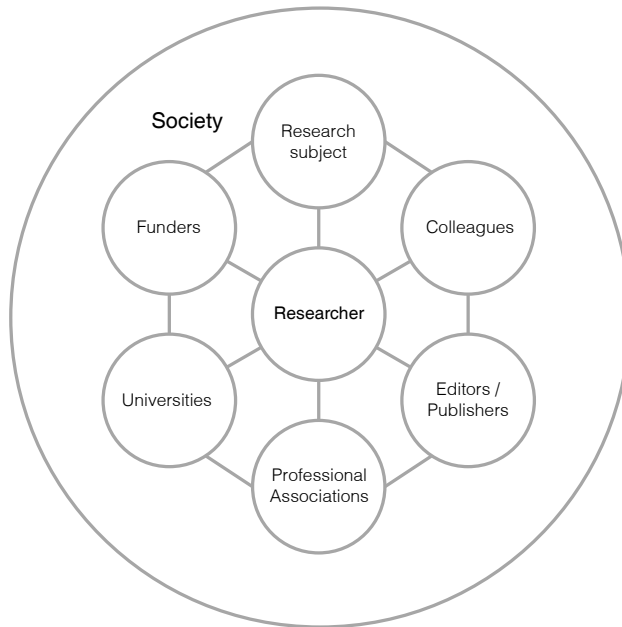


Figure 5.1: The research network as a network of responsibilities.

At the heart of the research process lies the **researcher** who is influenced by several stakeholders and factors. Academic competition poses pressure on researchers. Funding opportunities, prestige, and recognition are often dependent on the number of articles published, the magnitude of studies conducted, and the amount of high-profile journals published in. The difficulty to win research funds is even more exacerbated in times of austerity, while publishing higher numbers of papers to gain doctoral degrees and/or to have research careers might lead to arguable incentives for non-accurate research or even wasted research efforts. All these situations pose a challenge to researchers' scientific integrity. According to the Swiss Academy of Medical Sciences [10], scientific integrity can be termed as "the voluntary commitment by researchers to comply with the basic rules of good scientific practice: Honesty, self-criticism and fairness are essential for morally correct behaviour." However, researchers are pressured to achieve those stated requirements, not lastly by conducting so-called "scientific misconduct," which is defined as "fabrication, falsification, or plagiarism (FFP) in proposing, performing, or reviewing research, or in reporting research results" [11]. According to Bouter [[12], p. 150], many variances of misconduct or "questionable research practices" emerged in the grey zone between carrying out research according to the rules and three latter new "deadly sins" for scientific integrity (FFP). He states that the reasons for such behaviour can, in the best case, simply be unawareness of how it should be done or, in the worst case, that researchers know about the wrongdoing involved but proceed in those practices anyway for various reasons. Martinson et al. [13] argue that from an empirical study

about US researchers' behaviour in terms of integrity, commonplace unfavourable research practices are a bigger threat to science than those produced by "high-profile misconduct cases such as fraud" (p. 737). Their survey of more than 3,000 early- and mid-career researchers in the US about ten common and six other research behaviours that were previously determined in focus group discussions reveal that 33% of respondents acknowledged to have conducted at least one of those behaviours, which range from falsifying, polishing or "cooking" research data to using the ideas of others without obtaining permission or giving credit to changing the design or results of the study due to funding source pressures. Other questionable research practices of the grey zone include refraining from publishing disappointing study results, publishing the same data in several publications, withholding results in line with selective reporting or other details or using inadequate research designs.

Behaviours, which are affected by social structures, are also important to take into account. Those behaviours include authorship questions, such as who can or should be author or the promotion of young scientists or lack thereof [14]. Lack of self-criticism of scientists on the one hand and dealing with multiple obligations, which can be overwhelming, on the other hand - including promoting young academics, acquiring funding, engaging in review and university boards, publishing, and teaching - further facilitate misconduct when accuracy in every task cannot be accomplished. Additionally, questions about justly dealing with research resources emerge, not only since the economic crisis, which will further be touched upon in the paragraph concerning funders hereinafter.

Martinson et al. [13] rightfully claim that current analyses only focus on researchers and their misconduct but fail to consider the broader research environment, involving its structures, which often trigger the researchers' misconduct through what Bouter [12] and Sandel [15] for instance call "perverse incentives."

Taking the broader research environment into consideration extends the focus to the research network. In the researcher-centric network of responsibility, we see the following actors and stakeholders (figure 5.1). The researcher is connected to all of the different stakeholders. Even though the research environment is vast and complex, we identify 6 other stakeholders besides the researcher: research subjects, colleagues, editors/publishers, professional associations, universities, funders, and society at large.

The classic - and already mentioned above - relation to the **research subject** focuses on questions around avoiding harm and properly informing the research subject. Especially in the context of genomic research, big data, and digitalisation, new challenges continuously arise, such as aspects of the right not to know, data protection, and privacy, all of which have to be imbedded in the considerations for informed consent. Current research, as for example, advances in gene editing, is moving the frontiers of impacting only the single research subject but extends gained knowledge and its consequences to genetically related persons and thus future

generations. Here, existing and traditional models of informed consent, such as opt-out, waiver, no consent, and open or categorical consent, need to be revised in order to meet the challenges posed. Incidental findings of genomic data, e.g. predisposition for diseases, furthermore pose a challenge as to how to deal with this information with regard to truthfulness and individual autonomy. With regard to also protecting privacy of biological relatives existing models should be further revised.

It is furthermore important to focus on aspects of non-exploitation of research subjects. Especially in times of austerity, non-exploitation becomes relevant in studies where people become research subjects on the basis of the incentives - often of financial nature - that they receive [16]. Generating research subjects at costs of potentially adverse side effects of the respective study is morally unjustifiable, not only since the Tuskegee experiments and the Declaration of Helsinki. Some forms of exploitation continue to occur, often in low-income countries [17]. It is well established that in poor settings, such as underserved communities and countries, inequitable access to resources have an important role to play in people's decisions to partake in research [18,19] and that in resource-poor settings, voluntary informed consent is undermined by financial incentives [16]. Partaking in research can also be a way to attain better or even basic health care provision when otherwise health care services are not readily accessible. This would be the case of early accessible and usually costly genomic treatment during research studies, where research subjects are often patients who wish to access and aim to benefit from evolving treatments [20].

However, according to Chalmers and Glasziou [21] there is often a mismatch between the research questions and the expected outcome for patients. Data are moreover available too late, with an average of nine years later [21]. It must hence be a researcher's responsibility to ensure timely and unbiased publication of study findings and a matching of research questions and patients' expectations [21]. When these requirements are not guaranteed, the already vast amount of unused research - which is deemed to account for 85% [21] - is "waste."

In addition to research subjects, the researcher is related to his/her circle of **colleagues**, both from the academic environment as well as collaborators from other institutions at public and private levels. Here, it is important that the relation is defined through ethical principles of the professional roles, such as honesty in sharing study results or newly developed concepts and trust that the information is not used without permission or adequate credit. Also sharing confidential information, e.g. about participants who should stay anonymous, or failing to store study data securely, so that colleagues can access raw material remain questionable, as the moral duty towards research subjects to expose information only to participating researchers is undermined.

During the focus group discussions in the study by Martinson et al. [13], a concern was also raised about questionable relationships with students, research subjects, or clients. Concerning the former, the ethical concern about questions of authorship is central. While at least in Germany, it used to be (and is still the case in some disciplines) that students' theses are published without their name in the author list, it

also often is the opposite case, namely that colleagues who want to accelerate their career or PhD students are authors on various publications to which they have contributed little or nothing at all. This practice can be seen as undermining competition and thus has to be regarded as unfair.

On another similar note, peer review - according to Bouter [12] the dominant kind of quality assessment - often affects or is affected by the relationship between colleagues. When assessing research proposals or manuscripts, objectivity is rather problematic. In some biomedical or niche disciplines, colleagues' works can be identified even when manuscripts are submitted anonymously. Rejecting manuscripts of competitors, or punishing colleagues who reviewers are in dispute with could be an easy, yet untruthful and mendacious way to increase one's own research career [22]. Lawrence [22] even reports from his experience as editor, that half of all submissions he received asks for not sending the submission to certain reviewers due to "conflicts of interest" and fear that confidential data and ideas are misused. Lawrence, however, purports that this could be a fruitful way to circumvent especially critical or unfavourable reviewers. Reviewer activities for different journals can pose an even higher workload to scientists that is not recognised or valued as part of their research or faculty-related work. Whether the evaluation process of a reviewer should be recognised and in which ways this could be operationalised needs to be assessed and possible options are to be discussed. Transparency, anonymity, and disclosure issues are central issues to be taken into account therein [23].

Sharing study results and methods is another issue pertaining to the relationship with colleagues, which gains increasing attention with advances in genomic research. By improving sharing behaviours between colleagues, research waste can be reduced to an enormous extent, as already existing data and methods can be used and applied respectively [24]. New research can then refer to and use existent knowledge instead of duplicating research in new settings.

The quest for seeking the "right" reviewers is an issue which **editors** have to deal with daily, and which leads us to the next stakeholder in the network of responsibilities: the editors or publishers. For researchers, there is often a bias towards publishing in popular journals, as the probability of getting cited is deemed to be higher and impact factors count for their careers. That this system is morally questionable is discernible and leads to a domination of certain journals, whereas more unknown journals cannot compete. An unfair competition for researchers is recognisable in the long journey of publication, which can vary as long as several years from submission to actual publication depending on reviewers' availability and promptitude and editors' decisions whether to publish or not and in which volume of their journal. English natives also have a competitive advantage, since most journals publish in English, posing a barrier to scientists from other language-speaking countries. The responsibility of editors and publishers for ensuring progress in research is central, as they can most often decide what type of research papers get commissioned and published or not - and thereby receives a platform for further communication and discussion or not. Here, publication of negative results has to be addressed which is

often not seen as “successful” and interesting research to be published, but which nevertheless promotes knowledge and provides other researchers with information about which scientific approaches or experiments are not fruitful.

Editors and publishers have the power to put topics and theses on the agenda and hence shape not only the academic context to a great deal, but also society as a whole. The failure to focus on promising topics, however, also has an impact. Their role can be termed as being responsible towards society in shaping or pushing the research agenda into the “right” direction. They also have responsibility towards research subjects, which they ensure by checking granted research ethics approvals. However, many publishers and editors also come under pressure - or a “crisis” of publishing as Richard Horton [25] of *The Lancet* describes it. They experience a paradigm shift from a focus on quality of publications rather to quantity of publications issued by journals. With the emergence of so-called mega journals, which publish approximately 30,000 articles a year, other motives rather than scientific excellence are emphasised. These motives relate more to a high market share and connected benefits, such as “revenue growth, cost control, and profitability” [[25], p. 322], even more so in times of economic hardship. For publishers and editors who used to function as gatekeepers to scientific publications, which should be based on excellence, this change has affected their core values and decisions pertaining to what is deemed science and relevant research. Moral questions about the purpose of scientific publications arise, reflecting or indicating a change in publishers' values. Instead of only focusing on volume and market share, Horton sees it as publishers' responsibility to focus on the added value of science to society. Hence, publishers' integrity to not only engage in profitability is key in developing science in a time where big datasets would easily provide substance for all sorts of publications. The question however, remains whether gatekeeping research for publication with the aim to publish only high quality research adversely affects transparency. Finding the right balance in this regard will remain a challenge and key in the years to come.

Professional communities are often organised in **professional associations** - another stakeholder in the network of responsibilities. Professional associations pool their members' scientific experience and knowledge and can hence be intellectually supportive for their members. A prime responsibility professional associations should take on is the development of guidelines for conducting research or establishing links between researchers to strengthen research for example. Yet, promoting international collaborations in forms of scholarships or travel grants might get more difficult for professional associations, as their budgets in some cases were reduced in the last years due to unpaid membership fees. By steering the research of their scientific community in the direction they deem promising, professional associations take on a leadership role. However, as in every community, challenges can emerge with regard to internal power struggles, personal discrepancies or different values. Hence, defining a common value set can help to align motives and avoid conflicts of interest. In addition to interdependencies as well as responsibilities towards colleagues,

professional associations are accountable to society, and can and should aim to promote added value of their research activities.

Also **universities**, as institutional organisations within the research network, prescribe to the aim to promote added value to research. Their role as institutions is to provide safe working spaces and fruitful working environments for both researchers and their study results by securing proper storage of data, upholding anonymity of research subjects and providing the necessary infrastructure to support research endeavours. In light of scarce resources, buying new technology or renewing existing buildings or offices remains challenging. Prioritising what to invest in should be evaluated fairly and objectively so that standards are upheld and all departments within a university are equitably treated. With regard to meeting the obligation or legal requirement to regulate research by assessing ethical implications of research, institutional review boards have to be established and research ethics training should be institutionalised. Moreover, universities often set incentives for research, which however have to be arranged in a fair way.

Funders have a crucial role within the network of responsibilities, as research is in nearly all cases dependent on the funding agencies involved. These funding agencies or stakeholders can vary widely and can be embodied by stakeholders either from the public sphere such as government, advocacy groups or non-governmental, non-profit organisations; or can stem from private corporations with industry being the most ostensible. Various moral obligations are involved for each stakeholder, for example with regard to being accountable to where funding is from and for which purpose it is offered. Academics who are in advisory boards of industrial companies can easily get into conflicts of interests, which can result in exploiting either industry or university resources or people working there [26]. Governmental funding for an industry's purpose to expand its for-profit product range is morally questionable in terms of justice when research is publicly funded. However, as austerity measures heavily affect governmental budgets for research and development since 2008, private funding becomes more and more important and can yield new funding schemes, such as mutual funds or research bonds as proposed by Moses and Dorsey [27]. Evidence exists that austerity measures have negatively affected not only pharmaceutical growth [28] but that publicly funded independent clinical trials could not be carried out as funds were not disbursed since 2012 such as was the case in Italy [29]. The scheme from which funding was generated was based on a newly raised 5% tax on pharmaceutical marketing, established in 2005. This type of revenue for funding can be regarded as being a fair measure to balance excess profits from the pharmaceutical field to usually underfunded public or independent research. Funders have to respond to political interests or even “hypes” in certain research fields, for which the demand for distributing grants is strong. Acting on this demand can create inequalities between different fields of study [30]. Fewer funding opportunities have led to increased competition with regard to EU grants. Specifically for resource-poor countries, EU grants are often an essential possibility to fund research and maintain

research infrastructure, e.g. in EU member states that were hit hard by the economic crisis. Along the same lines, continuing low levels of funding will create more uncertainty for young researchers, who would rather search for a career in other, mostly private, sectors.

Here, the question arises whether the liberal approach of providing grants based on competition is still justifiable in times of austerity or whether mechanisms that put a bigger focus on solidarity should be installed. In short, low levels of funding have adverse consequences for society in general as biomedical or genomic research yields prosperity and other economic benefits by creating jobs and valuable products and methods [3,27].

Even if funds are available, further issues arise with regard to the already mentioned vast amount of 85% waste in research [21], such as whether it is ethically justifiable to fund research which cannot be translated into practice or which aims to answer irrelevant or already answered research questions. The open science movement raises novel questions as to how to deal with raw data and study results funded by public resources. There are arguments for sharing data publicly and making them available through open access, which promotes access and thus freedoms to lay persons, as well as arguments questioning whether such access might result in misuse or misinterpretation of data. A thorough discussion of this issue however, goes beyond the scope of this paper. The role of funders, in collaboration with other stakeholders, such as researchers, universities, and society, is crucial in order to define common standards for funding practices.

With regard to **society** - our last stakeholder - new challenges have to be met in times where amounts of data increase rapidly and funding for research is scarce. Society's role in research increased in the last years due to the fact that advocacy groups, e.g. patient advocacy groups, and community engagement actions were paid more regard to in defining research priorities on the political level [31]. By this engagement, societal values became part of the scientific undertaking. Resnik argues that even though science is deemed objective, evidence-based, and "value-free," it nevertheless involves researchers' epistemic and non-epistemic values [32]. Being aware and transparent about those values is central to improving the perception of science in society and strengthening their link. According to Meslin and Cho [3], research during the era of personalised medicine needs an update on what they call "social contract between science and society." Hitherto, research was based on the precautionary principle as well as non-maleficence and protectionism, which all resulted in a request for more regulation and requirements of researchers and delineates a lack of trust in the latter. This lack of trust is also noticeable in the unsteady support to scientists by society, when support comes easily if results are progressive, but can be withdrawn rapidly when researchers are deemed to be driven by personal or industry-related motives [3]. Due to the changing landscape in research following novelties in genomic understanding and big data availability, such lack of trust can hinder advances tremendously. Therefore, a new framework has to be established, which should still root in avoiding harm, but moreover provides scientists

with the necessary trust to conduct research freely, however with the best interest for society's needs and values. Hence, the social contract between scientists and society is increasingly based on integrity of scientists. Meslin and Cho propose within their "recipe for reciprocity" four ways by which researchers can confirm their integrity to society, namely by "(1) a clear articulation of goals and visions of what constitutes benefit, without overstatement of benefit, (2) a commitment to achieving these goals over the pursuit of individual interests, (3) greater transparency, and (4) involvement of the public in the scientific process" [[3], p. 379]. Society would return consequently "(1) trust in the process and goals of science, (2) a greater willingness to volunteer to participate in research, (3) sustained, reliable funding, and (4) support for greater academic freedom, free from manipulation by political goals or ideology" [[3], p. 379].

Besides emphasising values or principles for researchers to act upon, Meslin and Cho propose an increased inclusion of society in science. Citizen Science - as a relatively new term describing a rather old approach - includes laypersons as volunteers in research projects, e.g. in data collection, recruitment of research subjects or communicating results to society. Advantages include besides assistance in data collection, an improved insight for volunteers into science and scientific methods, and the possibility to engage in issues, which are relevant to them and their environment [33]. Ethical considerations emerge however, with regard to data integrity and sharing, intellectual property and authorship rights, responsible oversight and training of volunteers, and exploitation [34].

As regards scientists, strengthening their commitment to public benefit will contribute to their integrity and lead to valuable relationships, which have a greater potential to meet society's needs.

Concluding remarks

Research practice and the researchers' environment have changed in the last years - economic pressure in times of austerity and genomic advances can be seen as two drivers for research ethics 2.0. The network of responsibilities described above shows the many (more) ethical issues researchers and other stakeholders or actors have to face nowadays. The integrity of research - implying adherence "to the basic rules of good scientific practice (such as) honesty and sincerity, self-discipline, self-criticism, and fairness" [10] - is challenged on diverse levels. Our claim is that focusing on research ethics and integrity on those various levels and taking into account all stakeholders can make research better, more truthful and thereby more socially acceptable. It is important that research is socially acceptable since it influences support for research in general. As Gunn has already pointed out in his Editorial in 1917, scientific misconduct, waste, or sloppy methods can undermine the integrity of "the whole public health movement" and have a negative impact on human welfare [35]. Even though this statement has been made a century ago, it has not changed ever since but is even more crucial with regard to genomic research.

In some cases, integrity might hinder research, for instance when conflicts of interest supersede funding, in others it promotes research, e.g. when professional associations engage in research collaborations. However, applying ethics and moral values enhances research and as such is not only a means to an end but also a necessary end in itself. Moral values can thus be regarded as drivers for science as they provide accountability and public trust to society and vice versa. What is new with regard to the mentioned recent challenges is that research ethics cannot focus on the relationship between researcher and subject alone anymore [36]. All stakeholders within the broader research field build a network of mutual responsibilities, rights, and duties.

It is crucial to strengthen integrity in the years to come. An auspicious way to do this is by means of education. Bouter [12] suggests that education and training about scientific integrity for PhD students as well as for permanent academic staff should be implemented. This could not only be done by lectures, but more profoundly and according to successful didactic methods such as group work and case studies [37]. Moreover, existing policies are to be reframed on the basis of the established network of responsibilities in order to provide improved guidance for the various stakeholders involved, e.g. to better protect research subjects or involve volunteers by means of citizen science, especially for research in times of scarce resources.

The field of research ethics however is still developing, and more and more aspects of research collaboration are being discussed. Therefore, there is still a magnitude of issues undiscovered. The account provided in this paper thus does not aim to be comprehensive, but to provide a heuristic endeavour to involve all stakeholders concerned within a network approach. It extends the classic bilateral relationship between researcher and research subjects towards the network of responsibilities and aims to specify some challenges at hand. Due to the multitude of developments ahead, a continued discussion is needed in which ways ethic(ist)s can support research. Central topics and challenges in genomic research where further ethical assessment is needed include the issue of data sharing and making use of existing data, open science concepts, and the role of science in the age of digitalisation.

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Part 3: Perceptions of European decision-makers

Chapter 6 Ethical dimensions of decision-making by European policy-makers during the economic crisis

Abstract

The economic crisis posed various challenges to policy-makers who had to decide on health policy measures. The aim of this research was to assess the relevance of ethics and to highlight ethical considerations in decision-taking by policy makers with regard to policy and priority setting in health systems posed by the economic crisis. Semi-structured qualitative interviews were conducted with eight European policy-makers. All interviewees recalled difficult and strenuous situations where they had to prioritize between distinct areas to focus on and invest in, for example around choices between medications, health professional staffing, care specific equipment, or urgent infrastructure issues. Values could be identified which they deemed as important within the policy-making process, such as trust and responsibility. They explicitly expressed the need for ethical tools and assistance in terms of policy advice for reaching morally sustainable decisions in health policy matters. The study showed that ethical concepts and values frequently come into play in health policy-making, and that ethics is highly relevant in policy-makers' daily decision-taking. The study is of relevance since it can provide future decisions on austerity-related issues with an ethical underpinning and could identify areas of moral concern.

Introduction

Countries in Europe have employed different policy responses to the economic crisis that set off in 2008. Whereas Iceland or Sweden, for example, chose financial stimulus and consequently invested in social safety nets etc., countries such as Portugal, Spain and Greece had to employ austerity measures so as to receive funds issued by the International Monetary Fund (IMF) (Thomson et al., 2014; Stamati & Baeten, 2014). Here, the economic policy as a response to the crisis was to lower spending in social welfare areas, for example as in the case of Greece where among many cutback measures health programmes, such as HIV programmes, were stopped (Karanikolos et al., 2013; Mladovsky et al., 2012).

Such challenging health system modifications were shaped by policy-makers, who decided what measures and approaches to implement. One can assume that public (health) policy-makers had to confront various moral dilemmas in their decision-making. Especially in times of austerity, with its increase of inequalities and questions of just allocation of resources, the relevance of ethics in policy making is predominant even more. As Sullivan and Segers describe, politicians and policy-makers act in a “distinctive realm” as they “act for others but also serve themselves, they rule over others and can coerce people, and their decisions have broad, cumulative effects on present and future citizens” (Sullivan & Segers, 2007, p. 315). Previous research has shown that they often feel largely unprepared to reflect their decisions ethically (Gaare Bernheim, 2003).

In this context, the aim of this research was to assess the relevance of ethics and to highlight ethical implications in policy-makers’ daily conduct with regard to the challenges in terms of policy and priority setting in health systems posed by the economic crisis.

Apart from the European Union (EU) values for health, namely solidarity, universality, equity, access to good quality care (Council of the European Union, 2006), there is no specific explicit set of moral values or professional moral value system established for policy-makers – besides their political party affiliation and their individual or party’s perception of the good. In view of the lack of research about policy-makers’ moral values, it is necessary to uncover the relevance of such values in policy-making in a first step, assessed by means of the pressing example of the economic crisis and its impact on health and health care systems in Europe, and in how far ethics plays a role in guiding policy-makers’ actions.

Methods

In order to answer the main question – in how far and in what ways ethics does play a role in public health policy-makers’ decision-making during times of austerity in Europe – a qualitative, explorative approach was selected. An interview study with EU policy-makers aimed to assess how they a) perceived the economic crisis with regard to health, b) which values they perceive as essential to be integrated in policymaking

during challenging situations with regard to priority-setting and decision-making in health policy matters, and c) how they evaluate the role of ethics in political decision-making (from a bottom-up perspective).

Data collection

Accordingly, semi-structured telephone or video-supported telephone interviews with policy-makers at European, national or regional level within EU Member States were conducted. As policy-makers, persons were labelled who currently work or have worked in high-ranking positions at a governmental institution.

The interviewees were located according to two sampling methods. Firstly, a purposively sampling approach of maximum variation was adopted based on the participant's function and country of origin (recipient/donor country, austerity implemented or not). In this first stage only current or former Members of the European Parliament were contacted, since the initial aim was to focus on their perceptions of the crisis in the European Union exclusively. During this stage, 80 potential participants were individually contacted by email including a cover letter and a reminder email two weeks afterwards. Emails were sent out during two phases in mid 2015 and early 2016. While 9 emails could not be delivered due to expired email addresses, the majority did not respond or declined the invitation due to lack of time. After having achieved a response rate of 3.8% (n=3), a snowball sampling technique was embraced in a second approach for accessing possible interview partners. Additionally, the sample was broadened from involving former or current Members of the European Parliament only to including other health policy- or decision-makers who work at European, national or regional level in the European region.

For conducting the interviews, a semi-structured questionnaire was developed, which was clustered into three broad themes, precisely (1) values, including EU values for health, (2) ethical decision-making and priority setting during the economic crisis with regard to health, and (3) an evaluation on the usefulness of ethics assistance. According to Flick (2006), a semi-structured interview can be seen as a way to iteratively reconstruct 'subjective theories' about a set of themes, which is in line with the goal of this study. Data was sought to be retrieved about how European policy-makers perceive the situation of austerity measures in health care, to reveal whether ethics plays a role therein in their view, and in how far ethics could help in taking decisions in this regard. In order to ensure reliability, the interviews were recorded, transcribed and stored anonymously at a secured place.

Ethical considerations

The study was conducted in compliance with the Declaration of Helsinki and was reviewed by the medical ethics committee of the University Hospital Maastricht and Maastricht University (METC azM/UM) on December 19th 2014 (METC 14-5-097). In the invitation letter study participants were informed about the aims and procedures of the study, were given the choice whether to participate or not and were ensured about their anonymity. Their verbal consent was obtained in the beginning of the interviews and was recorded accordingly. (No written consent form could be obtained for all

interviews due to the fact that interviews were held via telephone where printing, signing and scanning consent form would have been extra charge for participants).

Data analysis

The collected information was summarized and categorised according to emerging categories and subcategories. By applying a content analysis in line with Mayring, policy-makers' perceptions about the questions outlined above could be revealed (Mayring, 2000).

Results

In total, 8 semi-structured explorative interviews were conducted between February 2015 and September 2016 until thematic saturation was reached, meaning that a sufficient number of persons were interviewed so that important features of the investigated topic could be revealed. According to Guest et al. thematic saturation in explorative interviews appears between six and maximum 12 interviews (Guest et al., 2006). The length of the interviews varied between 28 min and 1 h 18 min. Participants from 6 different countries could be sampled, covering several geographic regions within Europe: West (Great Britain, The Netherlands), South (Italy, Portugal, Malta), Central/East (Slovenia). Participants moreover show a mix of functions and level of actions, including (former) Members of the European Parliament, policy advisors or civil servants working at European, national and regional levels in health policy related matters. Table 1 presents an overview of the study participants, including their highest attained function during their career to date and level of action. Country and gender were purposively not declared explicitly in the overview so as to increase anonymity of participants.

Table 1: Overview of study participants

Participant	Function	Level of action
P01	MEP	EU & national
P02	MEP	EU
P03	MEP, Government advisor	EU & national
P04	Civil servant	National
P05	Civil servant	National
P06	Civil servant	EU
P07	Civil servant	Regional
P08	Member of government	EU & national

In the conducted interviews, six themes emerged from the data which were most significant, namely: 1) examples of difficult decisions in policy-making brought about by austerity measures, 2) decision-making and priority-setting, 3) ethics in dealing with decisions, 4) values in policy-making, 5) EU values for health, 6) recommended health policy measures in times of crisis. Table 2 gives an overview of the identified categories and subcategories, which will be described more thoroughly in the following.

Table 2: Summary of categories and sub-categories

Category	Sub-category
Examples of difficult decisions in policy-making under austerity	Medication Recruitment/staff Health care provision sites
Decision-making and priority-setting	Perception of decision-making and priority-setting as challenging Process of priority-setting Power plays between different stakeholders Lobbying
Ethics in dealing with decisions	Importance Need for ethics assistance
Values in policy-making	Political party's vs. individual values Lack of value set Economic vs. ethical values
EU values for health	EU values as passively guiding action Solidarity and responsibility
Recommended health policy measures in times of crisis	Among them recommendations for spending, other measures increasing health levels etc.

All interviewees¹ report an exceptionally difficult time for policy-makers with regard to having to make tough decisions in the aftermath of the economic crisis since 2008. They report that the most challenging time for them was in the years 2011 and 2012, when budgets were restricted:

“There was a real cash problem 2011/2012. It was not immediately after the crisis but it was the time when we were in the exit of the procedure and budgets were basically restricted.” (P05)

¹In order to increase anonymity, only the male form „he“ will be used for all interviewees (whether male or female) in the following.

1. Examples of difficult decisions in policy-making brought about by austerity measures

Giving examples of those tough decisions they had to take, they differentiate between making trade-offs in the areas of medications, health care staff and quality of health care provision. As one interviewee reports, prioritisation had to take place with regard to the medicines bought by government. The interviewee P05 perceives those decisions as prioritising between life and death.

“There was a time ..., when there was no budget to buy all the medicines. And every week I had to give directions on which medicines to prioritise. And in such a situation I can give a concrete example, I would say: Don't buy the statins, don't buy the anti-hypertensives. Those people can afford to buy and if they keep their statin for a month or two, it's not the end of the world. But I can't afford not to have medicines in my ITU, in my special care baby unit, in my A&D. that's the kind of example. Yes, unfortunately for a few months, I was in that very, very difficult situation. ... You have to prioritize what is a matter of life and death.” (P05)

“The other prioritisation for example was in terms of recruitment. What do you recruit? And again over there the priority was always to recruit the doctors and the nurses. We would leave the physiotherapists, the dietrists, we would leave those for a later time. The first money available was always going first for the doctors and the nurses because that was key impact.” (P05)

“Main challenges (with a reduced budget) are drug prices, staff prices, because we don't have money to have more staff, medical equipment, the old medical equipment cannot be repaired or be changed, and obviously at the end of the day quality of services. They will be affected. And again for very good hospitals the top level of the quality, it's difficult to protect. So usually the idea is to cut small hospitals and to invest more into big hospitals. But then ... citizens are complaining, “oh do I have to take a car and drive 20, 30, 40 km, why do I have to do so”. I close a small hospital and I invest more money in a big hospital, difficult.” (P07)

Personally, they perceived that time as challenging with responsibility on their shoulders, as one interviewee noted the importance of making the choices himself, rather than leaving it up to colleagues.

“That was a horrible time. I still look back and wonder how I coped. But the choice I had at that time was either to make the decision myself, or to leave it in the hands of people who would make it randomly.” (P05)

2. Decision-making and priority-setting

When asked about their perception about decision-making and priority-setting, most policy-makers considered it as very tough, even referring to it as a 'nightmare' when making decisions for or against certain types of population. Making decisions is however seen as inevitable.

„I mean, if you like, it's a nightmare – decision-making. Because there always will be cases like that where you have to weigh one lot of vulnerable people against another. And that's neither easy nor pleasant and if you are in government or running a health service, you have to take the decisions. ... You do have to take decisions. Otherwise the system breaks down.“ (P01)

A theme raised by interviewees when speaking about priority-setting was the importance of the process. Here, an important trait within the process was identified as 'listening' to others, e.g. patients, colleagues, professionals etc. in order to attain information and be able to negotiate in a second step.

„So you listen a lot, you listen to the patient but you are also listen to the health professionals, you listen to the managers, you listen to the specialists, you listen to the academics, and you try and listen, your job as a politician is to listen and learn and then ultimately to make decisions based on what you've heard and what you know and then what you can negotiate with other people in government. It starts with listening and ends with negotiating.“ (P01)

On the other hand, one interviewee states that listening to others results in difficulties for policy-makers to hold on and continue acting according to what they themselves perceive as right, but rather are driven externally by a power play between citizen interests, media, associations and more and their respective interests.

“I think that most politicians, at least well prepared politicians, they know what the priorities are, they know how it should be done. And when they are in the opposition, they always know in a very clear way. But when they become government and they have to take the decision on their own and they have to be responsible for the decision, they always look around. And to look around is, once again, to media and public opinion. So instead of going the way they know they have to go, they go a little bit to the side of what is popular in media and in public opinion once again. ... So, this [is] a game of power. Political power, citizen's power, associations, lobbies, economic interests. This is a game of power.“ (P03)

The majority of policy-makers also mentioned lobbying as a central element during the priority-setting process. In their comments, they implicitly referred to the criteria of trust, transparency and legitimacy as important with regard to lobbying. Another sub-theme raised with regard to priority-setting criteria was how decisions are reached and the role of procedural values to guide this process. While some policy-makers deem procedural values as important, others think they are rather needless. The procedural value granted most importance by the interviewed policy-makers was accountability. All in all, they express the need for objective criteria to base decisions on during priority-setting.

3. Ethics in dealing with decisions

The importance of ethics in dealing with difficult decisions during policy-making, not only during times of crisis but during political decisions in general, was perceived by all interviewees as high. What is more, they consider ethics as a helpful tool to guide decisions in making trade-offs, which cannot be prevented when money is not available for all needed areas. Deciding in which areas to invest and the ethical nature of such decisions is a theme which emerged during all interviews as the following quotes depict.

“Investments in health have to be balanced with all the other societal needs. And that is a responsibility of ethics.” (P02)

“Trade-offs are part of ethical behaviour” (P06)

“I think in times of austerity the ethics of decision-making becomes even more important. Because very often one is having to make difficult decisions between spending areas or projects and so its important when one is making most decisions one takes into account what is equitable” (P01)

When asked about whether ethics could be helpful in their decision-making, they expressed the need for specific advise, support and assistance in considering ethical dimensions. Regarding the form of such ethical assistance, retreats, master classes and workshops were mentioned as favourable and helpful in discussing and analysing involved values and potential options of decisions to be taken. Such assistance can help to educate and train policy-makers in identifying and prioritising values and norms during their decision-making. One interviewee suggests that by receiving ethics assistance he would feel less ‘troubled’ during the decision-making process. The interviewee suggests that by having better knowledge about the underlying ethical concepts he would gain more confidence in making decisions.

“I think had I before gone through the process, being exposed for example to some workshop or something for senior policy makers, which would have introduced the concept that in times of crisis different value sets may need to come into play, its okay to depart from the established norms and to work in a different reality, maybe I would have felt personally less bad and less troubled and would have been more able to cope on a personal level with the decisions that I would having to make. ... These kind of master classes, retreats if you wish, for senior decision makers involved in making these very tough decisions, could be a very useful kind of support.” (P05)

4. Values in policy-making

Reflecting on their policy- and decision-making during times of austerity, all of them reflected on the values considered at the time. The degree to which this was done however is diverging, ranging from very explicit reflection and mentioning of values to rather implicitly revealing them.

Some policy-makers – the ones following or being involved in a political party – reported that they make distinctions between their political party's values and ideology and their individual values. One interviewee stressed the fact that when their personal moral values conflict and clash with their political party's values, this would be often at the expense of personal values.

“When talking about the difference between a personal ethical decision and the party's ethical decision, you try and argue within your party of course for the ethical decision, but if the majority goes against you, sometimes you have to say okay I lost that argument so I go along with the majority for the moment, then I raise it again later. So it's sometimes that you put your personal view of the ethical decision on ice but without residing from it completely.” (P01)

While it is nothing new that often political party's values take precedence over individual values, such fact has however not been empirically confirmed and helps to better point towards moral conflicts in policy-making processes and their underlying causes. Another participant also regarded the value systems in place as disappointing, as values can be rejected due to strategic considerations to reach political or personal goals.

“For me it was quite a disappointment to see that we don't really find a cluster of values that are always present in the politician decision. Although each one has their own values. Mostly more political values than moral values. Politicians in general do not really make a sharp distinction between moral values and political values. So although they have them, they can just be bent over when other interests are in place. And those interests can be national interests, and also ideological interests, and also the way they believe that their decisions might be perceived by the public in their own countries. (P03)

“So at the highest level of decision-making and policy-making it is a permanent battle of interests, it's a permanent dilemma between values, principles, promises and so on. And that of course has everything to do with politics, setting priorities, which is making decisions, but the implications could hurt enormously parts of the population. So what is justice, what is real, what is honest, appropriate? That is a permanent ethical battle at an individual level of the policy responsible, such as a minister but also a collective one such as the health care insurance or the governments. There is no politics without ethical stance or positions you could take and ethical principles.” (P04)

Relating to political decision-making, the issue of trust was raised by several interviewees. That is the importance of trust when it comes to arrangements between colleagues and maintaining trust with regard to confidentiality as stated by interviewee P06.

“And there, it's almost like a confession in church, you don't go outside and say 'oh Mrs. X says she needs help in this area', you might say that to the people who could give her the help, but you won't say that just publicly because in a way there is a

degree of confidentiality between you and your constituents. You want to maintain that level of trust. So all these things, they are straightforward in theory, but are not so straightforward in practice.” (P06)

On the other hand, trust is regarded as a central element at the policy level at large. As another interviewee states, trust is closely related to having and acting according to a certain set of values, even depicting trust as the failure in politics. Acting to a certain set of values increases trust for policy-makers, while trust is vice versa a necessary prerequisite for valuable policy-making.

“For myself, the most important thing is to have a core set of values to which we are faithful, that we publicize, so we tell voters what are our values. And we are coherent in all our decisions, so we stick to those values. This is the only way to raise trust between the politicians and the common citizen. And without trust there is nothing valuable in politics, at least from my point of view. ... Trust is the main failure in politics for me.” (P03)

As regards different kinds of value sets applied in decision-making, interviewees reported that economic values are more in the foreground than social or ethical values.

“Economic values take the immediate priority.” (P05)

They however regarded ethics as important in dealing with difficult decisions. They particularly noted that the use of a set of criteria derived from ethics could be helpful.

“Ethics should be a very important aspect of politics because ethics is a set of criteria that could allow politics to take correct and balanced decision in terms of investment. Profit is taken most of the times as the only criterion. We should find some mitigation of this absolute criterion of profit.” (P02)

The interviewee's perception is that during the aftermath of the economic crisis and its resulting austerity measures investments in physical assets and orientation towards GDP are overestimated. Instead, he proposes to invest in 'immaterial' goods relevant to society. He sees this as beneficial for society as a whole as it ensures that each individual is still contributing.

„We have to train our parameters for investment in the sense that we until now have been oriented by the GDP, which is based on the physical output. ... So we have somehow to change our criteria for investment not only to be in the physical investments but also in investment into immaterial investment. That is mainly investment on the person taking into consideration the dignity of the person and other immaterial goods that are in the domain of common good and commons. That is something that also reflects on the investments in the national health services because that is a means to invest in the person to keep the person to its highest level of contribution to society.“ (P02)

5. EU values for health

Besides the values to employ, the interviewees also state their perception of the EU values for health. Half of the interviewees deem them as helpful in implicitly guiding action, whereas the other half perceives them as a lip service only, as one interviewee put it:

"I do have some doubts about the way they are used, just like slogans, just to be in the right jargon." (P03)

Interviewee P08 proposes to change the overall guiding values in European health systems from a more economic oriented system towards one focussing more on the patient and accountability:

"They should be important, but nowadays in the real world they are not important. Being honest we are struggling to include the patient in the health care system. ... It might be that we should rethink the main values in the health care system. It should be moving from efficiency and productivity to quality, safety, transparency, accountability, fairness, and other things should be added." (P08)

The value of solidarity was discussed more in depth in terms of its application towards health during the economic crisis. Here, it was regarded as not sufficient in dealing with health on an organisational macro level. The value of responsibility was considered as more important when it comes to negotiations between different countries on EU level.

"There are two values [solidarity and responsibility] that for me are fundamental and they ... ground the development of the European Union. Solidarity, because we want to become one. 28 member states that should function as one And we cannot really expect just to put our hands and beg for something, without giving something else with the other hand. ... So if we want to expect solidarity from others, we do have to show that we are responsible in the decision, in our decision-making. We are not just asking and spending the way we just feel its right. ... Now its your turn to prove that you are responsible and that you achieve those goals in the period of time that was given to you. This is responsible behaviour. ... But if you and me, we just decide something together, and then without telling you anything I just go the other way, how do you feel? Between states it's the same thing." (P03)

6. Recommended health policy measures in times of crisis

The last theme embarked upon by the interviewees was what they perceived as 'good' measures in terms of health policy as a response to the crisis. Among those recommended health policy measures was 1) the prioritization of vulnerable groups, 2) health literacy and empowerment as an instrument for saving costs, 3) and ensuring a minimum level of health care which is accessible for anyone. The latter includes safeguarding the provision of basic rights in health care. Moreover it was recommended to 4) increase the overall spending on health, while also changing

criteria for enabling more investments towards health services. In terms of overall spending, 5) expenditure in other sectors, e.g. defence, should be reduced, however, 6) waste in health spending should be reduced at the same time. Lastly, 7) no cuts should be made in preventive and primary care, as it only results in more ill cases in the end, and 8) the importance of public opinion and the often negative power of media has to be taken into account so as to receive appropriate support for policy measures undertaken.

Discussion

The research presented above is – to our knowledge – the first interview study involving policy-makers and assessing their perceptions of decision-making regarding health and ethics during economic crisis. Previous studies have assessed the perspectives of health care professionals on austerity measures in health care provision (Heras-Mosteiro et al., 2016; Cevero-Liceras et al. 2015), with one study shedding light on professionalism and ethical issues encountered by health care professionals (Kerasiou, 2015). None has, however, analysed policy-makers' perceptions of their conduct regarding health policy making in times of austerity in ethical terms.

The data derived in this qualitative interview study shows that ethical concepts and values frequently come into play in health policy-making and ethics is thus highly relevant in policy-makers' daily conduct, particularly in times of scarce economic resources. They perceived the consequences of the economic crisis as limiting health levels of the population and restraining health care provision in general. All interviewees recalled difficult and strenuous situations, where they had to prioritize between distinct areas to focus on and invest in, e.g. medications, health professional staffing or care equipment and sites. Their approach to how to deal with scarce resources depends on the underlying ideology of the respective policy-maker, political party's or the country's policy system behind: Political outcomes depend on which ideologies and concepts of justice are employed. Aiming to align those ideologies on individual, party or country level would not be suitable and desirable, however ethics could help to analyse and hence better understand the respective concepts of justice and value systems in place. When evaluating the policy recommendations proposed in the interviews, one can see that policy-makers involved in this study rather act and argue in line with concepts reasoning for a social minimum (for instance in line with utilitarian or egalitarian liberal theories).

In general, the interviewees rather refrained from explicitly mentioning *what* they decided or according to which concept of justice, but instead focused more on *how* decisions were reached. We would have expected that policy-makers talked more about their own difficult decisions taken and for which outcome (the *what*) they had decided. That they rather refrained from expressing the outcomes of their decisions could potentially be explained by the fact that policy measures and their outcomes

differ from individual to individual taking the decision, which is based on their respective ideological understanding, which they knowingly did not want to put forward in such a study assessing general concepts of ethics in policy- and decision-making. The recommendations given for health policy measures during economic crisis are however coloured by their ideological perception. As regards *how* decisions are taken within the policy process, the interviewees could take a more general view, where they altogether mentioned values or general conditions, which they perceive as essential (to the policy-making process). Trust, and thus accountability, between involved stakeholders are perceived as integral. Trust was understood as confidentiality between stakeholders when discussing topics, as well as doing what one said one would do. Strengthening trust and accountability values could be a first step to provide the ethical base for decision-making processes. A balance between solidarity on the one hand and responsibility on the other was also considered important, as they go hand in hand according to one interviewee. Responsibility has to be shown by policy-makers, political parties or EU member states complying with the decisions taken.

With regard to setting priorities within the decision-making process, resources were allocated according to what policy-makers deemed as having 'key impact'. We interpret their definition of key impact as measures which maximise population health, e.g. as investing in doctors and nurses, who could offer treatment of the health condition, instead of physiotherapists, who usually offer supporting services for improving treatment and healing. Hence, they act according to a utilitarian, egalitarian approach to setting priorities. Apart from the policy-makers own perceptions of how to make decisions, they however also take into account the power plays both between certain stakeholders within their own party as well as within society in general, such as media, voters, associations, lobbying parties among many more. Their own perception of the 'best' decision might then be placed in the background. Moreover, they are disappointed by the fact that economic values are usually more important than social values.

According to the interviewed policy-makers the need for ethics assistance in terms of tools or advice is increasing. They deem the degree of objectivity provided by ethical analysis as facilitating their decision-making tasks. In psychological terms, this could possibly be explained by objectivity giving them an increase in confidence when being in charge of tough and often emotional decisions. Regarding the form of such ethical assistance, retreats, master classes and workshops were mentioned as favourable and helpful in discussing and analysing involved values and potential options of decisions to be taken.

Despite the valuable information yielded in this interview study, some limitations should be mentioned. A first obstacle was the data collection itself. Only few interviews could be obtained, which might be due to the fact that scientific interview studies are rarely done with policy-makers. Policy-makers were often not available for research, giving the reason that they have time constraints. In view of the fact that

closer collaboration between researchers and policy-makers is needed (McDaid et al., 2015), the availability of policy-makers for research should be emphasized in the future. Previous studies have noted that such collaboration is difficult to achieve in practice, as objectives differ and distinct languages and frames of reference are used by policy-makers and scientists (McDaid et al., 2015). The discipline of (applied) ethics could help here as a bridge building instrument between science and policy-making, as it stems from the research arena but tries to address real-life discourses. Public health ethics frameworks can be used to help policy-makers to address those ethical issues in real-life decision-making (Grill & Dawson, 2017).

Other methodological limitations concern the study sample. Political talking behaviours should be regarded as a constraining factor for valid information, as well as the self-selection bias of participants during the sampling process, implying that those who have an interest in ethics might have been more likely to participate in the study. During the interviews, a certain degree of social desirability bias occurred, which nearly always is the case with regard to questions involving sensitive information. By guaranteeing anonymity to the interviewees, it was tried to minimize the degree of socially desirable answers. Given the small number of interviewees, the sample is not representative and results not generalizable, yet the derived qualitative data give a sufficient level of insight into the research questions posed.

Despite those limitations, it should be noted that the study is the first empirical and qualitative assessment of ethical concepts within health policy-making during economic crisis and therefore adds an important piece to the current state of research. Future directions for research could orientate towards ethical assessments of specific high-level decision-making processes or a larger study assessing policy-makers conduct and behaviour in policy-making processes, involving a greater number of participants. In the practice field, it would be valuable to integrate approaches of ethical support in diverse policy-making processes.

Conclusion

Policy-makers taking decisions in public health or health care, feel that they have to decide on ethical issues permanently, especially with regard to issues concerning resource allocation in times of poor economic resources due to crisis and austerity.

Values could be identified, which they deem as important within the policy-making process, such as trust and responsibility. Policy-makers explicitly express the need for ethical tools and assistance in terms of policy advice for reaching morally sustainable decisions in health policy matters.

The study is of relevance, since it can provide future political decisions on austerity-related issues with an ethical underpinning and could identify areas of concern, which might be at the expense of maintaining or achieving health.

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Chapter 7 Discussion

General Discussion

The objective of this thesis was to explore the consequences of austerity and scarcity resulting from the economic crisis of 2008 on health in European and particularly EU contexts through a public health ethical perspective. Even though various moral issues can be identified in the context of austerity measures and hence re-allocations and rationings of the existing scarce resources in health systems, explicit ethical assessments remain limited and no tentatively systematical ethical assessment from a public health ethics view has been done before. Some researchers however draw attention to the role of ethics by making reference to ethical principles such as 'do no harm' or to the adverse effects of inequality emerging from the economic crisis in terms of a justice point of view (Ruckert & Labonté, 2017; Ruckert & Labonté, 2012; Stuckler & Basu, 2013; Escolar-Pujolar, Bacigalupe & San Sebastian, 2014; Mladovsky et al., 2012; Lopez-Valcarcel & Barber, 2017; De Vogli, 2014; Ifanti et al., 2013; Reeves et al., 2013; Karanikolos & Kentikelenis; 2016; Gustafsdottir et al., 2017). The thesis at hand is the first endeavour to address this gap in academic analysis thereof by assessing which normative implications scarcity – here in the case of austerity measures arising from the economic crisis – has on health and different areas within European health care systems. By focusing on scarcity in the context of austerity measures arising from the economic crisis, the thesis shed light onto arising ethical issues and dimensions in specific examples of public health. In the following, first, the findings of this research will be summarised, followed by a discussion what ethics can provide for public health during times of austerity and the added value of this research. To conclude, limitations will be outlined as well as implications for policy, practice and research.

Main findings

The thesis consisted of two conceptual parts and one empirical part, each addressing specific examples within health care systems, namely health and health care provision (part one), pharmaceutical innovation, research (part two) and policy-makers (part three).

Part 1: Health and health care provision

In the **first conceptual part** of this thesis, consequences of the economic crisis and austerity on health and health care systems and provision were evaluated against normative ethical frameworks – the so-called 'capabilities approach of justice' (CA) in chapter two and Fritz Jahr's Imperative in connection with the principle of 'first do no harm' in chapter three.

Impact of austerity on health and health care provision: from the view of the capability approach

In **chapter two** a literature review gave an overview about the policy approaches to fiscal consolidation and austerity measures in health. By applying the CA by Amartya Sen, health outcomes of those policy approaches were examined in ethical terms, precisely with regard to how they affected equality of opportunity to gain or stay in good health. The question was addressed whether the crisis had an impact on health and health care systems and how this is evaluated in ethical terms when applying the capability approach.

The assessment showed that health outcomes and access to health care services were and are impacted in a negative way. From a CA point of view, austerity measures such as reducing resources for health care, further deregulating the health care market or moving towards privatisation are ethically challenging since they limit real opportunities and capabilities for individuals of a population. Public policies should thus aim to guarantee sufficient capabilities (options to access health care and possibilities to make healthy choices) for its populations. Prioritising those in need is a notion the CA particularly focuses on in its goal of supporting those with the least capabilities.

Applying the CA highlighted several cases which identified ethical perspectives where policy representatives should provide burdens of proof for certain actions, hence providing justification for or substantiation of their decisions. Moreover, the CA denotes that the success of policies should not only be considered within terms of overall life expectancy, incidence and mortality rates or cumulative figures such as GDP, but rather the distribution thereof within societies. Measures should involve other information about the well-being of human beings, both on overall population level, as well as taking into account the individual level, thus stressing the need to strengthen social safety nets. What the CA can provide for such ethical evaluation of austerity and health, will be discussed later on (see paragraph on added value of the research).

Impact of austerity on health and health care provision: from the view of 'first do no harm' and Fritz Jahr's Bioethical Imperative

The few existing proposed recommendations as to how to react to the economic crisis are using consequentialist approaches, as done by Stuckler & Basu (2013) who point out the consequentialist principle of 'first do no harm'. Stuckler was also the first to explicitly introduce ethical norms – stemming from the realm of the medical profession – to public health discussions of the economic crisis. Hence, it was inviting to assess this proposed normative guidance. Despite the clear ethical normative imperative that harm is to be avoided, the CA applied in chapter two offered a perspective to fill the wide term 'harm' with more concrete criteria, namely as the lack of capabilities which are spelled out by Sen. In order to fully grasp the ethical dimension of such a threat for health and health systems, a deontological theory was applied to the case under study. In **chapter three** therefore, another theory founding the roots of bioethics in Europe was applied, which is Fritz Jahr's Imperative. By juxtaposing the 'first do no

harm' principle stemming from the consequentialist realm with the deontological perspective of Jahr's Bioethical Imperative, further ethical implications of austerity measures for public health could be identified. Here, the aim was to identify which public health issues that are at stake during austerity ethics can bring on the agenda – from an individual ethics perspective (juxtaposing a consequentialist with a deontological approach).

Main findings were that the proposed normative guidance of 'first do no harm' focuses on a minimalist morality (Beauchamp & Childress, 2013), taking into account only one-to-one relationships, originally the one between physician and patient. 'First do no harm' suggests for instance to assess policy options according to their risks, benefits and intended as well as unintended effects. By adding Jahr's deontological perspective, the need to strengthen social safety nets in accordance with the Keynesian approach as identified by the CA is supported. What is more important is that Jahr's account adds a Kantian perspective that sees persons as an end in themselves and not as a means, reminding not to use people for the benefit of others. However, if the troika imposes austerity on some (southern European) states this seems to currently benefit only other (northern European) states. Jahr's Bioethical Imperative points more towards the positive value of creating benefits and the conditions for dignity, self-respect and respect for others. By this, Jahr's Imperative amends Stuckler et al., by showing that there is and should be more at hand from an ethical perspective than 'first do no harm'. Specific actions according to Jahr's Imperative could be identified for increasing public health during scarcity, such as

- supporting economically weak by strengthening social safety nets (in accordance with Keynesian ideology),
- strengthening advocacy towards health needs, e.g. by media coverage,
- increasing health literacy so as to avoid unhealthy habits,
- ensuring vital needs in line with equality of opportunity, e.g. through access to health care,
- actively engaging in health-promoting policies in line with principles of beneficence.

Part 2: Pharmaceutical innovation and research

The **second conceptual part** aimed to address the ethical challenges of scarce resources in pharmaceutical innovation and research – specifically the context of personalised medicine and genomics. Placing the issue under study – ethical consequences of scarcity and austerity measures – in a context of the specific field of personalised genomic medicine helps to give an example of how highly innovative and costly medicine is affected by scarce resources in ethical terms.

Challenges of scarcity for personalised medicine

In **chapter four**, the question was addressed which ethical challenges scarcity poses on pharmaceutical innovations, in this case personalised medicine, and which opportunities an ethical perspective, specifically the CA, can potentially provide. Arising questions in this context of scarce resources and pharmaceutical innovation ask under what conditions new investments are justifiable. The CA answers this question with the need for investing in treatments that might be necessary for survival. Whereas utilitarianism assesses whether the maximum number of people are able to receive personalised treatment – irrespective of an equal distribution of actual health benefits or the value of equality of opportunity, libertarianism stresses that there is no moral demand on social structures to invest in health and everyone is dependent on their ‘luck’ and self-responsibility in being able to afford personalised medicine. The CA added an important feature to the predominant perspectives of utilitarianism and libertarianism, namely the importance of individual and societal freedoms or opportunities, and especially the significance of the conversion factor of genetic profiles for receiving personalised medicine. The CA assesses how personalised medicine affects patients’ ‘real options’ to benefit from such treatments: it specifies that only individuals with corresponding genetic biomarkers are able to achieve a ‘real benefit’ from personalised treatments. In terms of scarcity of resources, it can thus be regarded as efficient to only offer treatment to those who can benefit and thus attain better health from personalised medicine, and to reduce the expenses of futile treatments for persons who do not possess matching genetic biomarkers. Genetic profiles constitute the only conversion factor with regard to personalised medicine that cannot be (for the time being) changed or influenced by social arrangements. Social arrangements can help to promote research and development of personalised medicines and introducing reimbursement schemes with the goal to enable access to those therapies for those who can achieve ‘real options’ to benefit from personalised medicine. By this opportunity costs can be reduced in an environment of scarce resources.

Challenges of scarcity for research

Chapter five gave attention to ethics in research and especially genomic research. The question was addressed which challenges scarce resources pose to research ethics and integrity in an innovative field such as genomic research. As scarce resources and limited funding opportunities resulting from the global economic crisis are recently posing various challenges to research in terms of increased competition among researchers and research institutions, ethical conduct is anew in the spotlight. However, existing approaches to research ethics failed to frame these challenges so far. In this chapter, a research network or network of responsibilities was established as a heuristic framework through which changes and complexities in research ethics are modelled and can be systematically conceived. Instead of focusing only on the relationship between researcher and research subject – as done in previous approaches building on informed consent –, research ethics

2.0 takes into account the broader social dimension of research. As a first, but not exhaustive attempt to shed light on the complex and intertwined research environment six other main stakeholders besides the researcher were identified, which are: research subjects, colleagues, editors/publishers, professional associations, universities, funders and society at large. The integrity of research is challenged on diverse levels, involving stakeholders to a different extent. Some of these challenges are e.g. unfair review processes, data sharing between colleagues and patients' right not to know about genetic predispositions, conflicts of interest with regard to funding and research results. Focusing on research ethics and integrity on various levels and taking into account all stakeholders can make research better, more truthful and thereby more socially acceptable, which is important since it influences support for research in general. By promoting accountability and public trust through such network of mutual responsibilities and rights, emphasis on moral values can be regarded as a driver for science. To uphold ethical standards in such a broad perspective is important in times of scarce research resources, so that integrity can be safeguarded in the long run and will not be diminished when competing for research grants.

Part 3: Perceptions of European policy-makers

The **third part** entailed an empirical assessment, precisely an explorative interview study with the ones in charge of health policy-making, so that their perceptions about ethics in policy- and decision-making could be revealed: In **chapter six** a reality-check was done as to find out how European policy-makers perceive the economic crisis with regard to health and which values and ethical implications are regarded as essential for policy and priority-setting.

For getting deeper insights in this regard, European policy-makers were interviewed about how they a) perceive the economic crisis with regard to health, b) which values they perceive as essential to be integrated in policy-making during challenging situations with regard to priority-setting and decision-making in health policy matters, and c) how they evaluate the role of ethics in political decision-making.

It could be shown that all policy-makers perceived moral dilemma situations within their daily decision-making, ranging from decisions involving trade-offs between different areas to invest in, e.g. drugs for hepatitis C medication or breast cancer therapies, to deciding upon strategies to centralize health care provision sites and closing down other, which led to geographic imbalances. Moreover it became apparent that hierarchies of values determine their actions, specifically with sequencing values according to their predominance: First, in the competitive policy-making arena personal values come second after political party's values. Second, economic values are usually more important than social or ethical values. Third, EU values are deemed as important in passively guiding action by some but are rather perceived as a lip service only when they are not binding and no consequences happen if countries or politicians do not comply with those values. Fourth, other values of importance to policy-makers were mentioned, for instance responsibility (which is

deemed as more important than solidarity), specifically when it comes to negotiations or agreements between different countries on EU level.

Policy-makers furthermore reported about possible health policy measures in response to the crisis, which they think could improve the overall health situation of EU citizens. Among them were the prioritization of vulnerable groups, enforcing empowerment and health literacy as an instrument for saving costs, not cutting preventive care and spending more on health while reducing spending in other sectors, e.g. defence.

The empirical data derived from European policy-makers showed that ethics is highly relevant in health policy making in times of scarce economic resources and that there is an increasing need for ethics assistance in terms of tools or advice. An overview of the main findings of this thesis is shown in figure 7.1.

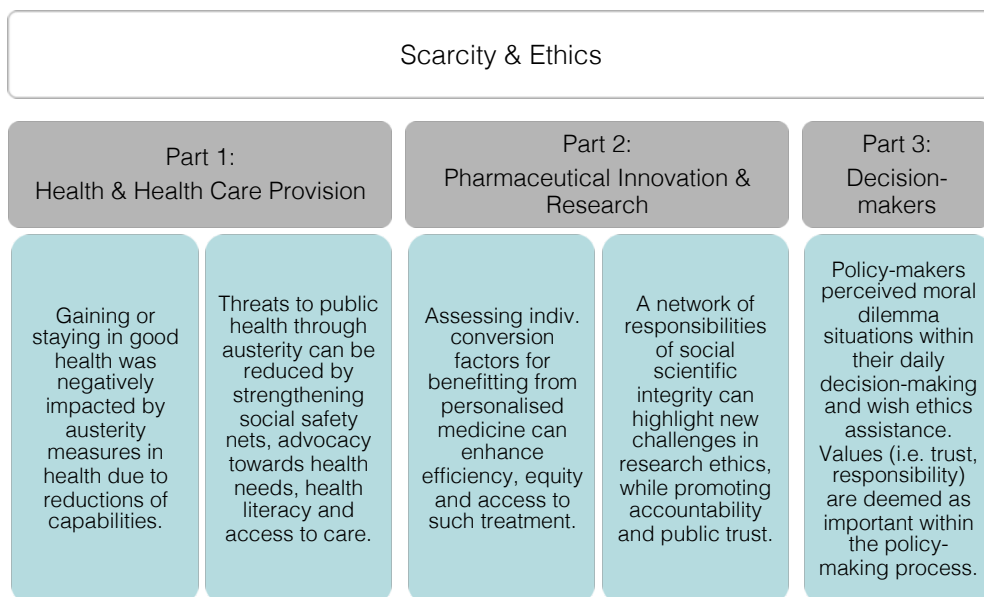


Figure 7.1: Overview of main findings of the thesis.

In the discourse that follows in the subsequent part of the general discussion, common core elements of the separate articles will be highlighted on a general level and the added value of this research and will be discussed. On an overall level, the question what ethics can provide for public health in times of crisis is addressed.

What ethics can provide for public health during times of scarcity

The following sub-chapter discusses what ethics can provide for public health during times of scarcity by elaborating on the aspects, which could be identified in the course of this thesis for improving policy-making from an ethical view, thus interpreting the findings from the separate chapters on an overall level.

Identified aspects to focus on in policy-shaping from an ethical point of view

When assessing the impacts of the economic crisis on the different levels within health care (which were health and health provision, pharmaceutical innovation, research and challenges for decision-makers) from an ethical point of view as done in the research presented above, several aspects could be identified which were raised on the different levels or contexts and seem important for dealing with scarcity on an overarching level in an ethically favourable way. The identified aspects came to the fore in the course of this study due to a) applying an ethical perspective and b) the specific context of challenging circumstances of scarce resources. Even though they are often overlooked, especially in contexts of non-austerity, focus on such aspects increases the social emphasis in otherwise merely economically oriented questions and policy approaches. Basu, Carney & Kenworthy moreover propose to place an increased emphasis on “pro-active and positive science” instead of only focussing on “negative science documenting atrocities” in the context of the economic crisis and health (2017, p. 206). Concepts suggested in the following can thus be regarded as the aim to develop recommendations for ethical policy-making.

Constituting a key aspect, which could be stressed throughout the research presented in this thesis, is the role of values. In all studies carried out, values played the central role in guiding action. Values are not only central in guiding morally favourable arrangements within research, e.g. on the level of institutions or organisations, but also affect behaviours of individual policy-makers, who act according to their personal or party’s value set. Values thereby shed light on how decisions are taken and influence what outcomes are sought (Schröder-Bäck, Stjernberg & Borg, 2013; Clark & Weale, 2012; Batifoulier, Braddock & Latsis, 2013). Throughout the research for this thesis, predominant values could be identified, which did not seem crucial for public health in general at first sight, but which were placed in the foreground when looking at public health during times of austerity. They are informed by employing the CA as the underlying theoretical framework, however go beyond the proposed values put forward therein. Those values identified in the course of this research are as follows (being clustered according to the different parts of the thesis, as also depicted in figure 7.2):

- (Real) freedom, (real) equality of opportunity, empowerment, worth of human beings, dignity, self-respect and respect for others, beneficence and non-maleficence (part 1),

- Equality of opportunity, empowerment, integrity, truthfulness, responsibility, fairness, trust, accountability (part 2),
- Trust, confidentiality, solidarity, responsibility, accountability (part 3).

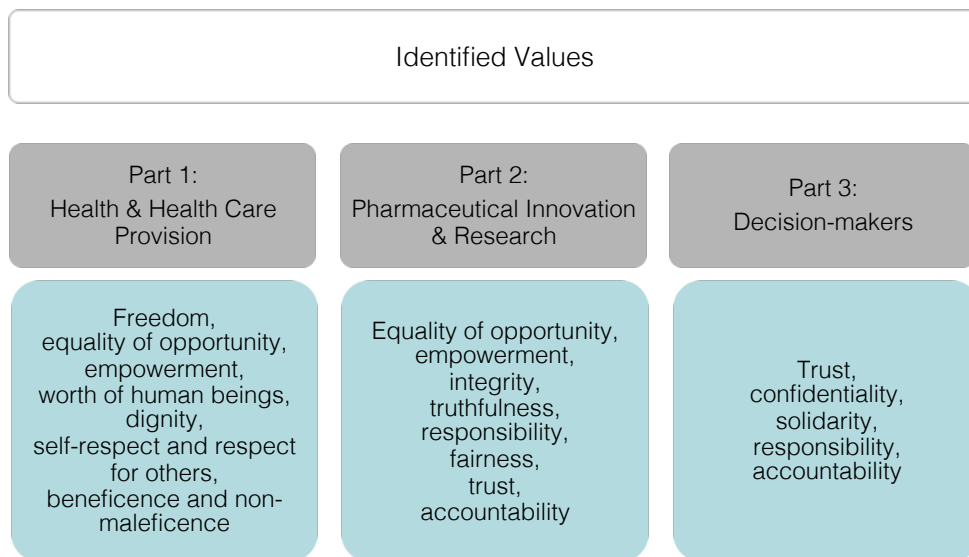


Figure 7.2: Identified values in this research.

What those values have in common is a shift away from hard economic measures and criteria – which policy-makers often have to deal with during their daily conduct – towards values strengthening the social and moral scope.

A value to be specifically discussed is dignity, as it was identified as an underlying value from all different perspectives taken and gained increased emphasis from the ethical assessment in the course of this thesis. Not only the two theories applied – the CA and Jahr’s Imperative, which both stem from a justice-oriented stance and therefore clearly embrace rather similar values, – underlined the special role of dignity of persons in health policy during times of scarcity: By rendering focus towards this value, the social orientation of health policy approaches can be increased. As outlined above, the need to focus on dignity of persons was explicitly raised by policy-makers, also in line with increasing wealth of the population by increasing health of its individuals, who should receive increased attention. The concept of dignity is furthermore relevant in research, where policies have to be shaped in order to safeguard those involved – the research subjects – but also the other stakeholders involved, such as researchers, publishers, professional associations, universities or funders. This concept should also more widely be applied in health policy in general, where the same standard applies: to protect those involved – the individuals or

citizens. Cost containment measures, which might reduce the personal contact in health care (which some call 'dehumanisation of care' (Molina-Mula, 2012)), should hence aim to maintain a sufficient level of dignity for patients in health care provision.

Another aspect, which could be identified throughout all chapters as having increased importance from a justice-ethics point of view, is health literacy. Both normative theories highlighted its significance for leading an autonomous life by using the opportunity for informed choice. In the context of pharmaceutical innovation and research (chapters four and five) its importance could furthermore be validated. It not only opens up opportunities for novel therapies – doors which would otherwise remain closed when no or only insufficient knowledge about those therapies would exist – but also renders research subjects an empowered stance in informed consent. Consequently, the concept is moreover closely related to empowerment. In line with the CA, empowerment can be seen as a main element in choosing the life one values. Empowerment should hence be emphasized on several levels in public health: On the patient or citizen level it can increase autonomy and informed choice in choosing health care options suitable for the individual. On the health care professional level it can furthermore contribute to improve patients' capabilities of accessing health care as well.

The role and accuracy of GDP in assessing economic growth was raised in chapter two, when applying the capability approach to available literature on the impacts of the economic crisis. It was affirmed that GDP rather hides inequities within a population as well as between populations, as it focuses on percentages of a set of macroeconomic indicators and does not take into account several parameters that are crucial to well-being, such as employment, life expectancy or health literacy. In policy contexts, GDP is however often used as a measure to material well-being as opposed to being used as a measurement of a nation's total economic activity solely. This critique of GDP as a measure to assess well-being of a state's population is also supported by findings from the interviews with policy-makers, who state that instead of focussing on GDP other factors should be taken into account when assessing well-being and defining parameters for investment. In the interviews, dignity was mentioned as one factor in assessing well-being. Such perspective is also fortunately adopted in actual government actions, when the French government employed the Commission on the Measurement of Economic Performance and Social Progress in 2008, where Amartya Sen also acted as Economic Advisor. Aim of this Commission was to find and establish new ways to measure wealth and social progress of a nation (Stiglitz, Sen & Fitoussi, 2011). That such endeavour is supported by a national government immediately after the onset of the economic crisis can only be seen as favourable in social, ethical, but also economic terms, as it delivers more suitable measurements for each of those areas.

Additionally, the role of media was identified as having a considerable impact on policy-making in general. As pointed out by the interviewed policy-makers, public opinion and possible negative power of media has to be taken into account in policy processes. Policy-makers should not be influenced by what is the common opinion presented in media, nor should media be influenced by economic interests (or at least policy-makers should be aware of the latter). A problem that arises for policy-makers is that their popularity and election chances are dependent on how media reports about them or their party to a large extent. Being in a critical stance towards media is however often no option for policy-makers, as one interviewee stated, that “either you are for the media or you just don't have a voice”, which they perceive as a vicious circle. The role of media should therefore be given an increased focus in the years to come in ethical assessments as well as in social research in general. The role of newspapers and media was also pointed out by applying Jahr's Imperative in chapter three, where he sees it as crucial for ‘character formation’. It follows that it is key to strengthen the social responsibility of newspapers and media agencies. In line with public health advocacy developments, it can be seen as a moral duty of media to report on ethical aspects of the economic crisis as well.

Strengthening social responsibility of media is also in line with the network of responsibilities established in chapter five. This network of responsibilities is also valuable for the policy context and this idea can thus be transferred from the narrower research perspective to the broader public health sphere: Every stakeholder has to jointly work together in order to improve health policy. This is also closely connected to the concept of ‘governance for health’, which is defined as promoting “joint action of health and non-health sectors, of public and private actors and of citizens for a common interest. It requires a synergistic set of policies, many of which reside in sectors other than health as well as sectors outside government, which must be supported by structures and mechanisms that enable collaboration” (Kickbusch & Gleicher, 2012, p.4). It follows that it should be more broadly recognised that actions and circumstances of one stakeholder also affect a variety of other stakeholders within the network. Looking at the interdependencies and thereby highlighting ethically challenging aspects helps to realise sustainable structures in the health policy field. Chapter five thus has provided a basis in rethinking networks in a way that every stakeholder holds responsibility towards the other stakeholders involved. Transferring this concept from the research network to the ‘public health policy network’ can help to highlight dependencies between single stakeholders involved. What is more, it enables to assess those dependencies from an ethical viewpoint. The policy network has policy-makers in the heart of an environment, which involves stakeholders such as citizens, political parties, (governmental and other) public institutions, associations and companies, all sectors relevant for health, as well as media. A depiction of such a Public Health Policy Network is shown in figure 7.3.

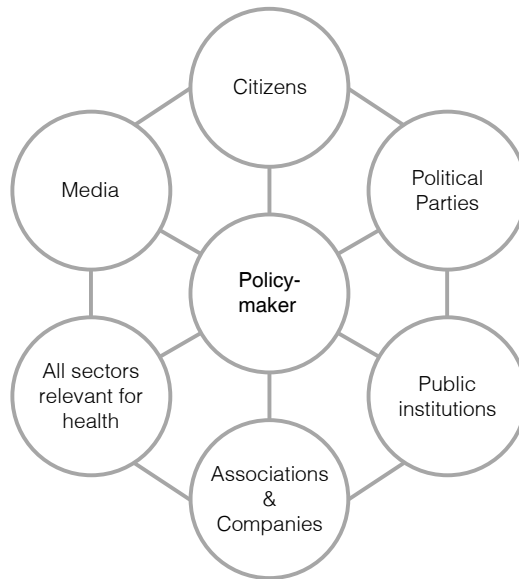


Figure 7.3: Public Health Policy Network (own figure, adapted from Brall et al., 2017).

With regard to the main stakeholder within the public health policy network – the policy-maker –, the interview study conducted within this research with policy-makers from six culturally diverse countries in the European Union revealed that political decision-making has to deal with various kinds of moral problems. Decisions have to be made, but decision-makers also need to be able to deal with moral uneasiness and residue, finding solutions for difficult trade-offs they have to make. The development of ethically sound decisions is needed and a field where policy-makers expressed their need for receiving support in terms of ethical assistance. Ethically sound decisions can moreover be seen as a precondition for socially acceptable and sound policy-making. In supporting policy-makers, actions should be taken on EU and national government level to offer ethics assistance, e.g. by offering workshops for specific issues or retreats in which ethical instruments are taught to policy-makers, which they can make use of independently for pressing queries and decisions thereafter.

A method, which can be applied when aiming to reach decisions, is the moral case deliberation method (Molewijk et al., 2008). It assesses the values of each stakeholder involved and the resulting norms they think as most reasonable to act upon. Closely assessing those values and norms can lead to alignment of actions deemed most reasonable from the perspective of different stakeholders and can supposedly help to bring political party's and personal values in line. This method is hence suitable and helpful in guiding practical decision-making processes in health care policy and can help to establish value-based leadership in the political context.

Having interpreted and conjoined the findings of the separate chapters on an overall level and having tentatively developed recommendations for ethical policy-making in this sub-chapter, the following sub-chapter will reflect on the added value of the research of this thesis.

Added value of this research

In this paragraph, the added value of the research will be discussed from three angles: Firstly, it will be recapitulated what has been learned in the last ten years since the onset of the economic crisis about its consequences on health and why it is important to perform such an assessment. Secondly, it will be discussed what could be learned about the added value of an ethical assessment of that matter. Thirdly, it will be addressed what could be learned about the ethical approaches used within this thesis.

Looking at the crisis: What was learned about the crisis and health?

When starting this research in late 2013, research results about the health effects of the economic crisis were not available to a great extent. With a time lag of approximately two years, health data about the years 2009 – 2011 just became available in 2013 and first had to be analysed and prepared for publication before any scientific evidence for the adverse effects could be provided (Stuckler et al., 2017).

Regarding consequences of the crisis, it was anticipated in the public health community that the effects on health would be severe. Yet, ten years after the onset of the economic crisis, it is observable that on the population level health indicators were not affected to such a large extent and that existing studies need to be taken cautiously due to an existing risk of bias from heterogeneous data (Tapia Granados & Rodriguez, 2015; Parmar, Stavropoulou & Ioannidis, 2016). Entitled “Greek economic crisis: not a tragedy for health”, an article in the BMJ already pointed out in 2012 that studies available until that date were exaggerated and that the health care system in Greece was inefficient even before the economic crisis hit the country (Liaropoulos, 2012). The study, however, also points out that the situation could have gotten worse after 2012 and would need to be reassessed in the years to come. Tapia Granados & Rodriguez compared the health outcomes of the crisis for Greece, Finland and Iceland until 2012 and concluded that health levels did not diverge between the countries, concluding that a ‘health crisis’ in Greece seemed overstated (2015). All in all, however, research that has been done to date widely confirms the negative consequences of the economic crisis on health and health care systems (Vandoros et al., 2013; Heras-Mosteiro, Sanz-Barbero & Otero-Garcia, 2016; Reeves, McKee & Stuckler, 2015) – even if a worst case scenario (luckily) did not emerge. Above all, mental health and suicide rates have been shown to increase as a consequence of the crisis (Branas et al., 2015; van Hal, 2015; Baumbach & Gulis, 2014; Parmar, Stavropoulou & Ioannidis, 2016; Reeves et al., 2015). Different health outcomes were

reported country-specifically (Asgeirsdóttir et al., 2014; Olafsdottir, Allotey & Reidpath, 2013; Tapia Granados & Rodriguez, 2015; Astell-Burt & Feng, 2013; Barros, 2012; de Belvis et al., 2012; Economou & Kaitelidou, 2014; Gené-Badia et al., 2012; Jankauskienė, 2010; Kentikelenis et al., 2011; Kentikelenis et al., 2014; Kondilis et al., 2013; Maresso et al., 2015; Millionis, 2013; Simou & Koutsogeorgou, 2014; Thomas et al., 2013; Thomson et al., 2014). For instance levels of self-reported access to health were considered low as in Portugal (Legido-Quigley, 2016), while unmet health needs are reported as high for instance in Greece (Zavras et al., 2016). In general, it can be concluded, that consequences of the economic crisis on health are negative, yet health disasters or worst case scenarios did not happen, in contrast to what was anticipated at the start of this thesis. However, views about the severity of adverse effects of the crisis remain diverse, which might be explained by re-citation patterns between existing economic studies where no new primary data are used (Stuckler et al., 2015). Also, it might depend on which data and parameters are used for evaluation.

What is the added value of an ethical evaluation of consequences of the economic crisis on health?

Despite those different perspectives on the severity of consequences on health (on an overall population level) and health care, the ethical assessment of spending cuts is important as it adds a social-humanitarian point of view. In the research presented in this thesis, first available studies about the effects of the economic crisis and corresponding austerity measures on health and health care were analysed by assessing the findings from an ethical perspective. Until the start of this thesis ethical assessments of the consequences of the economic crisis on health were rather limited to implicit discussions of ethical and moral issues arising in this context as outlined in the introduction section of this thesis. Systematic and explicit ethical assessments of the issue under study were not available. Adding the ethical stance towards the public health assessment yielded ideas on which values and factors play a role for equitable health policy and health care provision. Moreover, ethically relevant burdens of proof could be identified and the real value behind otherwise often 'empty' political statements and declarations could be revealed. The importance of ethical analyses in general and ethical policy analyses in particular, is that they provide lenses through which specific circumstances can be assessed, evaluated and morally challenging issues can be identified.

Yet, evaluations performed in previous chapters of this research do not provide an ethical, normative algorithm for reaching 'right' decisions or to take decisions for policy-makers. When only taking into account population level health indicators, impacts of the crisis on health do not seem severe from a retrospective angle. However, ethics points towards the importance of not only looking towards overall population health but that every single individual should be taken care of in terms of health and access to health care provision and should not be 'left behind'. Only looking at overall public health levels is an example of how the public health view can

conceal the perception that every individual should be taken into account when policy measures are to be shaped in an ethically favourable way. Estimating the severity of the crisis only with regard to quantitative overall measures on population level is thus maybe convincing from an empirical public health perspective, but not sufficient from an ethical point of view. Here again, the public health network can increase the scope of common public health ethics approaches: it extends the focus of looking at the underlying conflict between good for the population at the sake of good for the individual (which can be termed as public health 1.0 in analogy to our established distinction between research ethics 1.0 and 2.0) towards an overall ethical perspective involving all stakeholders involved. Therefore, it is crucial to assess public health measures and policies in a multidimensional way, instead of only placing emphasis on either the individual or the population. Applying ethics to economically oriented issues, where resources are limited and economic evaluations are usually in the foreground, can however provide lenses how to allocate those existing resources in a way that i.e. inequalities are reduced, access to health care is guaranteed and other opportunities to achieve a life one values are provided. As shown above values could be identified, which – when applied and taken into account during policy-making – could render an ethical basis towards more 'ethical' policy-making.

By adding the ethical stance towards the assessment of consequences of austerity on health, the existing gap in research, which was outlined in the introduction of this thesis, could tentatively be addressed. That there is a lack of ethical assessment and guidance was furthermore stressed by the interviewed policy-makers. They explicitly wish for ethics assistance in order to aid in moral dilemma situations with regard to rationing of resources for health care. When assessing the currently available literature about ethics and austerity a decade after the onset of the economic crisis (as outlined above and in the introduction chapter of this thesis), it moreover becomes clear that the need for ethics in policy-making mentioned in the empirical research with policy-makers has not been sufficiently addressed so far. Hence, it has to be concluded that a gap in research about ethics and austerity is still there. Unfortunately, ethics is still not a key priority within public health, as is shown by the still underdeveloped teaching of ethics within schools of public health curricula (Camps et al., 2015; Lee & Royo-Bordonada, 2015; Aceijas et al., 2012). The lack of ethics education in schools of public health as well as the wish of policy-makers for ethics assistance leads to the conclusion that ethics should receive more attention within public health circles. Firstly, more academic research on ethics with regard to scarce resources is needed, whereas secondly the practical application and use of ethical assessments and evaluations in policy-making should be emphasized. In general, awareness about ethics and its relevance should be increased, since it can provide valuable grounds and argumentation bases for more just, equitable and reasonable health policies.

Taking into account the strengthening of development and introduction of ethics within policy-making, it should be noted that, in contrast to the common view that the austerity agenda has most severe adverse effects on population health levels and

health systems, the global economic crisis could however also be seen as an opportunity to reinforce commitments to values such as equity, solidarity, justice and protection. Földes (2016) as well as Clemens, Michelsen & Brand (2013) identified that the crisis enabled to place health system goals on the EU agenda to a so far unseen extent. Given this increase in relevance of health objectives on the political agenda, it would be positive to also improve EU policy-maker's competence in terms of ethics, so that sound decisions can be taken in this highly sensitive field affecting lives of the entire EU population.

What has been learned about the applied ethical approaches?

For assessing the consequences of the economic crisis on health and health care provision in ethical terms, a theory stemming from social ethics (the CA) was applied as well as two theories stemming from individual (bio-)ethics, where the proposed normative guidance of 'first do no harm' was contrasted against a basic and foundational theories, namely the Bioethical Imperative of Fritz Jahr.

The capability approach (CA), which was applied as a theoretical framework in this research to assess main elements within a health care system, namely health care provision (and resulting health outcomes) and pharmaceutical innovation, helped to frame and identify justice-related questions, particularly taking into account vulnerable groups and their real options or opportunities to attain health. It addresses issues, which are at the core of moral questions arising from the economic crisis, including justice in terms of ensuring fair access to health care services and expensive pharmaceuticals and reducing health inequalities. Applying the CA framework, it was possible to detect where those values are restricted. Hence, the CA helped to evaluate which basic conditions need to be provided in public health and health care provision as well as how innovations in health care can be offered to the population, which were outlined in the chapters before. It addresses the importance of individual freedoms in view of social and economic determinants, thereby suggesting how inequity-proof policies can and should be constructed (Breton & Sherlaw, 2011, Robeyns, 2017).

What is more, is that the CA focuses on discrepancies between individual and society, which were identified as an aspect within public health that needs to be reconsidered in public health discourses as also outlined above.

By detecting social restrictions that limit well-being and for the purpose of exploring what is at stake in terms of health during times of austerity, the CA provides a useful framework for assessment given its practical applicability and focus on single components of just opportunities to achieve health. Therefore, applying the CA offers useful guidelines to realise policy-making according to requirements of justice, equity in access and reductions of inequalities. Given its practicability and operationalisation for practice, the CA already receives attention in existing international policy-making instruments and efforts, such as the Human Development Index (Robeyns, 2017).

In general, the CA was useful to identify issues and values arising during times of austerity, which are ethically challenging from a social ethics perspective.

The theories applied, which stem from bioethical approaches, namely the Bioethical Imperative of the founder of bioethics Fritz Jahr and the principle of 'first do no harm' offer useful guidance from an individual ethics perspective. They were helpful to take into account the individual, in line with "health for all" endeavours. 'First do no harm' sets out a minimalist principle that policies should be designed in a way that nobody is harmed. However when juxtaposed with Jahr's Bioethical Imperative, ethical challenges for public health could be further pointed out. Jahr's concept of bioethics helped to identify other relevant ethical criteria – such as dignity, self-respect and respect for others.

While the CA points the perspective towards overall population health and issues of equity and access, the individual (bio-)ethics perspective includes useful guidance on how to improve policies based on values of responsibility and dignity and to advocate for public health. By focusing on respect and dignity, Jahr adds and strengthens the role of choice as laid out by the CA, e.g. in the sense of respecting an individual's choice when opportunities are willingly not transformed into functionings. Combining those theoretical approaches stemming from bio-ethics and public health oriented social ethics is helpful in connecting views focusing on the overall population level in a first step and further refining it with view to the individual, who should not be 'left behind'.

Despite the usefulness of the chosen ethical approaches to shed light on the consequences of the economic crisis and austerity on health from a public health ethical perspective, ethical analyses cannot be regarded as completely exhaustive and definite, since different theories takes distinct and specific perspectives to analyse the issue at hand. It is almost impossible for a single theory to take into account all aspects involved and to fully convince. Hence, further development and elaboration, specifically for addressing austerity in health systems from an ethical perspective, is needed. When addressing austerity in health systems from a social justice point of view, other theories could be drawn on to, however, the CA revealed several advantages as already outlined above, including its practicability. Specifically elaborating on the advantages and disadvantages of other existing theories of or approaches to justice would go beyond the scope of this thesis. Here, it will be confined to state that the advantage of the CA lies in its basic approach to embrace and focus upon the real opportunities of an individual to achieve the functioning he or she values. In contrast to other theories of justice, the focus of the CA is here on rather immaterial goods and values in a real world setting than solely the distribution of economic resources in an ideal world (as e.g. laid out in other theories of justice, as e.g. by Norman Daniels following the ideal theory of John Rawls (Daniels, 1985; Daniels, 2008; Rawls, 1971).

In addition to the applied theoretical approaches, practical analyses from the stance of empirical ethics should be strengthened, as they uncover additional complexities

and other morally challenging conditions and aspects, thereby yielding helpful guidance and emphasis on what is at stake during times of austerity and scarcity of resources (in a real and not ideal world). Within the research presented in this thesis, the practical examples derived from the interviews with policy-makers provided valuable insights into ethically challenging issues in the real world – and highlighted additional complexities than the ones pointed out during the theoretical approaches. However, the applied theoretical approaches are helpful in defining challenging issues within the field first, providing a useful basis to further highlight and elaborate those identified peculiarities and specificities in the course of an empirical analysis. A combination is hence fruitful to grasp the issue in a holistic way.

In the subsequent sub-chapters, the limitations of the research as well as implications for policy, practice and future research will be depicted.

Limitations of the research

The presented research entails certain content-related as well as methodological limitations. As regards the former, not many economic studies were available when the research was commenced, since the consequences of the crisis on health only showed with a time lag as described above. In view of this, the conceptual, ethical analyses in part 1 and 2 were based on the limited existing literature about the consequences of the economic crisis since 2008 on health and health care in Europe. Moreover, the ethical analyses take a specific perspective, namely a justice-oriented point of view according to the capability approach from a social ethics perspective and bioethical analyses of Jahr's Bioethical Imperative and the principle of 'first do no harm', stemming from an individual ethics perspective, which inherently limits the scope of the assessment. In general, the topic as such already posed a difficulty since both concepts – ethics on the one hand and consequences of the economic crisis on the other – are rather vague and intangible and therefore hard to measure and assess. In addition, the topic of this thesis is inherently interdisciplinary, involving at least the disciplines of public health, economics and philosophy and touching others as well, for instance politics, finance, sociology or epidemiology. Each of those disciplines could raise the claim for taking a deeper understanding of their respective domain. Hence, the topic leaves ground for much more research, taking an in-depth perspective from each discipline. The thesis did not provide a comprehensive guideline, yet introduced certain criteria for enhanced policy-making during times of austerity from an ethical perspective, which can be regarded as important benchmarks to meet in policy-making. How these benchmarks should be met in practice depends on the political process and has to be established by policy-makers.

The interview study in the third part of this research tried to be more explicit by employing an empirical study while assessing ethical questions occurring to decision-makers, a method which is referred to as empirical ethics (Goldenberg, 2005; van der Scheer & Widdershoven, 2004; Molewijk, 2004). Addressing the research question

with qualitative empirical data, however also entails certain limitations, among them lack of generalizability, few available participants and social desirability bias, which were already mentioned more thoroughly in chapter six. Lastly, applying certain ethical theories (the CA and Jahr's Bioethical Imperative in this thesis) determine the perspective used for the research and hence cannot provide an all-encompassing ethical analysis from all ethical perspectives and theoretical stances available. Instead, selected frameworks for analyses were applied – as is common practice in bioethics and public health ethics.

Implications for policy, practice & future research

Arising from the thesis laid out above, several implications can be identified for policy, practice and future research.

An implication for improved policy and practice is to foremost include ethics in policy-making processes, in order to increase accountability. Apart from the economic crisis, there are other challenges for policy-makers and society in general, such as fake news, Euro-Scepticism leading to developments such as Brexit and other difficulties to deal with. Basu, Carney & Kenworthy even state that austerity should be regarded as an "alternative fact", implying that austerity and questions about capital distribution shape the public debate instead of emphasising "concepts like decency, rights, understanding, empathy, community" (2017, p. 204). Throughout various countries in the European Union, a shift to and strengthening of right-wing parties could be observed within the last few years. Analysing and referring to historical developments of the 1930s, McKee et al. connect this to economic instabilities and warn about the negative impact on politics in general (2017). Therefore, ethics and values such as responsibility and public information through media gain more and more importance in informing citizens in a sound and critical way and shifting the focus towards more socially oriented ambitions. In practice, ethics should be embedded in decision-making processes, since it can provide a kind of 'moral guidance' in times where trade-offs have to be made. Apart from basing trade-offs on values such as solidarity, equity and justice, procedural ethics, precisely in relation to justice, should be integrated and emphasized in policy-making (Schröder-Bäck, Stjernberg & Borg, 2013).

Albeit the economic crisis poses a threat to health care systems and yields adverse effects on health, it can also constitute an opportunity for public health to stimulate change (Marmot & Bell, 2009; Fineberg, 2013; Bezruchka, 2009; Stuckler et al., 2010a; Stine & Chokshi, 2012). Central for stimulating change will hence be strengthened advocacy for health. Stuckler et al. put forward that areas having strong advocacy also tend to be hit less by cuts in spending and services (2010a). In line with this, 'health literacy' should be improved for policy-makers, meaning that evidence should be better translated into easily understandable messages (Fineberg, 2013).

Further research with regards to the economic crisis on the one hand, and ethical assessments of policy processes and on-goings on the other, is indispensable. Here, past experiences have to be evaluated, however the focus should be on how to improve responses to future crises in line with suggesting recommendations instead of only documenting past miseries (Basu, Carney & Kenworthy, 2017). In order to achieve this, the following research efforts should be made.

Firstly, the knowledge gap has to be closed with regard to strengthening resilience to health threats resulting from economic downturns and which policy responses can result in a reduction of risks (Allebeck, 2013; Brand et al., 2013; Karanikolos et al., 2013; Williams & Maruthappu, 2013; Stuckler et al., 2011; Horton, 2009; Drummond, 2013). Also, evidence should be generated about the interaction between economics and health, which can also result in adjusting the interactions between security, health, economic development and foreign policy (Horton, 2009).

Secondly, measures how to reduce arising inequalities arising from scarce resource settings have to be assessed and implemented.

Thirdly, further ethical analysis of applied policy-making should be done. This would also lead to a better social acceptance of policies in general.

Fourthly, research has to be done with regard to improving research methods for ethics. The relatively new methodology of empirical ethics is a first step in this endeavour. Focusing specifically on the policy field would be an added value not only for research, but also for practice in the end. In translating knowledge between scientists and policy-makers, the discipline of (applied) ethics can help as a bridge-building instrument, as it stems from the research arena but tries to address real-life discourses. The relatively new field of translational ethics – which deals with the translation of ethical norms between the theoretical discourses of philosophers and practical discourses in public health – could be a valuable source of input for those discourses in the future. In general, it can be said, that the combination of empirical evidence and normative analysis is and remains important for (health) policy-making. As such, the Health and Financial Crisis Monitor provided by the European Observatory on Health Systems and Policies and the Andalusian School of Public Health (2018) can be regarded as an exemplary approach to offer advice and guidance, as it aims to foster evidence-based information on impacts of the crisis on health for policy-makers and other stakeholders.

Concluding remarks

Ethical questions with regard to scarce resources are a recurring issue in today's decision-making in society at large. However, little attention is given to ethics as such during those debates on public health. A PhD thesis cannot give an exhaustive and definite response to those ethical questions and how to tackle those challenging conditions scarcity brings about. It can however try to make those ethical challenges explicit, which was the aim of this thesis. In line with this, the research presented within this thesis meant to help bring ethics more on the agenda in actual public health debates around opportunities for health, health policy-making and research regarding health in general. It carved out some conditions and values that can provide policy-making with a better ethical basis as outlined above. Shedding light on the sub-questions, the thesis contributes to what is at stake during austerity in terms of ethics in the fields of health and health care provision, pharmaceutical innovation and research, and from the view of European decision-makers.

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Valorisation

Valorisation

This valorisation addendum aims to offer additional ideas and suggestions for value creation in practice, which can be generated from the thesis presented afore.

The underlying value (and thereby also challenge) this thesis brings forward is the interdependence and combined view of – broadly speaking – ethics, economics and politics with view to public health. Analysing the consequences of austerity and scarcity resulting from the economic crisis of 2008 on health in the European context, it becomes obvious, that the social relevance inherently is at the core of the research conducted in the course of this thesis.

Economic policy-making in the health sector can be informed by the results the thesis brings forward, such as investing in health instead of shrinking available budgets, which is also in line with the line of argument concerning 'health is wealth'. The latter stipulates that a society can only flourish when its population is healthy (Figueras & McKee, 2012). Providing the opportunities for individuals to achieve health is thus crucial for "societal well-being" (Figueras & McKee, 2012). In addition, the thesis brought forward that policy-makers experienced difficult and strenuous situations during decision-making at times of scarce resources, where they had to prioritise between distinct areas to focus on and invest in, e.g. medications, health professional staffing or care equipment and sites. According to the interviewed policy-makers the need for ethics advisory or assistance in terms of tools or advice is increasing. They deem the degree of objectivity provided by ethical analyses as facilitating their decision-making tasks (chapter six of this thesis).

Against this backdrop, three main ways of value creation derived from the results of this thesis are suggested:

1) Providing ethics assistance to policy-makers in Europe and building their ethics competencies

Results of the research of this thesis are relevant for policy-makers at national and international level. In supporting policy-makers, actions should be taken on EU and national government level to offer ethics advisory and assistance. This ethics advisory and assistance could be offered in various ways, e.g. by organising workshops for specific issues with the aim to assist in particular decision-taking processes involving ethical decisions. Also, more intensive retreats (of two or three days) could be offered in which ethical instruments are taught to policy-makers, providing them with a toolset, which they can make use of independently for pressing queries and decisions thereafter. The Brussels Campus of Maastricht University could be an optimal place to host those workshops and retreats, being close to EU level policy-makers working in Brussels and serving as a networking place. In addition, concrete tools, such as checklists or guidelines should be developed, that provide policy-makers with support in decisions-making situations involving ethical trade-offs. Those services and activities aim to build ethical competencies for policy-makers themselves, so that their ethical decision-making capacities are developed. Another target group that could profit from ethics education – or rather awareness rising of ethical issues – is media.

Providing ethics workshops for media could be a way to improve social responsibility and awareness thereof for media in general.

In order to increase the focus on developing ethics competencies of policy-makers themselves, certificates in ethics could be introduced for policy-makers with the aim to improve ethical decision- and policy-making in a sustainable and long-term way.

2) Informing the public and translating between science & practice

Results of the study can furthermore inform the general public about the ethical assessment of policy developments during the economic crisis. For the academic community, the thesis showed that an improved translation between science and practice is necessary so that scientific discourses or academic tools can be better integrated and made use of in everyday health policy-making. This translation can be achieved for instance through an increased engagement of scientists within public debates on the one hand, and an enhanced perceptibility of policy-makers and the public for scientific support on the other. In general, more public health discourses concerning ethical values within decision-making are needed, as those values are at the origin thereof.

3) Establishing ethical impact assessments

With the aim to strengthen the focus on ethics within policy processes as outlined in point two, impact assessments could be introduced assessing the impact in terms of ethics, thereby shedding light onto the ethical dimension. In addition to the common practice of policy impact assessments, which assess economic, social, and environmental effects of public policy (Adelle & Weiland, 2012), the dimension of ethics should be added.

Generally, the significance of ethics and focus thereof within the discipline of public health should be increased. Given that public health ethics is inherently distinct from medical, clinical or bioethics and that the discourse is rather limited, both research and advisory in public health ethics should receive a greater priority within health research and policy.

In conclusion, the introduction of ethical policy advice and awareness rising about ethical issues in policy processes in European contexts marks an important innovation towards an encompassing societal approach with regard to health.

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Summary

Summary

Recent developments in several EU countries such as Greece, Spain or Portugal have shown that the economic crisis, that started in 2008, had and still has an adverse impact on social arrangements, and as a result particularly on the health of citizens. Striving for economic recovery, governments of the above mentioned countries are required by the so-called Troika – consisting of the International Monetary Fund, the European Central Bank and the European Commission – to implement austerity measures. Yet, austerity measures are not only highly contested by economists. They also potentially come into conflict with justice, equity and solidarity – values that are considered to be central to the European Union including its health systems.

The objective of this thesis is therefore to discuss the consequences of austerity and scarcity resulting from the economic crisis of 2008 on health in European and particularly EU contexts by taking an ethical perspective.

Arguing from a right to well-being and justice point of view, an ethical assessment is performed, addressing distinct areas within the field of health, namely health and health care provision (part one), pharmaceutical innovation and research (part two) and policy-makers (part three). Whereas part 1 and 2 apply normative ethical frameworks or assessments, part three involves an interview study.

In **part one**, existing knowledge about the consequences of austerity measures resulting from the economic crisis is assessed by applying the ‘capabilities approach of justice’ (CA) by Amartya Sen (stemming from the consequentialist realm) and the Bioethical Imperative by Fritz Jahr (representing a deontological theory) in juxtaposition to the often used consequentialist principle of ‘first do no harm’ introduced parenthetically as an ethical criterion by austerity and health researchers Stuckler and Basu.

The assessment shows that health outcomes were and are impacted in a negative way, not only in terms of adverse effects on equality of opportunity to gain or stay in good health. Beyond that, the CA reinforces that health – and in particular the capability for health – should not be neglected in policy-making, but should constitute a key component within respective policies. It highlights where policy representatives should provide burdens of proof for certain actions, among them why Germany followed a different policy approach (stimulating its economy) as it itself imposed – via the Troika – on other countries (which had to adopt austerity measures, as for instance Greece). The CA moreover shows that the success of policies should not only be considered within terms of overall life expectancy, incidence and mortality rates, but rather the distribution thereof within societies. Measures should involve other information about the well-being of human beings, both on overall population level, as well as taking into account the individual level, thus stressing the need to strengthen social safety nets.

Jahr’s account adds a Kantian perspective that sees persons as an end in themselves and not as a means, reminding not to use people for the benefit of others. While ‘first

do no harm' focuses on a minimalist morality, Jahr's Bioethical Imperative points more towards the positive value of creating benefits and the conditions for dignity, self-respect and respect for others. Specific actions according to Jahr's Imperative are identified for increasing public health during scarcity, such as

- supporting economically weak by strengthening social safety nets (in accordance with Keynesian ideology),
- strengthening advocacy towards health needs, e.g. by media coverage,
- increasing health literacy so as to avoid unhealthy habits,
- ensuring vital needs in line with equality of opportunity, e.g. through access to health care,
- actively engaging in health-promoting policies in line with principles of beneficence.

Part two aims to address the ethical challenges of scarce resources in the specific context of personalised medicine and research.

Regarding the former, it is asked under what conditions new investments in innovative therapies such as personalised medicine are justifiable. The CA answers this question with the need for investing in treatments that might be necessary for survival. Taking into account the importance of individual and societal freedoms or opportunities, and especially the so-called 'conversion factor', the CA specifies that only individuals with corresponding genetic biomarkers are able to achieve a 'real benefit' from personalised treatments. In terms of scarcity of resources, it can thus be regarded as efficient to only offer treatment to those who can benefit and thus attain better health from personalised medicine, and to reduce the expenses of futile treatments for persons who do not possess matching genetic biomarkers. Social arrangements can help to promote research and development of personalised medicines and introducing reimbursement schemes with the goal to enable access to those therapies for those who can achieve 'real options' to benefit from personalised medicine. This can reduce opportunity costs in an environment of scarce resources, while efficiency, equity and access can be safeguarded.

In research, ethical conduct is anew in the spotlight due to increased competition arising from scarce resources and limited funding opportunities. A network of responsibilities is established as a heuristic framework through which changes and complexities in research ethics are modelled and can be systematically conceived. It takes into account the broader social dimension of research by identifying six other main stakeholders besides the researcher, which are: research subjects, colleagues, editors/publishers, professional associations, society at large and – especially relevant in times of economic crisis and austerity – universities and funders. Integrity of research is challenged on diverse levels, and can be addressed by applying the network of responsibilities. Focusing on research ethics and integrity on diverse levels and taking into account all stakeholders can make research better, more truthful and thereby more socially acceptable, which is important since it influences support for research in general, which in times of scarcity is often reduced. By promoting

accountability and public trust through such network of mutual responsibilities and rights, emphasis on moral values can be regarded as a driver for science, especially in times of increased competition.

In **part three**, an explorative interview study assesses how European policy-makers perceive the economic crisis with regard to health and ethics in decision-making. All interviewees recall difficult and strenuous situations where they had to prioritize between distinct areas to focus on and invest in, for example around choices between medications, health professional staffing, care specific equipment, or urgent infrastructure issues. Values are identified which they deemed as important within the policy-making process, such as trust and responsibility. Policy-makers furthermore report about possible health policy measures in response to the crisis, which they think could improve the overall health situation of EU citizens. Among them are the prioritisation of vulnerable groups, enforcing empowerment and health literacy as an instrument for saving costs, not cutting preventive care and spending more on health while reducing spending in other sectors, e.g. defence. They explicitly express the need for ethical tools and assistance in terms of policy advice for reaching morally sustainable decisions in health policy matters. The study shows that ethical concepts and values frequently come into play in health policy-making, and that ethics is highly relevant in policy-makers' daily decision-taking.

In the **final chapter**, the identified ethical aspects of austerity and relevant health values, which should be focused upon in policy-shaping, are discussed. Even though they would not seem crucial in a context of non-austerity, focus on such aspects increases the social emphasis in otherwise merely economically oriented questions and policy approaches. It is furthermore conceded that academic views about the severity of adverse effects of the crisis remain diverse. Despite those different perspectives about the severity of consequences on health and health care, the ethical assessment points towards the importance of not only looking towards overall population health, but that every single individual should be taken care of in terms of health and access to health care provision and should not be 'left behind'. The established public health policy network offers an ethical perspective involving responsibilities of and towards all stakeholders involved. It is concluded that the thesis carved out some conditions and values that can provide policy-making with a better ethical basis, contributes to what is at stake during austerity in terms of ethics in the fields of health and health care provision, pharmaceutical innovation and research, and for European policy-makers, and intends to bring ethics more on the agenda in actual public health debates.

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Curriculum Vitae

Curriculum Vitae

Caroline Brall was born on 25 August 1989 in Neuss, Germany. After obtaining Abitur from Quirinus Gymnasium in 2008, she decided to study European Public Health at Maastricht University, where she acquired scientific skills and knowledge in the health field on an international scale. From her second year onwards, she participated in the Honours Programme Governance of Health Care Innovations, which she chose because of the opportunity to discuss and learn about ethical issues of applying and regulating innovative treatments in health care. In 2010, she conducted one semester at the University of Buenos Aires, which gave her the opportunity to experience a different and more frugal approach to health than the one performed in Europe. Finalising her Bachelor studies in 2011, she held her bachelor thesis placement at the Association of Schools of Public Health in the European Region (ASPHER) in Brussels, Belgium, exploring how ethics is taught in European Schools of Public Health. In order to complement her knowledge in public health with a more management-oriented focus, she continued her studies with a Master in Health Care Policy, Innovation and Management at Maastricht University from 2011-2012.

After graduating, she worked as researcher at the Institute of Medical Ethics and History of Medicine, Ruhr-University-Bochum, Germany, from 2012-2014. There, she was involved in a project on the ethical aspects of personalised medicine and was responsible for conducting a qualitative interview study with key public stakeholders in the German health care system. In 2013 she received the Young scholar award of the European Association of Centres of Medical Ethics (EACME) and followed her wish to continue researching as an external PhD student at Maastricht University where Caroline started her PhD thesis in 2014. From 2014-2015 she worked as researcher and project leader in the clinical ethics unit of the University Hospital Bern, Switzerland. The main reason for this was to get acquainted with ethical dilemmas in real life settings. Within her tasks was - besides giving lectures, preparing publications and leading case discussions - the realisation of an evaluation project of clinical ethics support systems offered in the university hospital. In 2015, she spent two months at the Ethox Centre, University of Oxford, UK, as visiting researcher, where she worked on her dissertation. Later that year, she worked at Fresenius Kabi for three months, in Bad Homburg, Germany, as part of an international change management project before joining the Private Hospital Group Hirslanden in the performance management department in 2016. Her research interests include public health ethics, ethics education, allocation of resources and governance of healthcare innovations.

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