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Financial and commodity scarcity in health care

A philosophical analysis of prominent coping mechanisms and solutions in selected settings.

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Introduction

There's not enough of anything to go around except people and death.

Saša Stanišić (2006, 155)

This quote aptly captures the essence of the economic concept of scarcity. The latter denotes the situation which obtains whenever there is less of a good or resource available than needed to fulfill human wants and needs (Sobel et al. 2010). Such situations compel us to “make choices as to how to use and allocate scarce goods and services” (Denier 2008, 75). In short, scarcity entails the need to trade off various goods against others.

In order to better grasp the logic of trade-offs, it is helpful to distinguish between the so-called ‘external’ and ‘internal’ aspect of the dynamics of scarcity (Denier 2008). The former is closely linked to the concept of ‘opportunity cost’, i.e. the cost attached to pursuing one action at the expense of another. For example, if I wish to own both a house and a boat, but only have enough money to buy one of both, the cost attached to purchasing a house is the pleasure I would have incurred by enjoying regular boat trips. This external aspect “refers to scarcity as a natural condition of limited resources (such as, money, time, attention, et cetera)” (Denier 2008, 75). It is precisely because of my limited amount of *money, time and other resources* that I am committed to making trade-offs which, in turn, entail opportunity costs.

The internal aspect refers to scarcity as an anthropological construction. It alludes to the idea that, besides ensuing from limited resources, scarcity is also induced by *our unlimited wants and needs* (Denier 2008). Suppose that I win the lottery jackpot. At that point, I would no longer need to trade off the house against the boat. Nevertheless, new trade-offs would inevitably emerge as my unlimited needs make it impossible to buy everything my heart desires.

0.1 Scarcity in health care

Scarcity is omnipresent in health care. Intensive care beds, high-tech scanners, organs, and oocytes are but a few examples of scarce health care resources. For ease of reference, we introduce a distinction between ‘financial’ and ‘commodity’ scarcity in health care in this dissertation. We use the latter as an umbrella term for those goods which are inherently in short supply, i.e. goods which are, by nature, scarce. Organs and oocytes are typical instances of commodity scarcity. Financial scarcity, by contrast,

refers to those resources which are theoretically abundant, but nevertheless provided in limited amount (or not at all) due to financial constraints or considerations. Intensive care beds and high-tech scanners fall into this category of scarcity.

Even when narrowed down to health care, scarcity represents a vast topic of research. For example, it is the *raison d'être* of all issues pertaining to distributive justice in health care. Evidently, then, it is impossible to present an exhaustive analysis of any subset of issues relating to scarcity in health care, let alone to cover all the ground. In this dissertation, we mainly limit ourselves to a selection of ethical issues ensuing from the impact of population aging on scarcity. As we explain in this introduction, population aging is increasingly being perceived as a grave threat, in the realms of both 'financial' and 'commodity' scarcity. More specifically, this demographic phenomenon raises concerns with regard to the sustainability of customary approaches to making the necessary trade-offs among scarce goods. The main aim of this dissertation is to present some of the most prominent, newly proposed alternatives to the current trade-offs and assess their ethical soundness. Part one of this dissertation addresses the alternatives put forward in the context of financial scarcity, whereas part two analyzes the proposals made in the realm of commodity scarcity.

Below, we provide the reader with the necessary background information on, respectively, financial and commodity scarcity in health care. This overview will enable us to retranslate the aforementioned general aim of this dissertation into more specific research questions relating to both types of scarcity.

0.2 Financial scarcity in health care

Scarcity of financial resources entails a need for making trade-offs or allocation decisions at three general levels: the macro-, meso-, and micro-level (Putoto & Pegoraro 2011).

Health (care) is not the only valuable good within a society. Therefore, decisions must be made as to how to divide the overall budget between health (care) and other social goods, such as education, infrastructure, culture, defense, and recreation. The trade-offs which are made at this macro-level represent the key constraint within which allocation decisions at the lower levels are made.

At the meso-level, decisions are made as to how to allocate the health care budget across various projects, procedures, and services. Choices at this level "may involve the priorities attached to, for example, treatment services versus preventative medicine;

particular patient groups, for example those with renal failure versus drug addicts; or certain hospital services, for example cancer services, versus other services such as respiratory care” (Putoto & Pegoraro 2011, 65).

At the micro- or bedside level, clinicians decide how to allocate treatments and resources across individual patients. In determining the availability and supply of a particular resource, decisions at the meso-level influence the necessity and extent of patient selection at the micro-level.

0.2.1 Rising health care expenditures

At the macro-level, a clear trend is visible. For over three decades, health care expenditure in the Organization for Economic Co-operation and Development (OECD) countries has grown at rates exceeding the economy’s growth rate (Pammolli et al. 2012). As a result, it has absorbed an ever increasing share of the gross domestic product (GDP). Between 1970 and 2004, the average health expenditure as a proportion of GDP almost doubled in the OECD, increasing from 4.9% to 8.8% (Baltagi & Moscone 2010). During this period, per-capita health expenditure increased with an annual average rate of 11.5%. There are large differences in average per-capita health expenditure across the OECD member countries, with the US (\$6,037), Switzerland (\$4,045), Norway (\$4,103) and Germany (\$3,169) ranking highest and Turkey and Mexico (\$562 and \$655, respectively) occupying the bottom of the list in 2004 (Baltagi & Moscone 2010). Recent projections suggest that, by 2060, the OECD average health expenditure will amount to 12% of GDP. When health expenditure is combined with long-term care spending, this figure increases to 13.9% (de la Maisonneuve & Oliveira Martins 2013).

Given that EU member states are highly represented in the OECD, it is relatively unsurprising that these have also witnessed a growing ratio of average health expenditure to GDP (European Commission and the Economic Policy Committee 2012). During the 1960s and 1970s, health care expenditure increased rapidly in EU countries, mainly as a result of expanded population coverage. Although concerns over this trend caused the growth of public health expenditure to slow down in the 1980s and 1990s, it quickly picked up again from the late 1990s onwards. At present, the average health expenditure is 8% of GDP in the EU. Health care spending as a share of total government expenditure has also been growing and, on average, currently accounts for 12% to 15% of government outlays in EU countries.

The trend of increased spending on health care is most pronounced in the United States. Between 1960 and 2008, inflation-adjusted national health expenditures grew at an average annual rate of 5.7%, increasing from \$150.6 billion to \$2,156.1 billion. This observation cannot be accounted for simply in terms of an increased population size. After all, annual real per-capita national health expenditures also increased markedly

during this period (from an average of \$796 per person to \$7,080) (Chernew 2010). Between 1960 and 2006, real per-capita health care spending grew an average of 2.5 percentage points faster than GDP per year, producing an increase in the average health expenditure from 5.2% to 16% of GDP (Ginsburg 2008). It is projected that the growth rate of national health spending will continue to outpace that of GDP. As a result, the share of GDP devoted to health care is expected to reach 25% by 2037 (Emanuel et al. 2012). According to recent projections of the Congressional Budget Office (CBO), this figure will amount to 49% in 2082 (Ginsburg 2008).

0.2.2 Rising health care expenditures: positive evolution or crisis?

The rapid growth of health care expenditures elicits two opposing reactions: it is either labeled a positive evolution or a crisis. Proponents of the former view argue that increased spending on health functions as an economic engine for the community in that it creates employment opportunities in the sector. In addition, they point out that the observed trend translates into increases in life expectancy and other significant health benefits and, thus, provides value for money (Cutler & McClellan 2001). However, the view that we ought to embrace rising health care expenditures represents a minority position. There is a consensus that any positive effects are largely overshadowed by the severe threat which recent developments pose to the viability of our health care systems.¹ The fact that governments are increasingly putting the issue of cost containment in health care on the agenda lends credence to the widespread nature of the ‘crisis perception’ (de la Maisonneuve & Oliveira Martins 2013; UCL European Institute 2012). When enumerating the various downsides of rising health care costs, proponents of the ‘crisis view’ often distinguish between effects at the public and the private level. The discussion of such effects largely proceeds with reference to the US context. However, given that Europe is heading down a similar path of ever rising health care costs, many of the cited problems also apply in the European setting, albeit in a somewhat less pronounced way.

A *sustained* increase in health care spending relative to GDP has two deleterious effects at the *public* level. First, such a development can ultimately only be financed by higher

¹ Note that the problematic evolution is not the rise in health care costs as such, but the fact that health care costs are growing more rapidly than GDP. However, for ease of reference, we will use the terms ‘rising health care expenditures’, ‘rising health care costs’, and ‘increased health care spending’ as a shorthand for the observed trend that the growth rate of health care costs exceeds that of GDP.

taxes or higher debt. Second, this trend threatens to crowd out other public spending priorities. In the United States, 20% of the economy is, on average, devoted to federal taxes (Chernew 2010). Estimates of the Congressional Budget Office (2007) suggest that, under the assumption of a yearly 1% gap between health care expenditure growth and GDP growth, a 70% increase in taxes would be called for by 2050. Note that this represents a conservative estimate, given the historical trend of a 2.5% gap per year (Ginsburg 2008). A tax increase of this magnitude could have severe adverse economic implications. For example, it could lead to a decline in consumption by private individuals and the closing down of US branches of international companies.

An alternative strategy to finance rising health care expenditures consists in further increasing the national debt. The size of the national debt is often measured relative to the overall economy (the debt-to-GDP ratio). At present, the US debt-to-GDP ratio amounts to approximately 73% (Congressional Budget Office 2013). Although national economies can endure substantial debt for a prolonged period without any real adverse consequences, there is a threshold level of debt beyond which such effects start to materialize. Economists disagree as to where this threshold lies. Whereas the European Union has imposed a maximum debt-to-GDP ratio of 60%, economic research indicates that anything below 90% is manageable (Chernew 2010).² Under the most pessimistic scenario, projections by the Congressional Budget Office (2013) point towards a debt-to-GDP ratio of 190% by 2038 – an increase largely driven by health care. Such a prospect, in Chernew’s terminology, is tantamount to ‘economic Armageddon’: interest rates for all borrowers (government, businesses and individuals) would soar, “GDP would contract significantly leaving many out of work, and the government would have few levers to respond” (2010, 287).

Besides leading to an unsustainable tax level and debt-to-GDP ratio, a sustained increase in health care spending relative to GDP also implies that ever smaller amounts will be available for other public spending priorities, such as education, infrastructure, environmental issues, defense, development aid, and employment. Although these other public goals have value in themselves, their worth extends further still. For example, employment, education, safe water, clean air, and safe houses are important social determinants of health. In fact, their effect on health is greater than that of access to and use of health care services (WHO 2014). In short, devoting exorbitant levels of spending to health care may well prove an inefficient tool for promoting health.

² In the Euro area, the debt-to-GDP ratio amounted to 92.2% in the first quarter of 2013 and, thus, already exceeds the manageable threshold (Eurostat 2013).

At the private level, rising health care costs primarily translate into higher insurance premiums. The faster growth rate of health care spending relative to GDP further implies that such premiums rise more rapidly than workers' earnings. This effect, combined with increases in taxes aimed at financing rising health care costs, has sharply reduced the disposable income of American families. In this respect, Auerbach and Kellerman (2011) have calculated that, between 1999 and 2009, health care cost growth at a rate exceeding economic growth accounted for an average yearly loss of \$5,400 in disposable income for a median-income US family of four. In reducing private consumption of non-health care goods and services, rising health care costs affect the well-being of both families and the nation's economy (Chernew 2010). Equally important, however, is the observation that the growing gap between premium trends and earning trends has impacted upon the affordability of health insurance – even for those in the middle class (Ginsburg 2008).

Besides reducing individuals' ability to purchase health insurance, rising premiums have also affected the provision of employer-based insurance. Various employers have either stopped providing health insurance altogether or shifted the increasing costs onto employees (Gabel et al. 2004; Bodenheimer 2005). In the latter case, numerous employees have been compelled to decline employer-offered health insurance. Unsurprisingly, then, the combination of a steadily disintegrating system of employer-based insurance and the reduced affordability of personal health insurance has increased the numbers of people joining the ranks of the uninsured. Some of those losing insurance have been 'lucky' enough to qualify for Medicaid, the means-tested joint state and federal health insurance program for the low income and disabled. Nevertheless, their Medicaid status rests on shaky grounds. Medicaid has grown significantly over the past years, making the program a potential target for future cost containment efforts (Krugman & Wells 2006).

One might expect that the Patient Protection and Affordable Care Act ('ObamaCare'), in seeking to provide universal coverage, will render the problem of the increasing number of uninsured a thing of the past. However, doubts are increasingly being raised with regard to the Act's potential for success. For example, Avik (2014) points out that ObamaCare has, thus far, expanded coverage to a mere 660,000 people, i.e. much less than the 7 million projected by the Congressional Budget Office. Moreover, if the act indeed proves unsuccessful, it could well be repealed by the following legislature.

In addition to affecting employees, the rising costs attached to employer-based health insurance also threaten the viability of companies. Certain corporations cannot, due to binding institutional constraints, escape the provision of affordable health insurance for their employees. The ensuing higher cost structure of such companies compels them to impose higher prices on their products in order to remain profitable. As a result, they

incur a substantial competitive disadvantage relative to those companies which do not face such constraints. The introduction of the ObamaCare employer mandate, scheduled for 2016, is likely to magnify this adverse effect. This provision compels mid-sized and large companies – which comprise 4% of all US corporations – to offer affordable coverage to their workers (Luhby 2014).

All of the problems ensuing from increased health spending at the private level are exacerbated by the ongoing economic recession. Marmor et al. (2009) explain this as follows:

Widespread job losses mean that millions of Americans stand to lose health insurance. In this economic climate, employers also face intensified pressures to restrain health care spending and cut back on insurance coverage for those still employed. Meanwhile, rising unemployment levels mean that many more Americans are eligible for Medicaid. States face an acute fiscal dilemma: they must find a way to pay for growing Medicaid enrollment precisely when tax revenues are declining [...]. (Marmor et al. 2009, 485)

0.2.3 Exploring solutions to the health care cost crisis

It is generally agreed that a sustainable trajectory for health care spending lies close to overall GDP growth. In other words, health care costs should grow no faster than GDP, “so that the percentage of GDP spent on health care remains constant” (Berwick & Hackbarth 2012, 1514). However, there is disagreement as to the preferred approach for achieving this goal. At the most general level, there are two proposed routes, one presenting a painless and the other a painful prescription.

The painless route consists in the elimination of waste, defined as the costs incurred by deliberate fraud, administrative inefficiencies, and useless medical interventions. The arguments in support of this view are twofold (Brody 2012). First, its adherents point out that waste accounts for 30% of health care spending in the US - \$800 billion a year. Second, the administration of useless medical interventions, it is claimed, represents a source of harm to the patient. Futile treatments, for example, can cause complications. Moreover, useless diagnostic tests yield false positive results which, in turn, result in further tests and complications. Critics, however, warn that waste avoidance should not be hailed as the silver bullet for the health care cost crisis, for several reasons (Bloche 2012). To begin with, whereas interventions are easily recognized as useless post factum, they are rarely identified as such at the moment of clinical decision-making. Admittedly, critics claim, high-quality studies of clinical effectiveness would go a long way to resolving this issue. Nevertheless, the performance of such studies is likely to cost tens of millions of dollars and span many years - time which is not available given

that the ‘suffocating’ effects of the health care cost crisis are already being felt. Finally, any effect of waste elimination on health care spending growth will be temporary, at most. For example, suppose that we cut out waste by reducing the annual rate of health care spending growth by 3% over a decade. Assuming that health care expenditures and GDP grow at an annual average rate of, respectively, 5.7% and 3%, we could hereby bring health care spending growth slightly below the level of overall GDP growth throughout this period. However, health care costs would soon resume their rise once we had cut out all waste. As Bloche puts it: “eliminating [...] ineffective care would shift the cost curve down but wouldn’t change its slope” (2012, 1951).

The shortcomings of the waste reduction strategy expose an ugly truth: any proposed solution to the health care cost crisis which does not address *beneficial* forms of care sets itself up for failure. Suggested measures for achieving success on this front frequently single out the elderly as the group which ought to sacrifice beneficial care. Two observations are generally invoked to support this choice. To begin with, a reference is made to health care expenditure statistics that purportedly show that those over 65 years of age consume a disproportionate amount of health care. For example, whereas the elderly represent 13% of the population, they account for 36% of total health care expenditures in the United States. Furthermore, average per-capita health care expenditures for the elderly amount to \$11,089 per year – a significant departure from the \$3,352 per year for those aged 16 to 64 (Jecker 2013). Besides these statistics, the phenomenon of population aging is also appealed to in support of targeting the elderly. Population aging will reach its peak in 2030, at which point those over 65 will make up 21% of the population (Fleck 2010). Both factors combined, it is argued, constitute a recipe for disaster. In short, the rationale behind the focus on beneficial care in the elderly is the conviction that population aging represents a major driver of rising health care costs.

0.2.4 Saying ‘no’ to beneficial health care in the elderly

There are two strategies for curbing spending on beneficial health care in the elderly. We can reduce either the supply of or the demand for such care. Although both types of proposal can be traced back to the early 1980s, they remain highly relevant in the contemporary debate on the health care cost crisis.

0.2.4.1 Reducing supply of beneficial health care in the elderly

In 1984, Richard Lamm, then governor of Colorado, famously stated that the elderly “have a duty to die and get out of the way” (Binstock & Post 1991, 5). Despite its controversial nature, this quote functioned as the impetus for a widespread public campaign to limit health care for the elderly. Daniel Callahan was, without a doubt, the

most ardent spokesperson of this campaign. In his 1987 book *Setting limits: medical goals in an aging society*, he portrayed the elderly as “a demographic, economic, and medical avalanche, one that could ultimately (and perhaps already) do great harm” (1987, 20). In response to this perceived threat, Callahan suggested implementing a policy which denies all life-extending treatment to the elderly beyond a certain age.³ Callahan’s proposal instigated widespread discussion, both in the media and in academic circles. With regard to the latter, the issue of justice between age groups in the provision of health care increasingly started to figure in the writings of philosophers - to the extent that it replaced the heretofore dominant focal point of justice between the rich and the poor (Binstock 2011). Besides philosophers, economists and public figures also joined in the debate.

The proposals put forward by Callahan and others never made it to the level of official policy. Nevertheless, the idea of age-based rationing as a cost containment tool is still very much alive, both in (academic) theory and in practice. For example, as recently as last spring, Nancy Jecker (2013) published an article in the *American Journal of Bioethics*, advocating the denial of life-extending care to the elderly.⁴ Others make a somewhat less controversial claim. Rather than scrapping all life-extending treatment, their proposals impose an age limit on one specific intervention. For example, as a result of the growing number of elderly with end-stage renal disease, nephrologists are increasingly calling for a policy that would allow age-based rationing of expensive dialysis (see, for example, Knauf & Aronson 2009; Stevens et al. 2010).

Although it is condemned by various international organizations (e.g. WHO and UN) and outlawed by most countries, age-based rationing nevertheless frequently occurs in practice (Giordano 2005). In a survey of physicians from four European countries – Norway, Switzerland, the United Kingdom, and Italy – Hurst et al. (2006) found that over half of the respondents were inclined to ration medical interventions on the basis of age. Other studies provide insight into the specific types of treatments being (covertly) denied to the elderly in these and other countries. The most extensive rationing occurs in the United Kingdom, where physicians have admitted to employing age limits for heart bypass operations, ICU admission, angiograms and heart stress tests for angina, dialysis and kidney transplantation, and revascularization (Allin & Gusmano 2011; Williams 2009; Miranda & Nap 2006). A study in a Swiss university hospital found indications of significant underuse of stress tests and coronary angiography in elderly patients with acute coronary syndrome (Jenni et al. 2001). In addition, there was

³ We discuss Callahan’s proposal in more depth in chapter 1.

⁴ This, too, will be addressed more extensively in chapter 1.

evidence of age-based rationing of echocardiography and statins in patients suffering from congestive heart failure and hypercholesterolaemia, respectively. In the United States, elderly patients with colorectal cancer have a significantly lower chance of receiving both surgery and chemotherapy (Williams 2009).

The abovementioned practice of covert age-based rationing is likely to increasingly occur as the health care cost crisis further intensifies. Indeed, the ongoing health care reform in the United States already hints at the possibility of such a development. Besides providing universal coverage, ObamaCare also intends to significantly reduce health care expenditures. To this end, it has imposed cuts of \$533 billion on Medicare over the next decade – the US national health insurance program that provides coverage to persons 65 years or older. In addition, the reform efforts provide for the establishment of a fifteen-member Independent Payment Advisory Board (IPAB) which is charged with the task of suggesting measures for further cost reductions in Medicare (DeBolt 2010). Although the law prohibits the use of age as a rationing tool, some find it difficult to see how savings of the projected magnitude can be obtained without resorting to age-based rationing. As a result, it is feared that such savings will be achieved through covert age-based rationing (Kaplan 2010; Cannon 2011). Others even go as far as perceiving the health reform as a stepping stone to overt rationing – i.e. rationing as a matter of official policy (Binstock 2011).

The issue of *overt* age-based rationing also recently arose in the United Kingdom, where the Department of Health urged the National Institute for Health and Care Excellence (NICE) to consider taking the societal/economic contribution of a patient into account when deciding whether to pay for new drugs. However, NICE has rejected this government proposal on the grounds that it would – notwithstanding ministers' claim to the contrary – inevitably disadvantage the elderly (Age UK 2014).

0.2.4.2 Reducing demand for beneficial health care in the elderly

There are two commonly proposed avenues for reducing demand for beneficial health care in the elderly. The first strategy consists in the promotion of healthy aging, i.e. efforts to prevent or delay age-related disabilities and chronic diseases which are burdensome, both to individuals and the health care system. This proposal is most vigorously endorsed by the World Health Organization (WHO) – although the latter employs the term 'active aging', rather than 'healthy aging', so as to emphasize that there are other factors, besides health care, that affect the way in which individuals and populations age (WHO 2002). The second strategy applies uniquely to the US context and involves the privatization of Medicare.

Active aging

The WHO defines active aging as “the process of optimizing opportunities for health, participation and security in order to enhance quality of life as people age” (2002, 12). As is reflected by this definition, the WHO perceives one’s health status in older age as *largely* determined by factors which are (to a greater or lesser extent) *malleable*. These include, amongst others, determinants related to one’s lifestyle, one’s physical, social and economic environment. In devising recommendations for active aging, the WHO stresses the importance of addressing these determinants throughout the life course, i.e. from early life to late life.

At the behavioral and lifestyle level, tobacco, physical inactivity and unhealthy diets represent the most significant risk factors for major diseases in old age. In response to this observation, the WHO urges the creation of supportive environments which “make the healthy choices the easy choices” (2002, 17). Specifically, it recommends local, national, and international authorities to take measures aimed at controlling the marketing and use of tobacco products. In addition, community leaders are encouraged to develop guidelines on physical activity for the elderly and provide infrastructure conducive to regular exercise (e.g. safe parks and walking areas). Diet-related recommendations range from the prevention of malnutrition to the implementation of policies and practices that reduce the misuse and abuse of alcohol and drugs.

Inadequate levels of social support and physical environments that are maladapted to the elderly are also detrimental to health. The former is associated with increased morbidity, psychological distress, and a decrease in overall well-being and general health, whereas the latter is linked to isolation, depression, reduced fitness and increased mobility problems. With a view to reducing the risk for social isolation and loneliness, the WHO advocates the establishment of “community groups run by older people, traditional societies, self-help and mutual aid groups, peer and professional outreach programs, neighborhood visiting, [and] telephone support programs” (2002, 8). Measures aimed at the creation of age-friendly environments include, amongst other things, the implementation of fall prevention programs and the protection of older pedestrians in traffic.

Although poverty is a risk factor for ill health and disabilities at all ages, its adverse effects are magnified in the elderly. Relative to those with high incomes, poor older people have a 66% higher risk of developing lower levels of functioning. If we are to address this imbalance, the WHO (2002) claims, we ought to implement programs and policies targeting income inequities, low literacy levels, and lack of education.

Besides the approach advocated by the WHO, there exists yet another proposed strategy for achieving the goal of healthy or active aging. The latter proposal is much more radical than the former. It claims that the most effective route to increasing healthy life

expectancy consists in tackling the biological, rather than the behavioral and environmental determinants of age-related diseases. This view is rooted in a scientific optimism. Specifically, its proponents argue that developments in the novel field of biogerontology – research into the biology of aging – will soon allow us to intervene in the human aging process. As this process is the common, underlying cause of all age-related diseases, such interventions, it is argued, will enable us to address all of these pathologies *simultaneously* (Miller 2002). This, in turn, is said to offer the prospect of substantial increases in healthy life expectancy – increases of a much greater magnitude than those obtainable by the WHO approach.

Medicare privatization

Republican proposals to privatize Medicare have been around for years. The rationale behind such plans is that rising health care costs – which are largely attributed to Medicare growth – can be curbed by compelling private insurers to compete against one another for seniors’ business (Miller 2012). Under a recent proposal, put forward by Representative Paul Ryan, seniors and others currently on Medicare would be given an annual voucher of \$8000 to buy a health plan from a private insurer of their choice (Levey 2011). However, even if commercial insurers cost less to run than government plans, reliance upon the former would account for only *a part* of the projected cost savings. The Congressional Budget Office has calculated that the extremely low amount of the voucher would imply that out-of-pocket expenditures for the elderly are doubled under Medicare privatization (Levey 2011). For many seniors, such a doubling would be beyond their reach. In short, part of the cost saving potential of Medicare privatization is obtained by ‘artificially’ reducing demand for health care on the part of the elderly.

0.2.5 Research questions relating to financial scarcity in health care

As health care costs continue to rise, the aforementioned proposals to curb spending on health care in the elderly are likely to further gain ground. It is, therefore, important to ask ourselves whether they represent a morally acceptable solution to the health care cost crisis. This question has already received much attention. However, it has typically been interpreted in a rather narrow sense. For example, moral assessments of proposals to impose age limits on the delivery of health care tend to focus on whether or not this practice amounts to age discrimination. The debate on Medicare privatization, in turn, generally revolves around the morality of ‘artificially’ reducing demand for health care on the part of the elderly. Finally, in the case of the biogerontological approach to healthy aging, the emphasis most often lies on the moral implications of a substantially prolonged lifespan. Specifically, the following questions have taken center stage: “Is a

significantly increased lifespan in accordance with human nature?” and “Do the positive effects of a radically prolonged lifespan outweigh the negatives (e.g. overpopulation, impact on the ecology, etc.)?” These issues and questions are undoubtedly important. However, the moral acceptability of proposals to curb spending on health care in the elderly does not merely hinge on the answers to these questions. Their ethical soundness is also dependent on whether they are likely to actually achieve their ultimate aim, i.e. whether they will succeed in reducing spending growth in health care to the level of overall GDP growth. It would, for example, be highly unethical to deny the elderly – or any other group for that matter (irrespective of whether the group is defined in terms of age or another criterion) – life-extending care if this practice offered little prospect of substantially controlling health care expenditures.⁵ The effectiveness of proposals to curb health care spending in the elderly has seldom or never been addressed in the literature. This is lamentable. After all, the adverse effects of the health care cost crisis have already started to materialize. Therefore, we cannot afford to adopt a trial and error approach to the problem.

Part one of this dissertation will examine whether proposals to curb health care spending in the elderly represent an effective means of containing costs. It will do so by analyzing the extent to which these proposals tackle the root cause of the health care cost crisis. When assessing the efficacy of proposals aimed at reducing *supply* of beneficial health care in the elderly, we will take Callahan’s proposal as a case study. In a similar vein, we will use the biogerontological approach to healthy aging as a case study when determining the cost containing potential of proposals seeking to reduce *demand* for beneficial health care in the elderly. However, as will become clear during the course of our analysis, the conclusions for these two case studies can be extrapolated to any other proposal to curb health care spending in the elderly.

0.3 Commodity scarcity in health care

As noted at the start of this introduction, part two of this dissertation will be devoted to a discussion of ethical issues ensuing from population aging in the realm of commodity scarcity. We will predominantly focus on the stock example of commodity scarcity in

⁵ We are not hereby suggesting that age-based rationing automatically becomes ethically acceptable when it is found to be an effective cost containment tool. If it turns out to be an effective means of addressing the health care cost crisis, it could, for example, still be found to be unacceptable on the grounds that it constitutes age discrimination.

health care, i.e. the shortage of donor organs for transplantation. Within this context, we will mainly limit the scope of our discussion to kidney transplantation, given that the scarcity of this type of organ is most pronounced (Eurotransplant 2014; OPTN 2014). With respect to methods for dealing with the problem of kidney scarcity (and organ scarcity in general), it is useful to distinguish between ‘coping mechanisms’ and ‘solutions’. We introduce the former concept to refer to strategies which are *not* aimed at diminishing the magnitude of the kidney scarcity, but merely attempt to make the best of the shortage. In other words, the term ‘coping mechanisms’ denotes the activity of devising criteria for the allocation of kidneys in a way which strikes a balance between the goals of equity and utility. By contrast, ‘solutions’ are strategies which endeavor to reduce the kidney scarcity, either by lowering demand for or increasing the supply of donor kidneys.

Part two of this dissertation will be divided into two sections. Whereas the first section addresses ‘coping mechanisms’, the second is devoted to ‘solutions’.

Below, we provide the reader with an overview of, respectively, current ‘coping mechanisms’ and ‘solutions’ in the context of kidney scarcity. In doing so, it will become clear how population aging is increasingly (being perceived as) threatening the viability of current ‘coping mechanisms’ and ‘solutions’. This overview will enable us to formulate more specific research questions for both sections making up part two of this dissertation.

0.3.1 ‘Coping mechanisms’

Dialysis and kidney transplantation represent the two treatment options for patients with end-stage renal disease (ESRD). Renal transplantation is the preferred treatment modality in that it offers a longer lifespan, better quality of life, and lower economic costs for society (Vamos et al. 2009). Unfortunately, the shortage of donor kidneys remains a major barrier to access to transplantation. For example, as of February 14, 2014, there were 99,339 patients waitlisted for kidney transplantation in the United States (OPTN 2014). Records spanning the last decade suggest that annually only approximately 16,000 patients receive a kidney transplant, whereas more than 30,000 patients are added to the waiting list each year (OPTN 2013a).

The scarcity of donor kidneys gives rise to a need for policies governing their allocation. So-called ‘organ exchange organizations’ are charged with the task of devising such policies. All organ exchange organizations employ a point system with a view to rank ordering patients on the kidney transplant waiting list. Whenever a donor kidney becomes available, it is offered to the patient with the highest number of points. Transplant candidates’ scores are determined on the basis of a number of patient

characteristics and other, primarily medically driven, criteria. The nature of these criteria as well as the weight assigned to them varies according to the organ exchange organization. Two of the largest such organizations are Eurotransplant and the United Network for Organ Sharing (UNOS). The former is the supranational organization responsible for allocation of organs across eight European countries: Belgium, the Netherlands, Luxemburg, Germany, Austria, Hungary, Slovenia, and Croatia. UNOS is the administrator for the Organ Procurement and Transplantation Network (OPTN), the unified transplant network established by the United States Congress.

0.3.1.1 Eurotransplant

Within Eurotransplant, the scoring system is based on five factors: waiting time, human leucocyte antigen (HLA) matching, mismatch probability, the distance between donor and transplant center, and the import/export balance between the participating countries (Eurotransplant 2013).

Waiting time starts to accrue from the moment one initiates dialysis. Each waiting day accounts for 0.091 points, i.e. one can accumulate 33.3 points per year. Pediatric transplant candidates receive a 100 point bonus for the criterion of waiting time.

The criterion of HLA matching refers to the immunological compatibility of donor and recipient. The probability of a successful transplant increases with the number of identical HLA antigens. More specifically, the greater the similarity between donor and recipient HLA, the smaller the chance for rejection and the higher the chance of a long graft survival (Desschans et al. 2008). The number of points awarded for this criterion range from 400 (in the case of a perfect match) to 0 (in the case of a complete mismatch). These points are doubled for pediatric patients.

The mismatch probability criterion aims to ensure equitable access to kidney transplantation for (highly) sensitized patients by granting them bonus points. Sensitized patients have a low probability of finding a suitable kidney, given that their immune system makes antibodies against a general donor pool. Sensitization may occur as a result of pregnancy, a previous transplant, or blood transfusion.

When an organ becomes available in their own country, transplant candidates receive a bonus of at least 100 points. Additional points can be obtained when the kidney originates from their regional or local center. The rationale behind this criterion of distance consists in minimizing the cold ischemia time, i.e. the amount of time between the procurement and the transplantation of the kidney. A prolonged cold ischemia time adversely affects the survival of the graft.

In order to prevent countries with low donation rates from taking advantage of those with high donation rates, the import and export of kidneys between the different Eurotransplant member countries are constantly monitored. Transplant candidates in countries where the import rate largely exceeds the export rate are penalized.

Eurotransplant has established several special allocation programs aimed at specific groups of patients. One such initiative is the ‘Eurotransplant Senior Program’ (ESP), which automatically allocates all kidneys from donors ≥ 65 years to recipients aged ≥ 65 years. Only elderly recipients awaiting a first transplant are eligible for the ESP. Under this program, points are assigned on the basis of waiting time and location of the donor/recipient pair (Desschans 2008).

0.3.1.2 UNOS

In the United States, kidney allocation is governed by waiting time, sensitization, and HLA matching, i.e. a subset of the criteria employed by Eurotransplant. However, as a result of the growing disparity between supply of and demand for donor kidneys, waiting time has accrued an ever increasing importance – to the extent that its contribution to the allocation outcome largely surpasses that of the biological criteria (Friedewald et al. 2013). Therefore, in practice, the current allocation system is heavily skewed towards the principle of equity.

During the past decade, the kidney allocation system has increasingly come under attack. A principle concern is that it does not take into account transplant candidates’ projected life expectancy. Thus, under the current system, “higher priority could be given to transplanting a 65-year-old on dialysis with diabetes mellitus and extensive vascular disease who has accumulated more waiting time than a more recently listed 30-year-old with no comorbidities” (Reese et al. 2010, 1981). This aspect of the existing system, it is argued, is especially problematic in light of recent changes in the demographics of the kidney transplant waiting list. Population aging, combined with the epidemic of diabetes mellitus, has led to a tremendous growth in the number of elderly patients with ESRD (Reese et al. 2010). For example, since 2000, the prevalence rate of ESRD increased by 28% and 37% in the 65-74 and the ≥ 75 age group, respectively (Williams et al. 2012). According to the 2007 United States Renal Data System (USRDS) Annual Data Report, the overall median age of new ESRD patients amounted to 64.6 years in 2005 (Paraskevas et al. 2010). For patients ≥ 75 years, incidence rates of ESRD grew by 10% between 2000 and 2005. The increase in incidence and prevalence rates in the elderly has been accompanied by a corresponding growth in the number of elderly kidney transplant recipients. Whereas only 3% of deceased donor kidney recipients were older than 65 years in 1990, this figure rose to 16% in 2009 (Friedewald et al. 2013). Within the same time frame, the number of deceased donor kidneys going to persons aged 50 to 64 increased from 23% to 39%.

In the context of a growing elderly ESRD population, an allocation system which does not penalize recipient candidates with limited life expectancy inevitably has the effect

of shifting the average recipient age upwards. In producing this effect, the current system, critics claim, amounts to an inefficient use (or even a wastage) of kidneys:

A number of studies have shown that older adults with ESRD live longer with a kidney transplant than they would have lived on dialysis and therefore derive a benefit as individuals, but from a societal perspective, the *comparative* survival benefit derived from a transplant is greater in younger recipients. Specifically, younger patients gain more additional years of life from kidney transplantation than older patients do. Older kidney transplant recipients are more likely to die while their transplanted kidneys still function – an outcome that some view as a waste of valuable organs. Seen from the perspective of HTA [health technology assessment], a kidney transplanted into a younger person provides greater returns in terms of survival benefit, quality of life, and cost of therapy per year of life gained than a kidney transplanted into an older person. (Reese et al. 2010, 1981)

Besides shifting the average recipient age upwards, the current allocation system also has the effect of directing a growing number of kidneys from young donors to elderly recipients (Ladin & Hanto 2011). Critics point out that this constitutes an additional inefficiency, for two reasons (OPTN 2011). First, given that young donor kidneys have a substantially longer survival potential than kidneys from old donors, transplantation of the former type of kidney into elderly recipients is highly likely to result in unrealized graft years. In other words, due to their limited life expectancy, these recipients have a great likelihood of dying long before the young donor kidney has realized its full survival potential. Second, the flip side of a growing number of young donor kidneys going to the elderly is that young transplant candidates are increasingly receiving kidneys from older donors. The high life expectancy of young transplant candidates and the limited lifespan of an old donor kidney imply that this trend will lead to increased retransplantation rates in the young. In response to both types of inefficiency, critics of the current system advocate an allocation model which matches the survival potential of a kidney with that of its recipient.

0.3.1.2.1 Proposals for a new kidney allocation system

In 2003, the OPTN Board of Directors commissioned the Kidney Transplantation Committee to review the current allocation system and formulate suggestions for remediating the abovementioned concerns. The Committee devoted almost ten years to the fulfillment of this task (Friedewald et al. 2013). Over the course of this decade, it put forward three distinct proposals for revising the existing kidney allocation policy. The first proposal, developed in 2007, introduced two novel concepts: the ‘kidney donor profile index’ (KDPI) and ‘life years from transplant’ (LYFT). The former refers to a

metric which allows one to rank donor kidneys according to their quality and, thus, their potential for survival. The KDPI score for a donor kidney ranges between 0% and 100%. The lower the score, the higher the projected survival of the kidney (Friedewald et al. 2013). Various factors are considered in the calculation of the KDPI score, such as whether or not the donor had a history of diabetes or hypertension. The concept of 'life years from transplant' provides a measure for rank ordering kidney transplant candidates according to their projected life expectancy. More specifically, a patient's LYFT score reflects the number of extra years of life she could expect to live with a donated kidney compared with remaining on dialysis (Singh et al. 2009). The following patient characteristics adversely affect one's LYFT score: 1) diabetic status 2) advanced age 3) elevated body mass index and 4) retransplant candidate status (Reese et al. 2010). Under the 2007 proposal, donor kidneys with the least potential for long-term survival (i.e. with a very high KDPI score) are allocated primarily on the basis of dialysis time (Wolfe et al. 2009). By contrast, the LYFT criterion primarily governs the allocation of kidneys with a very low KDPI score. Finally, kidneys of average quality are allocated on the basis of both dialysis time and LYFT, where the former and the latter are given a weight of, respectively, 60% and 40% in the calculation of the patient's total allocation score. The implications of this proposal can be summarized as follows:

Kidney transplant candidates with the greatest expected LYFT have an allocation advantage for organs with the longest potential survival. This priority diminishes as the survival potential of the organ decreases. Conversely, wait-listed patients with the longest dialysis times have an allocation advantage for potentially short-lived donor organs, and dialysis-time priority decreases as the survival potential of the donor kidney increases. (Wolfe et al. 2009, 1525)

Given that age accounts for 25% of one's LYFT score, one can expect this model to adversely affect the elderly (Reese et al. 2010). Indeed, simulations suggest that, relative to the current system, this proposal would allocate significantly fewer kidneys to patients aged ≥ 65 years. Moreover, it would shift kidneys from young donors, many of which currently go to the elderly, away from this age group (Wolfe et al. 2009). After all, kidneys from young donors tend to have a high potential for long-term survival, whereas the elderly, on average, exhibit low LYFT scores. Despite the fact that it addresses both of the concerns raised with regard to the current allocation system, the 2007 proposal was ultimately rejected. In support of this decision, a reference was made to the limited accuracy of the LYFT system in predicting which patients derive the greatest survival benefit from transplantation (Reese et al. 2010).

In 2011, the Kidney Transplantation Committee issued a second proposal for revision of the current allocation system (Xu et al. 2012). Whereas the concept of KDPI was maintained, the LYFT criterion was dropped in favor of the so-called 'estimated post-

transplant survival' (EPTS). The latter merely refers to a patient's life expectancy with transplantation - as opposed to the difference between survival with and without a transplant (LYFT). Four factors come into play in the EPTS calculation: length of time on dialysis, any prior organ transplant, age, and diabetic status (Xu et al. 2012). The 2011 proposal consists of two components (Ladin & Hanto 2011). First, it dictates that the best kidneys ($KDPI \leq 20\%$) be allocated to the candidates with the highest EPTS (candidates in the top 20% for EPTS). Second, it states that the remaining kidneys ($KDPI > 20\%$) are to be allocated such that candidates who are within 15 years (older or younger) of the donor's age have highest priority. The age distribution of the current waitlisted population is older than the distribution of the current donor population. Thus, a system which prioritizes candidates within 15 years of the donor age will tend to result in a younger population of recipients (OPTN 2011). In this respect, OPTN (2011) simulations indicate that, relative to the current system, the 2011 proposal reduces the number of kidneys going to the 50-64 age group by 6%. For the ≥ 65 age group, a 5% decrease in the transplantation rate would occur. Besides allocating fewer organs to older transplant candidates, the proposed model, through its first component, also results in a redistribution of longer lived organs from the old to the young.

This second proposal of the Kidney Transplantation Committee also failed to make it to the level of official policy. In August 2011, the Department of Health and Human Services (DHHS) ruled that the ± 15 year age-matching algorithm constitutes a breach of the 1975 Age Discrimination Act (Ross et al. 2012). The algorithm, according to the DHHS, employs age in an arbitrary fashion, whereas the Act stipulates that age may only legitimately be used as a proxy for medical variables.

The Kidney Transplantation Committee's most recent proposal retains the first component of the previously outlined model, i.e. the best kidneys ($KDPI \leq 20\%$) are to be allocated to the candidates with the highest EPTS (candidates in the top 20% for EPTS). In addition, the proposal introduces two further provisions (Friedewald et al. 2013). To begin with, kidneys with a KDPI score between 20% and 85% (moderate quality kidneys) ought to be reserved for transplant candidates with a moderate EPTS score. The rank order of these candidates would primarily be established on the basis of waiting time. A final provision of the proposal stipulates that the allocation of kidneys with a KDPI greater than 85% (the worst quality kidneys) be governed by an opt-in system. Transplant candidates who choose to register for the waiting list for such kidneys would be rank ordered solely according to waiting time. It is expected that this opt-in system will primarily attract the elderly, given that the benefit of decreased time to transplant offsets the risk of decreased graft longevity in this patient group. In June 2013, the OPTN Board of Directors approved this latest proposal. The new kidney allocation system is expected to be fully implemented by the end of 2014 (OPTN 2013b).

0.3.1.2.2 Criticisms of the new kidney allocation system

Each of the aforementioned reform attempts has elicited an array of criticisms. The latter relate to the proposals' impact on 1) living donation rates 2) diabetics and 3) the elderly.

Impact on living donation rates

In significantly increasing young adults' chances of obtaining a deceased donor kidney, critics argue, the reform proposals are likely to considerably decrease this age group's reliance upon living donation (Hippen 2009). Relative to deceased donor kidneys, living donor kidneys exhibit a prolonged potential for survival. Currently, over one-half of all kidneys transplanted in young adults originate from living donors (Ross et al. 2012). Thus, a decrease in living donor kidney transplantation rates in this age group would represent a significant loss in efficiency. Depending on the exact extent of the decrease, this inefficiency may offset the efficiency gains obtained by the reform proposals.

Lower rates of living donor kidney transplantation in young adults, critics point out, would be accompanied by one of two scenarios, both of which exacerbate the aforementioned inefficiency. First, due to their poor prospects of obtaining a deceased donor kidney, the elderly may, under the reform proposals, experience a substantial increase in living donor transplantation rates (Hippen 2009). Such an outcome would entail a wastage of graft years, given that the lifespan of a living donor graft, in many cases, exceeds the life expectancy of elderly patients. Second, if the decrease in young adults' reliance on living donation is *not* counterbalanced by an increase in the elderly, we would experience a reduction in *overall* living donation rates (Ladin & Hanto 2011). This, in turn, would imply a decrease in the size of the donor pool and, thus, in the number of graft years available for distribution across the ESRD population.

Impact on diabetics

Some critics raise concerns regarding the inclusion of diabetic status in the calculation of the EPTS score (Xu et al. 2012). It is argued that the EPTS criterion crudely lumps together all diabetics, without consideration for important variations in cause, severity, and duration of the disease. In addition, critics challenge the idea of singling out diabetes when other disease states, such as cardiovascular disease, also adversely affect EPTS. Finally, given that diabetes disproportionately affects certain racial and ethnic minorities, fears exist that a focus on this disease status will exacerbate already existing racial barriers to kidney transplantation.

Impact on elderly

The most frequently cited concern relates to the reform proposals' effects on the elderly. With regard to this issue, we can distinguish three general lines of criticism. Some critics argue that systems which deprioritize the elderly are unjustifiable on equity grounds. They invoke several reasons in support of this claim. First, age is similar to race and gender in that it is a morally irrelevant criterion. Thus, in relying upon this criterion, the reform proposals commit an act of discrimination (Hippen et al. 2011). Second, older patients are, numerically speaking, most strongly represented on the waiting list, a fact which suggests that they have the greatest need for kidney transplantation (Hippen 2012). Third, the elderly are often denied access to the waiting list on arbitrary grounds. Consequently, in penalizing older patients who do make it onto the waiting list, the reform proposals "further discriminate against a group who are already missing out" (Pussell et al. 2012, 363).

Another line of criticism holds that decreased priority for the elderly need not necessarily represent an efficient use of the kidney donor pool. In this respect, Hippen (2009) claims that, besides maximizing benefit from transplantation, efficiency also involves a concern for minimizing harm. From the latter perspective, he claims, the reform proposals are counterproductive. Prolonged waiting times generally prove more fatal for the elderly, due to their decreased physiological robustness. Allocation policies which decrease priority for the elderly would, therefore, increase death rates on the waiting list. Whether or not the reform proposals can be seen as promoting *overall* efficiency, according to Hippen, largely depends on the trade-offs we are willing to make. As he puts it: "how many life years gained from transplantation are required to cancel out the harm of death?" (Hippen 2009, 1509).

A final criticism is of a methodological nature. It claims that age is too inaccurate a predictor of EPTS. Segev (2009), for example, points out that some 60 year-olds are healthier and, therefore, derive greater benefit from kidney transplantation than some 40-year-olds. In short, this line of reasoning laments the EPTS' disregard for the heterogeneity among the elderly. What matters, according to these critics, is functional status, not age per se.

0.3.1.3 Research questions relating to 'coping mechanisms' in commodity scarcity

UNOS/OPTN policy makers have failed to seriously address the aforementioned concerns over the moral irrelevance of age in kidney allocation. They have settled for 'easy point scoring', i.e. they merely make a hasty, uncritical reference to arguments that are commonly put forward in support of age-based rationing in the context of financial scarcity (see, for example, OPTN 2011). This response is disconcerting.

Criticisms of the organ allocation system should not be treated lightly. The perception that the new kidney allocation policy is based upon an irrelevant criterion may, if widespread, damage public trust in organ exchange organizations. This, in turn, could have serious consequences, such as a decreased willingness to register as an organ donor. It is, therefore, important that the transplant community provide the public with a solid argument for the moral relevance of age. The fact that other countries, such as Australia, are already considering a policy change similar to the one recently approved by UNOS only adds urgency to this task (Pussell et al. 2012). The first section of part two of this dissertation will, therefore, be devoted to the search for a more satisfactory account of the moral relevance of age than the one so far put forward by UNOS officials. In taking on this challenge, we will examine the moral relevance of age at both ends of the spectrum, i.e. at both the beginning and the end of life.

0.3.2 'Solutions'

Besides allocation schemes, it is also important that we devise 'solutions' to the problem of kidney scarcity. As the gap between demand for and supply of kidneys grows, waiting times increase. This, in turn, implies "that more medically suitable candidates will become sicker at the time of transplantation (resulting in worse outcomes) and more medically suitable candidates will become too sick to receive a transplant at all or will die on the waiting list" (Hippen 2012, 238-239). In short, the importance of developing solutions to kidney scarcity derives from both concerns of efficiency and beneficence. Solutions fall into one two categories: they seek to either reduce the demand for or increase the supply of renal grafts.

0.3.2.1 Reducing demand

A frequently proposed strategy to shorten the waiting list is to impose stricter guidelines for listing patients for kidney transplantation (Curtis 2006). More specifically, suggestions have been made to limit admission to the waiting list to those with 'adequate' life expectancy. It is hoped that, besides reducing demand for kidney transplantation by excluding high-risk candidates, this proposal will "also increase the longevity of grafts by reducing the number of patient deaths with functioning grafts and in turn decrease new listings for repeat transplantation" (Schold et al. 2008, 62).

Evidently, this strategy is premised on the assumption that a considerable number of high-risk patients are currently listed for kidney transplantation. Preliminary evidence confirms this presupposition. In the US, approximately 11,000 patients with poor prognosis are waitlisted (Schold et al. 2008). However, many more (80,000 people) are not admitted to the waiting list, despite a decent to good prognosis (Hippen 2012). In short, rather than decreasing in size, the waiting list is likely to considerably increase in

the event of the implementation of a stricter criterion ('adequate' life expectancy). This finding suggests that vigorous efforts to curtail the waiting list may already be taking place. Such efforts, if indeed they are occurring, are ethically dubious, to say the least. After all, "there is little comfort in an abbreviated waiting list if, in fact, many of those who may benefit from transplantation are simply not referred" (Pussell et al. 2012).

Another strategy aimed at curtailing the waiting list consists in preventing the onset of ESRD. At this stage, we already possess the know-how to prevent or delay the onset of chronic kidney disease (CKD), the precursor of ESRD (primary prevention) (Schoolwerth et al. 2006). In addition, we are capable of slowing the progression of both diabetic and non-diabetic CKD (secondary prevention). In the case of non-diabetic patients, sustained remission or regression of CKD has even been documented (Perico & Remuzzi 2012). Unfortunately, despite the availability of simple preventative measures, CKD and its modifiable risk factors remain highly under-treated and under-diagnosed (Schoolwerth et al. 2006). The preventative approach will be discussed in more detail in chapter 6.

0.3.2.2 Increasing supply

The most commonly pursued strategy to reduce the gap between supply of and demand for renal allografts is to increase the supply of donor kidneys, both from living and deceased sources.

In the context of deceased donation, proposals for increasing supply include the liberalization of donor eligibility criteria, the introduction of alternative consent regimes, and the creation of a system of financial incentives.

Over the past decades, continuous efforts have been made to expand the donor pool with less than medically ideal deceased donor kidneys. For example, in 2002, UNOS implemented a series of policies aimed at maximizing the recovery and use of so-called expanded criteria donor (ECD) kidneys. The latter include "all kidneys from donors 60 years of age or older as well as donors aged 50-59 years with any two of the following characteristics: history of hypertension, death caused by a cerebrovascular accident or terminal serum creatinine immediately prior to organ recovery > 1.5 mg/dl" (Wynn and Alexander 2011, 325). As a result of these policies, the number of transplants with ECD kidneys increased by 51% between 2002 and 2007 (Wynn & Alexander 2011). Besides ECD kidneys, the reliance upon other types of marginal donor kidneys, such as kidneys with long cold ischemia time and kidneys from diabetic donors, has also increased over the years (Abouna 2008). A more controversial category of marginal donors are HIV-infected patients. Although the use of HIV-infected donors is currently contraindicated in western countries, its potential utility for HIV-infected recipients is under consideration (Cofan et al. 2011).

Some argue that the adoption of an alternative consent regime offers the prospect of a significant increase in the kidney supply. At present, countries either operate under an opt-in or an opt-out (presumed consent) regime. Under presumed consent legislation, a deceased individual is classified as a potential donor in the absence of a registered objection to donation. However, in practice, in most countries, doctors seek relatives' approval for donation. By contrast, an opt-in system operates under the default assumption of non-donation, i.e. one must actively register as an organ donor if one's organs are to be removed after death. In countries currently employing an opt-in system, proposals have occasionally been made for a shift to an opt-out regime. The latter's potential to increase the organ supply is premised on the assumption that individuals tend to stick with the default option (Schold & Segev 2012). Another, more radical, proposal advocates the adoption of conscription. Under such a system, organs are automatically removed after death, regardless of whether or not the person has provided implicit or explicit consent (Spital 2005).

The introduction of financial incentives is perhaps the most controversial proposal to increase the supply of deceased donor kidneys. The nature of these proposed incentives ranges from explicit cash reimbursements to more subtle forms of payment. The prototypical example of the former is the so-called 'futures market', i.e. a system in which individuals would receive a payment, while alive, in return for the rights to their organs after death (Howard 2007). More subtle forms of financial incentives include payments to surviving family members of the deceased donor to support funeral costs or designated charities (Schold & Segev 2012). Moral concerns relating to commodification of the body and coercion have so far impeded the implementation of a system of financial incentives.

The persistent shortage of deceased donor kidneys has fueled efforts to increase the size of the living donor pool. One such initiative is known as 'altruistic' or 'Good Samaritan donation' (GSD). Whereas living donation is typically limited to genetically or emotionally related donor-recipient pairs, this proposal would extend donation to strangers. Although the practice of GSD is relatively uncommon, there is evidence of increased willingness to consider such cases in US transplant centers (Mandelbrot & Pavlakis 2012). By contrast, very few European countries allow this type of donation. The reluctance to accept GSD is linked to concerns regarding the donor's motivation and the potential for coercion and exploitation of the donor (Pascalev et al. 2013).

Another, less controversial initiative to expand the living donor pool, is 'paired donation'. The latter provides a solution in "cases in which there are two willing living donors who each turn out to be incompatible with their desired recipient but compatible with the other donor's desired recipient" (Veatch 2000, 186-187). Kidney

paired donation allows such incompatible pairs to exchange kidneys, thereby ensuring that each recipient is provided with a compatible kidney. Whereas this practice ultimately amounts to donation to strangers, it differs from GSD in that the donor's motivation consists in serving the interests of a genetically or emotionally related recipient. Since its introduction in the United States in 2000, kidney paired donation has experienced a rapid growth (Wallis et al. 2011).

As is the case with deceased donation, there is also an increasing tendency within living donation to relax the medical eligibility criteria for donors. For example, donors with hypertension, renal cysts, and kidney stones are no longer systematically excluded (Kumar et al. 2000). Some foresee a continuing liberalization of donor eligibility criteria in the future, to the extent that (mentally) incompetent patients may eventually increasingly be regarded as an additional and easy source of kidneys (Van Assche et al. 2014). Clearly, such a development would raise ethical issues concerning informed consent.

A final proposal to increase the supply of living donors is the institution of a financial market. Proponents of this usually envisage a government-regulated organ trade where vendors are paid a fixed price and kidneys are allocated by an algorithm similar to the current point system for deceased donation (Matas 2004). Concerns similar to those raised by financial incentives for deceased donation have so far impeded the implementation of a legitimate financial market in living donation. Iran is a well-known exception to this rule (Becker & Elías 2007).

0.3.2.3 Research questions relating to 'solutions' to commodity scarcity

The aforementioned strategies to increase the kidney supply have mainly been developed with the *current* extent of the kidney shortage in mind. Unfortunately, however, the effects of population aging and the obesity epidemic on the prevalence of ESRD are yet to fully materialize. In other words, the kidney shortage has far from reached its peak. Projections suggest that, by 2020, the prevalence of ESRD patients in the United States will approach 785,000, an increase of more than 60% from 2005 levels (Finn 2008). By 2030, the expected peaking point of population aging, the US ESRD population could reach 2 million (Bayliss et al. 2011).

As we have seen, population aging and its effects have fuelled a recognition among policy makers that the traditional kidney allocation systems (i.e. traditional '*coping mechanisms*') are no longer viable. Surprisingly, however, when it comes to devising *solutions* to the kidney shortage, the implications of population aging have gone largely unnoticed. In short, little or no thought has been given to the question of whether the currently proposed solutions are well-suited to accommodate an ever aging kidney transplant waiting list and the accompanying, projected surge in demand. Given that we

are quickly approaching the peak of population aging, an examination of this question is long overdue. In the second section of part two of this dissertation, we address this lacuna in the research on the merit of currently proposed solutions. We will mainly do so by analyzing the implications of transposing these solutions to the 2030 setting.

0.4 Overview of research questions

Throughout the previous sections, we have already formulated the specific research questions for this dissertation. However, as these have been presented in a dispersed fashion, it is useful to bring them together in a clear overview.

Financial scarcity in health care

1. Are proposals to curb spending on health care in the elderly an effective means of addressing the health care cost crisis?
 - 1.1. Is age-based rationing of life-extending care an effective means of addressing the health care cost crisis?
 - 1.2. Is the biogerontological approach to healthy aging an effective means of addressing the health care cost crisis?

Commodity scarcity in health care

'Coping mechanisms'

2. Are there acceptable moral grounds to use recipient age in the allocation of kidneys?
 - 2.1. Are there acceptable moral grounds to deprioritize the elderly in the allocation of kidneys?
 - 2.2. Are there acceptable moral grounds to prioritize pediatric patients in the allocation of kidneys?

'Solutions'

3. Are the currently proposed solutions to the kidney shortage well-suited to accommodate the projected surge in demand related to population aging?

In addition to the abovementioned questions, the background of which was provided in the previous sections, we will also take a look at commodity scarcity in health care in the Belgian context. Specifically, we will address the following question:

4. What are some of the recently proposed solutions to commodity scarcity in health care in Belgium and are these ethically sound?

0.5 Structure of the dissertation

Part 1: Financial scarcity in health care

As we have seen, health care costs are rising at an unsustainable rate. The cause of this trend is often attributed to population aging. As a result, proposed solutions to the health care cost crisis frequently target the elderly. Part one of this dissertation examines two solutions of this type: age-based rationing of life-extending care and the biogerontological approach to healthy aging.

Chapter 1 is devoted to age-based rationing. The aim of this chapter is twofold. To begin with, we wish to provide the reader with an extensive overview of the most common philosophical arguments put forward in support of denying the elderly life-extending care. There are two specific reasons why such an overview is important. First, given that many of these arguments are frequently misrepresented in the literature on age-based rationing, it is crucial to portray their content in an unbiased manner. Second, some of the philosophical arguments in defense of age-based rationing will reoccur in part 2 of this dissertation on commodity scarcity.

The second, most important, aim of this chapter consists in analyzing the extent to which age-based rationing represents an effective tool for combating the ever increasing rise in health care costs. We argue that age-based rationing ultimately fails as a solution to the health care cost crisis. More specifically, we show that, in failing to address the root cause of the problem at hand, it provides, at best, temporary relief from rising health care expenditures.

Chapter 2 addresses the biogerontological approach to healthy aging, i.e. the idea that we can significantly extend healthy life expectancy by intervening in the aging process. The structure of this chapter largely mimics that of the first chapter. The chapter starts out with an overview of recent developments in the field of biogerontology. This will help to shed light on what the biogerontological approach involves and what it hopes to achieve. In a subsequent section, we scrutinize the various assumptions underlying the claim that interventions in the aging process offer the prospect of substantially reducing the growth in health care costs. We show that each of these presuppositions is dubious and we, thus, conclude that the biogerontological approach fares at least no better than age-based rationing as a cost containment tool.

Although the failure of the biogerontological project as a cost containment device has so far not been picked up on in the literature, the idea of intervening in the aging process has nevertheless been criticized on other moral grounds. The biogerontological approach faces strongest opposition from deontologists. The latter consider the act of

intervening in the aging process impermissible on the grounds that it would (most probably) bring about an extended maximum lifespan – a state of affairs which they deem intrinsically bad. In a bid to convince their deontological opponents of the permissibility of this act, proponents of biogerontology invoke an argument which is grounded in the well-known doctrine of double effect. Surprisingly, their argument, which we refer to as ‘the double effect argument’, has gone unnoticed. **Chapter 3** exposes and critically evaluates the use of ‘the double effect argument’. To this end, we first give a brief account of the doctrine of double effect. Next, we review a series of excerpts from the ethical debate on biogerontology in order to substantiate the presence of double effect reasoning. We, then, attempt to determine the role which ‘the double effect argument’ is meant to fulfill within this debate. Finally, we assess whether the act of intervening in aging actually can be justified using double effect reasoning.

Part 2: Commodity scarcity in health care

As mentioned before, part two of this dissertation is made up of two separate sections. These address, respectively, ‘coping mechanisms’ and ‘solutions’ in the context of commodity scarcity. One of the main aims of part two consists in analyzing the implications of population aging for current ‘coping mechanisms’ and ‘solutions’ in relation to kidney scarcity.

Part 2, Section 1: coping mechanisms

As we have seen, the demographic phenomenon of population aging is perceived as jeopardizing the availability of kidneys for the non-elderly under the current allocation system. This observation has incentivized UNOS to formulate a new kidney allocation policy, the implementation of which will take place at the end of this year. Although the new policy has the important effect of deprioritizing the elderly and the middle aged, UNOS officials have so far failed to provide a satisfactory account of the moral relevance of age in kidney allocation.

In **Chapter 4**, we develop one argument which could serve to ground the moral acceptability of deprioritizing the elderly. We do so within a broader framework aimed at minimizing harm. For this, we draw on Feinberg’s conception of harm as a setback to one’s interests. Our argument supports the prioritization of those between their mid 20s and mid 50s. Thus, whereas the low priority accorded to the elderly and middle aged (55+) under our framework is in alignment with UNOS policy, our proposed system departs from the latter in that it also grants children lower priority.

Chapter 5 takes up where the previous chapter left off, i.e. it further builds upon our argument that, from a harm minimizing perspective, children ought to be deprioritized in kidney allocation. This view stands in stark contrast with transplant practice. Many, if not all, organ exchange organizations (including UNOS) prioritize pediatric patients

over all other age groups. Numerous arguments have been put forward in support of the practice of pediatric prioritization. If valid, these arguments would substantially weaken our position on the appropriate level of priority for pediatric patients. It is, therefore, crucial that we examine their soundness. We identify five commonly cited arguments in support of pediatric prioritization and show that none of these succeeds in justifying this widespread practice.

Part 2, Section 2: solutions

As we have seen, proposed solutions to the kidney shortage fall into one of two categories: they seek to either reduce the demand for or increase the supply of renal grafts. Section 2 will be devoted to supply-oriented strategies.

Chapter 6 focuses on a specific subset of strategies aimed at increasing the kidney supply, i.e. those which have so far not yet been implemented generally (e.g. conscription, financial incentives/markets, etc.). Moral debates on these supply-oriented strategies generally tend to revolve around issues such as autonomy, coercion, and commodification of the body. While these issues are undoubtedly important, they are only of practical relevance if these strategies prove to be a sustainable solution to the kidney shortage. In other words, we must first assure ourselves that these proposals are viable in the long-run. Chapter 6 examines this issue of long-term sustainability which has so far not yet been addressed in the literature. We argue that the aforementioned strategies aimed at enlarging the donor pool are shortsighted in that they are not well-suited to addressing the impact of population aging on future levels of demand, for 3 reasons. First, it would not be financially viable to fully utilize any significantly expanded kidney pool. We show that, as a result of this financial limitation, the supply-oriented strategies at hand are likely to necessitate rationing of both transplantation *and* dialysis. Second, leaving aside budgetary constraints, there are formidable obstacles to implementing these strategies in a timely fashion, i.e. before population aging reaches its peak. Third, these supply-focused proposals fail to acknowledge the global reach of the ESRD ‘crisis’.

Chapters 7 and 8 shift the focus away from population aging and kidney scarcity. An ethical analysis of currently proposed supply-oriented strategies would not be complete without a reference to the Belgian context. This is all the more important given that, very recently, there have been two changes to the Belgian law relating to supply-oriented strategies in the context of commodity scarcity. The first change relates to the relaxation of eligibility criteria for *living liver* donors. The second, by contrast, involves a shift from an opt-in to an opt-out regime in the setting of post mortem donation of *body material for research purposes*. Chapters 7 and 8 are devoted to an ethical analysis of these highly topical developments.

Chapter 7 addresses the tendency towards an increased reliance upon living donation as a means of increasing organ supply. As we have seen, donor eligibility criteria for living donation are becoming ever more lenient. A recent amendment of the Belgian transplantation law represents a radical move in the liberalization of these criteria. It allows minors as young as 12 to donate a liver lobe to a sibling under certain circumstances.

In the academic literature and professional guidelines, little attention is paid to the development of an ethical framework for the practice of living liver donation by minors. The focus is frequently limited to donation of regenerative tissues and kidneys. However, liver donation differs in important respects due to the increased medical risks and the lack of substitute therapies. Therefore, in this chapter, we assess whether living liver donation by minors is ethically appropriate. We argue that living liver donation by minors is only justifiable if minors are competent to consent to donation or if the procedure is in their best interests. Whereas minors may possess adult-like levels of *cognitive* maturity, they lack sufficient *psychosocial* maturity to give valid consent to donation. In addition, living liver donation is generally not in a minor's best interests. As regards the latter, the potential psychological benefits a minor may experience as a consequence of living liver donation are insufficiently empirically supported and are unlikely to outweigh the short- and long-term medical and psychological risks. Therefore, we conclude that minors should not be considered as potential living liver donors.

Chapter 8 swaps the heretofore dominant focus on *organ* shortage for an analysis of the broader category of scarcity of human biological material. Moreover, it shifts away from donation for *therapeutic* purposes to donation for *research* purposes. Research on human biological material holds great promise for developing better means of preventing, diagnosing, and treating diseases. Biological material removed post mortem is a particularly valuable resource for research as some tissues only become available after death. In order to obtain such tissues more easily, Belgium has recently extended its presumed consent regime for post mortem removal of organs for *transplantation* to post mortem removal of body material for *research* purposes. However, given that the Belgian public has not been informed of this extension, the new law, in practice, amounts to conscription or 'routine removal' of body material after death for research purposes.

In chapter 8, we attempt to determine which consent regime should govern the post mortem procurement of body material for research. Given that, in practice, the Belgian system boils down to conscription, we first analyze whether a regime of routine removal is ethically acceptable. In view of this aim, we assess the various arguments which could be put forward in support of a duty to make body material available for research purposes after death. Our analysis suggests that a duty to make one's body material available for research after death can be substantiated on at least two grounds

(a duty to refrain from free-riding and a duty to contribute to the maintenance of public goods) and possibly also on a third ground (a duty of easy rescue, depending on how such a duty is interpreted), but that this duty is always conditional. We conclude that this duty could support conscription but *only* as a last resort and *only* if a way were found to guarantee that two conditions that attach to the duty would be met. Since neither of these two criteria is currently fulfilled, conscription must be rejected. We conclude, however, that the duty to make body material available for research purposes after death is sufficiently strong to defend a policy of presumed rather than explicit consent.

In a final section of this dissertation, we will summarize the most important findings with respect to our research questions and objectives. In doing so, it will become clear how our research contributes to the general debate on scarcity in health care. In addition, this summary will reveal that financial and commodity scarcity are much more intertwined than one would, at first sight, assume. We will end our dissertation with some recommendations for future research.

0.6 References

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Part 1 Financial scarcity in health care

Chapter 1

Age-based rationing: an overview and analysis

Partially based on published article:

Capitaine, L., Pennings, G. and Sterckx, S. (2013) “Why Jecker’s capabilities approach to age-based rationing is incapable of containing health care costs”. *American Journal of Bioethics* 13: 22-23.

1.1 Introduction

As noted in the general introduction, proposals for age-based rationing first occurred in the 1980s, as an expression of growing fears that population aging would lead to an unsustainable rise in health care expenditures. In this chapter, we analyze these proposals, in both their original formulations and their present-day form.

The chapter consists of three sections. In a first section, we present an overview of the most important age-based rationing proposals. For each proposal, we put forward the main existing criticisms of it. In a second section, we provide an overview of general criticisms of age-based rationing, i.e. criticisms which target the concept of age-based rationing, independently of any specific proposal. In the final and most important section, we shift the focus away from a descriptive to a normative analysis. More specifically, we examine whether age-based rationing represents an effective means of addressing the health care cost crisis.

1.2 Overview of age-based rationing proposals and their criticisms

As it is impossible to provide an exhaustive overview of age-based rationing proposals, we limit ourselves below to five of the most prominent arguments: the prudential lifespan account, the biographical lifespan account, the original fair innings argument, the extended fair innings argument and the capabilities approach to age-based rationing.

1.2.1 Daniels' prudential lifespan account

Norman Daniels has played a pioneering role in the age-based rationing debate. He developed his views on the subject in his book *Am I My Parents' Keeper?* (1988). These views largely build upon Daniels' general account of justice in relation to health care, which he set out in his book *Just Health Care* (1985). In the following sections, we first examine some central tenets of this general theory. Next, we take a closer look at how Daniels applies his theory of just health care to the issue of age-based rationing.

In *Just Health Care*, Daniels seeks to provide a justification for the claim that there is a right to health care. He argues that only an acceptable, general theory of distributive justice can serve to ground this right. For this endeavor, Daniels relies upon John Rawls' theory of justice as fairness (Rawls 1973).⁶ In order to apply this general theory of justice to health care, Daniels argues, we must first address the following question: "Is health care special?". He uses this question as shorthand for a number of other questions, such as: "What explains the special importance we attribute to health care?" and "Why should health care be treated differently from other kinds of preferences?".

With a view to addressing the abovementioned questions, Daniels invokes David Braybrooke's (1968) distinction between two broad categories of need: *course of life* needs and *adventitious* needs. The former refers to needs that are independent from time and space, i.e. those things which are essential for the fundamental human projects. In short, the *course of life* needs are important, irrespective of the *particular* choices and preferences of individuals (Daniels 1985). A deficiency with respect to such needs endangers 'species-typical normal functioning'. Food is a prime example of a *course of life* need in that adequate nutrition is a prerequisite for living in the way characteristic of a typical member of our species. Other examples include clothing, shelter, and companionship. Whereas *course of life* needs are universal, *adventitious* needs originate from the wants and desires a particular person has at a certain point in time. They are less urgent, non-basic needs. For example, my desire to attend college induces the *adventitious* need for textbooks (Matthews & Russell 2005).

Health care needs, according to Daniels, fit the characteristics of *course of life* needs. Daniels' adherence to the so-called 'biomedical model of health and disease' accounts for this particular classification of health care needs. Under this model, health is defined in terms of the absence of diseases, whereas diseases represent "deviations from the

⁶ Daniels' account constitutes an extension of Rawls' theory in that the latter has no particular relevance to health. Rawls distinguishes 'primary *social* goods' from 'primary *natural* goods'. The former category includes rights and liberties, opportunities and powers, income and wealth, and the social bases of self-respect. "These goods are *primary* goods because they are things that persons need in their status as free and equal citizens, and as normal and fully cooperating members of society over a complete life. They are *social* primary goods in view of their connection with the basic structure: liberties and opportunities are defined by the rules of major institutions and the distribution of income and wealth is also regulated by them" (Denier 2007, 105-106). Health (alongside vigor, intelligence, and imagination) is considered by Rawls as a 'primary *natural* good'. The distribution of this type of good is not so directly influenced by the basic structure. 'The primary *natural* goods' fall outside the scope of Rawls' concern. As we explain later on, Daniels extends the scope of Rawls' theory to include health care by subsuming health care organizations under the basic arrangements in society that help to promote fair equality of opportunity (Denier 2007).

natural functional organization of a typical member of a species” (Daniels 1985, 28). Thus, health care needs refer to things we require in order to maintain or restore normal species functioning. What is it about normal species functioning that prompts us to attach such great moral importance to *course of life* needs and health care needs in particular? According to Daniels, it is the relationship between species typical functioning and opportunity. In order to clarify this relationship, he introduces the concept of a ‘normal opportunity range’. The latter denotes “the array of life plans reasonable persons in it [a given society] are likely to construct for themselves” (Daniels 1985, 33). The share of the normal opportunity range open to a specific individual is determined by her skills and talents. However, normal species functioning also influences the share of the normal range open to an individual. As Daniels puts it: “Impairment of normal functioning through disease and disability restricts an individual’s opportunity *relative to that portion of the normal range his skills and talents would have made available to him were he healthy*” (Daniels 1985, 33-34).

Everyone has a fundamental interest in preserving their share of the normal opportunity range. This, coupled with the impact of disease upon this share, explains why people treat health care needs as special and important. However, the mere fact that we attach importance to such needs does not necessarily imply that there is a social obligation to protect people’s share of the normal opportunity range. Nevertheless, we can easily establish a right to health care once we consider that disease and disability create *inequalities* in opportunity, i.e. they reduce the number of opportunities available to an individual, relative to a *healthy* individual with the *same* set of skills and talent. Such inequalities in opportunity, according to Daniels, imply that Rawls’ principle of fair equality of opportunity can be extended so as to also govern the design and function of health care institutions and practices.⁷

Am I My Parents’ Keeper?

In *Am I My Parents’ Keeper?*, Daniels (1988) addresses the problem of a fair or just distribution of resources between age groups. The prudential lifespan account is his answer to the problem. This solution involves a fundamental shift in perspective. The intergenerational equity debate, Daniels observes, tends to be construed in terms of various age groups competing for scarce resources in health care. For example, the

⁷ Upholding fair equality of opportunity does not require equalizing individual shares of the normal opportunity range. It merely dictates that such shares be equal for persons with the same skills and talents. In short, a fair share does not necessarily amount to an equal share.

interests of working adults who pay high premiums are pitted against those of the frail elderly who consume a vast portion of health care resources. Rather than viewing the various age groups (infants, adolescents, the middle-aged, and the elderly) as distinct groups of people, Daniels urges us to see them as different stages of one person's life. This shift from an *interpersonal* to an *intrapersonal* point of view implies that our task no longer consists in devising principles of justice which govern the distribution of resources between competing individuals. Rather, we must find a principle suitable for budgeting resources over our own lifespan. With respect to this intrapersonal resource allocation issue, Daniels claims, prudence is a safe guide to justice. Thus, the task becomes one of determining how prudent deliberators would distribute health care resources over the various stages of their lives.

The choice situation wherein prudent deliberators find themselves has three important characteristics. The first refers to knowledge which these deliberators are assumed to already possess. The remaining characteristics, by contrast, pertain to information constraints.

Prudent deliberators work under the assumption that they have a fair share of health care resources at their disposal to allocate over their lives. In other words, they know that the fair equality of opportunity principle governs the design of the health care system. Their concern is to refine this principle in such a way that it becomes amenable to governing allocations over a life.

Prudent deliberators assume that they will live through each stage of life under the system they are designing, i.e. they are blinded with regard to their age. The following example illustrates the necessity of this information constraint. Suppose that prudent deliberators know that they are old. In other words, they are aware that they will live under the institutions they are to reason about prudentially only through the late stages of their lives. Under such circumstances, deliberators would have a vested interest in allocating substantial resources to the old. In a similar vein, young deliberators, aware of their age, would distribute a significant portion of the resources to the young. The absence of an information constraint on age would entice prudent deliberators to pit the interests of their own age group against those of other age groups. Thus, the problem of age group justice would, once again, take on an *interpersonal* dimension. However, the appeal to prudence is only justifiable on an *intrapersonal* level. It is precisely in order to maintain this *intrapersonal* perspective that we must deny individuals information about their age.

Prudence, according to Daniels, dictates a concern for well-being *over one's whole lifespan*. For this reason, we must blind the rational deliberators from knowing their current conception of what is good in life. Such knowledge would skew their decisions towards their current plan of life. This type of bias is inconsistent with respect for lifetime well-being in that one's life plans are likely to change over time.

Before examining how prudent deliberators allocate their fair share of health care resources over their lifespan, Daniels refines the notion of a 'normal opportunity range'. In this respect, he introduces the concept of the 'age-relative normal opportunity range'. This variant on the original concept is designed to reflect the fact that lives have phases in which different general goals and tasks are central. For example, whereas nurturing and training are central during childhood and youth, adult years are devoted to the pursuit of a career and family. In short, the 'age-relative normal opportunity range' represents a much richer variant on the original notion in that it is sensitive to the differences in opportunities open to a person at each stage of life.

According to Daniels, prudent deliberators would, under the abovementioned constraints, favor a distribution of health care resources that allows them to enjoy, *at each stage of life*, their fair share of the normal opportunity range open to them. Thus, this distribution rule provides the answer to the question of what is just or fair between age groups. Daniels explains the rationale behind this adaptation of the fair equality of opportunity account to the age group problem as follows:

From their perspective, prudent deliberators do not know what their individual situation is or what preferences or projects they might have at a given stage of their lives. Still, they do know that they will have a particular plan of life, indeed, possibly different ones at different stages of their lives, and that this plan of life defines what is meaningful for them. This means that it is especially important for them to make sure social arrangements give them a chance to enjoy their fair share of the normal range of opportunities open to them at each stage of life. This protection of the age-relative normal opportunity range is doubly important because they know they might want to revise their life plans. Consequently, they have a fundamental interest in guaranteeing themselves the opportunity to pursue such revisions. But impairments of normal functioning clearly restrict the portion of the normal opportunity range open to individuals at any stage of their lives. Consequently, health-care services should be rationed throughout a life in a way that respects the importance of the age-relative normal opportunity range. (Daniels 1988, 76)

In order to further develop his account of age group justice, Daniels (1988) subsequently confronts prudent deliberators with a somewhat altered choice situation. This time, prudent deliberators face substantial resource limitations in addition to information constraints. The scarcity of resources is such that the provision of very expensive life-extending medical services in later stages of our lives comes at the cost of reduced access to such services in earlier stages of life. Under these circumstances, prudent deliberators have two distinct options, referred to by Daniels as 'scheme A' and 'scheme L'. 'Scheme A' amounts to age-based rationing in that everyone over the age of 70 or 75 –

identified by Daniels as the normal lifespan – is denied high-cost life-extending treatment. The resources that are hereby freed up secure greater access to life-extending treatment for the young. Thus, ‘scheme A’ increases the chances of the young of reaching a normal lifespan. ‘Scheme L’, by contrast, rejects age-based rationing in favor of an allocation based on medical need. The greater medical need of the elderly, then, calls for transferring to the elderly a part of the resources previously devoted to the young. As a consequence, ‘scheme L’ increases the chances of the elderly of living a longer-than-normal lifespan at the cost of reducing the probability of the young reaching a normal lifespan. With a view to quantifying the choice situation, Daniels ascribes (purely theoretical) numerical probabilities to the effects of both schemes. He invites us to imagine ‘scheme A’ as having a 1.0 probability of reaching the age of 75 (and of dying immediately upon reaching this age). ‘Scheme L’ should, for the sake of argument, be conceived of as offering a 0.5 probability of reaching 50 and a 0.5 probability of reaching 100.

Daniels claims that prudent deliberators would invoke the ‘Standard Rule’ as a tool for assessing both schemes. This rule dictates that one maximizes one’s expected net benefit or payoff when faced with choices. In the case at hand, where the payoff is defined in terms of the number of years lived, prudent deliberators ought, then, to maximize the expected lifespan. At first sight, the ‘Standard Rule’ seems to instruct prudent deliberators to be indifferent between the schemes as both produce an expected lifespan of 75 years. However, an attitude of indifference, Daniels argues, is only warranted in the absence of any knowledge concerning the distribution of diseases and disabilities over a lifetime. Prudent deliberators are not entirely devoid of such knowledge in that they are aware of the more frequent occurrence of diseases and disability in old age (say after age 75). According to Daniels, “this knowledge suggests that it would be imprudent to count the expected payoff of years late in life quite as highly as the expected payoff of years more likely to be free of physical and mental impairment” (1988, 89-90). Discounting of the years beyond age 75 tips the balance towards ‘scheme A’.

There is yet another line of reasoning which, under the ‘Standard Rule’, would also yield a preference for ‘scheme A’. On this alternative account, prudent deliberators define the payoff in terms of the success of their probable plan of life. On a general level, we can distinguish between two types of life plans. On the one hand, there are life plans the success of which hinges on the fruitful completion of the typical tasks of early and middle years. On the other hand, we can conceive of plans of life under which the later stages of life are deemed to contribute most to the overall meaningfulness of life. Despite being unaware of their own conception of the good, prudent deliberators nevertheless know that the former life plan is much more common than the latter. In

increasing their chance of living through the middle stages of their lives, 'scheme A' most ensures the success of their probable plan of life.

Daniels stresses that his prudential lifespan account should not be viewed as a blanket endorsement of age-based rationing. The latter only constitutes a prudent choice and, thus, a fair distribution of resources between age groups under specific circumstances. To begin with, age-based rationing is unwarranted when carried out in a piecemeal fashion. Thus, for example, Daniels rules out an age rationing scheme adopted by some hospitals or physicians only. Age-based rationing ought to *consistently* deny the elderly life-extending treatment. Only then will the unequal treatment of age groups (through age-based rationing) nonetheless amount to an equal treatment of persons. The fact that we all age implies that every one of us experiences the burdens and benefits attached to a *systematically* applied age rationing scheme. It is precisely in this sense, according to Daniels, that age-based rationing distinguishes itself from differential treatment on the basis of, for example, sex and race. In addition to the consistency requirement, Daniels also formulates a constraint relating to scarcity. The appeal to age-based rationing as a cost constraining device, he argues, is only justifiable under conditions of *real* scarcity. For example, if scarcity is merely attributable to wastage, such as runaway administrative costs, it does not qualify as real. Finally, the prudential lifespan account is part of an ideal theory, i.e. it assumes the presence of just institutions as well as compliance with the principles governing these. For example, prudent deliberators, as noted above, work under the assumption that health care institutions provide everyone with a fair share of basic goods. Absent these ideal conditions, age-based rationing is unwarranted.

Criticism

Criticisms of Daniels' account fall into one of two categories: they relate to either his general theory of justice in health care or his prudential lifespan account. Below, we examine the criticisms of Nancy Jecker and Margaret Battin as instances of, respectively, the former and the latter. Note that the distinction between both types of criticism is artificial in that any criticism of Daniels' general theory has ramifications for his prudential lifespan account.

Jecker's criticism of normal functioning

Jecker's criticism targets the claim that health care institutions have the societal obligation to protect the normal opportunity range and, thus, to address deviations from normal species functioning (1989). She argues that this claim is inconsistent with

our considered moral judgments.⁸ Her criticism has two distinct components. First, she shows that we do not generally believe that a disease ought to *necessarily* constitute a deviation from normal species functioning in order for it to qualify for public coverage. Second, she contends that we do not generally perceive deviations from normal species functioning as a *sufficient* condition for eligibility for public coverage. Below, we discuss both claims, in this respective order.

Jecker observes that old age is associated with various negative effects which qualify as species typical for the elderly, rather than as impairments of age-relative normal functioning. For the elderly in general, she cites the examples of mild hearing loss and mild vision impairments. In the specific case of elderly women, Jecker enumerates the following examples: “menopausal sympathetic nervous system disorders characterized by flushes and sweating episodes; loss of bone mass (which begins in the mid-thirties) leading to osteoporosis and to accompanying painful debilities, such as collapsing vertebrae and increased risk of spontaneous fractures; and relaxation of the pelvic supporting tissues frequently resulting in urinary stress incontinence” (Jecker 1989, 672). On Daniels’ account, there is no societal obligation to make available to the elderly interventions aimed at alleviating these negative effects as the latter do not represent deviations of age-relative normal functioning. In other words, given that the opportunities afforded by, for example, good sight are not normally available to the elderly, mild vision impairments cannot be said to diminish the age-relative normal opportunities of the elderly. Daniels’ reluctance to publicly fund remedies for the abovementioned impairments, according to Jecker, does not fit with our considered judgments. She concludes, contrary to Daniels, that medical interventions need not *necessarily* have the effect of restoring normal species functioning in order to be considered a requirement of justice.

In the following stage of her argument, Jecker considers the example of high-cost, high-risk interventions which, if successful, restore normal species functioning. Daniels, according to Jecker, is committed to the public provision of such treatments. By contrast, Jecker claims, our considered judgments instruct us to take into account costs and risks, in addition to the potential for restoration of normal species functioning.

⁸ The concept of considered moral judgments is at the heart of the method of reflective equilibrium. The latter is a coherentist method for the justification of moral beliefs. This method “consists in working back and forth among our considered judgments (some say our “intuitions”) about particular instances or cases, the principles or rules that we believe govern them, and the theoretical considerations that we believe bear on accepting these considered judgments, principles, or rules, revising any of these elements wherever necessary in order to achieve an acceptable coherence among them” (Daniels 2011).

Consequently, the mere fact that a medical intervention has such potential does not constitute a *sufficient* grounds for including it in the basic health care package.

Battin's senicide proposal

Margaret Battin (1987) has provided a highly provocative criticism of Daniels' account. Whereas she endorses the moral justifiability of age-based rationing, Battin disagrees with the specific policy which Daniels proposes in this regard. Recall that Daniels sanctions a redistribution of *life-extending* resources from the old to the young. Battin does not consider this to be far-reaching enough. She points out that, despite the elderly consuming a third of all health care, only a relatively small portion of these expenditures is devoted to life-extending measures. In other words, there would be no substantial redistributive achievement under Daniels' proposal. This, in turn, implies that the prospect of the young reaching a normal lifespan is only minimally increased. If, as Daniels himself suggests, rational self-interest maximizers seek to *optimize* the chances of reaching a normal lifespan, they will, according to Battin, redirect to the young *virtually all* medical resources currently reserved for the elderly.

Presumably, if care is to be denied, it will be the highest-cost [...] varieties of care, including care which does not directly serve to maintain life. [...] Expensive diagnostic procedures and therapies like CAT scans or nuclear magnetic resonance imaging, renal dialysis, organ transplants, hip replacements, hydrotherapy, respiratory support, total parenteral nutrition, individualized physical therapy, vascular grafting, major surgery, and high tech procedures generally would be ruled out. Hospitalization, and the nearly equally expensive inpatient hospice care, might not be permitted, except perhaps briefly; sustained nursing home care [...] would no doubt also be excluded. [...] At most, perhaps, minimal home hospice care and inexpensive pain relief could be routinely granted, together with some superficial care in transient acute illness not related to chronic conditions or interdependent diseases. (Battin 1987, 325-326)

Faced with a highly restricted right to the use of health care resources in old age, parties to the original position will, according to Battin, adopt a policy of senicide. In other words, they will consent to policies which impose the direct termination of life at the *onset* of profound illness or irremediable chronic disease in old age. There are two reasons why rational self-interest maximizers prefer being killed off over carrying on living in the face of minimal medical care. To begin with, whereas denial of treatment beyond minimal hospice care and inexpensive pain relief will occasionally result in immediate death, it will most often condemn the patient to a prolonged period of morbidity, only later followed by death. Endurance of suffering only represents a

prudent choice whenever there is hope of returning to normal health. Obviously, an extensive form of denial of treatment precludes this prospect. Therefore, rational self-interest maximizers will opt for senicide as a means of avoiding the discomfort, disability, and pain associated with disenfranchisement from medical care. Besides the avoidance of suffering, direct termination policies offer an additional advantage. In isolation, a policy of extensive treatment denial still involves some medical expenditures for the elderly, i.e. costs associated with minimal hospice and palliative care. When coupled with direct termination practices, a treatment denial policy succeeds in averting even these minimal costs. In short, senicide policies allow for a still greater transfer of resources to the young, thereby further increasing their chances of reaching old age.

Battin acknowledges that the implementation of direct termination age-rationing policies in 'real life' is likely to invite abuse. Therefore, she argues, such policies would need to be supplemented with the following three protective measures.

First, whereas the treatment denial-component of her proposal would be binding, the senicide-component would not be. In other words, beyond a predetermined age cut-off, one would consistently be denied access to virtually all forms of medical care. However, an elderly person who has just learned that her health is on a downhill course would, knowing that she will not receive the needed care, have two options. She could choose to 'tough it out' and wait for death to occur naturally. Alternatively, she could opt for the instantaneous, painless termination of her life. Despite the voluntary nature of the senicide-component, Battin is nevertheless convinced that her proposal would yield a near to maximal transfer of resources from the elderly to the young. After all, she foresees a shift towards a societal recognition of a *moral* 'duty to die' – a duty that will incentivize the majority to opt for senicide.

Second, Battin highlights the need for public awareness of the direct termination age-rationing policy. In addition, the public must understand that, whereas one loses out in old age under this policy, one nevertheless benefits from it *over one's lifetime*. With the exception of the first generation, all subsequent generations will experience an increased chance of reaching old age as a result of the previous generation opting for senicide. It is precisely this insight which will fuel the recognition of a moral duty to die. The latter in turn, will guarantee the success of the policy.

Third, the age cut-off for medical care does not imply that upon reaching this age one is expected to opt for senicide. For example, suppose that the age cut-off is set at 70. A healthy, vigorous 80-year-old would, then, not be expected to end her life. This expectation only falls on the shoulders of those who experience the first signs of profound illness or irremediable chronic disease.

1.2.2 Callahan's biographical lifespan account

Daniel Callahan's *Setting Limits* (1987) has highly impacted the debate on age-based rationing. The starting point of this book is an analysis of our current views on the goals of medicine (especially health care for the elderly). Developments in high-technology medicine, Callahan claims, have largely formed our views on this matter. He identifies the elderly as the group which has benefited most from the technological progress of recent decades. In this respect, Callahan cites the examples of dialysis and critical care units. In removing or bypassing many of the traditional frailties of old age, such advances have brought about significant increases in life expectancy. As a result, we have come to view the aim of medicine in relation to old age as one of producing ever greater increases in life expectancy. In other words, the goals of medicine are currently defined in terms of a 'modernization of aging'. This view resists labeling age-related declines in physical and mental vigor as inevitable, i.e. as inherent in the aging process. Rather, it considers such deficiencies to be equally amenable to medical intervention as conditions afflicting younger age groups. In short, the goal of modernizing old age consists in aggressively resisting the process of aging.

In addition to the emergence of high-technology medicine, the value system of western society has also encouraged the development of the modernized view of aging. According to Callahan, one of the cornerstones of this value system is individualism, the conviction that, insofar as they do not harm others, individuals have a right to pursue their own, private conception of happiness. Thus, individualism denotes the preoccupation of individuals with their own good, as opposed to the good for society as a whole. This value system dictates that medical care be concerned with the satisfaction of individuals' wants and desires. Whereas the implications hereof are merely left implicit by Callahan, Matthews and Russell (2005) succeed in eloquently capturing these:

Thus, since most individuals want to live as long as possible, a principal aim of medicine (on this view) ought to be to enable them to go on living, whatever age they have attained so far: as a principal aim, it ought to be pursued at however great a cost. Again, since most individuals want to continue to enjoy youthful levels of activity, a principal aim of medicine ought to be to enable them to do so (once more, whatever the cost). Medicine should aim to make it possible to be as active at 75 as one was at 35. (Matthews & Russell 2005, 65)

In holding that, in medicine, everything possible ought to be done, the goal of modernizing old age functions as a catalyst for endless, never satisfied progress. Testimony to this are the ever increasing expenditures on health care for the elderly. According to Callahan, such rising costs, combined with an aging population, pose a

grave economic threat. This issue compels us to reconsider our view that medicine ought to conquer all diseases and increasingly push back the frontier of death. Besides these economic concerns, Callahan identifies three further reasons for abandoning the goal of 'modernizing' old age. First, the latter approach is self-defeating in that for any disease conquered another will take its place. Second, it is questionable whether the modernizing view has increased the well-being of the elderly, given that its successes in terms of increased life expectancy have been accompanied by a steady increase in chronic diseases. Finally, the modernization project fails to confer meaning and significance on old age. A public philosophy on the meaning of aging is indispensable, Callahan argues, if efforts to limit expenditures on health care for the elderly are not to convey the message that the elderly are unworthy of any further investment.

Given the importance of imbuing old age with a sense of meaning and significance, Callahan embarks upon this task before exploring alternatives to the current conception of the goals of medicine. He distinguishes three specific sources of meaning and significance for the elderly, linked to past, present, and future. First, in representing a living link with the past, the elderly are in a unique position to pass on to the young – in a way that is reminiscent of preliterate societies – the hitherto accumulated knowledge and experience. Second, given the limited number of life years ahead of them, the elderly are compelled to cultivate the art of making the most of the present. In short, while people of any age may develop this disposition, it comes most naturally to the old. The latter, therefore, are well placed to instruct the young in this art. Finally, Callahan sees an important role for the elderly with regard to the future:

It should be the special role of the elderly to be the moral conservators of that which has been and the most active proponents of that which will be after they are no longer here. Their indispensable role as conservators is what generates what I believe ought to be the *primary* aspiration of the old, which is to serve the young and the future. [...] If the young are to flourish, then the old should step aside in an active way, working until the very end to do what they can to leave behind them a world hopeful for the young and worthy of bequest. The acceptance of their aging and death will be the principal stimulus to doing this. (Callahan 1987, 43)

Callahan draws upon this specific obligation of the elderly to the future when searching an alternative to the medical goal of modernizing old age. Pain and suffering, he claims, impede the elderly from assuming their active role of service toward the young. Therefore, medicine ought to be directed towards the relief of both. However, the scope of medicine for the elderly does not extend any further, i.e. it precludes the provision of

more life as such. In other words, medicine ought to align itself with the obligation of the elderly to withdraw and prepare for death.

These newly defined goals of medicine are still rather abstract in that they do not yet specify the point in old age at which one is no longer entitled to life-extending treatment. Callahan defines this point as occurring upon the fulfillment of a 'natural lifespan' (by our late 70s or early 80s). He stresses that, in introducing the concept of the 'natural lifespan', he is not committing the fallacy of deducing normative judgments from nature. Rather, the choice for this specific yardstick of late 70s or early 80s is meant to reflect the common cultural judgment that this is the amount of time needed to 'write one's biography'. In other words, there is a cultural sentiment that upon reaching the late 70s or early 80s, 1) one's life's possibilities have, on the whole, been accomplished and 2) one's parental responsibilities discharged. In addition, death at this stage, while generally considered a loss, is not perceived as an 'evil'. This is in stark contrast to the death of a child, an event which, without exception, elicits unbearable grief. In short, death after a natural lifespan qualifies, in Callahan's words, as a 'tolerable death'.

Callahan formulates a number of caveats in relation to his age-based rationing proposal. To begin with, he emphasizes that even in the absence of soaring expenditures on health care for the elderly, it would still be wise to implement his proposal. After all, as mentioned above, a sense of limitations is necessary if old age is to have meaning and significance. Next, Callahan acknowledges that his proposal gives rise to a classic policy dilemma: should we impose an exact cut-off age or employ an age range (e.g. late 70s-early 80s)? The former risks overlooking the unique features of individual biographies, whereas the latter may invite abuse. Extended public discussion, Callahan claims, would be needed to resolve this issue. This brings us to Callahan's final caveat. He stresses that his proposal is not fit for *immediate* implementation. As the goal of modernizing old age remains the dominant view, a proposal which imposes limits on health care is likely to be met with strong resistance at this point in time. Rather than forcing such a proposal upon unwilling elderly, it should be introduced democratically, "preceded by a decades-long period of changing our thinking, attitudes, and expectations about elderly health care" (Callahan 1987, 227). In other words, Callahan foresees an attitudinal shift in the elderly which, in turn, would incentivize them to self-impose his proposal. He deems the occurrence of such a shift realistic, for two reasons. First, a century and more ago, it was understood that old age represented an inevitable stage in life, swiftly followed by death. Thus, the past teaches us that it is perfectly possible for the elderly to cultivate a more accepting attitude towards aging and death. Second, once the elderly realize that the exclusion of life-extending treatment frees up resources for ensuring better basic health care coverage (e.g. long-term care, nursing and home care), any concerns of Callahan's proposal representing a reduced commitment to their welfare would soon be allayed.

Criticism

Whenever the term ‘age-based rationing’ comes up, Callahan’s name immediately springs to mind for those familiar with the subject. Thus, it should not come as a surprise that his account has received more criticism than any other theory of age-based rationing. Unfortunately, the deeply engrained nature of the tendency to link Callahan with the concept of age-based rationing also means that most of these criticisms target the general idea of using an age cut-off, rather than the specifics of his proposal. Such general criticisms belong under section 1.3 of this chapter. Below, we limit ourselves to critique at the level of the specifics.

The most controversial aspect of Callahan’s account is its central concept, i.e. the ‘natural lifespan’. Various critics object to the definition of the ‘natural lifespan’ in terms of 70 to 80 years of life (see, for example, Kilner 1988; Cohen-Almagor 2001). Peter Singer (1988) is the most renowned exponent of this line of criticism. He argues that the biographical lifespan is not as fixed and time-independent as Callahan takes it to be. In order to illustrate his point, Singer asks us to imagine that we live under circumstances where aging sets in at a later stage in life than it currently does. Under such conditions, he claims, “our reproductive systems might remain, at 50 or 60, in the condition that they now are at 30 or 40” (Singer 1988, 158). If, then, we chose to have children at the age of 60, our parental responsibilities could not possibly be discharged by the age of 70. However, Singer claims, we need not resort to such a far-fetched scenario in order to make the point. The job can also be done by a slightly more realistic scenario, i.e. that of freezing our sperm and ova and subsequently relying on IVF and surrogacy in order to have a child at a (highly) advanced age. In any case, both scenarios illustrate that the age at which we have discharged our responsibilities towards our children is not fixed for all time.

In a similar way, Singer argues, the age at which our life possibilities have been accomplished is also not ‘engraved’ in a time-independent manner. Rather, this age is highly relative to our circumstances and, more precisely, to our expectation of how long we shall live in health and vitality. For example, in a society where everyone can expect, on average, to live to 73, it may be reasonable to assume that life offers no new, radical opportunities to a 70-year-old. However, this assumption no longer seems tenable in a society in which everyone expects to live in health and vigor well into their 90s.

Given the considerations outlined above, Callahan finds himself in an awkward predicament. He has no choice, Singer claims, but to concede that the cut-off point for the ‘natural lifespan’ is place- and time-dependent in that it shifts according to the circumstances we face. Any failure to do so commits Callahan to a literal, non-biographical interpretation of the term ‘*natural* lifespan’ – precisely the interpretation which he wishes to avoid.

1.2.3 The original fair innings argument

The fair innings argument was first formulated by John Harris (1985). However, he put it forward as a purely theoretical argument, without endorsing it himself (see, for example, Harris 2005). He describes the argument as follows:

The fair innings argument takes the view that there is some span of years that we consider a reasonable life, a fair innings. Let's say that a fair share of life is the traditional three score and ten, seventy years. Anyone who does not reach 70 suffers, on this view, the injustice of being cut off in their prime. They have missed out on a reasonable share of life; they have been shortchanged. Those, however, who do make 70 suffer no such injustice, they have not lost out but rather must consider any additional years a sort of bonus beyond that which could reasonably be hoped for. The fair innings argument requires that everyone be given an equal chance to have a fair innings, to reach the appropriate threshold but, having reached it, they have received their entitlement. (Harris 1985, 91)

Harris emphasizes that the fair innings argument applies only to those cases where one individual has had a fair innings and the other not. In such cases, the argument dictates that the latter be given priority whenever it is impossible to provide life-extending treatment to both. By contrast, when both individuals are on the same side of the threshold age (either below or above it), we ought to be indifferent.

Criticism

Like other accounts of age-based rationing, the fair innings argument has not escaped criticism. Unfortunately, many of the criticisms are off the mark in that they misrepresent the content of the argument. Michael Rivlin's (2000) critical account is, in this respect, exceptional. He identifies the following three problems with the fair innings argument: (1) its reliance upon the concept of a 'fair share of life' (2) its narrow definition of fairness and (3) its unsubstantiated appeal to the distinction between what is unfair and what is unfortunate.

According to Rivlin, the concept of a 'fair share of life' is nonsensical. In support of this claim, he contrasts a person's life with a cake, i.e. an object in relation to which talk of a fair share indisputably makes sense. The reference to a cake which is to be divided suggests that three conditions must be met in order for there to be a (fair) share of a certain something. First, we must be able to ascertain the size of this 'something', i.e. it is only because we are able to assess the size of the cake in front of us that we can cut it in a way that is deemed fair. Second, this 'something' must be amenable to division.

Finally, possessing a share of something implies that one can give away one's share. How does (a) life fare with respect to these conditions? We do not, in advance, know the 'size' of a life. It is only once a life is over that we can determine its length. In addition, a life is not divisible. Finally, one cannot give, for example, five years of one's life to another person.

The nonsensical nature of the concept of a 'fair share of life', according to Rivlin, does not preclude one from passing judgment on the (un)fairness of age-based rationing as endorsed by the fair innings argument. After all, he argues, not all talk of fairness relates to the concept of a fair share. In this respect, Rivlin cites the case of a policeman planting drugs on an innocent person in order to gain a conviction. Although the concept of a fair share does not enter into the equation here, this case nevertheless elicits a judgment of unfair behavior on the part of the policeman. Having settled the possibility of judgments of (un)fairness outside the context of fair shares, Rivlin goes on to demonstrate the unfairness of policies based on the fair innings argument. Specifically, he finds fault with the argument's definition of fairness in terms of length of life only. In this respect, he contrasts a young drunk driver who has injured himself with an elderly person whose illness is not self-inflicted. In this case, Rivlin claims, it is unfair to prioritize the younger person over the older one. He stresses that his complaint about the fair innings argument "is not that older people are not receiving their fair *share*, but that the younger people are being treated unfairly, i.e. just because they are young" (Rivlin 2000, 3).

A final criticism of Rivlin pertains to the fact that the fair innings argument labels it an injustice when a person does not achieve the fair innings. Proponents of the argument, he claims, fail to explain why such an occurrence qualifies as 'unfair', rather than merely 'unfortunate'. In the absence of such substantiating material, the idea of an entitlement to a reasonable span of life cannot be taken seriously.

1.2.4 The extended fair innings argument

Alan Williams (1999) has reformulated the original fair innings argument. In keeping with his health economics background, Williams' starting point is the efficiency

criterion of QALY (quality adjusted life year) maximization.⁹ Although he sees value in distributing resources so as to maximize the output of QALYs, he also acknowledges that this criterion faces equity-based problems.¹⁰ One such problem is the so-called ‘double jeopardy’ issue – a concern frequently voiced by opponents of QALY maximization. Central to the ‘double jeopardy’ argument is the claim that those with a permanent disability or illness suffer a double disadvantage under the use of QALYs. Besides carrying the burden of their disability or illness, such patients will, all other things being equal, generally also lose out in the competition for health care resources due to their lower quality of life. John Harris (1987), who first invoked the ‘double jeopardy’ argument, formulates the problem as follows:

QALYs dictate that because an individual is unfortunate, because she has once become a victim of disaster, we are required to visit upon her a second and perhaps graver misfortune. The first disaster leaves her with a poor quality of life and QALYs then require that in virtue of this she be ruled out as a candidate for life-saving treatment, or at best, that she be given little or no chance of benefiting from what little amelioration her condition admits of. (Harris 1987, 120)

The concern for ‘double jeopardy’ incentivized Williams to adapt the traditional QALY maximization model (Oliver 2009). His extended fair innings model aims to balance this efficiency criterion with equity-based considerations. In other words, it expresses a willingness to sacrifice some overall efficiency for a more equitable distribution of health (Tsuchiya 2000). It does so by introducing equity weights for QALY gains. Rather than weighting every gained QALY as counting for one, irrespective of the recipient,

⁹ A QALY is a year of life expectancy adjusted for quality of life. A year in perfect health is assigned value 1, whereas death is worth 0. Thus, the quality of a year of life will range between 0 and 1 (although it may, in principle, acquire a negative value if the quality of someone’s life is considered worse than death). A medical intervention providing 10 additional years of life in a health state assigned a value of 0.6 will confer 6 QALYs on the patient.

QALYs can be used for various purposes. For example, QALYs may be relied upon to determine which of rival therapies should be preferred for treatment of a particular condition. Alternatively, they may be used to decide which conditions should be prioritized in the allocation of health care resources. In addition, QALYs can provide guidance when determining which of two patients should receive a particular scarce health care resource. In the latter case, the QALY maximization model dictates that preference be given to the patient who stands to gain the greatest number of QALYs. Williams’ extended fair innings argument is concerned with this use of QALYs.

¹⁰ Note that it is relatively rare for adherents of QALY maximization to acknowledge, let alone remedy, the inequitable nature of this criterion. Many proponents simply argue that nobody’s QALYs count for more than anyone else’s and that the QALY concept is, therefore, equitable (see, for example, McKie et al. 1996).

Williams' model allows the weight of a QALY to vary according to who gets it. Specifically, a QALY gain is valued more highly for people who are unlikely to reach a fair innings than for those who can expect to have a fair innings or more. Contrary to the traditional fair innings argument, Williams' model does not equate the fair innings benchmark with an entitlement to a certain number of life years. Rather, it defines the fair innings as the number of *quality adjusted* life years one is entitled to over a lifetime. This number is determined by the average quality adjusted life expectancy at birth. In short, every QALY gain incurred by a medical intervention is weighted more heavily the less likely one is to reach the average quality adjusted life expectancy at birth.

In order to assess the likelihood of any particular individual reaching the fair innings, Williams relies on two factors: a person's past accumulation of health and their expected future accumulation of health. The former factor refers to the number of QALYs the person has enjoyed so far. For those who have been fairly healthy so far, this number will be close to the number of life years lived. By contrast, in individuals who have been severely disabled all their lives, the QALY score will strongly diverge from the number of life years lived. The concept of a person's 'expected future accumulation of health' denotes the number of QALYs a particular individual can still expect to enjoy (from now onwards up until her death). This number will vary according to the person's age, sex, lifestyle, health status, social class, etc.

A person's 'expected lifetime experience of health' is the sum of her past QALYs and her future, expected QALYs. The smaller one's 'expected lifetime experience of health' is, the smaller one's likelihood is of reaching the fair innings (the average quality adjusted life expectancy at birth in society).

We can now take a closer look at the quantification process involved in assigning equity weights to the QALYs gained by a medical intervention. In this respect, Williams distinguishes three scenarios. First, if one's 'expected lifetime experience of health' is equal to the fair innings, every QALY gained will be assigned a weight 1. Second, if one's 'expected lifetime experience of health' exceeds the fair innings, a QALY will be assigned a weight <1 . Finally, an 'expected lifetime experience of health' beneath the fair innings level will result in a weight >1 .

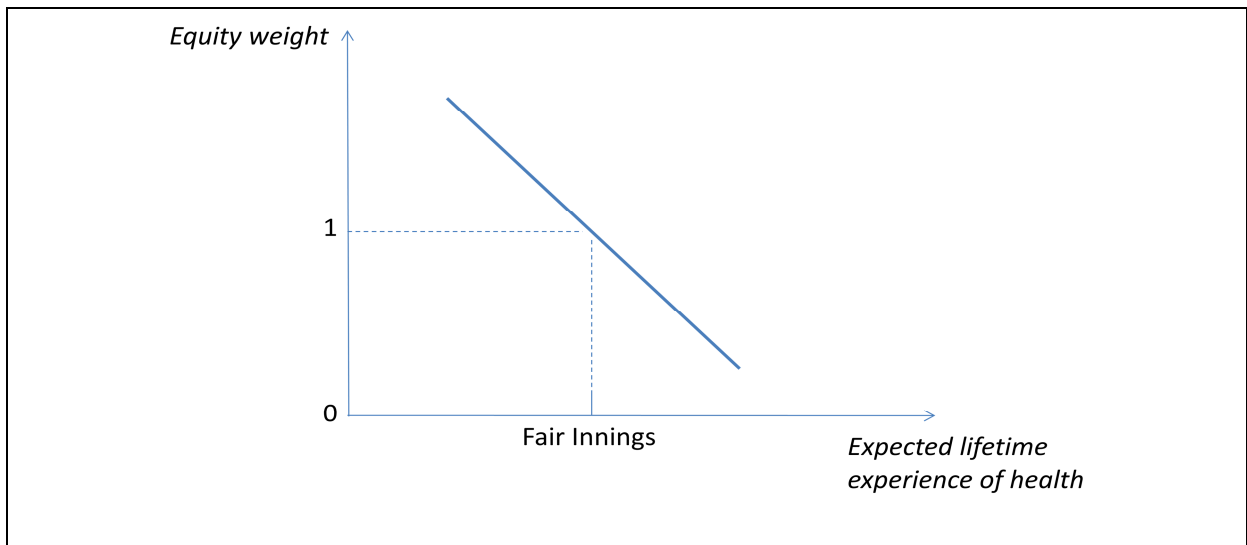


Fig. 1 Relationship between ‘expected lifetime experience of health’ and equity weight assigned to a QALY. Note that this visualization merely represents this relationship on a generic level. As Williams himself asserts, the exact shape of the curve will vary according to a society’s level of aversion to inequalities in lifetime experience of health as measured in QALYs.

An example will help to better grasp the implications of Williams’ extended fair innings model. Consider two persons, A and B, who are equal in all but one respect. A has a serious disability, whereas B is a non-disabled person.¹¹ Both are in need of a kidney transplant. A stands to gain 6 QALYs, while B incurs a gain of 9 QALYs following transplantation. Suppose that, absent a kidney transplant, A and B have an ‘expected lifetime experience of health’ of 50 and 60 QALYs, respectively. Furthermore, assume that, as a result of this difference, a QALY gain is accorded weight 2 for A and weight 1.2 for B.

Under the traditional QALY maximization model, B would be prioritized as she has more QALYs to gain from transplantation. However, as the abovementioned example illustrates, a greater QALY gain does not necessarily imply prioritization under Williams’ model. Despite A having fewer QALYs to gain, the weight accorded to each of these QALYs more than offsets this disadvantage (2x6 versus 1.2x9).

¹¹ We here follow the line of reasoning made by proponents of the ‘double jeopardy’ argument, i.e. we assume that a disabled person has a lower quality of life, relative to a non-disabled person. This assumption has four implications in the example: 1) A stands to gain fewer QALYs from the intervention than B; 2) A has a lower registered score of past QALYs; 3) without treatment, A has fewer QALYs to look forward to than B; 4) the combination of 2) and 3) implies that A has a lower ‘expected lifetime experience of health’.

Williams' model has important implications for various other social groups¹², besides the disabled. As we are concerned in this chapter with age-based rationing, we limit ourselves to examining its impact upon the elderly. This impact is twofold. To begin with, the elderly have, in most cases, fewer QALYs to gain from a treatment for the simple reason that they have fewer years left to live. In this respect, Williams' model shares the same bias against the elderly as the traditional QALY maximization method. As a result of this feature, QALY maximization models have been branded as 'ageist' (see, for example, Harris 1994). However, in weighting QALYs, Williams lends credence to the view, previously expressed by Kappel and Sandøe (1992), that the traditional QALY method is not ageist enough. The older you are, the higher the probability of reaching the fair innings or of already having achieved it. Therefore, the small number of QALYs gained by an elderly person will generally be assigned a low weight under Williams' model.

The abovementioned considerations do not merely illustrate how Williams' model diverges from the traditional QALY maximization method. They also allow us to contrast his proposal with the age-based rationing models previously discussed in this chapter. In establishing an age cut-off, the prudential lifespan account, the biographical lifespan account, the original fair innings argument, and the capabilities approach espouse a form of *direct* age-based rationing. In other words, age in itself functions as the discriminator in these proposals. By contrast, in Williams' model the rationing criteria are features that are merely correlated with age (i.e. 'QALY gains' and 'expected lifetime experience of health'). As a result of it being an *indirect* form of age-based rationing, Williams' proposal merely tends to disadvantage the elderly, rather than consistently denying them treatment.

Criticism

Erik Nord (2005) offers the most comprehensive critique of the extended fair innings argument. He sees two major problems with it.

First, Nord questions the relevance attributed to past suffering by Williams' proposal. In this respect, he asks us to consider the following scenario. Two 50-year-olds, A and B,

¹² Williams' model has a particularly interesting implication for the sexes. Men, as is well-known, have a lower life expectancy than women. Despite women experiencing a lower health-related quality of life, their advantage in terms of life expectancy nevertheless makes for a higher 'expected lifetime experience of health' (Williams 1999). Thus, all other things being equal, the extended fair innings argument attributes a higher weight to QALY gains incurred by men. We refer the reader to Tsuchiya and Williams (2005) for an interesting argument in support of such preferential treatment of men, i.e. an argument for treating the difference in 'expected lifetime experience of health' between men and women as an *inequity*, rather than merely an *inequality*.

require a medical intervention. Both stand to gain an equal number of QALYs. B scores lower on 'expected lifetime experience of health' due to her history of lifetime moderate illness – a stark contrast with A's healthy past. At present, A is severely ill, whereas B continues to be only moderately ill. Under Williams' model, B would receive priority over A. However, Nord challenges the intuitive appeal of this outcome. "Should not medical urgency be the decisive criterion?", he asks. In support of his claim, Nord refers to current medical practice, where past suffering is seldom or never taken into account. Current practice, according to Nord, has a sound moral basis in that medicine can alleviate only present and future suffering. Past suffering, by contrast, is 'sunk costs'.

Second, Nord draws attention to a hidden implication of the extended fair innings argument for the elderly. The original fair innings argument merely governs the distribution of life-extending medical resources. However, in focusing on QALY gains, the extended fair innings argument also regulates interventions that merely impact upon one's quality of life. As a result, the latter argument disadvantages the elderly both in the competition for lifesaving and non-lifesaving resources. Thus, for example, an 80-year-old in extreme pain would lose out in the competition for pain relief therapy to a 20-year-old with a similar condition. This is, for Nord, a step too far.

1.2.5 Jecker's capabilities approach to age-based rationing

The prudential lifespan account, the biographical lifespan account, and the fair innings argument all date from the 1980s. However, theorization about age-based rationing is still well and truly alive. Nancy Jecker's recent account (2013) of justice between age groups is testimony to this fact. The starting point of Jecker's analysis is her dissatisfaction with a feature shared by both social contract theories and the prudential lifespan account. Social contract approaches to justice require that contracting agents be perceived as having cognitive rational capacities sufficient for choosing principles of justice. As a result, they exclude as a contracting party certain mentally impaired individuals. This, in turn, implies that the interests of such individuals can be addressed, at most, as an afterthought, i.e. once the basic institutions have already been designed. Consequently, investments in services for the cognitively impaired, such as special education, are at risk of being shortchanged.

In making these observations, Jecker aligns herself with the well-established 'disability critique' of social contract theories. The novelty of her approach lies in the realization that the aforementioned concerns have implications for age group justice and, more specifically, for the prudential lifespan account. Presumably, prudential deliberation also presupposes a threshold level of cognitive rational capacities. However, this threshold requirement, Jecker points out, does not merely affect those with chronic

mental impairment. It also excludes certain age groups. To begin with, children lack the competency to choose principles of justice. The same holds true for (many of) the very old, due to the high prevalence of dementia in this age group. In excluding the very young and the very old from prudential deliberation, the prudential lifespan account fails to guarantee that equal consideration will be given to all parts of our life. It hereby undermines the rationale behind veiled prudence. As Jecker puts it:

Only if it were possible for individuals to deliberate at each and every stage of life from a first-person point of view could prudential planners place themselves under a veil of ignorance and reasonably assume that they could be members of any age group. Expressed differently, the condition of justifiability to all, mentioned earlier, cannot be met unless we could, at each stage of our life, consider and agree to justice principles. However, such a possibility could never be fully realized, for at both ends of the lifespan, our situation is similar in key respects to the situation of persons with lifelong disabilities. Just as persons living with chronic intellectual impairment may not be able to participate directly and on their own behalf in consenting to justice principles, so too healthy children lack the cognitive capacity to participate directly in choosing justice principles. Although in healthy children this deficit is temporary and due to immaturity, the practical result is the same, namely, consent is unattainable. At the other end of the lifespan [...] due to the high prevalence of dementia, the oldest old are frequently unable to understand and consent on their own behalf to justice principles. (Jecker 2013, 5)

The inability of prudential deliberators to fairly and equally represent both their younger and older selves, according to Jecker, renders the prudential lifespan account an inept approach to the problem of justice between age groups. The alternative favored by Jecker is Martha Nussbaum's capabilities account of justice. Nussbaum (2000; 2006) identifies a set of basic capabilities without which human flourishing is impossible. These include, amongst others, life, bodily health, bodily integrity, control over one's environment, and play. On this account, justice dictates that we bring *every* person's basic capabilities up to the threshold level required for human dignity. People require differing levels of resources in order to attain this threshold level due to their varying abilities to convert resources into functioning and capability. For example, a person in a wheelchair will, relative to a person with normal mobility, require more resources if both are to achieve a similar level of ambulatory ability (Denier 2007). In addition to health status, social determinants of health also impact upon one's ability to convert resources into actual functioning and capability. In this respect, Jecker cites the example of a poor person who, despite the generous coverage provided for her medication, cannot afford the out-of-pocket cost attached to it. Its ability to

accommodate our knowledge of social determinants of health is one of the main features which attracts Jecker to the capabilities approach. She also sees two other advantages of using this account of justice. First, it imposes an objective standard in that the criterion of human dignity sets the threshold level for the basic capabilities. In this respect, the capabilities approach stands in stark contrast with social contract theories and the prudential lifespan account, both of which define the requirements of justice in terms of distributive principles that individuals have rationally agreed to accept. Second, in supporting a set of basic entitlements for everyone, regardless of age or disability, the capabilities approach escapes the problems identified by the ‘disability critique’ and its offshoot.

Under the capabilities approach, Jecker claims, any specific age-based rationing scheme is justified on condition that it does not breach the central tenet, i.e. it must not result in certain capabilities being reduced to a level below the threshold for human dignity. With respect to the type of age-based rationing schemes it authorizes, the capabilities approach converges with other accounts of age group justice. In other words, it allows barring people from life-extending interventions (cure) after a normal length of life, while prohibiting the exclusion of the elderly from care. The former scheme is, according to Jecker, permissible on the grounds that the normal lifespan converges with the threshold level for the capability ‘life’. Jecker projects that the denial of life-extending interventions after a certain age will yield significant cost savings. She bases this projection on two facts. First, the largest share of the high health care costs associated with old age is incurred during the last year of life. Second, population aging entails that an increasing number of elderly will experience their last year of life after the threshold set by the capabilities approach.

Contrary to life-extending interventions, basic caregiving cannot justifiably be subjected to an age cut-off. In order to substantiate this claim, Jecker takes a closer look at long-term care, an important category of care for the elderly. Long-term care services are those that elderly people with “limited mobility, frailty, or other declines in physical or cognitive functioning may require in order to accomplish activities of daily living” (Jecker 2013, 12). A failure to provide such services, according to Jecker, brings the capability of ‘bodily integrity’ – the ability to move freely from place to place – below the threshold level required for human dignity.

Criticism

Given the recent nature of Jecker’s proposal, few criticisms of it are available in the literature. Therefore, we have chosen to provide our own assessment (Capitaine et al. 2013). Our criticism focuses on the cost saving potential of her account. Below, we argue

that the requirement to bring everyone up to the threshold level of the basic capabilities is, in terms of health care costs, highly burdensome.¹³

With regard to the capability 'health', Jecker does not clarify which health care services we are committed to providing in order to meet the threshold requirement. Nevertheless, it is fair to assume that we are dealing with a very demanding threshold as the latter is defined in terms of human dignity. In order to ensure a level of health in accordance with human dignity, we would be required to provide a wide array of services which currently do not qualify for public coverage. For example, one would seemingly be entitled to IVF, gender transition surgery, and stem cell therapy for Alzheimer's. A mere look at the cost of IVF suffices to show that public coverage for the latter type of procedures is likely to contribute to a substantial increase in health care expenditures. In 2002, the prevalence of infertility among married women in the US amounted to 7.4% (Stephen & Chandra 2006). In the US, the cost of a standard IVF cycle is \$12,513 (Chambers et al. 2009). The cost of public coverage for IVF soon becomes extravagant when we take into account that the dignity threshold for 'health' entails an individual's entitlement to an *indefinite* number of cycles.

Besides increasing the number of health care services eligible for public coverage, the dignity threshold for 'health' also commits us to 'upgrading' several of the currently provided public services. For example, consider traditional dialysis, a service which Medicare¹⁴ currently provides irrespective of the patient's age. Nocturnal home dialysis, which is only partly covered by Medicare, constitutes a substantial improvement upon traditional dialysis. In addition to contributing to higher energy levels, home dialysis also implies that patients need no longer spend 12 hours each week in a hospital (Garber 2004). The incidence of end-stage renal disease (ESRD) is projected to increase substantially due to the obesity epidemic. This, combined with the fact that home dialysis is more costly than its traditional counterpart, suggests that (full) public coverage for the former is likely to represent a significant financial burden.

One might object that we have employed the term 'dignity' too loosely, thereby overestimating the impact of the threshold requirement on health care spending. However, even if the sufficiency level for 'health' were low, Jecker's proposal remains open to the charge that it undoes the minimal savings achieved. After all, the threshold level for the capability 'life', i.e. the normal lifespan, is undeniably very demanding. The requirement to bring everyone up to the normal lifespan is highly susceptible to the

¹³ The sections below have been lifted from Capitaine et al. (2013).

¹⁴ Medicare is the US national health insurance program that provides coverage to persons 65 years or older. It also provides coverage for certain disabilities and end-stage renal disease, irrespective of the patient's age (Graham et al. 2010).

bottomless pit problem. Stein defines the latter as follows: “The problem is that even when it is impossible to raise people to the threshold, it is often possible to spend an unlimited amount of resources raising them *toward* the threshold. Often enormous investments – another doctor, another hospital, another medical research project – can make some improvement, however small, or can increase, however slightly, the likelihood of achieving a large improvement” (Stein 2009, 499). The bottomless pit problem is best illustrated by ‘last chance therapies’, so named because they are the only hope for patients facing death in the near future. Generally, these therapies offer only a relatively small prospect of a relatively small increase in life expectancy (Daniels & Sabin 1998). Examples include left ventricular assist devices (LVAD), totally implantable artificial hearts (TIAH), and total parenteral nutrition (TPN). Fleck (2002) identifies two main characteristics of last chance therapies. First, the cost of the therapy, per individual, is very high. For example, for infants suffering from necrotic small bowel syndrome, the costs of TPN range from \$50,000 to \$200,000 per year. Second, last chance therapies are frequently of benefit to a substantial number of patients. For example, TIAH and LVAD could, on a yearly basis, prolong the lives of 350,000 and 550,000 patients, respectively, in the United States. As these figures suggest, the aggregate cost of any specific last chance therapy would be extremely high. In the case of TIAH alone, we would witness a \$105 billion increase in annual health care expenditures (Fleck 2010). Thus, public coverage for *all* last chance therapies for everyone in the pre-normal lifespan stage of life, as prescribed by the normal lifespan threshold, is likely to be prohibitively expensive.

Admittedly, the abovementioned considerations do not alter the fact that the denial of life-extending treatment to the elderly produces cost savings. They do, however, render it questionable whether these savings will outweigh the exorbitant costs associated with the threshold requirement of human dignity. In other words, rather than yielding cost savings, Jecker’s proposal may exacerbate the health care cost crisis.

1.3 Age-based rationing: general criticisms

Above, we have examined several theoretical justifications of age-based rationing as well as criticisms targeted specifically at one or other of these proposals. However, the general concept of age-based rationing, viewed independently of any such specific justification, has also been heavily scrutinized. Below, we discuss a series of these more ‘general’ criticisms.

1.3.1 Age-based rationing as a discriminatory policy

The most frequently cited line of criticism questions the non-discriminatory nature of age-based rationing schemes. Critics have denounced such schemes as being biased against one or more of the following social groups: the poor, the elderly, and women. The first subset of criticisms is highly straightforward. In limiting the establishment of an age cut-off to publicly provided services, it is argued, age-based rationing schemes favor those elderly who could afford personally to pay for life-extending care (Levinsky 1990). The criticisms relating to the other social groups, by contrast, require further elaboration. Below, we first discuss the claim that age-based rationing is ageist. Next, we examine the feminist-inspired criticism.

Discrimination against the elderly

According to its proponents, age-based rationing cannot be faulted with discrimination of the elderly in that it respects the ethical principle of equality. This principle, they stress, does not require us to treat the young and the old equally. The old and the young differ in important respects (e.g. lifetime lived). These differences require and, therefore, justify the differential treatment of age groups. However, critics consider the practice of age-based rationing to be based on a misinterpretation and, consequently, a violation of the principle of equality. Given that human beings matter morally, they argue, “their claims on one another derive from their status as beings of a particular sort and not from contingent features of their lives like age, life expectancy, or quality of life [...]” (Harris 2005, 96). In short, the principle of equality dictates that society grant each person, regardless of their age, the same level of respect, concern, and protection. This reading of the principle, it is argued, has the advantage of being endorsed by virtually all declarations, conventions, and charters on human rights (Harris 2005; Giordano 2005). Moreover, it avoids the problems encountered by the alternative reading. According to John Harris (2005), the principle of equality, as interpreted by proponents of age-based rationing, has as an inevitable corollary the view that it is less of an injustice to murder the old than the young.

The abovementioned criticism of age-based rationing views the young and the old from a slice-of-time perspective. In other words, it focuses on age groups at a single instant in time, rather than perceiving them as different stages in a person’s life. As such, it is vulnerable to criticism on the part of adherents of Daniels’ account. Recall that, according to Daniels, differential treatment of age groups, when viewed from a diachronic perspective, does not amount to unequal treatment of persons. It is precisely in this respect that age-based rationing distinguishes itself from discriminatory practices, such as racism and sexism. There are critics who grant this distinction, while at the same time maintaining the charge of discrimination against age-based rationing

(see, for example, Kilner 1988). Sexism and racism, these critics argue, are deemed unjust, not merely because they treat people unequally over a lifetime. The repugnance felt towards these practices is also fed by their reliance upon an irrelevant, and thus, illegitimate criterion. Age, according to these critics, shares this feature of irrelevance, in various respects. For example, it is an unreliable predictor of the outcome of medical interventions in the elderly (see below). Moreover, one's age is a matter of fact, not of choice. In displaying at least one similarity with racism and sexism, these critics argue, age-based rationing does not entirely escape the charge of discrimination.

Discrimination against women

Other critics show less interest in the potential discriminatory effects of age-based rationing along the age-axis and concentrate instead on the male-female dimension. In this respect, it has been argued that age-based rationing disproportionately affects women. There are two ways in which age-based rationing schemes are thought to affect men and women differently (see, for example, Bell 1989; Howe & Lettieri 1999). First, the higher life expectancy of women entails that an age cut-off for life-extending care robs them of a greater number of life years. Second, as a result of their longer life expectancy, women are more highly represented among older age groups. Thus, a greater number of women than men would be subjected to age-based rationing. In 1991, Nancy Jecker argued that such unequal treatment of the sexes constitutes an inequity. Admittedly, she no longer adheres to this view, given that she now supports age-based rationing.¹⁵ However, as her analysis still serves as a reference point for many of those invoking the issue of women and age-based rationing, it is worthwhile taking a look at it.

Jecker assesses the differential effects of age-based rationing on the sexes against three distinct readings of the ethical standard of equality. On each reading, she argues, this principle is violated.

First, equality may be understood in the sense appealed to by Daniels, i.e. as necessitating equal treatment of people *over a lifetime*. While we all age, we do not

¹⁵ In her latest work, Jecker provides the following argument *against* the view that the differential effects on the sexes amount to an inequity: “[...] in response to these concerns [about the differential treatment of the sexes under age-based rationing], defenders of the capabilities approach can reply that after reaching a normal lifespan, neither men nor women are entitled to publicly funded life-extending care. Thus, even if women are disproportionately impacted by age-based rationing of publicly funded life-extending care, they are not being denied a resource that they are entitled to receive” (Jecker 2013, 11).

change sex. Therefore, on this account, differential treatment of the sexes cannot be acquitted of the 'discrimination charge'.

Second, the equality principle is sometimes interpreted in terms of equal *respect* for persons. Age-based rationing, according to Jecker, fails to convey equal respect for men and women (as well as for the young and the old) in that it qualifies as a 'person-centered' rationing device. She contrasts this notion with so-called 'resource-centered' rationing schemes. The latter appeal to the features of certain treatments, such as their cost or technological sophistication, as a grounds for denying them to people. By contrast, 'person-centered' rationing regulates access to treatment by reference to people's characteristics, such as age, sex, or ability to pay. In treating certain individuals as less deserving due to the kinds of people they are, this type of rationing defies the principle that all possess an equal worth and dignity. Jecker anticipates the response that age-based rationing relies on age, not sex, as a criterion and, therefore, cannot be faulted with signaling unequal respect for men and women. In short, this counterargument draws attention to the indirect, unintended nature of the harm to women under age-based rationing policies. However, Jecker argues, the inadvertent exclusion of social groups does not necessarily preclude injustices. In fact, implicit rationing, she warns, often poses a more daunting threat, relative to the overt use of a criterion. After all, in escaping public scrutiny, undeliberate rationing schemes are able to deflect attention away from themselves while nevertheless excluding certain people.

Third, the standard of equality may refer to a requirement of equal opportunity for all. In depriving them of fewer life years, Jecker argues, age-based rationing policies allow men to enjoy a larger share of the opportunities which life affords. She acknowledges that Callahan would object to this analysis on the grounds that life stages beyond the age cut-off do not open up any important, new opportunities anyway. Given that all of life's opportunities present themselves before the age cut-off, Callahan would argue, there is no inequality in that neither men nor women are deprived of any opportunities through age-based rationing. However, according to Jecker, this view assumes that, upon reaching the cut-off, men and women will have enjoyed equal opportunities. This is a problematic assumption owing to the discrimination women face in various areas of their lives. One might still object that this prior injustice is not remedied by granting women their expected lifespan – that is, at least, if one assumes once again that stages beyond the age cut-off are devoid of (important) opportunities. Jecker criticizes the latter assumption on the grounds that it takes the male life expectancy as a standard for determining when opportunities cease to present themselves in life. With a view to illustrating this claim, she asks us to imagine that life expectancy for men and women, respectively, is 70 years and 140 years. It would be foolish, Jecker claims, to suggest that the 70 additional years which women have at their disposal do not offer any opportunities. There is no reason why the same reasoning should not also apply to women's current edge over males. In short, in depriving women of their 'full' life

expectancy (and the corresponding opportunities), age-based rationing perpetuates and compounds the injustices they have previously endured.

1.3.2 Age-based rationing as a return-on-investment policy

The values underlying age-based rationing have also attracted the attention of critics. The exclusion of the elderly, it is argued, is driven by the (morally) questionable return-on-investment logic. In other words, this practice inscribes itself in a tradition which assigns worth to people on the basis of their societal contribution (understood in terms of employment), rather than their membership of the human species. Erich Loewy (2005a) is perhaps the most ardent exponent of this line of criticism. On his view, the return-on-investment rationale behind age-based rationing poses a grave threat to society in that it is partially reminiscent of Hitler's children's euthanasia and T-4 program. Others discredit the return-on-investment maxim by reference to a *reductio ad absurdum* argument. A consistent application of this maxim, they argue, would not merely single out the elderly as candidates for reduced health care. Rather, it would also affect all patients with chronic diseases, such as multiple sclerosis, muscular dystrophy, and cystic fibrosis (Kluge 2002). In fact, due to their longer life expectancy, such patients are likely to offer a lower return-on-investment than the elderly. The repugnance felt at the prospect of denying treatment to, for example, a young paraplegic, according to Rivlin (1995), suffices to illustrate the untenable nature of the return-on-investment logic in health care.

Besides questioning the merit of an economic index of social worth, critics have also challenged the soundness of the inference leading from this specific logic to age-based rationing. They have done so on two distinct grounds. Some argue that, rather than disadvantaging the elderly, a focus on economic productivity calls for prioritizing them over the young. With a lifetime of employment behind them, the elderly have already earned their credentials as productive members of society (Kilner 1988). According to others, the return-on-investment maxim dictates treating the elderly on a par with the young. This view is premised on the observation that the elderly still actively contribute to society, both directly and indirectly (Giordano 2005). Direct forms of productivity include, for example, the frequent participation of the elderly in voluntary sectors. Indirect contributions to the labor market refer to the fulfillment of 'babysitting' duties whereby the elderly enable younger adults to work outside the house.

1.3.3 Age-based rationing as a slippery slope

The next set of criticisms targets the tendency of age-based rationing policies to set in motion a slippery slope. We can distinguish three variants of this argument. To begin

with, some argue that the exclusion of the elderly sets the stage for the denial of life-extending treatment to other social groups. Robert Binstock formulates this concern as follows: “If elderly people can be denied access to health care categorically, then what group of us could not? Members of a particular race, religion, or ethnic group? [...] Any of us is vulnerable to social constructions that portray us as unworthy” (Binstock 1994, 39).

Other critics warn for ever increasing restrictions on the age groups, rather than the social groups, granted access to life-extending treatment. In other words, they fear that any initially chosen age cut-off will be susceptible to repeated downward pressure (Harris 2005; Rivlin 1995). In support of this assumption, these critics remind us that the exclusion of age groups beyond the selected cut-off age is premised on the high cost attached to their treatment. However, in barring these age groups from treatment, they argue, one creates a situation wherein those just below the age cut-off become the most expensive age group. At that point, the very *raison d'être* behind age-based rationing, i.e. cost containment, induces an incentive to also exclude the latter age group. This downward movement, it is expected, will only come to a halt once the age cut-off coincides with retirement age (Loewy 2005a). After all, the contribution of the working age population to society more than makes up for the medical costs incurred by this group.

The third variant of the slippery slope argument shares with the former the concern for the elasticity of the age cut-off. However, it considers this threshold to be susceptible to upward, rather than downward pressures (Rivlin 1995; Barry 1991). Suppose that the age cut-off is set at 75. Critics claim that it would be hard, if not impossible, to deny an elderly person who is one day past her 75th birthday a treatment which offers the prospect of an additional 10 years in relatively good health. In opening the door to ever further deviations from the official policy, such exceptions render age-based rationing subject to the whims of doctors. Once it has shed its image of a rigid, objective benchmark, critics argue, the concept of an age cut-off loses any of the appeal it may initially have had.

1.3.4 Age-based rationing as a last resort policy

Some critics argue that we need not resort to drastic measures, such as age-based rationing, in order to address the health care cost crisis. There exist, they claim, other effective cost-containing routes which, contrary to age-based rationing, are morally just. In the United States, the reigning in of the system's exorbitant administrative costs is frequently invoked as an alternative (Loewy 2005b). Other, more universally applicable, solutions have also been put forward. In this respect, Roger Hunt (1994) proposes a combination of three strategies. First, all futile treatments should be

withheld. Second, where it is not yet in place, we should consider instituting euthanasia on the basis of respect for the autonomy of terminally ill patients. Whereas Hunt stresses that voluntary euthanasia should never be driven by economic motives, he nevertheless grants that it would yield savings. Third, Hunt claims, treatment is frequently imposed upon a patient on the basis of the contrary-to-fact assumption that one is acting in accordance with the patient's wishes. He cites the example of a patient with advanced cancer who is prescribed expensive, aggressive treatment, when she, if offered an informed choice, would opt for a palliative approach. Hunt claims that "a more educated and empowered patient population, an improved awareness of the palliative mode of care, a co-ordinated multidisciplinary approach, and improved medical communication skills will lead to treatment that better meets the needs and interests of patients, and at less cost" (Hunt 1994, 54). While Hunt's recommendations are rather abstract, David Thomasma (1991) provides a concrete measure for keeping in check doctors' tendency for overzealous use of invasive, expensive treatments. He proposes a system whereby retirees are compelled to execute an advance directive concerning certain optional treatments. Thomasma conceives of such a program as follows:

The ideal of autonomy can be underlined in such a program by permitting a wide range of choices about the optional treatments. However, because society must be protected from increasing health care costs, individuals would not be able to exercise complete freedom over the choices to be made. A good compromise would be to require that persons make decisions about their care in the future, but that society would not mandate that specific decisions be made. Limits could be placed on certain technological interventions for certain categories of diseases, but individuals could choose which of the available technologies should be used in the event he or she succumbs to specific illnesses. (Thomasma 1991, 157-158)

1.3.5 Age-based rationing as a myopic view on the cure-care distinction

The cure-care distinction, which lies at the hearth of age-based rationing proposals, is also an object of criticism. In proposing a departure from life-extending treatment in favor of interventions aimed at improving quality of life of the elderly, proponents of age-based rationing conceive of the cure-care distinction as clear-cut. However, critics argue, clarity with regard to this matter is relatively rare. It is generally confined to cases involving a patient who is suffering from a clearly terminal illness and whose life expectancy is measured in days or weeks (Cassel & Neugarten 1991). Such cases allow us to select interventions which unambiguously belong to the 'care category'. However,

when multiple chronic diseases are at play – as is the case in the majority of elderly patients - the boundaries of care and cure become much more fuzzy. Especially in very old people, interventions that improve the quality of life may inevitably prolong life. In this respect, Cassel and Neugarten (1991) cite the hypothetical case of a 99-year-old woman who is experiencing attacks of fainting caused by cardiac arrhythmia. With a view to preventing further fainting episodes and the corresponding risk of falls and fractures, she is prescribed a pacemaker. Despite the prescription being aimed merely at ‘care’, it will nevertheless have a life-extending effect due to the beneficial impact of the pacemaker on the patient’s heart rhythm. Cassel and Neugarten identify a large range of similar cases: “The observation that treatments that improve life and those that extend life are often indistinguishable applies to almost any palliative measure, ranging from the administration of insulin to persons with diabetes and the administration of oxygen to persons who suffer from shortness of breath, to modern, technology-intensive treatments for health failure or symptomatic malignancies” (Cassel & Neugarten 1991, 86).

1.3.6 Age-based rationing as a blunt instrument

A final line of criticism states that the practice of age-based rationing fails to capture the heterogeneity among the elderly. Age-based rationing, it is argued, is driven by the assumption that, above a certain age, people stand to benefit little from certain medical procedures. This assumption holds true for the elderly taken as a group. In other words, the outcome of such procedures is, *on average*, worse in the elderly because the prevalence of impairments that adversely shift the risk/benefit ratio increases with age (Evans 1997). However, critics stress, we can infer from this statement of probability absolutely nothing about the individual patient in front of us (Evans 1997; Loewy 2005b). Other than requiring intensive care or surgery, the patient may very well be in good health. In such a case, the outcome of treatment will differ little from the outcome in younger patients (Giordano 2005). Given that health status, rather than chronological age, predicts outcome, these critics argue for favoring a case-by-case approach over the outright exclusion of the elderly from medical treatment.

1.4 Age-based rationing: a promising route to cost containment in health care?

How do age-based rationing proposals fare in terms of their ethical credentials? Do they represent ethically acceptable solutions to the health care cost crisis? Above, we have outlined the main concerns put forward by critics of age-based rationing. Although it may, from a *theoretical* point of view, be interesting to assess the validity of these criticisms, *practical* considerations do not necessarily call for such an evaluation. In practice, questions related to the soundness of these concerns are rendered obsolete if it is established that age-based rationing proposals defeat their own object, i.e. the achievement of *substantial* cost savings. In other words, age-based rationing, as a proposed solution to the health care cost crisis, is automatically rendered morally unacceptable if it turns out to be an ineffective cost containment tool. Therefore, we believe that in any ethical analysis of age-based rationing proposals inquiries into their efficacy ought to precede all other questions. Despite its primary moral importance, the issue of efficacy is seldom addressed in the literature. We have already briefly touched upon this issue in relation to the discussion of Jecker's proposal. The capabilities approach to age-based rationing, we concluded, runs the risk of exacerbating the health care cost crisis. Of course, the specifics of Jecker's account do not allow for extrapolation of this finding to other age-based rationing proposals. Below, we examine the cost saving potential of age-based rationing in a way which makes abstraction of any specific account. In other words, we analyze the general claim that, in introducing an age cut-off beyond which life-extending cure is denied in favor of care, one obtains savings of a sufficient magnitude to solve the health care cost crisis. Specifically, we assess the two main presuppositions underlying this assertion.

The elderly commonly receive heroic care at the end of life

The first presupposition underlying age-based rationing proposals relates to the so-called 'high cost of dying'. Research has repeatedly shown that the age-related increase in health care expenditures is largely attributable to the high costs incurred during the last year of life and the high mortality in old age. A study by Lubitz and Riley (1993) is frequently invoked as a means of illustrating the magnitude of the expenses associated with the last year of life. This study provides data on the medical costs in the last year of life of Medicare enrollees who died in 1988 ('decedents'). These costs were almost seven times higher than those incurred by 'survivors' during that year (\$13,316 versus \$1,924 per person-year). Although these decedents made up a mere 5.1% of Medicare enrollees, they accounted for 27.2% of total Medicare payments in that year. Unfortunately, we have not found any up-to-date information on Medicare payments per person-year for

decedents in their last year of life. However, updated data suggest that the *share* of total annual Medicare expenditures devoted to persons in their last year of life has remained relatively constant (25.1% in 2006) (Riley & Lubitz 2010). A comparable situation appears to obtain in the Netherlands, where expenditures on people in their last year of life account for 26.1% of total annual medical costs for the retired population (Polder et al. 2006).

The high costs associated with the last year of life are sometimes deemed ‘wasteful’. On this view, these costs are interpreted as resulting from the application of aggressive treatment to patients who are *clearly* terminal. From this perspective, the solution is simple: we should refrain from resorting to such treatment in futile cases, i.e. patients headed towards their last year or last months of life (see, for example, Fries et al. 1993). Unfortunately, things are much more complicated. Although aggressive interventions in the last year of life clearly qualify as futile from a *retrospective* perspective, they are unlikely to be viewed as such at the moment they are administered. The current state of the art in medicine makes it close to impossible – with the exception of cancer patients – to predict death twelve or six or even three months in advance (Scitovsky 2005). Given the difficulty of prospectively identifying those in their last year of life, the only reasonable means of addressing the high costs incurred during this period consists in introducing an age cut-off beyond which life-extending treatment is denied. This is precisely the rationale behind age-based rationing proposals (Scitovsky 2005).

The specific presupposition underlying the claim that age-based rationing has significant cost saving potential exhibits the following structure:

1. The largest share of health care costs for the elderly is incurred during the last year of life.
2. A considerable part of the health care costs incurred during the last year of life is attributable to the provision of life-extending care.
3. In denying people life-extending care beyond the normal lifespan, we can significantly attenuate the costs associated with the last year of life.¹⁶

The intuition underlying the second premise – the belief that it is common for older persons to receive heroic care at the end of life – is widespread. It stems from the abovementioned finding that a large portion of annual Medicare expenditures (around

¹⁶ While this line of reasoning is implicitly present in various age-based rationing proposals, Jecker (2013) appeals to it explicitly.

30%) is devoted to the small percentage of enrollees who die (approximately 6%). However, these data are misleading in that they represent the *total* costs incurred during the last year of life, rather than merely those associated with life-extending care. Only about 3% of Medicare beneficiaries who die receive aggressive life-extending care. Spending on the latter type of intervention accounts for only a very small portion of the Medicare expenditures related to the last year of life (Pan et al. 2007). Thus, in setting limits on life-extending care, we are unlikely to achieve cost savings of the magnitude envisaged by proponents of age-based rationing.

Population aging is an important driver of rising health care costs

As noted in the general introduction, age-based rationing proposals operate under the assumption that the aging of the population represents an important, if not the most important, contributor to rising cost pressures in the health care sector. In severely limiting access to health care for the elderly, it is claimed, such proposals address this key driver of increasing expenditures and thereby guarantee substantial cost savings. However, this second presupposition is no less problematic than the first. Past spending trends suggest that population aging, by itself, has been only a minor driver of the annual growth in health care expenditures. For example, analysis of health care expenditure in British Columbia between 1975 and 2005 indicates that population aging increased health spending by only 0.7% per year (Lee 2006). British Columbia is an interesting object of study given that it has a higher than average proportion of elderly relative to other provinces. In Australia, population aging has been responsible for only 10% of increases in federal government health care costs over the last decade (Coory 2004). Moreover, spending patterns between 1995 and 2009 across OECD countries show that population aging accounted for a mere 0.5% of the annual increase in health care expenditures (4.3%) (de la Maisonneuve & Oliveira Martins 2013).

Analysis of past spending patterns is only meaningful to a certain extent. After all, population aging has yet to reach its peak, which is expected to occur around 2031 (Lee 2006). However, projections suggest that population aging will remain a minor driver of increases in health spending during this period. Richardson and Robertson (1999) present projections for Australia for 1995-2051. Regarding the effect of population aging on health expenditure, they conclude: “if ageing were the only source of expenditure growth the relative size of the health sector would significantly decline as GDP would be expected to rise more rapidly than health expenditures” (Richardson & Robertson 1999, 14). Data for the European Union and the US also point towards a small effect of population aging on future increases in health spending (Przywara 2010; Fogel 2009).

Medical technology is the prime determinant of the increase in health care costs (Dormont et al. 2006; Przywara 2010). Given the rather abstract nature of the term

‘medical technology’, it is useful to consider more closely what it is generally understood to encompass. The various available definitions tend to converge on a broad construal of the term, as illustrated by the following two definitions:

Technological innovation in medicine includes new physical capital and equipment, new surgical procedures, drugs and treatments, as well as new procedures based on original combinations of the above. (Pammolli et al. 2012, 627)

We define new medical technology as new products, procedures or practice styles related to new knowledge about disease or diagnostic or treatment technologies that alter the mix of medical goods and services that are used. (Chernew & Newhouse 2012, 7)

Depending on the country studied, medical technology accounts for 27% to 75% of the annual growth in health spending (European Commission and the Economic Policy Committee 2012). Between 2007 and 2060, technology *alone* is projected to yield a 6% increase in the share of GDP devoted to health care (from 6.7% to 13%) within the European Union. This effect is more than the threefold of that of population aging. In Belgium, the effect of medical technology, relative to population aging, is even greater (a 4:1 ratio) (Przywara 2010).

New medical technologies impact upon spending growth in ways that extend beyond their unit cost and uptake rate. The aggregate effect of a new technology on health care costs is also determined by the way it influences the use of existing services. A new technology can either increase or decrease the dependence on already available services and products. The former effect is known as ‘complementarity’, whereas the latter is referred to as ‘substitution’ (Chernew 2010).

There are various mechanisms through which an innovation can create complementarity (Chernew & Newhouse 2012). For example, it can do so by extending *life expectancy* as patients are likely to consume additional health care services in these extra years of life. While such incremental services are undoubtedly beneficial, they have a general tendency to significantly increase health care expenditures. An example of this mechanism is the potential link between innovations in treating coronary artery disease and the increased incidence of end-stage renal disease. Heart disease patients have an elevated risk of developing renal disease. Thus, whereas such patients are likely to have died prior to the introduction of this innovation, they may now live long enough to develop end-stage renal disease and become dependent upon dialysis.

A second type of complementarity occurs when *health outcomes* (risk-benefit ratios) for a certain patient population improve as a result of the fine-tuning of a surgical procedure.

As a result, patients who otherwise may not have been treated are drawn into this procedure (Chernew 2010). This type of complementarity explains the observation made by Fuchs (1999) that, from 1987 onwards, the rate at which various treatments (angioplasty, hip replacement and knee replacement) were provided to the oldest old rapidly increased. Another example of this type of complementarity relates to surgical advances in the procedure of cholecystectomy (surgical removal of the gallbladder) in the 1990s. These resulted in a 60% increase in the use of the procedure. The innovation mainly drew into treatment asymptomatic or mildly symptomatic patients, for whom the risk-benefit ratio was previously unfavorable. The subsequent increase in health care expenditures was not only related to the rise in the number of procedures performed, but also to growing numbers of office visits and diagnostic testing. Complementarity of this type can increase the cost of a new technology by as much as 50% (Chernew & Newhouse 2012).

Substitution generally occurs when an innovation replaces an established service. For example, “coronary angioplasty may substitute for more invasive coronary artery graft bypass surgery” (Chernew & Newhouse 2012, 9). In a similar vein, laparoscopic techniques can supplant traditional open procedures. Whether or not substitution will lead to cost increases, depends on the relative unit costs of the two services (supplanted versus supplanting) and the magnitude of any quantity changes. The latter refers to the process whereby, for example, a new pharmaceutical, in supplanting an old one, decreases (or increases) the frequency of the recommended daily intake.

In *aiming* to address population aging, rather than medical technology, age-based rationing proposals fail to tackle the root cause of the health care cost crisis. Consequently, they do not represent a promising solution to the problem. Admittedly, in denying life-extending treatment to the elderly, such proposals inadvertently address the issue of medical technology. However, they do so only *partially*. After all, although the use of medical technology is likely to be highly concentrated in life-extending treatment, it is not limited to the latter. Moreover, and most importantly, medical technology is not limited to, nor largely concentrated within, the elderly population. In fact, its use is approximately evenly distributed between the young (<65) and the old (>65) (see, for example, Polder et al. 2002). Thus, any savings obtained through limiting the use of technology in the elderly will quickly be undone if its use remains uncontrolled in the younger population. An example will help to illustrate the temporary nature of the cost savings achieved under age-based rationing. Suppose that we implement Callahan’s proposal of denying life-extending treatment to the elderly.

Life-extending treatment for those over 65 years of age accounts for 25% of total annual health care expenditures (Polder et al. 2002).¹⁷ In 2010, health care accounted for 7.1% of GDP (Przywara 2010). Thus, if Callahan's proposal had been implemented in 2010, the share of GDP devoted to health care would, in that year, instead have amounted to approximately 5.3% (i.e. a reduction of 1.8%). Between 2010 and 2030, the use of technology in those *under 65 years of age* is projected to increase the share of GDP devoted to health care by 1.5% (Przywara 2010). Thus, it would only take a little over 20 years before the cost savings induced by Callahan's proposal are nullified by uncontrolled technological growth in the younger population. From that point onwards, we would once again face rising health care expenditures. Note that this example still overestimates the (temporary) cost saving potential of Callahan's proposal, for two reasons. First, we have assumed a denial of life-extending treatment to those over 65 years of age, whereas Callahan's proposed cut-off age lies around 80. Second, our example assumes that, in being denied life-extending treatment, the elderly are also deprived of any other form of medical care. However, on Callahan's account, the denial of life-extending treatment is accompanied by the provision of care. Moreover, in certain cases, treating a condition works out cheaper than offering care (Clarke 2001).

1.5 Conclusion

Despite having its roots in the 1980s, the idea of age-based rationing is still very much alive. The fact that it continues to enjoy a relatively large constituency is disconcerting, irrespective of whether or not age-based rationing amounts to age discrimination. It is highly unethical to exclude the elderly – or any other group for that matter (irrespective of whether the group is defined in terms of age or another criterion) – from beneficial forms of treatment when this practice defeats its own object, i.e. it fails to provide a solution to the health care cost crisis. Age-based rationing rests on the misguided assumption that population aging represents a major driver of rising health care expenditures. Although it addresses medical technology (the true driver of rising health care costs), it does so only partially and inadvertently. Consequently, age-based rationing provides, at best, a temporary relief from rising health care costs. As we will

¹⁷ The facts we base our example upon hold for the Netherlands. However, projections suggest that the Dutch figures are representative for other EU- countries (Przywara 2010).

see in the next chapter, other proposed solutions to the health care cost crisis also fail to recognize the important role of medical technology.

1.6 References

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Chapter 2

Biogerontology: a promising route to cost containment in health care?

Based on published book chapter and published article:

Capitaine, L. and Pennings, G. (2013) “Biogerontology: a promising route to cost containment in health care?”. In: Schermer, M. and Pinxten, W. (eds.) *Ethics, health policy and (anti-)aging: Mixed blessings*. Dordrecht: Springer Verlag: 251-266.

Capitaine, L. and Pennings, G. (2011) “Biogerontologie: wetenschappelijke ontwikkelingen en ethische implicaties”. *Tijdschrift voor Geneeskunde* 67: 174-180.

2.1 Introduction

Population aging is now a global phenomenon. This shift in society's age structure has been a gradual process in developed countries, spanning over more than a century. In more developing regions, however, population aging has only recently begun and is proceeding at a much faster pace than it did in developed countries (Kinsella & Phillips 2005).

The current demographic situation is the result of both improvements in life expectancy and declining fertility rates. The baby boomers will soon accelerate the process of population aging as they enter old age en masse.

Graying populations are a human success story in that they represent the culmination of social and technological progress. Nevertheless, population aging is generally viewed as a burden, rather than a blessing. 'The coming entitlement tsunami' and the 'demographic earthquake' are just a few of the expressions that are frequently used to characterize this phenomenon (Beard & Williamson 2010). One of the concerns is that an aging population will cause health care costs to spiral out of control. For example, according to projections made by the trustees of Medicare the program will go bankrupt in 2018 (Callahan & Prager 2008). Such dire predictions have initiated a widespread search for effective 'remedies'.

In the previous chapter, we examined one of the proposed measures for constraining the feared escalation of costs related to population aging. Another type of cost containment proposal consists in reforming Medicare in the US. The first cries for reform can be traced back to the early years after Medicare's enactment in 1965, and ultimately resulted in a partial privatization of the program. Since the 1990s, attempts to further privatize Medicare have been ongoing (Geyman 2004). These reform proposals distinguish themselves from the earlier ones in that they are framed as a much needed answer to the challenges of population aging. The underlying idea is that competition between private insurers will reduce health care costs (Wiener & Tilly 2002). Congressman Paul Ryan has recently proposed that Medicare move toward a system wherein the government gives seniors a fixed payment to purchase a private plan of their choice (Cannon 2011). Critics fear that such a system will burden seniors with high out-of-pocket expenditures, rendering many of them unable to receive the needed care. In addition, critics point to existing data which suggest that, in the area of cost containment, private plans perform worse than traditional Medicare (Geyman 2004).

Proposals pertaining to age-based rationing and Medicare reform have been around for quite some time. A more recent cost containment proposal (see, for example, Micans 2005; Dorshkind et al. 2009; Olshansky et al. 2006) is to invest more in biogerontology -

research into the biology of aging. The idea is that such research will enable us to tackle age-related diseases simultaneously, thereby ensuring that the elderly enjoy an increased healthspan (i.e. that they enjoy an increase in the number of years spent in a disease-free state). This, in turn, it is believed, will reduce the pressure on the health care system. To date, this argument has received no attention, which is surprising given the highly recognized need for cost containment in health care. The aim of this chapter is to evaluate this argument, which we will refer to as ‘the cost containment argument’, by critically examining its most fundamental presuppositions. Before we embark upon this task, however, we provide a more detailed account of what the biogerontological approach involves and what it hopes to achieve.

2.2 The biogerontological approach

Research aimed at tackling age-related diseases is primarily focused on developing methods for treating or preventing these pathologies individually. This approach, however, has only very limited potential for prolonging the healthspan of the elderly. The incidence of most age-related diseases increases exponentially during the last stage of life so that comorbidity is an inescapable fact for many elderly (Butler et al. 2008). Consequently, even if we succeeded in eradicating any one of the major age-related diseases, its place would immediately be taken by yet another.

It is only by tackling age-related diseases simultaneously that one is guaranteed a substantial impact on the overall length of healthy life. This approach amounts to intervening in the aging process as aging is the common, underlying cause of all age-related diseases. Depending on the extent to which the healthspan is prolonged, significant increases in either average life expectancy or maximum lifespan are expected (Vincent et al. 2008). The endeavor of intervening in aging is, therefore, commonly referred to as ‘lifespan extension’¹⁸. Given the combined benefit of increased healthspan and lifespan, many biogerontologists deplore that less than 0.1% of the National Institutes of Health (NIH) budget goes to anti-aging research (Olshansky et al. 2006).

Biogerontology was long viewed as a fringe science (Fishman et al. 2008). However, recent developments within the field have caused it to gain scientific legitimacy.

¹⁸ We use the terms ‘lifespan extension’ and ‘anti-aging’ interchangeably throughout this chapter.

A large part of the research efforts has been devoted to caloric restriction – an experimental setting wherein caloric intake is reduced to about 40% below ad libitum levels. Contrary to malnutrition, the intake of important nutrients, such as vitamins and minerals, is still guaranteed. Studies on laboratory animals demonstrate that caloric restriction results in a substantial increase in both average life expectancy and maximum lifespan (Hackler 2004). Moreover, age-related diseases are postponed and their incidence is reduced (Ingram et al. 2004).

Most humans would probably have difficulty adhering to such a drastic dietary regimen. This recognition has initiated the search for substances that are able to mimic the effects of caloric restriction in the absence of a reduced caloric intake. Resveratrol, a chemical found in the skin of black grapes, potentially offers promising prospects in this respect (Baur 2010). According to various studies, resveratrol activates sirtuins, enzymes that possibly form the basis of the beneficial effects of caloric restriction (Canto & Auwerx 2009). Resveratrol appears to markedly prolong the lifespan of yeast, fruit flies and roundworms (Baur 2010). In obese mice, the administration of resveratrol produces a positive effect on health and survival. Although non-obese mice exhibit a noticeable improvement with regard to certain age-related forms of deterioration, resveratrol does not appear to produce a life-prolonging effect in this population (Pearson et al. 2008).

Researchers are also investigating the role of gene mutations in longevity. The importance of gene mutations became apparent upon the release of data concerning the lifespan of the so-called Ames dwarf mice (Miller 2002). This phenotype is a result of a mutation in the PROP-1 gene (Liang et al. 2003). Ames dwarf mice lack growth hormone, prolactin, and thyroid stimulating hormone (Dollé et al. 2001). Research indicates that the *average life expectancy* of male Ames dwarf mice is 49% longer than that of normal control mice (Liang et al. 2003). Females exhibit a 68% increase in average life expectancy. In addition, the *maximum lifespan* of both male and female mutants is, respectively, 20% and 50% longer, compared to the control group. Moreover, at an advanced age, Ames dwarf mice still score well with regard to locomotor activity and cognitive functioning (Kinney et al. 2001). Finally, they exhibit a much lower prevalence of adenocarcinoma of the lung, relative to the normal control group (Ikeno et al. 2003). To our knowledge, only one study has, so far, examined the life-extending potential of a similar mutation of the PROP-1 gene in humans. The study population of this research consisted of individuals who, due to a mutation in this gene, have a specific form of dwarfism (Laron 2005). Although the observations recorded in this isolated study do not allow us to draw definite conclusions, they nevertheless suggest that there could possibly be a connection between this specific variant of human growth hormone deficiency and a prolonged lifespan.

There is much disagreement concerning the expected outcomes of biogerontological research. The different opinions on this matter can be translated into four 'life extension scenarios': prolonged senescence, compression of morbidity, decelerated aging, and arrested aging.

Prolonged senescence amounts to the failure of the anti-aging research enterprise: life itself is prolonged, while the healthspan is not. For instance, decrepitude would start to set in at the age of 55 and one would die at the age of about 95 (Derkx 2009).

The prospect of a prolonged senescence is sometimes invoked as an argument against anti-aging research. However, this argument is not compelling. As previously noted, most age-related diseases show an exponential increase from a certain age onward. Each age-related disease increases our risk of death. It is, thus, unlikely that we could live to experience a period of decrepitude of the length envisaged by the prolonged senescence scenario (de Grey 2005).

Those who anticipate a compression of morbidity believe that interventions in the aging process would have but a marginal effect on the length of our lives. Individuals would live long, healthy lives and then die rather quickly after experiencing a negligible period of decrepitude (Juengst et al. 2003).

The fact that the absence of age-related diseases is extremely beneficial in terms of mortality risk explains the implausibility of the compressed morbidity scenario. The considerably extended healthspan, envisaged under this scenario, amounts to a substantial postponement of the onset of age-related diseases. It is, therefore, highly unlikely that no similarly meaningful extension of life would occur (Gems 2009; de Grey 2006).

Proponents of decelerated aging argue that we can postpone age-related diseases to such an extent that both average life expectancy and maximum lifespan are increased. Under this scenario, 90-year-olds would, for example, enjoy the health and vigor of today's 50-year-olds (Juengst et al. 2003). Miller (2002) envisages an average life expectancy of around 112 and a maximum lifespan of around 140.

We see no reason to question 'decelerated aging' as an outcome of anti-aging research. Most biogerontologists seem to share this view (Gems 2009).

Arrested aging undoubtedly constitutes the most radical scenario. It is tantamount to achieving total mastery of the aging process in that its harmful effects would be entirely prevented. This approach involves the continuous repair of the molecular and cellular damage responsible for the onset of age-related frailty (de Grey et al. 2002). The aim is to repair the damage before it reaches a level at which it induces age-related pathologies. Whether or not the scenario of 'arrested aging' is plausible, depends upon the feasibility of the SENS-project (Strategies for Engineered Negligible Senescence), the

single proposed project for achieving this feat. Aubrey de Grey, the man behind SENS, has identified several forms of damage responsible for age-related pathologies and degeneration. For each type of damage, he has formulated a strategy targeted towards its repair (de Grey et al. 2002). Suggested therapies for repairing the damage range from genetic interventions to stem cell therapies. Although de Grey (2003) acknowledges that these fixes will initially be imperfect, he expects the added years to be sufficient for us to develop improved fixes. The latter, in turn, would provide us with still more life years, enabling the production of still better repair methods, and so on. As long as we keep developing new, improved therapies fast enough, we should be able to postpone age-related diseases *indefinitely*. As these pathologies would no longer occur, a state of ‘virtual immortality’ would be attained in the sense that death would only result from accidents, suicide, wars, and so forth (Binstock 2004).

The SENS-proposal lacks persuasiveness for several reasons. First, each of the therapies proposed by de Grey is unlikely to be realized any time soon. This renders the prospect of all of the proposed strategies being implemented very remote (Warner et al. 2005). Second, even if we were able to accomplish this feat, there is no guarantee that we would hereby have arrested the aging process. There appear to be other types of damage, besides those identified by de Grey, contributing to age-related decline (Estep III et al. 2006). Moreover, still other important forms of age-related damage could well be discovered in the future. In sum, we would probably end up having to repair an insurmountable amount of damage in order to arrest the aging process.

2.3 Presuppositions underlying the cost containment argument

The authors who advance the cost containment argument (i.e. the claim that the biogerontological approach represents a viable route to cost containment in health care) rely on a number of presuppositions. We will scrutinize the four main assumptions.

2.3.1 Life extension will decrease the frailspan

Proponents of the cost containment argument support their reasoning by reference to the ability of anti-aging interventions to prolong healthspan. However, what is required for financial gains to be conceivable are not so much increases in healthspan as absolute reductions in frailspan (i.e. the period of age-related frailty). Thus, although most of

them do not explicitly state this, all proponents of the cost containment argument must presuppose that any increase in healthspan will be accompanied by a decreased frailspan.

Most proponents of the cost containment argument seem to think that various life-extending scenarios are plausible. Holliday, for example, advocates “measures to prevent or delay the onset of these [age-associated] diseases” (Holliday 1996, 90). Along the same lines, Micans speaks of the possibility to “slow or prevent the signs of aging from occurring” (Micans 2005, 550). None of them rule out the possibility of decelerated aging. The latter is, as we have argued, the most plausible scenario. Thus, we need to analyze its implications for the frailspan in order to assess the above presupposition.

It is often thought that decelerated aging will be accompanied by a curtailed frailspan. This prediction is based on the observed reduction in frailspan in rodents whose aging process has been slowed down through caloric restriction. Extrapolations of this kind are, however, unwarranted (Gems 2011).¹⁹ Moreover, even if extrapolations from rodents to humans were somehow justified, there would be little point in employing studies on caloric restriction as a reference point. For reasons previously cited, most humans are unlikely to engage in this dietary regimen as a method for decelerating aging.

We are currently unable to decelerate the human aging process. Rather than enticing us into making uneducated guesses, this fact should encourage us to refrain from any judgment concerning the effect of decelerated aging on the human frailspan. Thus, contrary to what proponents of the cost containment argument presuppose, we cannot exclude the possibility of the frailspan retaining its current length or even increasing in length.

One might argue that a curtailed frailspan is not required in order for health care savings to occur. Harris (2004), for instance, attempts to show that life extension, even when accompanied by an increased frailspan or a frailspan of the current length, still makes good economic sense. His argument relies on economic discounting, a technique used to determine the present value of a financial cost that will be incurred at some point in the future. By enabling us to translate future costs into their present value, economic discounting provides us with a sound way for comparing costs incurred at different moments in time. Economic discounting is not to be confused with an adjustment for inflation. Future costs need to be discounted in order to account for the time value of money.

Harris reasons that we gain financially from life extension because the latter amounts to postponing the moment in time when we start incurring frailty-related health care

¹⁹ Evidently, the same holds true for extrapolations from findings in Ames dwarf mice to humans.

costs. He uses the example of a newborn. Under present circumstances, this newborn will reach the period of frailty and its associated costs at around 70. In Harris' example, the newborn will reach this period only after 1000 years²⁰ in the case of life extension. According to Harris, the present-day discounted cost of treating that person in 70 years will be substantially higher than the present-day cost of treating that same person in 1000 years. There is, however, no reason why this should necessarily be the case. Harris does not seem to take into account that, over time, health care costs can increase considerably in real terms. Thus, health care costs could, between year 70 and year 1000, increase to such an extent in real terms that the discounted cost of treating that person in 1000 years is higher than that of treating the same person in 70 years. In sum, there is no guarantee that an increased frailspan or even a frailspan of the current length would be financially beneficial. Proponents of the cost containment argument must, therefore, presuppose the occurrence of a reduction in frailspan.

2.3.2 Life extension will enjoy a considerable uptake rate

Let us accept for the sake of argument that the deceleration of the aging process will be accompanied by a decrease in frailspan. The reduction in health care costs, envisaged by proponents of the cost containment argument, is substantial. The prospect of considerable savings presupposes a sizeable amount of people using life-extending, anti-aging technologies. However, this is, as we argue below, a problematic presupposition.

The little available research concerning community attitudes towards life-extending technologies points towards a rather low uptake rate. In a recent study (Partridge et al. 2011), for instance, only 35% of the respondents answered affirmatively when asked whether they would use a life-extending technology. Another study (Underwood et al. 2009) found just over half of the participants willing to consider lifespan extension. Despite appearances to the contrary, these outcomes need not be more reassuring than the ones from the former study. After all, whether or not these respondents would actually opt for lifespan extension, as opposed to merely considering it, depended on a number of conditions being fulfilled. Some participants stated that they would only use life-extending technologies if their loved ones were to do so. Others referred to the absence of any negative impact on society as a prerequisite. Thus, if life extension technologies become available, far fewer than 50% of these respondents would actually end up using them.

²⁰ Although we have previously argued that a lifespan of 1000 years is highly unrealistic, we have chosen to stick to Harris' example in order to offer an accurate representation of his argument.

Interesting results have also emerged from a study conducted by Lang et al. (2007). Participants were randomly assigned to one of 3 conditions. Whereas those in the first condition were informed that research on aging offered hopeful prospects with respect to physical, mental, and psychological fitness in old age, participants in the second condition were told the opposite. The control group received no information concerning research on aging. Participants in each group were asked which age they would like to reach. Surprisingly, the answers did not vary significantly across the 3 conditions. In each of the 3 conditions, the average desired lifetime was approximately 86 years – well below the current maximum lifespan. Less than 10% of the respondents wanted to live to 120 or beyond.

There is another reason why it is problematic to presuppose a substantial uptake rate of life-extending technologies. These technologies will, like any other new medical technology, be very expensive. Thus, very few people will have access to them. In fact, relative to many other types of new technology, the cost of lifespan extension can be expected to be of an even higher order as it will most probably involve higher research and development costs. Firstly, human aging is a highly complex biological process, which suggests that any intervention designed to tackle it would need to be equally complex. Secondly, many aging mechanisms seem to act over the entire lifespan. The effectiveness of anti-aging interventions would, therefore, probably be inversely related to the age at which they are begun (Hadley et al. 2005). The early administration age, combined with the (current) lack of valid biomarkers of aging, suggests that clinical trials would probably span the entire lifetime of the enrolled subjects (Spratt 2010).

Proponents of the cost containment argument might respond that the cost of life-extending technology will diminish after a while. Although this is likely to happen, this fact does not necessarily do much to further their cause. Given the complexity of aging, one will most likely have to undergo numerous, different types of interventions in order to achieve the desired effect. For example, a combination of stem cell treatments, pharmaceuticals and genetic consultations could be required (Ehni & Marckmann 2009). Thus, even if each of the needed interventions became cheaper over time, the ‘whole package’ would probably still not be affordable for a significant part of the population.

Another response might be that public coverage of the needed interventions will be provided in order to guarantee wide access to life extension. Mackey (2003), for instance, puts forward this argument. This line of reasoning is problematic. Various considerations are involved in deciding whether or not a drug or intervention qualifies for public coverage. The financial cost of the drug/intervention is obviously an important consideration. As noted above, life extension involves the application of various, very expensive interventions. Thus, public coverage might not be feasible in

budgetary terms. However, even if budgetary feasibility were not an issue, there would, from a purely financial perspective, probably be little incentive to provide public coverage. After all, as we will argue further on, life extension is likely to be more expensive than the current approach of treating or preventing age-related diseases individually.

Another important consideration is the extent to which the drug/intervention is medically necessary. In the case of life extension, the question of medical necessity tends to be framed in terms of whether or not aging is a disease (Caplan 2005). The latter issue is currently highly debated (Butler et al. 2004). The controversy surrounding this issue makes it difficult to predict the final outcome of the debate.

The level of public support for coverage of a drug/intervention is also taken into account in coverage decisions. The widespread reservations about using life extension among the public will need to subside for it to score well on this criterion. Once again, it is difficult to predict the chances of this happening.

We have discussed only a few of the important criteria involved in coverage decisions. Nevertheless, our discussion suffices to show that it is premature to posit public coverage of life-extending interventions as a solution to the problem of access.

2.3.3 Population aging is an important driver of rising health care costs

Even if we accept, for the sake of the argument, the correctness of the two previous presuppositions, then the cost containment argument still lacks persuasiveness. After all, it encompasses a questionable presupposition concerning the problem in response to which anti-aging interventions are put forward. The argument has as its starting point the claim that population aging will cause health care expenditures to rise to an unsustainable level. Thus, it presupposes that the aging of the population is an important, if not the most important, contributor to rising cost pressures in the health care sector.

As we have discussed extensively in the previous chapter, population aging represents but a minor driver of rising health care costs. In exaggerating the role of population aging in (future) health care cost increases, proponents of the cost containment argument overestimate the cost saving potential of life-extending interventions. The problems facing the cost containment argument, however, potentially go much deeper. In the following, we argue that life-extending interventions not only save less than proponents of this argument claim, but could actually increase health care expenditures.

Recall that medical technology is the prime determinant of the increase in health care costs. New technologies and the intensified use of old ones are responsible for about 50% of the annual growth in health spending (Callahan 2009). Thus, it seems that life extension, by relying on technology, would be part of the problem, rather than the solution, when it comes to keeping health care costs in check. Proponents of the cost containment argument might respond that life extension distinguishes itself from the average new technology in that it would save more resources than it costs. In other words, they might claim that the savings achieved through the reduction of the frailspan would outweigh the costs of the technology needed to bring about this reduction. However, the expected characteristics of life extension render this claim dubious. Life extension will, most probably involve various types of new technologies being periodically applied from an early age until the final stages of one's significantly extended lifespan.

There is yet another way in which life extension would contribute to an intensified use of medical technology. This second route relates to the 'complementarity' effect of new medical technologies which we discussed in chapter 1. As noted above, we are here assuming that life extension will both increase the healthspan and reduce the frailspan. Obviously, a person incurs many different types of medical costs other than those related to old age. Thus, an increase in healthspan amounts to an increase in the number of years during which such other medical costs are incurred. A part of these 'extra' medical costs will inevitably be related to the use of medical technology. In sum, life extension is likely to increase health care costs as both the increase in healthspan and the reduction in frailspan imply an intensified use of medical technology.

2.3.4 Any negative effects of life extension are outweighed by the achieved health care savings (and other perceived benefits)

Given the problematic nature of the above presuppositions, we currently have no reason to believe that anti-aging interventions constitute an effective means of containing health care costs. However, let us suppose for a moment that such interventions do have a (substantial) cost containing potential. If this potential is to be a compelling reason to increase funding for aging research, one must presuppose that these health care savings outweigh any negative effects of anti-aging interventions.

It is obviously extremely difficult to predict how anti-aging will affect our lives. However, as we are here assuming a considerable uptake rate of life-extending interventions, we can reasonably expect a substantial population increase to occur. Projections of the US Census Bureau illustrate how profound the effects of increased longevity can be:

Each 10-year prolongation of life expectancy will increase the eventual population of Earth at stability by 1.3 billion persons [...]. If world longevity follows the patterns that will be achieved first in the more developed countries and reaches 115 years, 5 decades longer than the current worldwide longevity, that would mean a further increase of 6.5 billion persons. Instead of the current estimated final population at stability of about 10 billion persons, there would be almost three people for every one now living worldwide. (Louria 2005, 317)

Marked population increases would have several detrimental effects. Biodiversity loss, deforestation, global warming, and depletion of resources (energy resources, food, water, and open space) are just a few of the expected problems.

The severity of each of the above problems is undeniable. It is, therefore, not obvious that the positive effect of cost containment outweighs these negative effects. Proponents of the cost containment argument must argue why this is so. They can follow one of two strategies in making this argument.

The first strategy consists in showing that the probability of overpopulation occurring is negligible. In this case, the obvious argument is that societies which adopt lifespan extension will most probably restrict the number of offspring people are allowed to have (Bostrom & Roache 2008). Such a policy is, however, problematic for several reasons. To begin with, ensuring compliance with any population control program will prove challenging. For example, fining people in case of non-compliance is likely to have not much of a deterrent effect. The very poor will rely on the fact that they are unable to pay the fine, while the very rich will gladly pay it. It seems that only the use of unethical means (e.g. forced sterilization) guarantees compliance. Furthermore, the question arises as to whether people who do not opt for lifespan extension should also be subjected to reproductive restrictions. If so, one would probably have a hard time justifying this. Finally, the introduction of reproductive restrictions could, by further lowering fertility rates, induce a further aging of the population. China's one-child-policy, having contributed to the dramatic aging of its population (Zhang & Goza 2006), is illustrative in this respect. Population aging could prove to be equally challenging in a world of extended life spans, even if we assume a reduction in frailspan. The sustainability of pension systems, for instance, might still be an issue as we cannot simply assume that people will be willing to work longer.

A second strategy is to acknowledge the occurrence of overpopulation, while arguing that its negative effects can be remediated. For example, one might, following Mackey (2003), claim that societies facing food shortages would find methods for genetically engineering more nutritionally efficient food. However, it remains to be seen whether such methods will actually be developed. Nevertheless, even if we could rely on

remedies being developed for some problems, there would be little reason for optimism. After all, other problems, such as the loss of biodiversity, are amenable at the most to mitigation, not remediation.

Given the problems with both of the outlined strategies, proponents of the cost containment argument will most probably be unable to successfully argue that health care savings outweigh the identified negative effects.

Most proponents of the cost containment argument clearly posit the cost containing potential of anti-aging interventions as a sufficient reason for investing more in aging research. Other proponents (Farrelly 2008; Butler et al. 2008), however, mention several other benefits²¹ attached to anti-aging interventions, besides their cost containing potential. One of the additional perceived benefits, for example, is that longer lives contribute to a substantial growth of the national economy. The inclusion of these additional benefits could imply that, for this group of proponents, the cost containing potential of anti-aging interventions in conjunction with these other benefits constitute a sufficient reason for investing more in aging research. If this is so, they must presuppose that all of these benefits together outweigh the bad effects of overpopulation. Once again, however, an argument will need to be put forward in support of this presupposition – an arduous task, to say the least.

2.4 Concluding remarks

Health care costs are rising at an unsustainable rate. Proposed measures for tackling this problem include age-based rationing and Medicare reform. A more recent proposal is to rely on life extension as a means of containing health care costs. We have identified four presuppositions underlying this cost containment argument. Each of these presuppositions is problematic. They raise serious questions concerning both the morality (the last presupposition) and the efficacy (the other presuppositions) of life extension as a cost containment measure. Thus, life extension fares no better than ‘older proposals’. The failure of all these proposals is mainly due to their misconstruing the problem of rising health care costs as one rooted in population aging. Society’s heavy reliance on medical technology is the main driver of health care cost growth. Cost

²¹ The term ‘longevity dividend’ is generally used to refer to these other benefits as well as to the expected benefit of health care savings.

containment policy should, therefore, redirect its focus away from population aging towards medical technology.

There are many challenges involved in achieving a more responsible use of medical technology. A first challenge consists in specifying what constitutes the appropriate attitude towards medical technology. This attitude does not imply putting a stop to all technological innovation. Neither does it imply a reluctance to say 'no' to efficacious but overly expensive technologies. In sum, society stands for the difficult task of striking a balance between both extremes; between allowing too little and too much.

A second challenge consists in overcoming the widespread opposition to the proposed shift towards a more limited use of medical technology. We can expect strong resistance from the many industries involved in the production and distribution of medical technologies. However, the public at large will also be reluctant to embrace the required changes. In fact, relative to age-based rationing and Medicare privatization proposals, our proposal will likely elicit even more public criticism. The former proposals 'merely' jeopardize the interests of the elderly population. However, our proposal jeopardizes an interest shared by everyone as both young and old can benefit from medical technology.

A final challenge relates to the deeply ingrained nature of the attitude which needs turning around. Society's attachment to medical technology has its roots in the Enlightenment idea of infinite progress. As such, it is part of our cultural heritage. It will prove difficult to change such a deeply rooted mindset.

Despite the many challenges involved, we will need to find a way of putting the issue of medical technology at the top of the agenda. It is the only way out of the problem.

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Chapter 3

Biogerontology and the doctrine of double effect

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3.1 Introduction

During the past century, the developed world has witnessed an important shift in disease patterns. Degenerative diseases have replaced infectious and parasitic diseases as a major cause of death. This phenomenon is commonly referred to as the ‘epidemiologic transition’. As degenerative diseases tend to occur at a much older age than infectious diseases, this transition amounts to a redistribution of diseases and deaths from the young to the old (Olshansky & Ault 1986). If we are to further increase the healthspan – i.e. the number of years spent in a disease-free state – we will have to devise means of combating age-related diseases. As we mentioned at the start of the previous chapter, there are two distinct approaches to tackling these pathologies. This chapter analyzes the views of deontologists with regard to these strategies. The impact of the latter on both healthspan and maximum lifespan, as we shall see, largely influences deontologists’ position on the matter. For this reason, it is useful to start out by briefly recapitulating the two approaches to tackling age-related diseases as this will allow us to draw attention to their effects on healthspan and maximum lifespan.

A first approach consists of the traditional prevention and treatment of age-related diseases. This piecemeal strategy, in which the diseases of aging are addressed *individually*, is known as the ‘weak’ approach (Lucke & Hall 2006). This terminology refers to the latter’s limited impact on the healthspan and maximum lifespan²². As we saw in chapter 2, the last stage of life sees an exponential increase in the incidence of most age-related diseases. Consequently, once any one of the lethal diseases is eradicated, it is only a matter of time before its place is taken by yet another. Scientists, therefore, concur that, whereas this approach is likely to increase the *healthspan*, the increase will be of a small magnitude. Furthermore, they agree that an increase in the *maximum lifespan* is highly improbable (Carnes et al. 2002). Any such increase that would occur, would be only minimal.

A second strategy, known as the ‘strong’ or ‘biogerontological’ approach (Lucke & Hall 2006) is to intervene in the *aging process itself* – the underlying cause of age-related diseases. This strategy has the advantage of addressing all age-related pathologies *simultaneously*. Biogerontologists are currently exploring the merits of gene therapy, caloric restriction (CR) and CR mimetics (i.e. substances which mimic the beneficial effects of caloric restriction while avoiding the need for dietary restrictions) (Marques

²² The current maximum human lifespan is 122 years (Pamplona et al. 1998).

et al. 2010; Miller 2002; Barazzetti & Reichlin 2011). Recall that the diverging views concerning the outcomes of biogerontological research can be captured in four scenarios: prolonged senescence, compressed morbidity, decelerated aging, and arrested aging. For reasons that will become clear later on, the scope of this chapter is limited to the last two scenarios. Thus, whenever terms such as ‘biogerontology’ and ‘intervening in aging’ are used throughout this chapter, they should be interpreted as referring merely to decelerated and arrested aging.

The deceleration of the aging process would markedly postpone the development of old-age frailty and its accompanying diseases, thereby producing a substantial increase in both the *healthspan* and *maximum lifespan* (Gems 2009). Interventions such as caloric restriction appear to decelerate aging in animal models. Extrapolating from the findings of these experiments, Richard Miller (2002) anticipates that the deceleration of the human aging process will bring about an average life expectancy of 112 and a maximum lifespan of 140.

The act of arresting the aging process would also increase both *healthspan* and *maximum lifespan*, albeit to a much greater extent. Recall that under this approach, which is strongly advocated by Aubrey de Grey (2003), the age-related diseases are postponed *indefinitely*. As these pathologies would no longer occur, a state of ‘virtual immortality’ would be attained in the sense that death would only result from accidents, suicide, wars and so forth (Binstock 2004).

The biogerontological project is met with strong resistance, especially by deontologists. In a bid to convince the latter of the permissibility of intervening in aging, proponents of biogerontology appeal to the doctrine of double effect. Surprisingly, their argument has gone unnoticed. Our aim in this chapter is to expose and critically evaluate this argument. But before we embark on this mission, we should briefly give an account of the doctrine of double effect.

3.2 Double effect in contemporary bioethical debate

The doctrine of double effect (henceforth just ‘DDE’) was originally invoked as a solution to an action problem, where an absolute²³ deontological principle prevents actions

²³ Note that, despite its origin being absolutist, non-absolutist accounts of the DDE have also been put forward (see, for example, Quinn 1989).

which are good, or even morally required (Bica 1999). Such a problem occurs, for example, when an agent wishes to engage in self-defense so as to protect her own life, but cannot do so without killing her assailant (i.e., without infringing the prohibition against killing human beings). In short, the DDE has evolved as a means of resolving situations where an agent wishes to do good, but cannot do so without causing serious harm. The DDE attempts to solve this problem by stating that it is sometimes permissible to bring about such harm, provided that it is a foreseen, but unintended side-effect of promoting some good end.

Focusing on action problems introduced by the prohibition against killing human beings, Bica (1999) describes the function of the DDE as follows:

The DDE, then, “redefines” the scope of the absolute prohibition’s [the prohibition against killing human beings] application. That is, by focusing upon the moral significance of intention and its relevance to moral agency and responsibility, it morally distinguishes “accidental” killing from murder, claiming that only the latter is absolutely prohibited. Consequently, while alleging to preserve the absolute nature of the prohibition, with the application of the DDE, it is sometimes permissible to knowingly kill [...] human beings – if only one withholds intention. (Bica 1999, 131)

Disagreement about the meaning and function of the DDE has resulted in various formulations of the doctrine. These formulations have in common the idea that the permissibility of bringing about certain kinds of harm hinges on a number of conditions being met. Since it is not our aim to discuss the validity of the DDE, we will simply use Joseph Mangan’s (1949) formulation²⁴, a plausible and, in medical ethics, influential version of the doctrine. According to this formulation, for an action which has at least one good and one bad consequence to be permissible, four conditions need to be met:

- (1) That the action in itself from its very object be good or at least indifferent;
 - (2) That the good effect and not the evil effect be intended;
 - (3) That the good effect be not produced by means of the evil effect;
 - (4) That there be a proportionately grave reason for permitting the evil effect.
- (Mangan 1949, 43)

Note that actions which satisfy all of these conditions are ‘merely’ *permissible*; the DDE imposes no moral *obligation* to perform such actions. The DDE only entails an obligation

²⁴ Note that there exist newer versions of the DDE (see, for example, Quinn 1989; Boyle 1991; Sulmasy 2007; Nelkin & Rickless 2012). Our discussion throughout this chapter is relative to Mangan’s version.

when dealing with actions which do not meet at least one of the above conditions. The latter type of actions are impermissible, i.e. one has an obligation to refrain from such actions. Thus, the DDE has more force as a prohibitive principle than it has as a permissive principle (Raus et al. 2013).

The DDE has important applications within medical ethics and clinical practice. One of the most common applications occurs in the abortion context, where its use is generally illustrated with a pair of contrasting cases: the hysterectomy and the craniotomy case. In the hysterectomy case, a pregnant woman has cancer of the uterus. A hysterectomy is required to save her life. The craniotomy case features an unborn child, whose head is lodged in the mother's birth canal. If the head is not dislodged, the mother will die. The head can only be dislodged through a craniotomy (crushing of the unborn child's head). Below, we present a commonly encountered approach to both cases. Alternative analyses are possible (Boyle 1991). However, it is not our intention to endorse one or other approach. The discussion of these cases merely serves the purpose of *illustrating* the use of the DDE.

In both the craniotomy and hysterectomy case, the action under consideration has the same positive (the mother's life is saved) and negative (fetal death) effect. However, important differences between these cases become apparent once we apply the four conditions specified by the DDE:

(1) While performing a hysterectomy is in itself good or neutral, this does not hold true for the crushing of the unborn child's skull.

(2) The assessment of this condition is generally approached in one of two ways. Some believe that this condition rarely poses a problem when dealing with medical applications of the DDE as we may reasonably assume that medical professionals are not malevolent (see, for example, Spielthener 2008). Proponents of this view would, thus, argue that, in both the hysterectomy and the craniotomy case, only the good effect of preserving the mother's life is intended. Others, however, reject this baseline assumption of benevolent intention. Beauchamp and Childress (2009), for example, argue that one cannot but intend the bad effect of fetal death when performing a craniotomy. They reason that fetal death is a means (see condition (3) below) to save the pregnant woman's life. A means to one's end, they argue, is always intended.²⁵

(3) The removal of the uterus, not the death of the child, is what saves the mother's life in the hysterectomy case. Thus, the hysterectomy case satisfies the third condition. However, the craniotomy case does not. Since crushing the child's skull amounts to

²⁵ We analyze this line of reasoning in greater detail further on in this chapter.

killing the baby, the good effect of preserving the mother's life is obtained through the bad effect.

(4) The hysterectomy case satisfies the proportionality requirement in that saving the mother's life constitutes a proportionate reason for allowing the child to die. Leaving aside the difficulty that *killing* could affect proportionality differently than *allowing to die*, we may suppose that the fourth condition is also met in the craniotomy case (Raus et al. 2013).

The above analysis suggests that the hysterectomy case satisfies all four conditions of the DDE, whereas the craniotomy case does not. Thus, according to the generally held view, the hysterectomy is permissible, whereas the craniotomy is prohibited under the DDE.

The DDE also plays an influential role in the debate about end-of-life decisions. It has been invoked to justify the administration of pain-relieving medication to terminally ill patients in doses which would most probably hasten death, but where the death is an unintended side-effect of administering the medication. It distinguishes such actions from euthanasia and assisted suicide, in which the death of the patient is a means to reduce suffering (Sulmasy & Pellegrino 1999).

As mentioned earlier, the DDE is a controversial doctrine, and has been discussed extensively. The issues discussed range from the moral relevance of the intended/foresight distinction to the precise formulation of the principle (Spielthener 2008). However, these issues lie beyond the scope of this dissertation. We will only touch upon them insofar as they are relevant for the purpose of this chapter

3.3 Double effect in the ethical debate on biogerontology

In this section, we first examine three passages from the debate on the merit of various approaches to tackling age-related diseases. Next, we argue that the authors of these passages engage in double effect reasoning, albeit only implicitly. Finally, we analyze the role which the argument appealing to the DDE is meant to fulfil. We claim that the argument, which we will refer to as the 'double effect argument', is appealed to by proponents of biogerontology in order to reach out to some of their (deontological) opponents: those who adhere to double effect reasoning.

A first excerpt is from the work of John Harris (2002):

Remember that immortality is not unconnected with preventing or curing a whole range of serious diseases. It is one thing to ask whether we should make people immortal and answer in the negative; quite another to ask whether we should make people immune to heart disease, cancer, dementia, and many other diseases and decide that we shouldn't, because a "side effect" of the treatment would be an increase in life expectancy. We are then, unlikely ever to face the question, Should we make people immortal: Yes or no? We may rather be called upon to decide whether we should treat this disease when we know an effective treatment will extend lifespan. It might then be appropriate to think of immortality as the, possibly unwanted, side effect of treating or preventing a whole range of diseases. Could we really say to people, "You must die at the age of 30 or 40 or 50, because the only way we can cure you is to make you immortal or let you live to be 200 or 300"? (Harris 2002, 10)

An implicit appeal to double effect is also present in the work of David Gems (2011):

Decelerating human ageing would have two outcomes that are very different in ethical terms. Firstly, it would greatly reduce the frequency of ageing related illness at any given age. (...) Secondly, it would lead to extended lifespan – perhaps, eventually, of a large magnitude. (...) Yet, the possibility of very large increases in lifespan – let us say, for argument's sake, to 150 years – is one that many find unnerving. (...) But given the health benefits of decelerated ageing, although we may not particularly want life extension (...), we may simply have to accept it as a side effect of a greater benefit. (Gems 2011, 111)

Aubrey de Grey (2007) also implicitly refers to the DDE:

(...) the only realistic approach to greatly postponing bad deaths is to combat aging itself, (...) thereby (...) greatly raising life expectancy, with all that that entails. The question that humanity must face up to is clear: is the prevention of the suffering currently associated with most deaths from old age valuable enough to justify the inevitable side-effect of radically increased lifespans? The question is not whether that side-effect is good or bad – a question on which opinions will surely remain divided for some time to come. The question, rather, is whether that side-effect is so bad as to outweigh the benefits of eliminating aging-related suffering. (de Grey 2007, 3)

The above passages exhibit a common structure in that they feature an action with a good and a bad effect. In each case, the identified bad effect is a (radically) increased maximum lifespan. Concerning the action at play, it is clear that both Gems and de Grey are discussing the ‘strong’ approach to tackling age-related diseases, i.e. the act of intervening in the aging process itself. After all, de Grey speaks of combating “aging *itself*”. Gems, on the other hand, refers to “decelerating human aging”, a recognized instance of intervening in aging. In Harris’ case, the reference to “treating or preventing a whole range of diseases” initially suggests that he is discussing the ‘weak’ approach. However, on closer inspection, he appears to be using the latter phrase as a misnomer for the ‘strong’ approach. Harris speaks of the bad effect in terms of “immortality”. As noted in the introduction, an increase in maximum lifespan of this magnitude can only be achieved through the ‘strong’ approach. Harris’ reference to the good effect as “immunity to age-related diseases” further supports our claim that he is indeed addressing interventions in the aging process. Such immunity after all, is only achievable through the ‘strong approach’. Let us now turn to the good effect identified by Gems and de Grey. They respectively speak of “greatly reducing the frequency of aging related illness at any given age” and “the prevention of the suffering associated with old age”. Despite the differences in the terminology employed by these authors in reference to the good effect, there appears to be a common denominator. All of the identified good effects amount – as these authors themselves acknowledge – to the (indefinite) postponement of age-related diseases. The common structure of the above passages is illustrated in Fig. 1.

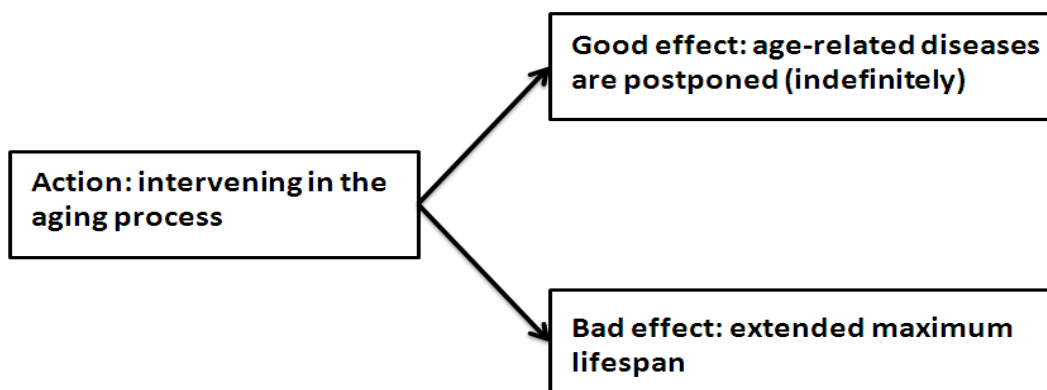


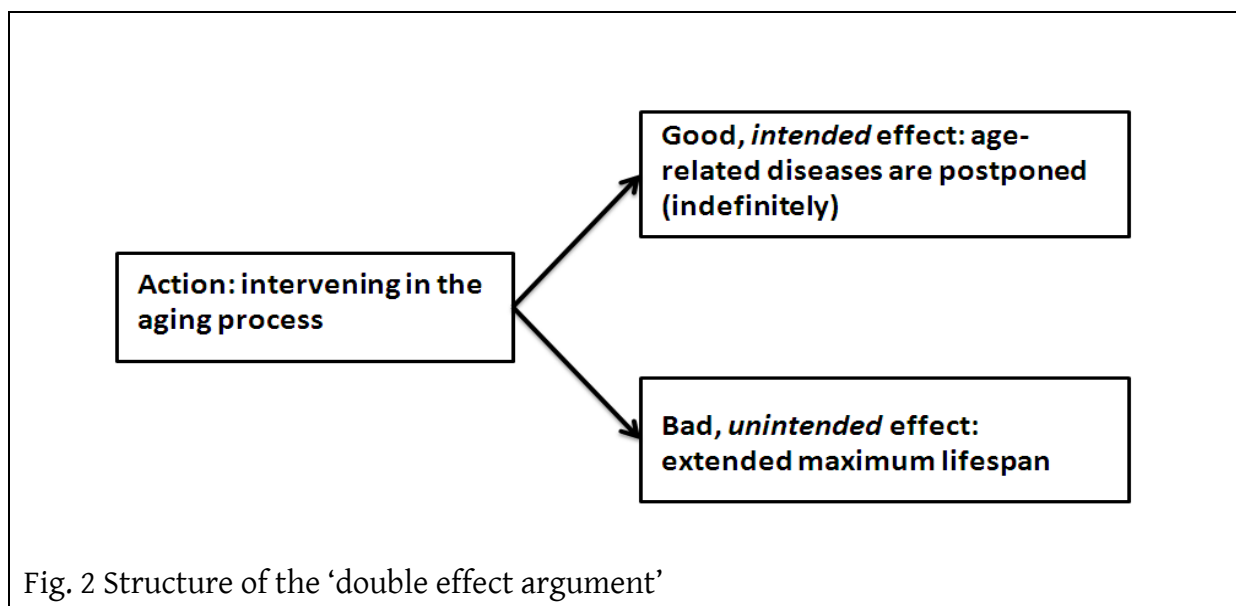
Fig. 1 Common structure of the passages

3.3.1 Establishing the presence of the DDE

In featuring an action with a good and a bad effect, the quoted passages incorporate a basic characteristic of double effect reasoning. However, more is needed in order to establish the presence of the DDE. The key characteristic of double effect reasoning is the intended/unintended distinction. Below we argue that Gems, de Grey, and Harris appeal to this distinction, albeit implicitly.

There is a broad consensus among proponents of biogerontology that the field's *goal* or *objective* consists in increasing the human healthspan (see, for example, Farrelly 2012; Vincent 2007). Terms such as 'goal' and 'objective' undeniably denote intention. As they are ardent proponents of biogerontology, Gems, de Grey, and Harris very likely endorse the claim that interventions in aging are intended to increase the healthspan. The good effect which these authors refer to in the quoted passages amounts precisely to an increase in the healthspan. Thus, when Gems, de Grey and Harris mention this good effect, we may reasonably interpret them as saying that this is the intended effect of intervening in aging. The fact that they juxtapose the good effect with an *unwanted* bad effect further strengthens our claim that the good effect is what they consider to be the intended effect.

We have established the presence of the first component of the intended/unintended distinction, i.e. the fact that the good effect is intended. Are there any grounds to interpret the bad effect as referring to an unintended effect? As suggested above, the term 'unwanted', which is used in reference to the bad effect, could be considered as denoting a lack of intention. However, there is another, much more sound basis for inferring the presence of the intended/unintended distinction. According to Cavanaugh (2006), the latter distinction can interchangeably be referred to as the 'intended/side effect' distinction. Gems, Harris, and de Grey each refer to the bad effect in terms of a side effect. This, combined with the already established presence of a good, intended effect, implies that the quoted passages contain the characteristic distinction of the DDE (see Fig. 2).



3.3.2 The role of the 'double effect argument'

Advocates of biogerontology face strongest opposition from those whose beliefs are grounded in deontological arguments. Many deontologists consider the act of intervening in the aging process impermissible on the grounds that it brings about an extended maximum lifespan – a state of affairs which they deem intrinsically bad (Partridge & Hall 2007).²⁶ Most proponents of intervening in the human aging process do not themselves adhere to the DDE. Thus, in appealing to this deontological model, the latter seemingly attempt to win over their aforementioned opponents. In sum, advocates of biogerontology hope to convince their deontological opponents of the permissibility of intervening in aging by framing this act within the DDE. In light of its rhetorical purpose, how exactly should we understand the double effect argument? We should *interpret* those appealing to this argument as saying the following: Deontologists claim that an extended maximum lifespan is a bad state of affairs. Anyone would agree that there is much value in having age-related diseases postponed. The latter can be achieved by intervening in the aging process. Admittedly, such interventions would also bring about an extended maximum lifespan, thereby breaching a deontological prohibition. Does this imply that deontologists necessarily ought to condemn the act of intervening in the aging process? No. Once we frame this act within the DDE, it becomes permissible. After all, the act of intervening in aging is morally neutral. The extended maximum lifespan (the bad effect) is an unintended effect of intervening in aging. The

²⁶ Note that, as we argue further on, deontologists do not (necessarily) consider the act of intervening in aging as bad in itself.

intention is merely to bring about the good effect, i.e. the postponement of the onset of age-related diseases. In addition, the bad effect is not a means to the good effect. Finally, there is a proportionately grave reason for permitting the bad effect.

As noted above, many deontologists consider an extended maximum lifespan a bad state of affairs. When defending their position on this matter, deontologists differ somewhat in the aspects which they emphasize (Derkx 2009).

A first group appeals to human nature (see, for example, Fukuyama 2002; Kass 2003). The good is that which conforms to human nature, whereas the bad is that which represents a perversion of the latter. Leon Kass is one of the most renowned proponents of this view. With regard to the issue at hand, he asks: “Is it really true that longer life for individuals is an unqualified good?” (Kass 2004, 309). His answer is a clear “no”. Not only is an extended life not an unqualified good. It is, according to Kass, an evil. He states his view of an increased lifespan being inconsistent with human nature as follows:

For to argue that human life would be better without death is, I submit, to argue that human life would be better being something other than human. To be immortal would not be just to continue life as we mortals know it, only forever. The new immortals, in the decisive sense, would not be like us at all. (Kass 2004, 311)

As Kass himself acknowledges, when he speaks of “life without death”, he is not merely referring to immortality. The phrase also denotes modestly extended lifespans. Kass suggests that, for example, a lifespan only 20 years longer than the current one, may already constitute a deviation from human nature.

A second group of deontologists appeals to the concept of the ‘life cycle’, the normative natural order present in life’s events and in their pacing in an individual’s life (Juengst et al. 2003). An extended lifespan, according to this view, represents an unacceptable disruption of this order. Life cycle traditionalism also appeals to the concept of human nature – albeit merely indirectly – in that it views the life cycle as an important characteristic of all living organisms. Thus, in breaking with the life cycle, an extended lifespan compromises the essential identity of human beings.

3.4 Testing the soundness of the ‘double effect argument’

The question remains whether those who appeal to the ‘double effect argument’ would succeed in winning over their deontological opponents. The argument will only be successful if these deontologists view the act of intervening in aging as satisfying each of the 4 conditions of the DDE. Below, we reconstruct the way in which deontological opponents of biogerontology are likely to assess interventions in aging against the standard of the DDE.

Condition 1: is the action in itself morally good or neutral?

Is intervening in the aging process a good or at least morally neutral action, independent of its consequences?

Some deontologists will *a priori* reject interventions in the aging process on the grounds that aging is not a disease; it is a normal process that should not be intervened in. In short, on this view, interventions in the aging process are unacceptable as they constitute ‘enhancement’, not ‘therapy’ (Partridge & Hall 2007).

Deontologists, such as Kass, who are primarily concerned with preserving human nature may accept *natural* interventions in the aging process. We have described the action to be justified as ‘intervening in the aging process’, but there are different ways of doing so. For example, one could do this by administering a drug that switches on a gene associated with longevity, or one could intervene in the aging process using caloric restriction. Whether a deontologist concerned with preserving human nature regards a certain intervention in the aging process as good or neutral will depend on how she understands ‘unnatural’. If ‘unnatural’ is understood as all that is human-made, then she may accept caloric restriction but reject all medical-technical interventions. However, given the radical implications of this view (i.e. the need to renounce medicine altogether), few deontologists would advocate this interpretation of ‘unnatural’. Another, for deontologists more plausible view, equates ‘unnatural’ with a significant deviation from ‘normal’ processes; in this case from ‘normal’ bodily functioning. Caloric restriction (mimetics) could then be accepted because it respects the normal bodily processes, whereas gene therapy would be rejected. When we deprive the body of food, as is the case in caloric restriction, we merely trigger a programmed reaction in the body. Obviously, caloric restriction mimetics would trigger the very same reaction. However, in the case of gene therapy, we are reprogramming the body’s normal reaction, rather than addressing its latent potential.

‘Life cycle traditionalists’ will most probably reach the same verdict as those concerned with preserving human nature. After all, as noted above, they too draw upon the concept of human nature, albeit implicitly.

One may object to this analysis by pointing out that one can always redescribe the action to be justified in such a way that it *is* neutral or good, and, thus, always meets the first condition. This is the ‘re-description problem’ first mentioned by Philippa Foot (1978). The problem is that the first condition separates the action from its effects or consequences. It stipulates that the action *in itself* has to be good or neutral, independent of its effects or consequences. But if we have to consider the action independent of its effects, we can always describe it in a neutral way. For example, in the infamous craniotomy case, the action could be described as killing the fetus, but also as reducing the size of the fetus’s skull. Likewise, one could describe the action ‘intervening in the aging process through genetic manipulation’ as ‘administering a drug’ with one side-effect that a gene associated with the aging process is switched off and another side-effect that an extended maximum lifespan is obtained. The action to be justified might then be considered good or neutral by deontologists. One proposed solution to this problem is to implement a criterion of closeness, linking intended actions to their closely related side-effects so that they are inseparable from the action. Since the drug works by switching off a gene that plays a crucial role in the aging process, it surely is more plausible to describe the action as ‘a genetic intervention in the aging process’. It is plausible that one cannot separate the means used (i.e. the drug) from the mechanism (i.e. switching off a gene) through which the means works.

So depending on the mechanism involved, some deontologists will not consider the action to be justified as good or neutral. If condition 1 is not met, then the argument appealed to by defenders of biogerontology to convince some of their opponents will not hold. However, for those deontologists who regard the action as neutral or good, the argument could still work if the other conditions are met.

Condition 2: is the bad effect unintended?

Does the agent only intend the good effect? Is the bad effect – the extended maximum lifespan – merely a foreseen but unintended side-effect? Before answering these questions, we would like to address a common misconception. The DDE is sometimes interpreted as making the permissibility of an action turn on the *actual* intentions of a *particular* agent (see, for example, Rachels 1994; Thomson 1999; Scanlon 2008). According to this interpretation, the act is permissible when the individual performing it merely intends the good effect. Conversely, the act becomes impermissible when conducted by an individual who intends the bad effect. FitzPatrick (2012) has convincingly refuted this interpretation of the DDE. According to FitzPatrick, the requirement which needs to be met in order for condition 2 to be satisfied, is situated on an abstract, theoretical level – as opposed to the practical level of the particular individual and her intentions. All that is required for condition 2 to be met, is that it is *theoretically conceivable* that one acts without intending the bad effect. Thus, where a

particular agent acts with malevolent intentions, condition 2 could still be met. What matters for an act to be permissible is that one *could* act without intending the bad effect. Conversely, condition 2 is violated when, *whatever the circumstances considered*, one cannot but act with malevolent intentions.

Controversy exists about how to determine whether an effect of an action is an *intended* effect (Marquis 1991). A commonly applied test to account for the distinction between intended and merely foreseen effects is the counterfactual test (Donagan 1991). This test asks whether an agent would still do the act if she thought that the bad effect would not occur. If the non-occurrence of the bad effect would deter the agent from performing the relevant action, we may conclude that she intends the bad effect. In light of our abovementioned remark, the agent referred to in the counterfactual test should be interpreted as an agent ‘in the abstract’, rather than a particular agent. Applied to the question at hand, the counterfactual test goes as follows: can a doctor who intervenes in the aging process reasonably say that if she could do so without obtaining an extended maximum lifespan, she would? We believe that she could. Suppose that a patient has a genetic predisposition for developing an age-related disease, or a set of age-related diseases. Furthermore, suppose that a doctor knew that, if she intervened in the patient’s aging process, the onset of the age-related disease(s) would be postponed, but the patient’s life would not be extended beyond the maximum lifespan (say, because her patient is a Death Row inmate). It is plausible that the doctor would still perform the action – intervening in the aging process – if this is the most efficient, or the only way of postponing the (set of) age-related disease(s). Does our Death Row scenario provide sufficient grounds for concluding that condition 2 is met? Recall that condition 2 is violated when, *whatever* the circumstances considered, an agent intervening in the aging process necessarily intends the bad effect. Conversely, then, condition 2 is met when one can conceive of at least one case – set of circumstances – under which one *could* intervene in the aging process without intending the bad effect. Our Death Row scenario provides precisely such a counterexample.

Condition 3: is the bad effect used as a means to the good effect?

Is the extended maximum lifespan a means to the (indefinite) postponement of age-related diseases? The general idea behind this condition is that a harm that might permissibly be brought about as a side-effect in promoting a good end could not be permissibly brought about *as a means* to the same good end.

There are two ways of approaching the assessment of this third condition, depending on how one views its relationship to the second condition. While some consider both conditions as interchangeable, others regard them as separate conditions which cannot

be reduced to one another. Below, we determine, from each of these perspectives, whether the third condition is satisfied.

Marquis (1991), who advocates the interrelatedness between the second and third condition, argues as follows:

In general, if Mangan's condition (3) is violated, then the good effect is produced by means of the evil effect. If we grant the doctrine that he who intends the end also intends the means, then the evil effect is intended. And if the evil effect is intended, then condition (2) is violated. Hence, if condition (2) is satisfied, then so is condition (3). (Marquis 1991, 520)

Following this line of reasoning²⁷, we can simply deduce whether or not the third condition is met from our findings regarding the second condition. In our analysis of condition 2, we have established, using the counterfactual test, that the bad effect, i.e. the extended maximum lifespan, is unintended. Therefore, since one's means are always intended, the bad effect cannot be a means to the good effect (i.e. the (indefinite) postponement of age-related diseases). In sum, the third condition is met on this view.

Is the third condition met from the perspective of those who repudiate its interconnectedness with the second condition? On this view, both conditions differ clearly in that the second asks whether the bad effect is intended *as an end*, whereas the third inquires whether it is intended *as a means*. How does 'intending as an end' differ from 'intending as a means'? It has been argued that if an agent believes that her action has a certain direct effect and this belief is the rationale behind her action, the agent intends this effect as an end (Spielthener 2008). For example, if I write a book because I believe it will make me famous, then I intend becoming famous as an end. The concept of 'intending as a means' amounts to the following: "If an agent believes that φ -ing [where φ stands for some verb of action] has a certain effect (E_1) and believes that E_1 is related (causally or otherwise) to another effect (E_2) and the latter belief is a reason for her to φ , then the agent intends E_1 as a means to E_2 and she intends E_2 as an end" (Spielthener 2008, 468-469). Suppose that a murderer turns herself in. She believes that this will lead to her being executed, which in turn will relieve her of the remorse that haunts her. The murderer, then, intends her being executed as a means to ending her psychological suffering, which she intends as an end.

²⁷ Note that Beauchamp and Childress (2009) appeal to this line of reasoning in their analysis of the craniotomy case. From the fact that the bad effect (the death of the fetus) constitutes a means to the good effect (preserving the mother's life), they deduce that the bad effect must be intended.

On this view, the fact that the second condition is satisfied ‘merely’ tells us that the bad effect (the extended maximum lifespan) is unintended as an end. This, in itself, does not give anything away concerning the third condition as the bad effect may very well be unintended as an end, yet intended as a means. We, therefore, need a way of independently assessing whether or not the bad effect constitutes a means to the good effect. Several tests have been proposed. Below, we apply two widely applied tests to the case at hand. We show that, on both tests, the bad effect (extended maximum lifespan) is not a means to the good effect.

A first test is the ‘inevitable connection test’ (Marquis 1991). According to this test, if the action is inevitably connected to the bad effect, we may conclude that the latter is used as a means to the good effect. The idea behind this test is that the presence of such an inevitable connection implies that the action and the bad effect merge into one another. Given that the action is necessarily a means to the good effect, the bad effect must, then, also be so. Note that the inevitable connection test is, for example, implicitly relied upon in the analysis of the craniotomy case. Here, crushing the fetus’ skull (the action) is considered identical to the fetus being killed (the bad effect). For this reason, the fetus’ death is taken to be a means to the good effect.

Is the action of intervening in the aging process inevitably connected to the extended maximum lifespan? It seems that it is not. In being (temporarily) relieved from aging and its concomitants, one is not in any way protected against other potential causes of death, such as fatal non-aging-related diseases, suicide, murder, etc. One may not reach the current maximum lifespan, despite having undergone treatment to decelerate or arrest aging. Thus, according to the inevitable connection test, the extended maximum lifespan does not constitute a means to the good effect.

A second test simply consists in applying another definition of ‘means’, one which better approximates the common-sense understanding of the concept. Dan Brock (1999), for example, offers such a definition: “The means are what an agent does because he believes them to be causally necessary or sufficient on the particular causal path taken to achieve his end” (Brock 1999, 532). The case for a prohibition against euthanasia and physician-assisted suicide under the DDE, for example, is built on an implicit use of this ‘causal criterion’. The reason why a doctor performs such actions is the belief that the patient’s death (the bad effect) will be causally sufficient for relieving the patient’s pain (the good effect), suggesting that the former is used as a means to the latter.

Contrary to the euthanasia/assisted suicide case, our case does not appear to satisfy the above definition of a means. It seems incorrect to say that the extended maximum lifespan (the bad effect) is either causally sufficient or necessary for obtaining the good effect (the postponement of age-related diseases). Rather, the opposite seems to be the

case. As mentioned before, our current scientific knowledge suggests that the most promising way of obtaining an extended maximum lifespan is to tackle all age-related diseases simultaneously. This implies that the good effect is causally necessary²⁸ for obtaining an increased maximum lifespan, but not vice versa. In sum, the extended maximum lifespan represents the last stage in the causal chain and is, therefore, not a means to the good effect on the causal criterion test.

On both positions concerning the relationship between the second and third condition of the DDE, the increased maximum lifespan is not a means to the postponed onset of age-related diseases. Therefore, the third condition is met.

Condition 4: does the good effect outweigh the bad effect?

In order for an action to be justified by the DDE, the bad effect must not only be unintended as an end or as a means, the good effect must also be proportionate to the bad effect. Alan Donagan (1977) explains the proportionality condition as follows:

Whether or not the good effect is a proportionately serious reason is determined according to the principle that evil is to be avoided or prevented wherever possible, except at the cost of an equal or worse evil. If the nonoccurrence of the good effect would be as great an evil, or a worse evil, than the occurrence of the bad effect, then it is a proportionately serious reason for it. (Donagan 1977, 161)

Thus, we need to determine, from a deontological perspective, how the non-occurrence of the postponed onset of age-related diseases compares to the evil of an extended maximum lifespan. In order to make this assessment, we consider two scenarios, one in which interventions aimed at decelerating/arresting the aging process are widely performed and one in which they are not. As we argue below, the outcome of the proportionality assessment differs in both scenarios. In this respect, the case at hand diverges from 'classical' applications of the DDE, where the frequency with which the actions are performed does not affect the outcome. For example, in the hysterectomy case, the good effect is considered proportionate to the bad effect, irrespective of whether such hysterectomies are performed on a small or large scale.

²⁸ That the good effect is not causally sufficient for obtaining an increased maximum lifespan follows from the fact that in decelerating/arresting the aging process, one does not protect oneself against non-aging-related causes of death.

Let us start with the easiest scenario, where interventions in the aging process are performed on a small scale. Consider first a (rather implausible) situation in which only one person in the world requests her aging process to be decelerated/arrested. In granting the patient's request, the doctor ensures the postponed onset of all age-related diseases (the good effect). Since these diseases are responsible for (premature) death, the good effect brought about by the doctor's action may be redescribed as that of saving the patient's life.²⁹ Thus, the 'evil' that would be brought about by the doctor's omission can be interpreted as that of letting the patient die. The doctor thereby breaches her duty of rescue or beneficence. Given that interventions in the aging process increase the number of healthy life years, continued life of a good quality is at stake here. It is, therefore, reasonable to assume that deontologists would consider the evil of letting the patient die much worse than that of the patient obtaining an extended lifespan. Thus, in the simple case, the good effect is likely proportionate to the bad effect.

Now suppose the number of patients requesting decelerated/arrested aging is, although still relatively small, greater than one. In denying these patients' requests, the medical community is now letting *various* people die. Conversely, in granting these patients' requests, it causes *various* people to obtain an extended lifespan. However, there is no reason why this (numerical) difference with the simple case should change the proportionality verdict. On the contrary, given that more lives are at stake, the case for proportionality between the good and bad effect might be stronger still.

When advocates of decelerated/arrested aging label these interventions morally permissible, they do *not* do so with the proviso that they be performed on a small scale only. Thus, proponents of these interventions are committed to defending interventions in the aging process, irrespective of the scale on which these are performed. If they are to convince their opponents that the DDE can justify these interventions, then *both* the small and large scale performance of these interventions must satisfy the proportionality condition. As we have seen, the 'small scale scenario' passes the test.

²⁹ de Grey (2005) also characterizes the 'war on aging' as a lifesaving act. He states that in (indefinitely) postponing age-related diseases, "we are giving the beneficiary a greater remaining healthy potential lifespan than they would have if we held back, which is the beginning and end of what we mean when we say we have saved their lives [...]" (de Grey 2005, 622).

Below, we argue that this does not hold true for the ‘large scale scenario’. Therefore, the fourth condition is not met.³⁰

Consider a scenario in which a significant part of the population requests an intervention in their aging processes. Here, as is the case with the ‘small scale scenario’, omitting to bring about the good effect amounts to letting people die. The number of people that would die is much greater in the ‘large scale scenario’ than it is in the ‘small scale scenario’. At first sight, then, the case for proportionality appears still stronger in the former scenario, relative to the latter. Nevertheless, a closer look at the bad effect in both scenarios compels us to revise this initial assessment. In the ‘small scale scenario’ the bad effect ‘merely’ amounts to a breach of the prohibition on an extended maximum lifespan. However, in the ‘large scale scenario’, the ‘evil’ inherent in the bad effect may go well beyond a breach of this single prohibition.

Many deontologists (see, for example, Kass 1985) fear that there is a serious threat of overpopulation when faced with a large scale use of anti-aging interventions. A marked increase in the world population could cause an array of adverse effects. Louria (2005), for example, expects an increase in the number of large urban centers with slums, the unhygienic conditions of which would give rise to infections and epidemics. Other potential harms include: “increased poverty and malnutrition; resource depletion that, together with ethnic, religious, and tribal animosities, leads to ferocious conflicts; population-related global warming that, in turn, could create hundreds of millions of refugees and political instability that could lead to more strife” (Louria 2005, 318).

Deontologists with these concerns could argue that in breaching the prohibition on an extended maximum lifespan, the medical community may also be breaching its duty not to inflict harm upon people. For these deontologists, the harm inflicted as a result of providing interventions in the aging process will likely even amount to letting people die. After all, they view overpopulation as creating a situation in which people are inevitably deprived of basic needs for continued life. Ultimately then, they could reformulate the bad effect in terms of letting people die. Recall that the non-occurrence of the good effect also amounts to letting people die. From the perspective of the above deontologists, the proportionality condition will probably not be met in the ‘large scale

³⁰ The high cost of interventions in aging, one might object, makes it highly unlikely that these will be performed on a large scale. Therefore, one might argue, we should only take into account the small scale scenario and, thus, conclude that the proportionality condition *is* met. However, the *likelihood* of the large scale scenario is irrelevant to our analysis. After all, proponents of interventions in aging argue that the DDE can justify *both* the small and large scale use of the latter. Therefore, if one of the scenarios (i.e. the large scale scenario) does not satisfy the proportionality condition, their argument no longer holds. The improbability of the large scale scenario does not change this.

scenario'. First, in bringing about the bad effect we are breaching two prohibitions; we are both obtaining an extended maximum lifespan and letting people die. In refraining from intervening in the aging process, on the other hand, we are merely breaching one prohibition. Second, population-related global warming and other harms attached to overpopulation may affect people worldwide. As Billings (2011) argues, a harm affecting society generally carries more weight than one affecting merely an individual. Therefore, the globally felt effect of people dying likely constitutes too great an evil to justify interventions in the aging process. The latter holds true, regardless of the magnitude of the good effect.³¹

One might object that the reformulation of the bad effect in terms of harm to others is only obtained through an 'aggregative view', i.e. through considering the numerous interventions in the aging process by many doctors *together*. More specifically, one might argue that on a 'piecemeal view', where every single intervention in the aging process is considered separately, the bad effect merely amounts to one person obtaining an extended lifespan. Is the 'aggregative view' then the correct one to take? We think it is. Adopting the 'piecemeal view' in a context where one's action impacts not only upon the patient, but also on others, seems wrong. The 'piecemeal view' is oblivious to the potential effects of a large scale use of anti-aging interventions on society at large. Parfit's 'Harmless Torturers' case (1984) supports the use of the aggregative view in the 'large scale scenario'. In this hypothetical scenario, a thousand people each push a button that turns the dial of a torture machine one click. Whereas a single click causes imperceptible pain to the victim, the pain associated with a thousand clicks is excruciating. According to the 'piecemeal view', none of these torturers ever acts wrongly given that a single turn of the dial merely causes imperceptible pain. This conclusion is absurd. What matters is that, taken together, these torturers' acts inflict severe pain on the victim. Likewise, taken in aggregate, each doctor's intervention in the aging process harms society at large.

³¹ One might object that this verdict of non-proportionality is based on a problematic assumption, i.e. the conviction that overpopulation and its detrimental effects will occur. However, whether or not we will actually be confronted with overpopulation and its detrimental effects is irrelevant. We are merely interested here in reconstructing the way in which deontological opponents of biogerontology may assess interventions in aging against the standard of the DDE. From this perspective, all that matters is that there are deontologists who fear overpopulation and who, on this basis, would reject the idea of the proportionality condition being met.

3.5 Conclusion

Proponents and opponents of biogerontology have generally criticized each other's arguments from within their own moral frameworks. Recently, however, we observe a departure from this trend, with advocates of biogerontology seemingly appealing to arguments tailored to their opponents' normative theory. We have here examined one such argument, the 'double effect argument'. Although this argument deserves credit for breaking with a long-lasting tendency, it stands little chance of winning over its target audience, i.e. deontologists who consider the act of intervening in the aging process impermissible. Our analysis suggests that deontologists may plausibly deem such interventions impermissible under the DDE. While it is plausible that interventions in the aging process satisfy the second (the bad effect is unintended) and third (the bad effect is not a means to the good effect) conditions of the DDE, the first (the act is good or neutral) and fourth (the good effect outweighs the bad effect) conditions are problematic. Many deontologists may find the act of intervening in the aging process not neutral or good in itself. Some may condemn it outright on the grounds that aging is a normal process that should not be intervened in. Others may deem such acts morally good or neutral on condition that they constitute *natural* interventions in the aging process. In any case, deontologists could plausibly argue that neither unnatural nor natural interventions satisfy the proportionality condition as both types of intervention involve an unacceptable trade-off between saving the lives of some (patients who undergo the interventions) and letting others die (those who suffer the consequences of large scale interventions in the aging process). The assessment of the proportionality condition brings to light an important difference between the case discussed here and classical medical applications of the DDE. In these classical cases, the bad effect of the agent's act merely affects the patient (or the fetus, in cases where unborn life is at stake), never society at large. Therefore, the scale on which such 'classical' acts are executed does not impact upon the outcome of the proportionality assessment.

In this chapter, we have tried to 'reconstruct' the way in which deontological opponents of biogerontology may assess interventions in aging against the standard of the DDE. One might contest the soundness of our reconstruction, arguing that interventions in aging are permissible under the DDE. However, even if the latter could be convincingly argued, it may not further the cause much of those appealing to the 'double effect argument'. Presumably, the whole point of winning over deontological opponents consists in securing the much needed (public) funding for biogerontological research. Therefore, an argument is needed which provides these opponents with an incentive to act in a way which enables the development of interventions in aging. However, the

incentive provided by the DDE is not as strong as it could be, given that the DDE merely confers a permission to act, not an obligation.

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Part 2 Commodity scarcity in health care

Part 2, Section 1: coping mechanisms in the
context of commodity scarcity

Chapter 4

Age-based rationing of donor organs: a question of minimizing harm

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4.1 Introduction

As mentioned in the general introduction, the elderly represent the fastest growing group of patients on the kidney transplant waiting list. Where young and old compete for the same pool of organs, a steadily aging list implies that the young increasingly lose out in the competition for a donor kidney (Curtis 2006; Friedewald et al. 2013). This observation recently incentivized the United Network for Organ Sharing (UNOS), the US's organ exchange organization, to formulate a new kidney allocation policy which, on average, has the effect of prioritizing young transplant candidates (<50 years) over older (>50 years) patients (Tso 2014).³² This policy proposal, which was officially approved in June 2013, constitutes a significant departure from the previous algorithm which prioritized patients mainly on the basis of waiting time. The implementation of the new kidney allocation policy is scheduled to take place in several stages throughout the course of this year (OPTN 2013).

There is much controversy surrounding the new policy. A frequently cited concern is that age is a morally irrelevant criterion (Eidelson 2013). To our knowledge, UNOS policy makers have, so far, failed to address this criticism. In other words, they have not provided an account of the moral relevance of age in kidney allocation. This is disconcerting. The perception that the new kidney allocation policy is based upon an irrelevant criterion may, if widespread, damage public trust in organ exchange organizations. This, in turn, could have serious consequences, such as a decreased willingness to register as an organ donor. It is, therefore, important that the transplant community provide the public with a solid argument for the moral relevance of age. The fact that other countries, such as Australia, are already considering a policy change similar to the one recently approved by UNOS only adds urgency to this task (Pussell et al. 2012).

In this chapter, we develop an argument in support of the moral relevance of age. In doing so, we do not merely limit ourselves to the role of age in kidney allocation. We also provide a moral account of the relevance of age in the allocation of other organs. Our argument is founded in a concern for minimizing harm. It draws on the concept of harm as conceived by Joel Feinberg (1984). We conclude that the new UNOS policy, when assessed against this harm minimizing framework, is not far reaching enough. In addition to penalizing the elderly, a concern for minimizing harm also calls for deprioritizing pediatric patients.

³² We gave a more detailed explanation of the new UNOS kidney allocation policy in the general introduction of this dissertation (see section 0.3.1.2.1).

4.2 Harm as a setback to one's interests

In *Harm to Others* (1984), Feinberg states that one is harmed when one's interests are thwarted, set back, or defeated. In turn, one has an interest in something if one has a stake in its well-being. "In general, a person has a stake in X [...] when he stands to gain or lose depending on the nature or condition of X" (Feinberg 1984, 34). For example, if you own a share of a company's stock, you have a stake in its well-being in that the better off the company is financially, the better off you are financially. Feinberg summarizes his account of interests as follows:

One's interests, then, taken as a miscellaneous collection, consist of all those things in which one has a stake, whereas one's interest in the singular, one's personal interest or self-interest, consists in the harmonious advancement of all one's interests in the plural. These interests, or perhaps more accurately, the things these interests are *in*, are distinguishable components of a person's well-being: he flourishes or languishes as they flourish or languish. What promotes them is to his advantage or *in his interest*; what thwarts them is to his detriment or *against his interest*. (Feinberg 1984, 34)

Feinberg distinguishes two tests to determine whether or not harm has occurred. The 'worsening test' states that a person is harmed if, due to another's act, she is worse off than she was before the act. For example, a person is harmed in this sense if someone sets fire to her house. In order to include other cases of harm, not covered by this test, Feinberg added the 'counterfactual test'. The latter states that a person is harmed if, due to another's act, she is in a worse condition than she would have been in if the other had acted differently. Here, the reference point for deciding about harm is the state of affairs that would have obtained if the person had acted in accordance with a normative rule, rather than the actual state of affairs resulting from the person's act. Suppose you are at the top of a college admissions waiting list. A college place becomes available. A person lower down on the waiting list is given the place as a result of bribery. Your interests have not actually been set back in that you are still ranked first on the waiting list. However, the normative rule dictates that the order of the waiting list be respected when assigning college places. Thus, compared to the situation that would have obtained had the normative rule been respected, you have been harmed by the bribery.

In determining the interest at stake for patients awaiting an organ, we need to differentiate between organ transplants which are *immediately* lifesaving (e.g. liver, heart, and lung) and those which are *not immediately* lifesaving (e.g. kidney and

pancreas) (Desschans et al. 2008). Kidney transplants³³ represent the prototype of the latter category, given that pancreas-alone transplants are rarely performed. It is the availability of dialysis as an (albeit less effective) alternative to kidney transplantation which renders the latter ‘not immediately lifesaving’. In other words, patients on the kidney transplant waiting list are generally not at risk of *imminent* death. Thus, kidney transplantation is more a matter of improving the patient’s quality of life than ensuring her immediate, continued survival (Segev 2009).³⁴ However, in the case of liver, heart, and lung failure, there is no alternative to transplantation. Thus, transplantation of these organs is, although also a matter of improving quality of life, primarily a matter of ensuring immediate, continued survival.³⁵ In sum, the primary interest at stake for patients on the transplant waiting list is that in continued life and/or a reasonable quality of life.

We have an interest in continued life/reasonable quality of life because they enable us to (fully) pursue ‘life projects’. The latter include all those plans which people can reasonably be expected to pursue during a lifetime. Generally, for example, people wish to get an education, settle down with a partner, establish a career, a family, a social network, and so on. Given the link between the continuation of life/the attainment of a reasonable quality of life on the one hand and life projects on the other hand, we can redescribe the interest we have in the former in terms of an interest in life projects. Thus, the ultimate interest at stake for patients on the transplant waiting list is that in life projects.

We are not the first to identify a close relationship between the continuation of life/the attainment of a reasonable quality of life and life projects. The connection between both has, for example, already been acknowledged by Daniels (1985), in his analysis concerning the status of health care. According to Daniels, health care is a special social good as it protects an individual’s share of the normal opportunity range. He defines the normal opportunity range for a given society as “the array of life plans reasonable persons in it are likely to construct for themselves” (Daniels 1985, 33). Once we consider that health care services enable the continuation of life/the attainment of a reasonable quality of life, the similarity between our account and Daniels’ becomes evident. The

³³ Kidney transplants are lifesaving in the sense that they confer a survival advantage, relative to dialysis. However, they are not *immediately* lifesaving in that patients on the kidney transplant waiting list are generally not at risk of *imminent* death. Admittedly, there are certain exceptions to the latter observation – the so-called ‘high urgency’ status patients on the waiting list (Desschans et al. 2008).

³⁴ For this reason, we will refer to kidney transplantation throughout this chapter as a ‘non-lifesaving’ transplant. The latter term is shorthand for ‘not-immediately lifesaving’.

³⁵ For this reason, we will refer to liver, heart, and lung transplantation throughout this chapter as ‘lifesaving’ transplants.

interest in continued life is arguably the most fundamental human interest. The redescription of this interest in terms of an interest in life projects implies that the latter interest is equally important. One might argue that, in attributing such great importance to the interest in life projects, we are committed to too much of an instrumental view on life. Life, one might claim, ultimately revolves around the pursuit of happiness or self-realization, rather than the pursuit of life projects. Our view, however, does acknowledge the importance of the human interest in happiness and self-realization, albeit indirectly. The realization of life projects, after all, significantly contributes to a state of happiness and self-realization.

4.3 The interest in life projects: a further specification

Above, we have suggested that the interest in life projects is at stake for patients awaiting a transplant. In the following, we further specify this interest. First, we identify the various states in which a life project may find itself. Next, we attribute (a) specific interest(s) to each of these states.

At any moment in time, a life project finds itself in one of 3 states: it has either not yet been started, is ongoing, or has been accomplished. Most life projects do not pass through all of these stages. The beginnings of our social networks (in the form of the presence of our parents) and our education (i.e., learning how to crawl, walk, speak) are part of our lives from the very start. Thus, these life projects are never really in a state of being unstarted. In the same way, only certain life projects go through the last stage. One's education and one's career, for example, are such that they reach the stage of accomplishment at a definite moment in time. The attainment of this stage is marked, respectively, by one's graduation and one's retirement. However, other life projects appear to hover in a state of 'ongoingness' quasi indefinitely, lacking such a clear-cut ending. It is, for example, difficult to pinpoint the exact moment during one's lifetime, assuming such a moment exists, when life projects such as one's family and one's social networks come to an end.

Ongoing life projects and accomplished ones have a common characteristic in that both were started at a certain point in time. Henceforth, we use the umbrella term 'started life projects' to include life projects in either of these states, thereby reducing the 3 initially identified states of a life project to 2 main ones: unstarted and started life projects.

We can now further specify the interest one has in life projects. One may have one of two types of interests in a life project, depending on its current state (i.e. started or unstarted). In the next section, we discuss the interests one has in a started life project. Subsequently, we take a look at the interest one has in an unstarted life project. For both types of interest, we illustrate the changes they exhibit throughout a lifetime.

4.3.1 The interest in a started life project

If we are to define the interest one has in a started life project, we need to take a closer look at the value ascribed to the latter. A started life project has ‘final value’³⁶, i.e. it is valuable as an end, for its own sake. For example, part of the value attributed to the higher education one is currently enjoying (ongoing life project) or to one’s higher education diploma (accomplished life project) relates to the mere fact of enjoying and having enjoyed a higher education, respectively. However, a started life project also has instrumental value, i.e. it is valuable as a means to securing other valued goods. For example, social networks imply that we have people whose help we can count on when faced with certain problems. An education, while it is ongoing, provides one with the skills and knowledge necessary for pursuing a career. Once accomplished, the education allows one to put to use the acquired skills and knowledge so as to successfully perform one’s job. A career, in turn, enables one to provide for oneself and for one’s family.

The dual value of started life projects suggests that, for every started life project, one has two interests in it. First, one has an interest in being able to (continue) enjoy(ing) the life project for its own sake. Second, one has an interest in being able to (continue) us(e)(ing) the life project as a means to securing some other valued good. We shall use the terms ‘interest related to the final value of the life project’ and ‘interest related to the instrumental value of the life project’ to refer to the former and latter interest, respectively. For example, my education implies that I have an interest in being able to

³⁶ Christine Korsgaard (1983) draws attention to 2 distinctions in goodness. On the one hand, there is the distinction between final goods (things valued as ends, for their own sakes) versus instrumental goods (things valued as means, for the sake of something else). On the other hand, there is the distinction between intrinsically good things (things which have their value in themselves) versus extrinsically good things (things which derive their value from some other source). The former distinction refers to the way we value a thing, whereas the latter refers to the location or source of the goodness. Korsgaard argues that these 2 distinctions are often wrongly perceived as collapsing into one another. Generally, it is believed that something that is valued as an end must necessarily be intrinsically valuable. Korsgaard argues that this need not necessarily be the case, i.e. there are final values that are extrinsic. She gives the example of something that is good as an end because of the interest someone takes in it or the desire someone has for it. Other philosophers (e.g. Kagan 1998; Rabinowicz & Rønnow-Rasmussen 2000) have endorsed Korsgaard’s claim of there being final values that are extrinsic.

(continue) experienc(e)(ing) the satisfaction induced by the mere fact of enjoying (if my education is still ongoing)/having enjoyed (if my education is accomplished) an education.³⁷ In addition, I also have an interest in being able to (continue) acquir(e)(ing) the skills and knowledge necessary for a career/in being able to (continue) put(ting) to use the skills and knowledge acquired during my education.

How great a stake one has in started life projects depends on the number of interests one has. In turn, the number of interests one has obviously increases with the number of life projects one has initiated. The strength of one's interests, besides their number, also determines how great a stake one has in started life projects. Below, we look into the way in which both the number and strength of one's interests vary throughout a lifetime.

During the early stages of life one generally has only a few started life projects. Typically, children and adolescents have established a social network and are in the midst of their education. All of the other important life projects – settling down with a partner, establishing a career and a family – are generally only started at a later stage. In the past, the latter life projects were typically initiated around one's early 20s. Today, however, their initiation is most often postponed until one's late 20s.

In the period between one's late 20s and one's death, some started life projects might change 'shape' somewhat. For example, one's social network tends to shrink in size when one reaches a more advanced age. Nevertheless, even at an old age, one generally does have at least one person – whether it be a friend or nursing staff – constituting one's social network. Thus, social networks rarely, if ever, dissolve. The same holds for other started life projects. The only exception are partnerships, which obviously dissolve at the moment one's partner dies. In sum, from one's late 20s until one's death, the number of started life projects roughly remains constant and is at its highest. Consequently, one has the most interests at stake during this specific period.

Although one's interests remain constant in number from one's late 20s onwards, this does not hold true for their strength. Recall that for every started life project, there are two types of interest one has in it: an interest related to its final value and one related to its instrumental value. As we argue below, both types of interest diminish in strength after a certain age.

³⁷ Notice that we are here implicitly stating that the started life project of an education is something that is valued as an end and extrinsically good (it is good as an end because of the satisfaction one derives from it). Although the characterization of something as a final value that is extrinsically good might sound odd, it is nevertheless unproblematic (see previous footnote).

Consider a pensioner. Although her career has come to an end, she may still see it as having final value, insofar as she values the mere fact of having enjoyed a career. However, the final value attributed to the career is likely to be smaller than that attributed to it when it was still ongoing. The latter implies that the pensioner's interest related to the final value of her career is weaker than it was in the period preceding her retirement.

The pensioner's interest related to the instrumental value of certain started life projects is also diminished. Consider the pensioner's past career and education. Despite the latter being accomplished, certain instrumental usages of these life projects (i.e. certain possibilities for using these life projects as a means to some end) are still available to the pensioner. For example, she might still be able to pass on to others the skills and knowledge acquired during her education and career. However, other instrumental usages of these life projects are now ruled out, both in theory and in practice. For example, the pensioner's education no longer serves the purpose of securing a career, while her career no longer constitutes a means to ensuring her financial security. In sum, fewer instrumental usages of these life projects are available to the pensioner than was the case prior to her retirement. The latter implies that these life projects have less instrumental value than was previously the case. This, in turn, implies that the pensioner's interest related to the instrumental value of these life projects is weaker than it was in the period preceding her retirement.

The above suggests that there comes a moment in one's life (around retirement age) when the instrumental and/or final value of certain started life projects – one's education and career – become(s) weaker. Accordingly, one's interest related to the instrumental value of these life projects and/or one's interest related to their final value become(s) weaker. We will use the term 'strength level B' to refer to the diminished strength which the interest(s) in these life projects exhibit from retirement age onwards.³⁸ The term 'strength level A' will henceforth refer to the higher strength these interests have in the period preceding retirement age.

The above representation of variations in the number and strength of interests throughout a lifetime is a generic one in that it is applicable to the average person only. A specific individual might, contrary to the average person, not embark on all of the life projects mentioned here. Some people, for example, remain childless or single. Others initiate these life projects at an earlier or later age than the average one identified here.

³⁸ Note that the final and/or instrumental value of the other started life projects (one's family, social networks, and relationship with one's partner) is/are unlikely to diminish in strength after a certain age. Therefore, we assume here that a person's interests in the latter life projects retain the 'strength A' level throughout her entire life.

Still others might, contrary to the average person of their age, attribute no/little value to a certain life project so that they have no/little interest in it. However, we will ignore such deviations from the average in devising an allocation criterion aimed at minimizing harm. In sum, we will assume that everyone resembles the average person of their age (with regard to the number and strength of their interests). Any allocation scheme must do just that if it is not to collapse into a mere case-by-case analysis. The average person, then, has the greatest stake in started life projects in the period between her late 20s and mid 60s. It is then that one's interests in these life projects are the greatest in *both* number and strength.

4.3.2 The interest in an unstarted life project

Besides having interests corresponding to started life projects, one also has an interest in unstarted life projects. Take the case of a 10-year-old girl. Like her peers, she has only a few started life projects. Assuming she develops into an average person, she will want to initiate all of the so far unstarted life projects at some point in her future. Once she initiates these, she will develop all of the aforementioned corresponding interests in them. However, there is a possibility of the development and/or exercise of these interests being undermined in advance, before she reaches the age at which she would be in a position to initiate these life projects – the age at which the average person initiates these life projects. For example, the girl might have a form of cancer, the treatment of which could impair her future fertility. If nothing is done to preserve her fertility, she might never be able to start a family and develop the corresponding interests. Thus, she has an interest now in her gonadal tissue being harvested and stored as this safeguards the development and the subsequent exercise of these interests.

Alternatively, the girl might have a condition which hinders, not so much the initiation of a life project and the exercise of the corresponding interests, but their being exercised to a full extent. Suppose, for example, that she has a condition which, if left untreated, physically condemns her to a life of part-time work. Once started, the life project of a career entails an interest in being able to use one's job as a source of income. Compared to an average person who is able to work full-time, she will have fewer means available to provide for herself and her family. Therefore, the girl now has an interest in seeking treatment as this will enable her to exercise the relevant interest more fully.

In sum, as long as one has unstarted life projects, there are 'future interests' at stake – those interests which one ordinarily develops once these life projects are initiated. Thus, for every life project so far unstarted, one has an interest in safeguarding the development and full exercise of these 'future interests'. Henceforth, we use the term 'interest in unstarted life project' to refer to the latter type of interest.

In recognizing that people have an interest in unstarted life projects, we have followed a line of reasoning which is commonly adopted in the discussion of children's rights. Feinberg (1992) distinguishes a group of rights called 'rights in trust'. These are rights which a child cannot yet exercise, but which ought to be protected or 'saved' so that the child can exercise that right once she reaches adulthood. Feinberg points to the possibility of adults violating these rights in advance, before the child is even in a position to exercise these rights. According to Davis (1997), the right to reproduce is an example of such a 'right in trust':

A young child cannot physically exercise that right, and a teenager might lack the legal and moral grounds on which to assert such a right. But clearly the child, when he or she attains adulthood, will have that right, and therefore the child now has the right not to be sterilized, so that the child may exercise that right in the future. Rights in this category include a long list: virtually all the important rights we believe adults have, but which must be protected now to be exercised later. (Davis 1997, 9)

As is the case for one's interests in started life projects, so do one's interests in unstarted life projects also vary in strength throughout a lifetime. The closer one is to the age at which people, on average, initiate the life project, the stronger one's interest in the unstarted life project. The phenomenon of time preference – the preference for immediate utility over delayed utility – accounts for this relationship between the strength of this interest and the proximity to the initiation of a life project.³⁹ Consider a 10-year-old and a 20-year old. The latter is closer to initiating certain life projects and, thus, to enjoying the associated utility. Consequently, the 20-year-old has a stronger

³⁹ Jeff McMahan (2002) has also acknowledged the existence of this relationship, albeit without referring to life projects. According to McMahan, an interest becomes stronger the closer one is in time to the interest being satisfied. However, rather than relying on time preference, he relies on the concept of 'psychological continuity' when accounting for this relationship. The latter concept refers to those psychological connections that link ourselves over time. The psychological connections that link an individual at, for example, the current point in time and some future point can take on varying strengths. For example, a very young child has negligible levels of psychological continuity with her future self at age 40, whereas a 35-year-old has strong continuity with herself as a 40-year-old. According to McMahan, the stronger the level of psychological continuity is between an individual now – and her current interest in a certain good – and the time when her interest in this good is satisfied, the stronger the individual's interest in this good. Translated into the terminology of life projects, the latter amounts to the following: the stronger the level of psychological continuity between an individual now – and her interest in a certain unstarted life project – and the time when the relevant life project can be initiated, the stronger the individual's interest in this unstarted life project.

preference for being able to initiate these life projects. Assuming a direct link between the strength of one's preference for and the strength of one's interest in something, the 20-year-old, then, also has a stronger interest in these unstarted life projects.

4.4 How being denied a transplant impacts upon one's interests in life projects

In the above, we have merely claimed that the harm involved in being denied a transplant is that of a setback to the interests corresponding to life projects. We have not yet *demonstrated* that these interests are indeed set back so that one is, thus, actually harmed in terms of one's life projects. If we are to establish this, we need to show that, when denied a transplant, people's interests in life projects either fare worse than before or fare worse than they would have done in the event of transplantation. In sum, we need to show that the conditions of either the 'worsening test' or the 'counterfactual test' are met. In the following, we demonstrate that the harm incurred when denied a transplant is that of a) a setback to the interests in started life projects and/or b) a setback to the interest in unstarted life projects.

We argue that both types of setback are a case of being made worse off than before in the event of lifesaving transplants, whereas they generally constitute counterfactual harm in non-lifesaving transplants. For each type of harm, we identify the group of people for whom the setback is the greatest.

4.4.1 Setback to the interests corresponding to started life projects

4.4.1.1 Is the setback a case of actual harm or counterfactual harm?

In practice, if a waitlisted patient is denied a specific *lifesaving* organ, there is uncertainty as to whether or not she will survive. Her survival is dependent on various factors, such as the urgency of her condition and how soon, if ever, another suitable organ becomes available. However, if in devising allocation criteria, we assume such uncertainty, we have nothing to go by. It is impossible to pass judgment in terms of harm, not knowing whether or not a patient will die if denied a certain organ. Thus, we

here assume a situation of true scarcity⁴⁰: once a person is denied a lifesaving organ, no other organ will come along. Feinberg's conditions for the 'worsening test' are, then, clearly met when a person is not given a lifesaving organ. Death sets back, once and for all, all interests a person had in started life projects.⁴¹

In the case of *non-lifesaving transplants*, we assume, once again, a situation of true scarcity so that a person denied a kidney is condemned to dialysis for an indefinite length of time. Whether or not the conditions of the 'worsening test' are met in this case, depends on whether or not the waitlisted patient is on dialysis. If she is (which is the case for most waitlisted patients), she does not actually become worse off when denied a kidney. Thus, we need to determine whether this case passes the 'counterfactual test'. Do the interests corresponding to one's started life projects fare worse when remaining on dialysis, compared to the situation which obtains after receiving a kidney? The many restrictions imposed by dialysis suggest that a kidney transplant allows one to exercise these interests more fully.

Dialysis imposes irregular school attendance on children, thereby impeding the acquisition of the skills and knowledge required later on in life (Samhan et al. 2007). Adults on dialysis are unable to continue working full-time or even at all (Wadd et al. 2011). As a result, they are hindered in applying their skills and knowledge to the everyday challenges faced in the workplace. In addition, they have to make do with fewer means of providing for themselves and for their families. Dialysis also impacts on family life. When on dialysis, a parent's role in the family shifts from one of independence to one of dependence, prohibiting the full exercise of her role as a caretaker (White & Grenyer 1999). Furthermore, dialysis alters the dynamics of the relationship with one's partner. Many couples' sex lives become compromised, given the high prevalence of sexual dysfunctions among dialyzed patients (Leão et al. 2010).

⁴⁰ The term 'true scarcity' is taken from Kamm's work (1993).

⁴¹ One might, along the lines of Epicurus, object that the view of death being a harm for the person who dies is untenable. The main difficulty with this view, according to Epicurus, is that the evil of death seems to lack a subject: death cannot harm one while one is still alive and neither can it harm one once one dies as one, then, no longer exists. In sum, if anything is to be bad for a person, it must be bad for that person at a certain time, yet there is no time at which death is bad for the one who dies. Feinberg (1984), however, has convincingly argued that death does, in fact, constitute a harm for the person who dies. He summarizes his argument as follows: "Death can be a harm to the person who dies in virtue of the interests he had antemortem that are totally and irrevocably defeated by his death. The subject of the harm in death is the living person antemortem, whose interests are squelched. The fact of a person's death "makes it true" that some of his antemortem interests were going to be defeated and to that extent the antemortem person was harmed too, though his impending death was still unknown to him" (Feinberg 1984, 93). Most scholars today share Feinberg's view that death constitutes a harm for the person who dies.

Finally, the physical limitations imposed by dialysis bring about a decrease in social life (White & Grenyer 1999).

4.4.1.2 Who suffers the greatest setback to their interests in started life projects?

Above we have argued that, regardless of which life projects one has started, one's interests in these started life projects are set back when one is denied a transplant. Everyone is, thus, harmed in this respect when denied a transplant. However, the magnitude of this harm (i.e. of the setback to one's interests in started life projects) is not distributed equally across the population.

Suppose we devise a scoring system for measuring the magnitude of the setback incurred to one's interests in started life projects. As we have already seen, how great a stake one has in started life projects depends on both the number and strength level of one's interests in these projects. Therefore, a person's score is greater (1) the greater the number of interests she has in started life projects and (2) the greater the strength level of these interests. We use the terms 'numerical factor' and 'strength factor' in order to refer to the first and second factor, respectively.

Besides these factors, there is yet another factor which is determinative of one's score. As noted earlier, one's interests in certain started life projects diminish in strength level around retirement age. The latter suggests that people will differ with regard to the number of years they have ahead of them during which their interests can be sustained at the highest strength level – strength level A. The greater the number of years during which each of one's interests can be sustained at strength level A in the event of transplantation, the greater the setback incurred when denied a transplant (and, thus, the higher one's score). We use the term 'duration factor' to refer to this third factor.

If we are to determine the group of people which suffers the greatest setback to interests in started life projects, we must identify who scores highest on the product of these 3 factors. We do so below, using a 2-step method. First, we identify the group of people which scores highest on the product of the 'numerical' and the 'strength' factor. Next, we determine who scores highest on the third factor, the 'duration factor'.

As noted earlier, one's interests in started life projects are the greatest both in number and strength (strength level A) from one's late 20s until one's mid 60s. Thus, waitlisted

patients in this age category score highest on the product of the ‘numerical’ and the ‘strength factor’.⁴² Those who have not yet reached their late 20s, score significantly lower than the former age category given that they have fewer started life projects and, thus, fewer interests at stake (i.e. they score lower on the ‘numerical’ factor). Those beyond their mid 60s, on the other hand, score significantly lower, not because they have fewer interests at stake, but because their interests in certain started life projects are of a diminished strength (strength level B) – i.e. they score lower on the ‘strength’ factor.

If we are to determine how the different age categories score on the ‘duration’ factor, we need to know how long a transplanted organ lasts. The term ‘graft half-life’ indicates the median lifespan of a graft, i.e. the number of years after which 50% of the grafts in a cohort fail (Ouellette et al. 2009). Deceased donor kidney transplants have a graft half-life of 8.8 years (Lamb et al. 2011). Out of all the lifesaving organs, the liver’s half-life (8.5 years) comes closest to that of the kidney.⁴³ Therefore, we limit ourselves to these 2 organs in discussing the implications of a harm minimizing framework for the allocation of both non-lifesaving and lifesaving transplants.

As mentioned before, the strength of some interests in started life projects diminishes to level B around one’s mid 60s. Thus, assuming a median graft lifespan of 10 years⁴⁴, all waitlisted patients up until their mid 50s would have all of their interests in started life projects sustained at a strength of level A throughout the whole duration of the graft. Patients between their late 50s and mid 60s score less well on this ‘duration’ factor. Only some of their interests – those that remain at the highest strength level throughout one’s whole life – would be sustained at strength level A throughout the whole lifespan of the graft. Their other interests – those of which the strength diminishes to level B around retirement age – would be sustained at level A for fewer than 10 years. The

⁴² One might object that while the average person’s interests in started life projects are of strength level A from her late 20s until her mid 60s, this does not hold true for the interests of people in this age range awaiting transplantation. Specifically, one might argue that, like pensioners, these people’s interests are of strength level B, given that certain instrumental usages of started life projects are ruled out for them. For example, the application of one’s skills and knowledge to the everyday challenges of the workplace is ruled out for waitlisted patients who are unable to work. However, this instrumental usage of the person’s career would become possible again once the person has undergone a transplant. In other words, for waitlisted patients between their late 20s and mid 60s, any instrumental usages of their life projects that are ruled out, are so only in practice, not in theory. For pensioners, on the other hand, any instrumental usages that are ruled out are so both in theory and in practice. This difference between waitlisted patients of the specified age category and pensioners entails that the interests of the former are of strength level A, whereas the interests of the latter are of strength level B.

⁴³ Lungs, hearts, intestines, and pancreases have a graft half-life of 5.2, 11, 3.6, and 16.7 years, respectively (see Lodhi et al. 2011).

⁴⁴ For the sake of convenience, the graft half-lives of kidneys and livers are rounded off upwards here.

precise duration for which the latter are sustained at strength level A obviously depends on how far the person is removed from her mid 60s. Finally, waitlisted patients beyond their mid 60s obtain the poorest score, given that some of their interests have already reached strength level B. This contrasts with the previously mentioned age categories, for which all interests can be sustained at level A for at least a certain period of time. It is between one's late 20s and mid 50s that 1) one has the greatest number of interests of strength level A *and* 2) that, if given a transplant, all of these interests would be sustained at this level throughout the whole duration of the graft. Thus, it is this age category for whom the setback to interests in started life projects is the greatest.⁴⁵

4.4.2 Setback to the interests corresponding to unstarted life projects

4.4.2.1 Is the setback a case of actual harm or counterfactual harm?

Just as it defeats one's interests in started life projects, so is death also the ultimate setback to one's interest in an unstarted life project. Thus, anyone who has unstarted life projects is made worse off than before when denied a *lifesaving transplant*. We assume here that a life project is unstarted for a person as long as she has not yet reached the age at which the specific project is, on average, initiated.

One's interest in an unstarted life project is also set back when denied a *non-lifesaving transplant*. Recall that, in general, there are two ways in which the interest in an unstarted life project might be set back. First, one may, now already – i.e., before having reached the age at which people usually start the life project – be hindered in the future initiation of the life project. In sum, one may be hindered in developing those interests people usually acquire once they have initiated the relevant life project. Second, one

⁴⁵ Our analysis is based on the concept of graft half-life, a concept which does not reflect the effects of certain demographic characteristics on graft survival rates. UNOS data which take into account these effects, suggest that children up until the age of 11 have higher long-term kidney and liver graft survival rates, relative to other age categories (http://optn.transplant.hrsa.gov/ar2009/508a_agecat_ki.htm and http://optn.transplant.hrsa.gov/ar2009/908a_agecat_li.htm). Thus, on the basis of these data, children up until the age of 11, rather than merely everyone up until their mid 50s, would score highest on the duration factor. However, we would like to emphasize that these children have only slightly better long-term graft survival rates, relative to other age categories. The latter implies that the advantage they enjoy with regard to this duration factor is not big enough to compensate for their disadvantaged position regarding the numerical factor (i.e. the fact that they have very few started life projects and, thus, very few interests). In sum, even if we took into account the (slightly) better graft survival rates for children up until the age of 11, this would not affect the final outcome of our analysis in that the late 20s-mid 50s age category would still suffer the greatest setback to their interests.

may, now already, be hindered, not so much in developing, but in fully exercising these interests in the future. We argue below that, when denied a kidney transplant, one's interest in the unstarted life project of a family is set back in the first way, whereas one's interest in other unstarted life projects is set back in the second way. In either way, the setback is a case of counterfactual harm - of one's interest faring worse under continued dialysis than it would have fared in the event of a kidney transplant.

Take the case of a waitlisted person who has not yet reached the age at which one usually starts a family. Assuming she meets our definition of the average person, she will want to start a family once she reaches that age. However, given our assumption of true scarcity, the person will most likely be unable to do so if denied a kidney transplant. Both men and women with chronic kidney disease suffer from impaired reproductive function (Watnick & Rueda 2008). Transplantation can restore fertility in both men and women and thereby protects one's interest in the unstarted life project of a family.⁴⁶

Note that *everyone* who has not yet started a family has their interest in this unstarted life project protected through transplantation. Thus, this interest is not only protected for those who would be in a position to start a family at some point within the (10-year) lifespan of the transplanted graft. In other words, it is not only those in their late teens for whom the interest in the unstarted life project of a family is protected through transplantation. The broadness of the term 'safeguard' accounts for this finding. Recall that we specified one's interest in an unstarted life project as an interest in safeguarding the development and full exercise of future interests - those interests one acquires once the relevant life project is initiated. There are varying degrees in which the development of these future interests - i.e. the initiation of the life project - can be safeguarded. In its strongest sense, the term 'safeguard' implies that a person is guaranteed to be able to initiate the life project. Those who are in a position to start a family within the (10-year) lifespan of the transplanted graft, have their interest in the

⁴⁶ One might object that the prospect of starting a family need not be ruled out when condemned to lifelong dialysis, given the availability of 'backup options' such as adoption and assisted reproductive technology (ART). However, pregnancy is not recommended for dialysed women, due to the risks involved for both mother and child (Hladunewich et al. 2011). Although ART is a theoretical option for dialysed men, it might not be a practically viable one. The conditions faced by dialysed patients (fatigue, physical limitations, limited or no employment prospects, etc.) are not exactly conducive to child-rearing. Thus, chances are that these limitations would deter male patients from turning to ART. For the same reason, dialysis patients would likely be reluctant to pursue adoption. However, even if they were not, they are unlikely to be found fit to adopt due to their decreased life expectancy (Moncrief 1982).

unstarted life project of a family protected in this sense. In a weaker sense, the term 'safeguard' implies that, the possibility of starting a family at some point in the future is merely left untouched. Those who have not yet reached their late teens have their interest in the unstarted life project of a family protected in this weaker sense. For these people, a transplant merely ensures that the possibility of starting a family is not ruled out outright. It does not guarantee that they will actually be able to start a family at some point in the future. Whether or not they will actually be able to start a family, depends on whether or not they will receive (a) retransplant(s) once their initial graft fails.

We now take a look at the way in which one's interest in the other unstarted life projects is set back when denied a kidney. Earlier on, we discussed how dialysis prohibits the full exercise of the interests one has in these other life projects *once they have been initiated*. For example, dialysis impedes a healthy sex-life as well as the full application of one's skills and knowledge in the workplace. Consider a waitlisted person who has not yet reached her late 20s, i.e. who has not yet settled down with a partner, initiated a career or a family. If she is denied a kidney transplant, the prospect of fully applying her skills in the workplace is already ruled out *in advance*, before she has even had the chance to initiate a career. In the same way, the prospect of a healthy sex-life is also precluded. The prospect of being unable to fully exercise these 'future interests' amounts to a setback to the interest in her unstarted life projects⁴⁷ of a career and a stable relationship.⁴⁸

4.4.2.2 Who suffers the greatest setback to their interests in unstarted life projects?

The magnitude of the setback to one's interests in unstarted life projects is greater, (1) the greater the number of interests one has at stake in unstarted life projects and (2) the greater the strength of these interests. Below, we identify the group of people for whom the product of these two factors is the highest.

Given that one's education and social networks are built up from the very beginning of life, the only life projects that are ever unstarted include one's career, family, and a stable relationship. The latter projects are all initiated at approximately the same stage

⁴⁷ Obviously, the person's interest in the unstarted life project of a family is also set back, in the manner previously discussed.

⁴⁸ Once again, this setback is not only endured by those who, if they received a transplant, would be in a position to start a career and a stable relationship at some point within the (10-year) lifespan of the graft. For the same reason as mentioned before, *everyone* who has not yet initiated a career and a stable relationship has their interest in these unstarted life projects protected through transplantation.

in one's life – one's late 20s. Thus, all those with unstarted life projects, have the same number of unstarted life projects and, thus, the same number of corresponding interests at stake. However, as mentioned before, time preference suggests that the strength of their interests will differ depending on how close they are to initiating these life projects. Consequently, those approaching their late 20s will suffer the greatest setback to their interests in unstarted life projects.

4.5 Minimizing harm: practical implications for organ allocation

Age is a morally relevant factor in that it serves as a proxy for the magnitude of the setback incurred to the interests in unstarted/started life projects when denied an organ transplant. Therefore, we suggest introducing 'age' as a criterion alongside the existing allocation criteria. Current allocation criteria vary depending on the type of organ. The allocation of donor kidneys, for example, proceeds on the basis of the following factors within Eurotransplant: waiting time (i.e. time on dialysis), distance between donor/transplantation center, balance between import/export of the participating countries, HLA typing, and mismatch probability (Persijn 2006). For each of these factors, there is a scoring system in place. When a donor kidney becomes available, transplant candidates are rank ordered based on their total number of points. Thus, if we are to introduce age as an additional allocation criterion, we need to devise a scoring system for this item. We limit ourselves below to presenting the basic outline of such a scoring system.

Those at the very beginning of life receive very few points for the criterion 'age', given the small amount of started life projects and the weak interest in their unstarted life projects. As one's interests in unstarted life projects grow stronger throughout the years, one's points gradually increase. One's score reaches its peak around one's mid/late 20s, when one's interest in one's unstarted life projects are highest in strength due to the fact that one is very close to initiating these projects. From that moment onwards, one's score plateaus out until one's mid 50s. The period across which this plateau stretches itself (mid/late 20s – mid 50s) represents the age category which has most at stake, in terms of the interests in unstarted and/or started life projects. After one's mid 50s, one's score drops, reflecting the fact that one's interests in started life projects can no longer all be sustained at strength level A throughout the whole lifespan of the transplanted graft. As one has fewer interests of strength level A in started life projects after one's mid 60s, one's score decreases further from this point onwards.

There are two remarks we would like to make with regard to our scoring system. A first remark concerns the series of rather specific cut-off points (mid 20s, mid 50s, etc.) introduced here. We urge readers not to take the specified boundaries too literally. These cut-off points are culturally specific and may change in the long run.

A second remark concerns our reliance on age as a proxy for harm as opposed to assessing harm on a case-by-case basis. The fact that age functions as a *proxy* for harm implies that a person's age is a reliable predictor of the magnitude of harm suffered insofar as we assume that this person resembles the 'average' individual of her age. One might argue that the use of age as a proxy for harm is unfair to those who represent a deviation from the 'average'. Consider a rather extreme case: a 40-year-old person who is adamant about remaining unemployed, single and childless. She, therefore, has no interest in being able to settle down with a partner, establish a career or a family. Now consider a 20-year-old with a thriving career, a partner, and children. Both are in need of a transplant. Our proposal dictates giving the 40-year-old a higher score on the 'age' criterion, despite the 20-year-old actually having more interests at stake. In sum, assuming all other things are equal, our proposal commands the prioritization of the 40-year-old, despite her suffering less harm. Thus, one might argue that we ought to modify our proposal so as to assess harm on a case-by-case basis, rather than use age as a proxy for the harm incurred. However, such a modification would come at too high a price, for two reasons. First, if our proposal were to be implemented in a case-by-case fashion, one would consistently disadvantage those who are (likely) unable to start certain life projects, such as the (mentally) handicapped and the infertile. Second, there would be various practical obstacles to implementing the aforementioned modification. If we were to assess harm on a case-by-case basis, we would need to determine the number of started/unstarted life projects an individual has. The process involved in obtaining this information would likely be intrusive and highly bureaucratic. For these reasons, we do not support the assessment of harm on a case-by-case basis.

4.6 Concluding remarks

The aging of the transplant waiting list pushes the question concerning the morality of age-based rationing to the forefront. We have put forward a novel (utilitarian) argument for the moral relevance of age, one situated in a harm-minimizing framework. Our argument supports the prioritization of those (roughly) between their mid/late 20s and mid 50s. From the perspective of this framework, the new UNOS policy is sufficiently restrictive at the end of life, i.e. it rightly deprioritizes the elderly and middle aged (>50 years of age). However, it is insufficiently restrictive at the other end

of the spectrum, i.e. it ought to also deprioritize pediatric patients and those in their early 20s.

Admittedly, the account we have put forward in this chapter has its limitations. We have not analyzed whether the numerous arguments⁴⁹ contra age-based rationing are valid. Strictly speaking, these arguments must be proven invalid in order for our account to be *truly* convincing. Although an assessment of such arguments lies beyond the scope of this dissertation, our account nevertheless represents an important first step towards filling the argumentative void left by UNOS officials.

Our account is undoubtedly controversial. This especially holds true for its claim that pediatric patients should also be deprioritized in kidney allocation. This aspect of our account, therefore, warrants further consideration. We take on this task in the next chapter.

⁴⁹ For an overview of these arguments, see sections 0.3.1.2.2 and 1.3 of this dissertation.

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Chapter 5

Pediatric priority in kidney allocation: challenging its acceptability

Based on accepted, forthcoming journal article:

Capitaine, L., Van Assche, K., Pennings, G. and Steckx, S. (2014) “Pediatric priority in kidney allocation: challenging its acceptability”. *Transplant International* (forthcoming).

5.1 Introduction

In the previous chapter, we established that, from a harm minimizing perspective, there are reasons to grant pediatric patients lower priority in the allocation of kidneys, relative to those in the +/-25 to +/-55 age group. This argument, however, goes against current practice. Various organ sharing organizations have kidney allocation policies in place which accord pediatric patients (some) priority. Within Eurotransplant, pediatric priority consists in the attribution of bonus points. For example, relative to adults, pediatric patients' points for HLA antigen mismatches are doubled. In addition, children also receive bonus points for waiting time (Eurotransplant 2013). Within the United Network for Organ Sharing (UNOS), kidneys from donors less than 35 years old – i.e. the 'qualitatively better organs' – are offered preferentially to pediatric patients (Smith et al. 2012).^{50,51} This policy is referred to as 'Share 35'. It was instituted in 2005, after the observed failure of a previously implemented, 'milder' pediatric priority policy (Gritsch et al. 2008). Along the same lines as UNOS, Scandiatransplant prioritizes pediatric recipients when a suitable HLA matched kidney is available from a donor less than 40 years old (Grunnet et al. 2005). Other organ sharing organizations which accord priority to children include France Transplant and the NHS Blood and Transplant (NHSBT) (Hoyer 2008; Johnson et al. 2010).

Official policy documents offer no arguments in support of pediatric priority. However, such arguments can be found dispersed across the academic literature on pediatric renal transplantation. If valid, these arguments would substantially weaken our claim that pediatric patients ought to receive lower priority than certain other age groups in kidney allocation. It is, therefore, crucial that we examine their soundness. This chapter brings together and critically analyzes these arguments for the first time. We show that none of these succeed in justifying pediatric prioritization. In addition, we point to some inadvertent consequences of this practice. We argue that these effects may further undermine the legitimacy of pediatric priority policies.

⁵⁰ Note that the pediatric priority accorded by UNOS comes with a qualification. If a highly sensitized adult or an adult with no HLA mismatches is waitlisted, she receives priority for kidneys from donors less than 35 years of age (Pape & Ehrich 2008).

⁵¹ Share 35 will soon undergo a slight change. Rather than receiving priority for kidneys from donors aged <35 years, children will be prioritized for kidneys from donors with a KDPI (kidney donor profile index) score <35%. This change was recommended by the OPTN Pediatric Committee after simulation modeling forecasted that it would not alter the level of access of pediatric candidates. It is estimated that the new pediatric kidney allocation policy will be implemented by the end of 2014 (personal communication with Gena Boyle, liaison to the Kidney Transplantation Committee at UNOS).

5.2 Critical analysis of arguments for pediatric priority

In analyzing the arguments put forward in support of pediatric priority, we make two distinctions. A first distinction is that between arguments grounded in the principle of utility and those based on the principle of equity. A second distinction pertains to the type of pediatric priority which the arguments aim to justify. Some arguments are put forward in support of Share 35-like policies, where children are prioritized for the ‘qualitatively better organs’. Other arguments merely justify Eurotransplant-like policies, where priority is granted to pediatric patients, irrespective of the quality of the organ.

5.2.1 Utility-based arguments

The growth and development argument

The most common utility-based argument in support of pediatric priority points to various complications of end-stage renal disease (ESRD) that are unique to the pediatric population. To begin with, the demands of ongoing treatment, combined with fatigue and unexpected medical problems (e.g. infection) severely limit children’s school attendance (Tong et al. 2013). In addition, children with ESRD have great difficulty attaining normal adult height. According to an analysis of the North American Pediatric Renal Transplant Cooperative Studies, 47% of children on dialysis exhibit severe short stature (Seikaly et al. 2006). Finally, children with ESRD are also at risk of neurodevelopmental delays and deficits. Compared to the general population, children with ESRD have lower IQ levels and academic achievement. Furthermore, they score lower on tests assessing functioning in specific cognitive domains such as language, visuo-spatial perception, attention, memory, and executive function (Icard et al. 2010). Growth failure and neurodevelopmental delay are aggravated by increased duration of renal insufficiency (Hoyer 2008). Moreover, while both types of deficits may somewhat improve following renal transplantation, the latter does not appear to normalize statural growth and developmental status (Icard et al. 2010; Nissel et al. 2004).⁵² It is

⁵² Although transplantation, *in itself*, does not usually result in normal adult height, the latter can sometimes be achieved through additional measures. For example, steroid withdrawal has been associated with attainment of adult height within the normal range (see, for example, Klare et al. 2012). Nevertheless, it remains important to prevent growth retardation in the pre-transplant period. After all, a lower degree of stunting at the time of kidney transplantation increases the chance of attaining normal adult height under steroid avoidance protocols.

argued that expedited transplantation, in preventing the aforementioned complications from taking on a full-blown form, minimizes their adverse impact on quality of life (QoL). Children are also expected to derive additional QoL benefits from early transplantation through the restored ability for regular school attendance (Pape & Ehrich 2008). In short, this argument supports prioritization of pediatric patients on the basis that they stand to gain considerable QoL from timely transplantation (Pape & Ehrich 2008; Bratton et al. 2006).

The abovementioned argument, which we shall label the ‘growth and development argument’, presupposes that the deficits in growth and development take on a substantial magnitude in the absence of expedited transplantation. There is relatively strong evidence in support of major disruptions in growth after long-term dialysis (Gorman et al. 2008). However, in the case of neurodevelopmental problems, the quality of the evidence is low to moderate. For example, across the various studies pointing towards significant developmental deficits in the absence of pediatric prioritization, there is no uniform assessment of neurocognitive functioning. Cross-study comparison is further hampered by the fact that, in the majority of studies, the samples are of mixed age, mixed gender, and mixed severity of kidney failure (Gerson et al. 2006). In addition, most of the studies are cross-sectional and use only a small sample size. However, in pediatric research, it is difficult to overcome such problems.⁵³ Despite the limitations of the evidence, *the large number* of studies pointing towards important developmental deficits in the presence of long-term dialysis suggests that it is reasonable to assume that delayed transplantation significantly affects (neuro)cognitive development.

Another presupposition of the growth and development argument is that the various deficits encountered by children on dialysis significantly affect QoL. However, contrary to widespread belief, severe short stature does not impair QoL (see, for example, Downie et al. 1997; Kranzler et al. 2000). The same applies to deficits in (neuro)cognitive development. The reasoning underlying the presumed link between the latter type of deficit and impaired QoL is that (neuro)cognitive delays lead to a lower education level, thereby thwarting job opportunities. The high level of unemployment, in turn, is said to adversely affect QoL (Haavisto et al. 2012). However, follow-up studies of children

⁵³ There are several reasons why these limitations are difficult to overcome in pediatric research. First, various diseases, including ESRD, affect only a small number of children. Second, investigators are often reluctant to enroll children in randomized clinical trials. Third, in the absence of such reluctance, investigators face the challenging task of obtaining agreement for enrollment from both the child and the guardian. Finally, study instruments, including those to measure cognition, must be tailored to specific pediatric age groups.

transplanted prior to the introduction of a (full-blown) pediatric priority point towards an employment level similar to that of the general population, despite a lower education level (see, for example, Broyer et al. 2004; Offner et al. 1999). One might argue that a lower education level adversely affects QoL via a route other than that of (un)employment. However, the available studies suggest that there is no correlation between education level and QoL (see, for example, Veenhoven 2008).

Contrary to growth/developmental deficits, the limitations imposed by ESRD on everyday school life significantly affect children's QoL. When confronted with their lack of freedom to engage in school activities, pediatric patients receiving in-center hemodialysis reported an array of negative feelings. The latter ranged from a sense of failure to meet expectations to a feeling of being 'trapped' and 'stuck'. Anger and frustration were the most commonly described experiences (Tong et al. 2013).

Besides the mere constraints it imposes on full-time education, dialysis exerts yet another negative effect on children's school experiences. A recurrent theme in interviews with ESRD-children is the inability to focus on homework in the overbusy hospital environment (Tong et al. 2013). Strongly related to this is the commonly cited struggle to perform well academically. These difficulties elicit feelings of inferiority, incompetence, depression, and school phobia.

The inability to engage in certain extracurricular activities, such as contact sports and swimming, further compounds children's negative school experience. Generally, children cite a sense of abnormality and a failure to fit in as a result of these social restrictions (Tjaden et al. 2012).

As deficits in growth and development do not impact upon QoL, proponents of the growth and development argument overestimate the impact of delayed transplantation on children. Nevertheless, pediatric patients still stand to gain considerable QoL benefits from expedited transplantation, as illustrated by their adverse experience of school and extracurricular activities. However, the growth and development argument seems to ignore that the adult population also faces unique complications which are reversed or significantly improved following transplantation (Pourmand et al. 2007; Filocamo et al. 2009; Richman & Gohh 2012; Eng et al. 2012). For example, adults with ESRD experience sexual dysfunctions (Leão et al. 2010), infertility (McKay & Josephson 2006) and high levels of unemployment (Matas et al. 1996). Below, we show that each of these problems is both highly prevalent and substantially damaging to QoL.

Erectile dysfunction affects approximately 82% of patients on hemodialysis (Pourmand et al. 2007). Over 50% of women on chronic dialysis report decreased libido and reduced ability to reach orgasm (Basok et al. 2009). Unsurprisingly, these sexual dysfunctions result in a marked decrease in the frequency of intercourse. In 33% of patients on hemodialysis, there is no sexual activity at all (Rathi & Ramachandran 2012). Sexual

dysfunction elicits anxiety, psychological depression, marital problems and loss of self-esteem, all of which severely impair QoL (Moriyama 2011).

The unemployment rate among long-term dialysis patients varies from 70% to 90% (Helanterä et al. 2012). The regained ability for (full-time) employment post-transplantation is a clinically relevant index of improved QoL (Russell et al. 1992). Depression, which affects over 60% of adult hemodialysis patients, is strongly correlated with unemployment (Panagopoulou et al. 2009).

Both men and women with end-stage renal disease suffer from impaired reproductive function (Watnick & Rueda 2008). Over 50% of men on hemodialysis encounter impotence, due to spermatogenic abnormalities and impaired testosterone production (Zeyneloglu et al. 2005). Women exhibit disturbances in menstruation and fertility, generally resulting in amenorrhea and anovulation (Bahadi et al. 2010). Early menopause has also been reported. Moreover, pregnancy is contraindicated for the very few fertile women on dialysis, given the risks involved for both mother and child (Hladunewich et al. 2011). Infertility is associated with grief and depression, a sense of worthlessness, inadequacy, isolation, and feelings of anger and resentment (Greil et al. 2009).

Evidently, prioritization of one group over another, on the basis of QoL considerations, is only warranted if transplantation provides the former with a *greater gain* in QoL. Can we conclude that children stand to gain more QoL from transplantation than adults (or vice versa)? The above discussion suggests that, in terms of QoL, both children and adults stand to gain substantially from transplantation. Of course, from this, it does not necessarily follow that children and adults stand to gain equally. However, whereas one group *may* stand to gain (significantly) more QoL, the current evidence does not allow one to determine whether this is, *in fact*, the case. In the absence of evidence pointing either way, it seems unjustifiable to side with either children or adults. Thus, in choosing the side of pediatric patients, proponents of the growth and development argument shoulder themselves with the burden of proof. In other words, they will have to gather evidence substantiating the claim that children stand to gain more QoL, relative to adults. This may prove to be a challenging task. Although further confirmation is required, preliminary studies suggest that an earlier onset of ESRD is associated with better coping mechanisms (Tong et al. 2013).

The life expectancy argument

Another utility-based argument in support of pediatric priority states that children, given their longer life expectancy, stand to benefit more from transplantation than adults (Horslen et al. 2007; Veatch 2000). This argument, however, is problematic in that it relies on an incongruous use of the term 'medical benefit'.

When assessing medical benefit, we generally focus on the gain brought about by *one single* intervention. For certain types of treatment, the medical benefit so understood, is that of restoring the patient's life expectancy back to the average for her age. Examples include a mastectomy and the closure of an atrial septal defect⁵⁴. Such treatments may confer lifelong relief from the underlying condition.

In the case of an organ transplant, the medical benefit does not amount to life expectancy being restored to normal. A graft does not last a lifetime. For example, deceased donor kidney transplants have a half-life of 8.8 years (Lamb et al. 2011). A child will, therefore, often need several retransplants if we are to even come close to normalizing her life expectancy. Thus, in equating the benefit children derive from kidney transplantation with restoration of life expectancy, proponents of the life expectancy argument take into account the gain associated with *several* retransplants, rather than a single transplant. As such, the argument is at odds with the customary understanding of 'medical benefit'. Factors such as organ scarcity imply that there is no guarantee that a child will receive the number of retransplants needed to approximate normal life expectancy. In the absence of such a guarantee, why equate medical benefit with the gains incurred by several transplants, i.e. with normalization of life expectancy? In sum, it makes good sense to adhere to the common usage of 'medical benefit'. It, therefore, seems advisable to abandon life expectancy as a criterion of medical benefit in the context of organ transplantation. The medical benefit incurred by receiving a transplant at a certain age is more accurately represented by the graft survival rates for that specific age group.

When switching to the criterion of graft survival rates, the pediatric priority rule comes under fire. Of all age groups, those between 0 and 11 years of age have the best 10-year-graft survival rate for deceased donor kidney transplants. In contrast, adolescents (12-17 years of age), who represent the largest group of kidney transplant recipients in the group of children, have the poorest allograft outcome of all age groups except for recipients aged 65 and older (OPTN/SRTR 2009). This finding is largely explained by widespread non-compliance with the immunosuppressive regimen among adolescents (Rees 2009).⁵⁵ Given that there is a subgroup of adults with better outcomes than a subgroup of children, the prioritization of *all* pediatric age groups seems untenable. One

⁵⁴ An abnormal opening in the wall separating the chambers of the heart.

⁵⁵ Non-compliance in adolescents is, amongst others, related to the cosmetic side-effects of corticosteroids, such as acne, a swollen face, and increased BMI. Therefore, it has been hypothesized that steroid withdrawal protocols can be relied upon as a means of decreasing the risk of non-compliance. There exists preliminary evidence in support of this assumption (see, for example, Chandraker 2005). If steroid withdrawal protocols increase the adherence to the immunosuppressive regimen, they offer the prospect of improved graft survival rates in adolescents.

might object that, despite the criterion of life expectancy relying on an incongruous use of 'medical benefit', it nevertheless represents a preferable alternative to the use of the graft survival rates criterion. Ladin and Hanto (2011), for example, argue that in disadvantaging adolescents in kidney allocation, as the reliance on the criterion of graft survival rates seemingly compels us to do, we are punishing them for their tendency to non-compliance. This, they claim, is problematic as it goes against current practice which, at most, penalizes *actual* non-compliance, not a mere tendency to non-compliance. However, there are several problems with this objection. An allocation based on graft survival rates is indifferent towards the underlying cause of allograft outcomes. Thus, what the criterion of graft survival penalizes are adolescents' bad outcomes, not their tendency to non-compliance. Moreover, even if the latter were being penalized, the objection remains problematic since there might be compelling reasons for starting to penalize certain tendencies towards non-compliance. For example, we may thereby prevent an inefficient usage of organs. Moreover, such a penalization scheme might succeed in winning over those currently reluctant to donate out of fear of their organs going to waste. One might still object that this scheme is unfair for those adolescents who, when given an organ, would be compliant. However, this is a problem faced by any policy of prioritization. For instance, a policy emphasizing the criterion of life expectancy implies that, even though some adults may turn out to outlive children, they are nevertheless penalized.

The cost argument

The final utility-based argument defends pediatric prioritization on the basis that it enables financial savings. Proponents of this argument make two distinct claims. They foresee a reduction in both social welfare costs and health care costs.

The expected reduction in social welfare costs is premised on the same assumption as the growth and development argument. Pediatric prioritization, it is argued, enables a better psychosocial rehabilitation which, in turn, enhances employment prospects (Pape & Ehrich 2008). As noted earlier, however, adults transplanted in childhood prior to the introduction of a (full-blown) pediatric priority rule have employment levels close to that of the general population. Pediatric prioritization, therefore, offers only little room for improvement. Admittedly, any cost reduction, regardless of its magnitude, might be worth pursuing. Nevertheless, the cost argument ignores the strain which the adult ESRD population puts on the social welfare system. Adults are likely to represent a much greater burden than the pediatric population, for two reasons. First, unemployment rates in dialysis patients with adult-onset ESRD are substantially higher than in those with childhood-onset ESRD (Groothoff 2005). Second, whereas adults already strain the social welfare system, children will do so only in the future. This difference in timing is relevant in terms of 'discounting', an economic

theory according to which a certain cost X represents a greater financial burden when incurred now than when incurred in the future. Thus, even if unemployment for childhood-onset ESRD were as high as that for adulthood-onset ESRD, the latter would still put more strain on the social welfare system. Taking this into account and given that a significant proportion of the adult ESRD population resumes work after transplantation, expedited transplantation for adults is likely to achieve greater financial savings than pediatric prioritization (Russell et al. 1992; Helanterä 2012).

The appeal to *social welfare costs* serves to support pediatric prioritization policies of any kind. The prospect of a reduction in *health care costs*, on the other hand, is put forward specifically in defense of Share 35-like policies, where children are prioritized for *the 'qualitatively better' organs*. The idea behind this argument is that such policies ensure better graft survival rates for children, thereby reducing the number of retransplants as well as the number of expensive dialysis days (Pape & Ehrich 2008; Hoyer 2008). However, this argument too is problematic. In improving pediatric graft survival rates, one is likely to merely reduce costs associated with pediatric care, rather than overall costs.

In reducing the number of qualitatively better organs going to adults, Share 35-like policies might not reduce the *total* number of retransplants performed. Any reduction in the number of *pediatric* retransplants might merely be met by a comparable increase in the number of retransplants among *adults*. Moreover, even if such policies do reduce the *total* number of retransplants, the argument still fails. A reduction in the demand for organs (i.e. a reduction in the total number of retransplants) only decreases overall transplant costs in an ideal world, where supply meets demand. Under conditions of organ scarcity, however, total costs are determined by the supply of, not the demand for, donor kidneys.

The same zero-sum logic applies to the claimed reduction in the number of pediatric dialysis days. Adults faring worse under Share 35 than they otherwise would have, might experience an increase in the number of dialysis days of a comparable magnitude to the decrease enjoyed by children. One might object that this is an unlikely scenario. It presupposes that, relative to children, adults stand to gain an equal number of graft years in receiving organs from donors under 35 years as opposed to organs from donors over 35. There are no data available which allow us to verify this assumption. However, data do exist comparing the graft years gained by both adults and children for other types of qualitatively better and worse organs. For example, data of the 2009 OPTN/SRTR *Annual Report* suggest that adults and children stand to gain more or less equally in

receiving a living donor kidney as opposed to a deceased donor kidney.⁵⁶ If these data are anything to go by, Share 35 will merely shift all the dialysis costs previously incurred by children to adults.

5.2.2 Equity-based arguments

The fair innings argument

A first equity-based argument for pediatric prioritization appeals to the idea of a fair innings. The latter is a well-known justification for age-based rationing of health care services. The fair innings refers to some normal span of years, for example the traditional three-score and ten, to which everyone is entitled. Anyone who fails to live out this number of years has been cheated of a reasonable length of life (Williams 1997). Therefore, the fair innings argument grants all those who have yet to attain the threshold age equal entitlement to health care. Beyond that point, however, one is living on borrowed time, an idea which is reflected in the very low priority accorded to patients from that moment onwards (Harris 1999).

The concept of a fair innings is appealed to in two different ways in the debate on pediatric prioritization. Some invoke the concept in support of a pediatric priority for the ‘qualitatively’ better organs. Others use it to justify Eurotransplant-like policies, where pediatric priority is granted regardless of the quality of the donor kidney. We refer to the former and latter reliance on fair innings, respectively, with the terms FI_1 and FI_2 . In both cases, the fair innings is equated with life expectancy at birth.

FI_1 is similar to the traditional fair innings argument in that it seems to recognize that *everyone* (both children and adults) under the threshold age has an *equal* right to a fair innings. However, it departs from the traditional fair innings argument in that it views children and adults as having different *needs* in order to secure their fair innings. Children have many more years to bridge before reaching a reasonable lifespan. Therefore, proponents of FI_1 argue, they are in need of a greater number of ‘graft years’ (Gulati & Sarwal 2010). The latter, in turn, implies that children have a greater need for better functioning grafts. According to FI_1 , then, the magnitude of one’s need for a ‘qualitatively’ better organ is a function of the distance one is removed from a fair

⁵⁶ Compare the data in Table 5.8a (http://optn.transplant.hrsa.gov/ar2009/508a_agecat_ki.htm) with the data in Table 5.8d (http://optn.transplant.hrsa.gov/ar2009/508d_agecat_ki.htm).

innings. However, this formula is plausible to a certain extent only. Admittedly, a kidney of a lesser quality will suffice to bring a 73-year-old up to the average human life expectancy. Therefore, this person has no need for a better functioning kidney. But what about those adults for whom the number of years left to bridge is greater than or equal to the number of graft years to be gained from a qualitatively better organ? Consider, for example, a 25-year-old with ESRD. Assuming that this person has as much right to attain her fair innings as a child, she needs a better functioning kidney just as much as a child does. As the latter observation illustrates, Share-35-like policies do not merely affect the chances of those with *adult*-onset ESRD of attaining a fair innings. Ironically enough, such policies do not do much to further the chances of those with *childhood*-onset ESRD either. After all, if one receives a transplant in childhood, one is still likely to need one (or more) retransplants during adulthood (Levine et al. 2012). At that point, however, one would obviously no longer belong to the group receiving priority for the ‘qualitatively’ better kidneys. In sum, if one is truly committed to the goal of granting everyone a fair innings, a policy which restricts priority for the better kidneys to children is not far-reaching enough. A better approximation of the fair innings goal would be obtained by extending the priority for better quality kidneys to young adults.

Can the notion of a fair innings plausibly be appealed to in defense of a broad pediatric prioritization, i.e. one which is independent of donor kidney quality? FI₂ defends this type of policy on the basis that children have not yet had a fair innings (Ladin & Hanto 2011). Although proponents of FI₂ use the term ‘fair innings’ in reference to their argument, this is clearly a misnomer. The fair innings argument is merely concerned with whether or not one has had a fair innings. *How much* of a fair innings one has had is irrelevant.⁵⁷ If FI₂ does not amount to a fair innings-based line of reasoning, how should it be understood? The claim appears to be the following: the fewer life years one has had, the greater one’s entitlement to an organ. Veatch (2000), an advocate of this view, argues that the younger one is, the fewer opportunities for medical well-being one has enjoyed. A concern for equalizing such opportunities, he argues, calls for prioritizing children over adults. This argument uses age as a *proxy* for opportunities for medical well-being. However, as we argue below, this is unwarranted.

Age is not the only determinant of opportunities for medical well-being. More specifically, the critical role of social determinants of health, such as working

⁵⁷ As noted above, the fair innings idea commits us to an equal treatment of all those below the threshold age, children and adults alike. Thus, one cannot coherently appeal to the notion of a fair innings in support of a policy which merely prioritizes *pediatric* patients.

conditions, income and education level, is well-documented. A recent report from the WHO (2008) indicates that such factors are responsible for a major part of health inequities within and between countries. A child, therefore, need not necessarily have had fewer opportunities for medical well-being than an adult. For example, a 10-year-old growing up in a rich, well-educated family may well have had more of such opportunities, relative to a 25-year-old deprived of these privileges. In invoking this example, we are not claiming that kidney allocation ought to take into account the candidate recipient's social class, working conditions, education level, etc. With our example, we merely intend to demonstrate that mistaken judgments concerning a patient's opportunities for medical well-being cannot be ruled out when using age as a proxy for such opportunities. Admittedly, this need not necessarily imply that the use of age as a proxy for opportunities for medical well-being is unwarranted. After all, any allocation criterion is likely to be subject to a certain degree of error. What matters is whether age is a *sufficiently* reliable predictor of opportunities for medical well-being. However, it is, at present, unclear how much of the variance in opportunities for medical well-being is accounted for by the factor 'age'. Given the high stakes involved in kidney allocation, it seems unwarranted to employ a factor the predictive strength of which is unknown. In short, a person's age should not be relied upon in an effort to determine the number of opportunities for medical well-being.

The minority argument

The other equity-based argument is grounded in the observation that children represent a numerical minority (1-4%) on the kidney transplant waiting list. According to proponents of this argument, this reality implies that, absent a priority rule, children stand less chance of receiving a kidney, relative to adults (McDiarmid 2001). Moreover, children's chances will deteriorate, given that the adult ESRD population continues to rise, whereas the pediatric population remains relatively stable. The pediatric priority rule, it is argued, serves to rectify children's disadvantaged position. As we argue below, there are several problems with this argument.

The view that children are disadvantaged in the competition for an organ results from a focus on children as a group, rather than on the individual members of this group. As a group, children only stand a 1-4% chance of receiving a kidney. However, this focus on group-level chances is misguided since children have an interest in acquiring an organ as individuals rather than as a group. Consequently, it makes much more sense to concentrate on an individual child's chances for an organ. How does an individual child fare, relative to an adult, in this respect? Absent a pediatric priority rule, and all other things being equal, an individual child and adult have an equal chance of obtaining a kidney. Admittedly, all other things are not equal. The kidney donor pool to which

pediatric kidney transplant candidates have access is smaller than that available to adults. Due to higher rates of graft thrombosis and technical failures, kidneys from pediatric deceased donors younger than 5 years are rarely, if ever, allocated to pediatric recipients (Sharma et al. 2013). The majority of such kidneys is transplanted into adult recipients, either as single or en bloc grafts. However, the disadvantage experienced as a result of this restriction in the donor pool is minimal, given that only 4% of all donors originate from donors under 5 years of age (OPTN 2013). More importantly, this setback is more than made up for *in practice*. After all, both in Europe and the United States, pediatric candidates have *always* had *significantly* shorter waiting times compared to adults (Magee et al. 2008; Offner et al. 1988; Van der Vliet et al. 1982). In short, despite being a numerical minority on the waiting list, children are not disadvantaged in the competition for a kidney.

Even if the group-level perspective were the correct view to take, the disadvantaged position of children, as a group, may not necessitate their prioritization. The minority argument appears to be premised on the assumption that we ought to prioritize the numerically smallest group. If we accept this premise, the argument only holds if, as a group, children satisfy this numerical requirement. However, we can easily define categories of possible recipients which are likely to be numerically smaller. For example, within the adult population, the 18-22 age category might count fewer waitlisted patients, relative to the pediatric population. If so, we would have to prioritize the former group. Moreover, the minority argument remains problematic even if the pediatric waitlisted population would indeed represent the numerically smallest group. Proponents of the minority argument need to justify why the numerically smallest group ought to be accorded special consideration. After all, in the case at hand the small size of the pediatric population might just as well be an indication that this group has a smaller need for organs, relative to the adult population. Following this interpretation, it is fitting that those with a smaller need stand a smaller chance of obtaining an organ.

5.3 Unexpected effects of pediatric priority policies

The above discussion raises a number of important concerns regarding the legitimacy of pediatric priority rules. Unfortunately, the problems do not end here. Pediatric priority rules have had some inadvertent consequences. Since the introduction of Share 35, the number of living donor (LD) kidney transplants for pediatric recipients has declined (Axelrod et al. 2010). Thus, in reducing pediatric patients' waiting time for deceased

donor (DD) kidneys to just a few months, Share 35 appears to have created a disincentive to identify living donors for children. Admittedly, living donation rates for both adult and pediatric recipients have been declining over the past several years in the United States (OPTN 2013). One might, therefore, object that it is difficult to verify the extent, if any, to which Share 35 has contributed to the observed decline. However, the living kidney donation rate for pediatric recipients has seen a much more substantial decline over the past years than that for adult recipients (Abraham et al. 2009).⁵⁸ Thus, while Share 35 might not be the sole cause of the observed trend, it has most probably contributed to it.

As we argue below, the decline in living donation rates for pediatric recipients may further undermine the legitimacy of Share 35. We have not come across any literature discussing living donation rates in the wake of the introduction of other pediatric priority policies. However, this does not necessarily rule out the possibility of such other policies having had a similar effect on living donation rates as Share 35. Thus, while the considerations outlined below are undoubtedly relevant for Share 35, they may also apply to other pediatric priority policies.

A first consideration pertains to a condition to which many pediatric priority policies were subjected. During discussions leading up to their introduction, it was widely agreed upon that such policies would only be acceptable if they did not heavily penalize adult patients (Loirat et al. 2001). This condition was deemed to be clearly met, given that pediatric patients represented only a very small proportion of all waitlisted candidates. In view of the limited information available at that time, this was a reasonable assessment. However, in light of our current knowledge, it is perhaps less clear whether this condition is still met. The decrease in the number of children receiving a living donor kidney implies that the overall deceased donor pool is increasingly being tapped for a waitlisted child (Abraham et al. 2009). Thus, the availability of deceased donor kidneys for adult patients is compromised to a greater extent than initially expected. It will be important to monitor the effect on adult transplant candidates in the long term. In the meantime, however, we should ask ourselves how much of an adverse effect on adults we are willing to accept in turn for reduced pediatric waiting times.

⁵⁸ Between 2004 (i.e. the last full year before the introduction of Share 35) and 2007, the number of living donor kidney transplants for pediatric recipients dropped by over 20%. In the same time period, the number of living donor kidney transplants for adult recipients decreased by less than 10% (Abraham et al. 2009).

A second consideration is that the unexpected effect of Share 35 may further weaken the growth and development argument as well as the fair innings argument. Recall that the former argument rests on the assumption that children suffer a significant loss in quality of life following long-term dialysis. We have already established that this argument fails to acknowledge the problems faced by adult patients with ESRD. However, despite having called attention to these problems, we are still likely to have somewhat underestimated the loss in quality of life incurred by such adults. After all, we have thereby not yet taken into account the implications of the observed decrease in pediatric living donor kidney transplant rates. The latter trend entails a further increase in the average waiting time for adult recipients of DD kidneys. Any loss in quality of life which adults experience in the absence of expedited transplantation will hereby be magnified. Thus, while there is currently insufficient empirical evidence to determine whether the loss in quality of life incurred by children is greater than that for adults, the above does add weight to the adults' side of the scale.

As we have already argued, it is problematic to appeal to the fair innings idea in support of policies which prioritize children for the 'qualitatively' better organs. One of our criticisms was that such policies fail to give those with *childhood-onset* ESRD the *best possible* chance of attaining a fair innings. In making this criticism, we went along with FI₁'s underlying assumption, i.e. the idea that Share 35-like policies do *somewhat* increase the chances of those with *childhood-onset* ESRD of attaining a fair innings. At first sight, this appears to be a reasonable assumption. After all, Share 35-like policies have significantly shortened pediatric waiting times (Abraham et al. 2009). Time on dialysis is negatively correlated with kidney graft survival (Meier-Kriesche & Kaplan 2002). One would, therefore, expect Share 35-like policies to have improved pediatric graft survival rates, thereby having increased children's chances of attaining a fair innings. However, some of the recently observed implications of Share 35 may nullify the latter effect. First, recent data show that children receiving a kidney from a LD have a superior 7-year graft survival rate than recipients of a DD kidney (80.5% versus 67.9% respectively) (NAPRTCS 2010). Thus, in increasing pediatric recipients' reliance on DD kidneys, Share 35 could adversely affect long-term pediatric graft survival rates. Experience with 2-year graft survival rates in certain centers already suggests an adverse impact of Share 35 (Abraham et al. 2009). Second, Share 35 has reduced the degree of human leukocyte antigen (HLA) matching between pediatric recipients and their allografts (Levine et al. 2012). As such, the policy may exert a further adverse effect on pediatric graft survival rates. Although some maintain that the impact of HLA matching on graft survival has diminished in recent years, others argue that it remains highly significant (Opelz & Döhler 2007). Third, the chances of children with ESRD of attaining a fair innings are not only dependent upon graft survival, but also on the likelihood of receiving a retransplant later on in life. A decreased degree of HLA matching in primary pediatric transplants may contribute to greater sensitization (Levine et al. 2012). As a result, those

with childhood-onset ESRD may have more difficulty finding a compatible second transplant. In sum, rather than merely failing to give children the best possible chance of attaining a fair innings, Share 35-like policies may actually be reducing their chances.

Finally, besides further weakening arguments in support of pediatric priority policies, the adverse effects of Share 35 may even provide us with a *positive* argument for condemning such policies. One may arrive at such an argument by appealing to the utilitarian criterion ‘life years obtained by the donor pool’. This criterion dictates that we ought to allocate kidneys such as to maximize the number of life years which the kidney pool may produce. Thus, it would, for example, prohibit us from allocating a good quality organ to a 75-year-old as such an organ would have a longer functioning time in a young adult.

Share 35-like policies have three effects which are relevant to the life years criterion. First, the decrease in living donation rates for pediatric recipients has not been met by an increased rate of this type of donation for adults (Abraham et al. 2009). Share 35, therefore, has decreased the size of the kidney donor pool, thereby reducing the number of life years we are able to allocate. Second, Share 35 allocates a proportion of the ‘qualitatively better’ organs to adolescents. Given that the latter have very bad graft survival rates, the policy makes suboptimal use of these organs. Admittedly, both of these effects are moderated by a third effect, i.e. the fact that Share 35 allocates some of the ‘qualitatively better’ organs to the 0-11 age group which has the best graft survival rates. However, while serving as a moderating factor, the latter effect is unlikely to offset the abovementioned negative effects. After all, adolescents represent the largest group of kidney transplant recipients (Horslen et al. 2007). In sum, Share 35 is likely to have reduced the number of total life years gained from the kidney pool.

5.4 Conclusion

Any organ which is allocated to one individual represents a missed opportunity for someone else. Given the important repercussions which organ allocation policies inevitably have for certain people, any prioritization policy should be solidly rooted. In our view, none of the arguments put forward in support of pediatric prioritization succeed. However, even if a compelling argument exists, questions may still arise concerning the future sustainability of pediatric priority policies. Specifically, one would need to determine whether pediatric prioritization is still reconcilable with minimal harm to adults. In addition, research is needed to establish whether the decline in adult-to-child living donation adversely affects pediatric graft survival rates in the

long run. In the event of an adverse effect, the latter must be balanced against the positive outcomes of pediatric prioritization. If we are unwilling to accept shorter graft survival rates in return for reduced waiting times, the question arises as to whether it is feasible to increase living donation rates while maintaining pediatric prioritization policies.

5.5 References

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Part 2, Section 2: solutions in the context of
commodity scarcity

Chapter 6

Strategies to increase the kidney supply: dead-end solutions

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6.1 Introduction

The discrepancy between the supply of and demand for donor organs remains a major challenge. The problem is greatest for renal transplantation. As of February 14, 2014, there were 99,339 patients waitlisted for kidney transplantation in the United States (OPTN 2014). Records spanning the last decade suggest that annually only approximately 16,000 patients receive a kidney transplant, whereas more than 30,000 patients are added to the waiting list each year (OPTN 2013).⁵⁹ Unfortunately, these figures merely represent the tip of a much bigger iceberg. Population aging and the obesity epidemic are contributing to an ever increasing prevalence of diabetes, the leading cause of end-stage renal disease (ESRD). Therefore, despite a recent stabilization in ESRD incidence rates in western countries, the total ESRD population will (continue to) grow dramatically in the coming decades (Eggers 2011). According to the latest projections, the prevalence of ESRD patients in the US will approach 785,000 by the year 2020, an increase of more than 60% from 2005 levels (Finn 2008). Forecasts for the current decade, however, do not yet capture the full extent of the problem, as population aging is only expected to reach its peak by 2030. The few available estimates indicate that the ESRD population could reach 2 million in the US by that time (Bayliss et al. 2011; Szczech & Lazar 2004).

The predominant response to the *current* gap between supply and demand is to tackle the supply-side of the problem. In this chapter, we argue that strategies aimed at enlarging the donor pool are shortsighted in that they are not well-suited to addressing the *projected surge* in demand, for 3 reasons. First, it would not be financially viable to fully utilize any significantly expanded kidney pool. We show that, as a result of this financial limitation, supply-oriented strategies are likely to necessitate rationing of both transplantation *and* dialysis. Second, leaving aside budgetary constraints, there are formidable ethical and scientific obstacles to implementing these strategies in a timely fashion. Third, supply-focused proposals fail to acknowledge the global reach of the ESRD ‘crisis’.

⁵⁹ Eurotransplant statistics show that, during 2013, only 2,959 of the 10,757 waitlisted patients received a transplant (Eurotransplant 2014).

6.2 Overview of supply-oriented proposals

Before developing our arguments, we provide a concise overview of proposals for increasing the kidney supply. For ease of reference, we subdivide these into two categories: radical and conservative approaches. We use these terms to distinguish between strategies which aim to optimize the procurement of organs from currently available sources (conservative) and those which tap novel organ sources (radical).

Radical strategies

Xenotransplantation, the transplantation of organs from nonhuman species into humans, is an example of a radical supply strategy. Swine are generally considered a suitable source species for xenografts. Relative to nonhuman primates, the use of porcine grafts is less fraught with ethical issues. In addition, swine are easier to breed and their organs provide a better size match for humans (Yang & Sykes 2007).

Renal regeneration constitutes a second radical supply strategy. There are currently 3 investigational approaches to the development of functional, self-sustaining renal substitutes: tissue engineering, development biology and stem cell research (Orlando et al. 2011a). Tissue engineers aim to manufacture tissue and organs *ex vivo* from biological materials, such as stem cells. Specifically, the goal consists in seeding cells on or into a supporting scaffold and reimplanting the latter into the patient in an attempt to replace or restore damaged tissues (Ghosh & Ingber 2007). Development biology approaches are being used to engineer kidneys from embryologic precursors of the urinary tract. A primordial kidney structure has been obtained through *in vitro* culturing of such precursors in the presence of specific growth factors (Orlando et al. 2011b). With a view to tapping into the kidney's intrinsic capability for injury repair, stem cell researchers are currently identifying niches within the kidney where cells with regenerative capacities may reside (Orlando et al. 2011b).

Both xenotransplantation and renal regeneration, if successful, offer the prospect of a limitless kidney supply (Cooper & Ayares 2011; Chapekar 2000). Renal regeneration may help overcome an additional hurdle facing current transplantation practice. In the presence of an autologous cellular component, the creation of a bioengineered kidney would solve the problem of toxicity deriving from lifelong immunosuppression (Orlando et al. 2011a).

Conservative strategies

Rather than relying on the development of novel organ sources, proponents of conservative supply strategies devise various means of increasing procurement rates

from deceased and/or living kidney donors. Some advocate a shift to a presumed consent regime for countries currently operating an opt-in system (see, for example, English 2007). Others defend the adoption of organ conscription, i.e. the routine removal of usable organs from all cadavers. Under this plan, exemption from donation would only be granted to religious objectors (Spital 2005). Another proposed route to increasing donation rates is the introduction of financial incentives. Often, a distinction is made between direct and indirect payments. The former refers to actual monetary compensations in the form of cash payments, whereas the latter involves the trading of organs for goods or services of cash value (Rodrigue et al. 2009). Indirect payments may take on various forms, ranging from a funeral expense voucher to reductions in health care premiums. Direct payments are most often associated with a living donor market. Proponents of the latter usually envisage a government-regulated organ trade where vendors are paid a fixed price and kidneys are allocated by an algorithm similar to the current point system for deceased donation. In addition, some advocates of a living donor market stress the need for strict donor evaluation criteria and donor protection safeguards (Matas 2004). Although it generally receives less attention in the literature, a system of direct payment has also been proposed for deceased donation. In this case, the options include either a cash payment to the donor's family or a futures market. The latter implies that individuals receive a payment, while alive, in return for agreeing to have their organs removed for transplantation after death (Howard 2007).

This overview of supply strategies is not exhaustive. However, the arguments we develop in this chapter generally hold for any proposed means of increasing the kidney supply. Therefore, when assessing the merit of such means, we limit ourselves to referring to the supply strategies outlined above.

In the section below, we assess the financial viability of both radical and conservative supply-oriented proposals. Next, we examine whether these strategies can be implemented in a timely manner, i.e. well before population aging reaches its peak. In a final section, we make the case for a preventative approach as a means of addressing the projected rise in the number of ESRD cases.

6.3 Financial viability of supply-oriented proposals

6.3.1 Financial viability of radical supply strategies

Due to their ability to generate an unlimited kidney supply, radical supply strategies are generally portrayed as a silver bullet, capable of eradicating, rather than merely mitigating the organ shortage problem. Assuming that these strategies will be implementable in the near future, we concede that they may well succeed in eradicating kidney shortages of the current magnitude. However, as we argue below, it is financially prohibitive to rely on such approaches as a means of eliminating the projected, future gap between supply and demand. Several reasons account for this finding. First, the number of transplants required to satisfy future levels of demand is exceedingly high. Second, adding to this exorbitant aggregate cost of transplantation, are the high expenses related to the procedures of xenografting and renal regeneration. Third, the aggregate cost of bridging therapy prior to transplantation is also likely to reach high levels. We discuss each of these reasons in more detail below.

High number of transplants required to satisfy future levels of demand

As noted earlier, the ESRD population will expand to approximately 2 million by 2030. Presumably, a (small) portion hereof will be medically unfit for transplantation. At first sight, then, this figure appears to somewhat overestimate (true) demand. However, further considerations suggest that the number of transplants required to accommodate future levels of demand, in fact, exceeds 2 million. To begin with, demand is not merely a function of the need for a first transplant. It is also determined by the need for retransplants. A graft does not last a lifetime. Deceased donor kidney grafts, for example, have a half-life of 8.8 years (Lamb et al. 2011). Patients, therefore, often require one or more retransplants during a lifetime - a need which, in many cases, goes unmet due to the limited kidney supply. The need for retransplantation is likely to persist under radical supply strategies. Xenografts are likely to succumb to the major causes of graft failure witnessed in human allografts (Ekser & Cooper 2010). It is, therefore, doubtful that half-lives would be (any much) longer than under current circumstances. Some even foresee significantly reduced half-lives. For example, Bhattacharya and Stubblefield (2013) anticipate that chronic rejection will be more aggressive in xenografts, relative to allografts. This, coupled with the sheer size of the future ESRD population, suggests that the implementation of xenotransplantation would be accompanied by a substantial demand for retransplantation. Relative to xenotransplantation, the use of autologous bioengineered kidney grafts (if successful) is likely to induce lower levels of need for retransplantation. This practice addresses the

problem of rejection, thereby enabling longer lived grafts. However, other relatively prevalent causes of graft failure, such as recurrent kidney disease, would probably still occur under the scenario of kidney bioengineering. Thus, whereas the latter would constitute an improvement upon xenotransplantation, it may nevertheless still engender significant demand for retransplantation. As their goal consists in eradicating the gap between supply and demand, proponents of radical supply strategies are committed to meeting *all* needs for retransplantation.

In assessing future levels of need for transplantation, we must also take into account the highly elastic nature of demand. Since the inception of kidney transplantation, the pool of patients deemed medically eligible for transplantation has steadily grown. This development is largely attributable to technological advances, sophisticated surgical skills, and progressive improvements in immunosuppressive regimens (Jafarey & Moazam 2009). Radical supply strategies represent the epitome of scientific progress in that they promise the prospect of a limitless kidney supply. It is, therefore, reasonable to assume that xenotransplantation and kidney bioengineering would trigger a similar, if not magnified, increase in demand. For example, whereas ‘need for a transplant’ is currently attributed to the ESRD population, the concept might be widened so as to include those in advanced stages of chronic kidney disease (CKD), the precursor of ESRD.⁶⁰ The rationale behind this specific reinterpretation of the transplantable population would be twofold. First, the burden of symptoms and loss of quality of life in patients with advanced CKD is comparable to that experienced by the ESRD population (Abdel-Kader et al. 2009). Second, the risk of cardiovascular events increases with ascending stages of CKD (Go et al. 2004). If radical supply strategies are to *eradicate* the kidney shortage problem, the inclusion of advanced-stage CKD patients into the transplantable population commits one to an additional 30 million transplants (Davids 2007).

High expenses related to the procedures of xenografting and renal regeneration

The financial burden of accommodating high levels of future demand becomes heavier still once we consider the cost of a single transplant. The specific features of radical supply strategies suggest that the latter would render transplantation much more expensive than it currently is. For example, kidney bioengineering would most probably involve a long, complicated cultivation procedure. In addition, it necessitates specific

⁶⁰ This broadening of the patient group is a perfect illustration of the ‘complementarity’ effect of new medical technologies. Recall that this effect refers to the tendency of technological innovations to increase the reliance upon an already existing technology (in this case transplantation). This effect was discussed in chapter 1.

storage conditions (Berthiaume et al. 2011). These factors point towards the need for considerable investments in highly qualified personnel and instrumental assets (Orlando et al. 2010). Xenotransplantation is unlikely to fare any better, for several reasons. First, it requires the production of transgenic source animals in order to reduce rejection. Genetic manipulation of pigs is inefficient, time and labor consuming and reliant upon advanced techniques in biochemistry, reproductive biology, molecular biology, and cell culture (Niemann et al. 2012). Second, breeding of source animals would need to take place in an infection-free environment. Finally, xenotransplantation puts human recipients and the wider population at risk of xenozoonoses, i.e. infections by a porcine microorganism (Ekser & Cooper 2010). Clinical applications of xenotransplantation, therefore, warrant the implementation of screening programs (Fishman et al. 2012).

High aggregate cost of bridging therapy prior to transplantation

Expenditures related to radical supply strategies are not limited to transplantation. It is often assumed that xenotransplantation and kidney bioengineering would obviate the need for dialysis. However, this assumption only holds to a certain extent. Presumably, some time would elapse between the diagnosis of ‘need for a transplant’ and receipt of a graft. First, as we have seen, the cultivation process for a bioengineered kidney is likely to span a significant period of time. Second, initially, production capacity is likely to be limited, with only a few centers possessing the instruments and technology required for xenotransplantation and kidney bioengineering. Thus, whereas radical supply strategies render long-term dialysis redundant, patients with ESRD would still be dependent upon short-term dialysis. The financial burden of the latter is considerable, given both the high monthly cost of dialysis⁶¹ and the projected size of the ESRD population.

6.3.2 Financial viability of conservative supply strategies

Proponents of conservative supply strategies generally fall into one of two categories. Some hold that implementation of this type of proposal would fully close the gap between supply and demand (see, for example, Gaston et al. 2006). This claim is made with regard to the introduction of financial incentives and conscription. Others argue that conservative strategies, while unable to eliminate the kidney shortage, would reduce the latter to a minimum (see, for example, Kerstein 2009). Unlike the former claim, this argument is not merely invoked by proponents of financial incentives and

⁶¹ See footnote 64.

conscriptio. It is also appealed to in defense of presumed consent. Below, we analyze both claims in this respective order. We argue that these assumptions are shortsighted in that they do not hold for kidney shortages of the magnitude projected for the future.

Conservative strategies as a means of eliminating kidney shortage

In assessing their potential to eliminate the gap between supply and demand, we make a number of presuppositions with regard to conscription and financial incentives. To begin with, we assume, for the sake of argument, that these conservative supply strategies are able to eradicate kidney shortages of the *current* magnitude. If we are to determine whether full closure of the future gap is attainable, we need to estimate the magnitude of future demand under these strategies. However, this is a challenging task. Specifically, it is not clear whether conscription and financial incentives would induce a shift towards inclusion of advanced-stage CKD patients into the transplantable population. Therefore, for the sake of simplicity, we presume that, under these strategies, ‘need for a transplant’ will merely be attributed to ESRD patients requiring a first transplant or a retransplant. We hereby grant proponents of conservative supply strategies the best case scenario.⁶² Finally, we also presuppose that enough kidneys will be available to, at least, accommodate future demand in the previously defined sense.

Do conservative supply strategies represent a financially viable means of fully satisfying future levels of demand? As we argue below, it appears that they do not.

Despite the (presumed) absence of any commitment to transplantation of late-stage CKD patients, the number of transplants required to fully close the future gap between supply and demand remains substantial. In significantly reducing (or even eliminating) the reliance upon living donation, conscription and financial incentives for deceased donation are likely to cause grafts to fail earlier, relative to current circumstances. Financial incentives for living donation would have the opposite effect. Nevertheless, given that the half-life of a living donor kidney amounts to ‘a mere’ 11.9 years (Lamb et al. 2011), need for (frequent) retransplantation is likely to persist.

The financial burden of transplanting and frequently retransplanting approximately 2 million people is further aggravated due to the high cost of a single transplant. The estimated equilibrium price⁶³ for a cadaveric kidney amounts to \$150,000 (Wellington & Whitmire 2007). Due to the potential risks involved, the equilibrium price for a living

⁶² Transplantation is more expensive than care for advanced-stage CKD (see Smith et al. 2004; Rocha et al. 2012).

⁶³ The equilibrium price is the price under which the number of people willing to sell their kidney matches the number of people demanding a kidney.

donor kidney is likely to be higher still. Moreover, a regulated market would most probably necessitate the establishment of a national agency overseeing transactions in order to prevent abuse (Voo et al. 2009). Admittedly, conscription does not run into these problems. In fact, in eliminating the need for donor registries and educational campaigns aimed at incentivizing donation, the cost of a single transplant may decrease under organ conscription (Spital 2005).

Despite the presumption of a sufficient kidney supply to meet future demand, there would still be a need for short-term dialysis under conservative supply strategies. After all, it could take a while for a well-matched organ to become available.

We have assumed that conscription and financial incentives would provide a supply sufficient to meet future demand. However, as we argue below, this is a highly unrealistic scenario. In reality, a substantial kidney shortage would obtain. As a result, the financial outlook becomes even more dim for conservative supply strategies. Whereas a sufficient kidney supply obviates all need for long-term dialysis, a considerable number of patients become reliant upon the latter in the event of a significant shortfall in kidneys. As a mode of treatment, dialysis is more expensive than transplantation.⁶⁴

Only 2% of the deceased satisfy the medical requirements for donation (Kahan 2009). At the current rate of 2,468,435 annual deaths⁶⁵, conscription would provide 74,053⁶⁶ renal transplants in the US per year. Thus, even under the most favorable assumption of future demand for transplantation reaching ‘only’ two million, the shortfall in kidneys would assume alarming proportions.

Financial incentives for deceased donation encounter the same natural constraint on the number of retrievable organs as conscription. However, the former is likely to score even worse than the latter in that it does not guarantee 100% efficiency in converting potential donors to actual donors. Indeed, population surveys suggest that a system of payment for deceased donation would yield (significantly) fewer kidneys still. For example, a 2005 Gallup poll assessing respondents’ willingness to donate their own and

⁶⁴ Note that, despite the highly inflated cost of transplantation under a financial market in kidneys, transplantation remains the cheaper option. A single transplant, on average, replaces 8.8 years on dialysis (in the case of a deceased donor kidney). At a yearly cost of €28,000, 8.8 years of dialysis amounts to € 246,400. Under current circumstances, a transplant costs, on average, €12,000 per year, bringing the total cost of transplantation to €105,600 (Rocha et al. 2012). The equilibrium price of a transplant in a financial market is \$ 150,000 (i.e. approximately €112,000) (Wellington & Whitmire 2007).

⁶⁵ This is the US death rate for 2010 (Hoyert & Xu 2012).

⁶⁶ Cadaveric donation supplies, on average, 1.5 kidneys (Wellington & Whitmire 2007).

family members' organs after death found that 17% and 19%, respectively, were more inclined to do so when offered some kind of payment (The Gallup Organization 2005). These figures may still overestimate the potential for kidney retrieval under a scheme of financial incentives. We must consider the possibility of a 'crowding out' of altruistic organ donation. This phenomenon, whereby financial incentives weaken one's sense of moral obligation, has been documented in several experimental settings (Rippon 2012). If applicable to organ donation, people currently willing to donate (i.e., altruistically motivated donors) may view financial incentives as tainting the value of donation. As a result, they may refrain from donation altogether in the presence of a system of payment (Rothman & Rothman 2006).

Obviously, a system of financial incentives for living donation is not constrained by the requirement that death occur under circumstances conducive to donation. In partly escaping the limitations inherent in proposals for increasing deceased donation, this system appears more promising. Nevertheless, the prospect of fully satisfying future demand remains remote under this scenario. In a Dutch population survey, a mere 5% of respondents rated the likelihood of donating a kidney in return for payment as high (Kranenburg et al. 2008). Results from a survey among Swiss medical students suggest that 27% would *consider* selling a kidney in a regulated market (Rid et al. 2009). However, 66% of the latter would only *actually* sell their kidney under certain, well-defined circumstances, such as financial hardship. Various factors may bring the potential for kidney retrieval below the rate suggested by these attitudinal assessments. To begin with, living altruistic donation may also be susceptible to 'crowding out', a phenomenon described in the previous paragraph. Furthermore, while the requirement for 'donation-conducive deaths' does not apply to financial incentives for living donation, other constraining factors still obtain. In short, a portion of individuals willing to donate in return for payment will be medically unfit to do so. Moreover, the obesity epidemic suggests that an increasing number of altruistically motivated candidates is likely to be medically ineligible for donation. Donation by obese individuals may pose an increased risk for both donors and recipients (Espinoza et al. 2006; Nogueira et al. 20120). Therefore, there is widespread consensus that only carefully selected obese individuals should be allowed to donate.

Conservative strategies as a means of reducing kidney shortage to a minimum

Recall that proponents of conservative supply strategies make one of two claims. In the previous section, we discussed the first claim, i.e. that conservative strategies can eliminate the kidney shortage. We now turn our attention towards the second claim, i.e. that conservative supply strategies can reduce the gap between supply and demand to a minimum. Assuming that this claim holds true with regard to the current gap, it inevitably fails when it comes to the future, projected disparity between supply and

demand. After all, our analysis suggests that conservative supply strategies have a very limited kidney retrieving potential. Thus, this second claim runs into the same financial problems as the first.

6.3.3 Implications of the financial non-viability of supply strategies

As argued above, supply strategies cannot succeed in substantially tackling, let alone fully closing, the future, projected gap between demand for and supply of donor kidneys. Admittedly, in theory, radical supply strategies provide the amount of kidneys required to fully close the gap. However, it is not financially viable to satisfy all future demand for kidney transplantation. In short, radical supply strategies merely transform the problem of kidney scarcity from one of commodity scarcity into one of scarcity of financial resources. Consequently, radical supply strategies cannot obviate the need for rationing of kidneys. The sheer magnitude of future demand for renal replacement therapy, combined with the high cost of dialysis, suggests that provision of the latter mode of treatment would also encounter financial constraints.

Conservative supply strategies fail to substantially reduce the future gap between supply and demand in that they are likely to only marginally increase the number of donor kidneys. Thus, under these strategies, kidney scarcity would retain its current form of ‘commodity scarcity’. The resulting large need for dialysis implies that, whereas provision of organs would most likely escape budgetary constraints, dialysis would not.

6.4 Timeliness

The prevalence of ESRD is already growing rapidly, with its peak projected to occur around 2030. Thus, if it is to avert a large part of the burden, any proposed solution to the ESRD ‘crisis’ ought to be implementable in the foreseeable future. Below, we argue that supply strategies, even if financially viable, do not meet this criterion.

6.4.1 Timeliness of radical supply strategies

Timeliness of xenotransplantation

Demonstrated safety and efficacy of xenotransplantation in nonhuman primates is a prerequisite for initiation of clinical trials in humans. These standards are likely to be

much more strict for renal xenotransplantation, relative to other organs, due to the ready availability of dialysis.

The understanding of xeno-immunobiology has progressed substantially over the past decades. This is largely attributable to the increasing availability of transgenic pigs, a development which, to a certain extent, protects transplantable tissues from the human immune response (Pierson et al. 2009). As a result, hyperacute, acute antibody-mediated, or cellular rejection no longer appear to represent a substantial barrier to xenotransplantation in nonhuman primates (Ekser et al. 2012). Despite these advances, there are still numerous impediments to attaining the required safety and efficacy thresholds. A major remaining problem is the development of life-threatening consumptive coagulopathy (the formation of small blood clots throughout the body) at an early stage following pig kidney xenotransplantation (Ekser et al. 2012). Besides immunologic and coagulation barriers, it remains unclear whether a pig organ can carry out all of the required functions in the primate bodily environment. At present, pig kidney transplantation in nonhuman primates is accompanied by the development of proteinuria (an abnormally large amount of protein in the urine). The latter induces hypoalbuminemia (an abnormally low concentration of albumin in the blood) which, in turn, leads to complications such as peripheral edema⁶⁷ (Ekser & Cooper 2010). While continuous intravenous infusion of human albumin is theoretically able to remediate this problem, it does not represent a practically feasible option.

Even if the abovementioned problems could be solved within a reasonable timeframe, the potential for the development of a xenozoonosis may prove to be an insurmountable obstacle. While the occurrence of a xenozoonosis is now considered to be much less likely than previously thought, it cannot, at present, be excluded (Hunter 2009). Admittedly, the small *magnitude* of this risk does not constitute a contraindication to the initiation of clinical trials. However, its potential widespread *reach* may very well do so. If cases of xenozoonosis were to occur, unknown and undetected infectious agents could easily and quickly spread beyond national borders. As the risks of infection would not be confined to those nations undertaking clinical trials, the global population should arguably be involved in the decision-making process about whether or not to proceed with experimentation in humans. In short, a process of global consent would be required (Sparrow 2009). Given the many practical difficulties with a requirement of obtaining *actual* consent from the global population, *hypothetical* consent would ‘merely’ need to be sought. Such global hypothetical consent is obtained “when it is reasonable

⁶⁷ Peripheral edema is defined as “an abnormal increase in the volume of fluid within a defined tissue space” (Jaffe et al. 1999, 308).

to believe that the procedure would receive majority support from a fully informed global community, if such a debate and vote were possible” (Sparrow 2009, 124). The distribution pattern of risks and benefits of xenotransplantation suggests that majority support is unlikely to be forthcoming. As noted above, xenotransplantation will not be accessible to Third World countries. At the same time, the latter will bear most of the risks as their health care systems are much less suited to coping with an infectious pandemic. A similar risk-benefit distribution is also likely to apply to the poor in developed nations lacking universal health care. Thus, the poor in both developed and developing countries do not have an interest in consenting to xenotransplantation trials (Sparrow 2009).

Timeliness of kidney bioengineering

Recently, the field of kidney bioengineering has witnessed some interesting developments. Most noteworthy are the advances, achieved through whole organ decellularization techniques, in the production of scaffolds for organ engineering (Arenas-Herrera et al. 2013). In enabling one to obtain a scaffold from a readily available organ by stripping it of functional cells, such techniques obviate the need to build an organ from scratch. Relying on this methodology, scientists succeeded in producing a functional rat kidney earlier last year. Song et al. (2013) used a detergent perfusion to wash away the native cells of a healthy donor rat kidney. The resulting scaffold did not run the risk of being rejected by the recipient as it consisted of collagen, a biologically inert material. The rat kidney scaffold was seeded with epithelial and endothelial cells. Next, this cell-seeded construct was perfused in a whole-organ bioreactor. Finally, the team transplanted the organ into a living rat. The graft provided urine production and clearance of metabolites. Nevertheless, it displayed a much lower level of functional maturity, relative to a non-bioengineered donor kidney. For example, the bioengineered kidney performed significantly worse in terms of the glomerular filtration rate (GFR)⁶⁸. Although the abovementioned experiment provides proof of principle, many hurdles remain to be overcome in the process of translating this technology into the clinic (Arenas-Herrera et al. 2013). To begin with, a better understanding of the way in which the scaffold drives cell fate determination is required in order to obtain functional integration of the former into the surrounding tissue (Orlando et al. 2010). In addition, the optimal organ donor source from which to obtain a kidney scaffold needs to be identified. In this respect, some have suggested using porcine acellular matrices. The latter provide a number of advantages. As noted above, porcine tissues provide a good

⁶⁸ This refers to how well kidneys filter blood.

size match for humans. Moreover, the use of acellular porcine tissue is not unprecedented. Heart valves, for example, have already been used in the clinic. Nevertheless, ‘semi-xenotransplantation’ – the repopulation of acellular porcine organ matrix with autologous human cells – is not unproblematic in that it involves ethical and unknown safety issues (Arenas-Herrera et al. 2013).

Besides problems associated with the scaffold, kidney bioengineering also faces difficulties concerning repopulation. Specifically, the task of obtaining a sufficient number of cells which maintain function over time appears challenging (Orlando et al. 2010). The average patient requiring a kidney transplant is relatively old. This renders seeding with the recipient’s differentiated cells suboptimal as the latter are likely to have entered replicative senescence – a state in which a cell has lost its ability to divide. Advanced age is also associated with reduced cell functionality. In order to obtain a more functional, longer-lived cell population, researchers are examining the use of stem cells (Orlando et al. 2010). However, renal stem/progenitor cells may also be less than ideal candidates for kidney bioengineering due to their restricted growth and differentiation potential as well as their low prevalence (Yokote et al. 2012). Identification of the most suitable source of stem cells for de novo kidney regeneration remains an important research goal (Feil et al. 2011; Yokote et al. 2012). In any case, the production of a bioengineered kidney is likely to prove a challenging endeavor as the human kidney is a complex tissue, consisting of more than 20 cell types (Franquesa et al. 2013).

The use of stem cells for *in vivo* renal repair also faces major challenges. For example, it is unclear whether or not kidneys of patients with ESRD are beyond repair. Some argue that the total disruption of the kidney’s sophisticated structure as a result of ESRD renders stem-cell based therapy unable to entirely regenerate the damaged tissue (Yokote et al. 2012; Harari-Steinberg et al. 2011). They maintain that stem cell therapy for rejuvenation or regeneration of individual cell types is only a viable option for patients in the slow progression route from CKD to ESRD. Others, however, suggest that *in vivo* renal repair may also prove feasible for ESRD patients (Perin et al. 2011). Nevertheless, the latter admit that there are many obstacles to overcome, ranging from the delivery of stem cells into solid organs to the functioning of these cells in an *in vivo* environment.

6.4.2 Timeliness of conservative supply strategies

The timely implementation of conservative supply strategies does not hinge on scientific advancements. However, any change in organ procurement policy should only be introduced when considerable public support exists for it. The unsuccessful law

change in Brazil is illustrative in this respect. In 1997, the Brazilian government implemented a presumed consent regime under circumstances of deep public distrust of the health care system. Reported cases of difficulties in opting-out aggravated public fears (Ammann 2010). A year later, the presumed consent statute was repealed (Liddy 2000). As this example suggests, trust in the medical community is not ubiquitous. As a result of the multicultural make-up of many societies, levels of trust are likely to vary, not only between countries, but also within a country. So far, little or no effort has been made to gauge levels of trust and other determinants of public support for the various conservative supply strategies. Moreover, the few available studies point towards a considerable variation in the level of support (see, for example, UK Organ Donation Taskforce 2008). Therefore, it is, at present, unclear whether any of these strategies will gather sufficient support for it to be implementable in an effective way.

Recently, various expert advisory committees have assessed the merit of conservative supply strategies. If their reports are anything to go by, implementation of this type of strategies is far from imminent.

In 2008, the UK Organ Donation Taskforce was asked to investigate whether the introduction of a presumed consent regime would be advisable. The panel, consisting of, amongst others, ethicists, medical lawyers and clinicians, advised negatively (UK Organ Donation Taskforce 2008) – although it should be noted that Wales has recently decided to bring a system of presumed consent into law by 2015 (Welbourn 2014). A similar inquiry was conducted in the US in 2004 on behalf of the Health Resources and Services Administration (HRSA) and The Greenwall Foundation (Institute of Medicine 2006). The Institute of Medicine (IOM), commissioned with this task, also opposed the introduction of a presumed consent regime.

Proposals for paid organ donation have met with strong resistance from various international groups, such as the World Health Organization, the Council of Europe, the Asian Taskforce, and the Declaration of Istanbul (Moazam et al. 2009). The latter, which was drawn up in 2008, documents the consensus view obtained throughout meetings with leading organ transplant organizations, bioethicists, and social scientists (Moazam et al. 2009). The Declaration approves payments which merely cover costs incurred through donation (e.g. lost income, medical expenses incurred for post-discharge care). In short, it sanctions the removal of socio-economic disincentives to donation. However, it strongly condemns any form of payment which renders donors or their families better off postoperatively– financially or otherwise (Voo et al. 2009). Numerous professional and governmental groups have endorsed these guidelines (Moazam et al. 2009).

In the case of financial incentives, layman and expert opinions may not be the only factor hindering (timely) implementation. Recall that the introduction of payments for

donation is potentially subject to the ‘crowding out’ phenomenon. The most reliable means of testing the occurrence hereof consists in a provisional implementation of financial incentives. However, such a dry run may not be feasible in practice. Some studies suggest that the effects of crowding out are irreversible. For example, in response to parents being late to pick up their children, an Israeli day care center decided to impose a fine for lateness (Rothman & Rothman 2006). Contrary to expectations, the number of late pickups increased. This higher level of lateness persisted after the abolition of the fines. Consequently, it may be argued that the introduction of financial incentives for organ donation will *always* be prohibitively risky.

6.5 Exploring the other option: reducing demand

We have identified two reasons why strategies aimed at increasing kidney supply will fail to satisfactorily accommodate future levels of demand. Below, we examine whether the alternative approach to kidney scarcity – strategies aimed at reducing demand – fares any better. More specifically, we assess the merits of preventative strategies. We argue that the latter are both implementable in a timely manner and less costly than supply strategies, thereby reducing the need for rationing of dialysis and donor organs. Prevention has the added advantage of offering a global solution to a global problem.

6.5.1 Timeliness of preventative strategies

There are two reasons to believe that a substantial reduction in the burden of ESRD is attainable. First, we possess the knowledge to prevent or delay the onset of CKD (Schoolwerth et al. 2006). Second, we are equally capable of slowing the progression of diabetic and non-diabetic CKD. In the case of non-diabetic patients, sustained remission or regression of CKD has even been documented (Perico & Remuzzi 2012). Primary prevention is concerned with forestalling the development of risk factors for CKD, such as diabetes and hypertension. In addition, it involves treating those at increased risk of developing CKD. Lifestyle changes, such as moderate weight loss and regular physical activity, can reduce the incidence of diabetes in high-risk individuals (American Diabetes Association 2013). A decrease in blood pressure and the incidence of hypertension is, for example, obtainable through reductions in dietary salt intake. Strict

glucose control or use of angiotensin-converting enzyme (ACE) inhibitors⁶⁹ prevent or delay the development of albuminuria (an abnormally large amount of the protein ‘albumin’ in the urine)⁷⁰ in diabetics (Levey et al. 2009).

Secondary prevention consists in detection and treatment of CKD. Two simple tests are available for detection of CKD: a urine test for albumin and a blood test for serum creatinine to estimate GFR (Levey et al. 2009). The progression of diabetic and non-diabetic CKD can be slowed through control of hypertension and proteinuria, using inhibitors of the renin-angiotensin system (Perico & Remuzzi 2012; Gansevoort et al. 2013). By contrast, management of late-stage CKD is likely to require a multifactorial approach, including strict glucose control, angiotensin-converting enzyme inhibitors, other hypertensive agents, aspirin and lifestyle interventions. Such a strategy has proven successful in normalizing albuminuria and preventing loss of kidney function in patients otherwise condemned to rapid progression to kidney failure (Gansevoort et al. 2013).

Despite the availability of simple preventative measures, the major, modifiable risk factors for CKD are under-treated. CKD, in turn, is both under-treated and under-diagnosed. In short, although the knowledge for successful prevention of CKD/ESRD is at hand, the extent to which it has been applied is disappointing. Thus, if we are to tackle the problem lying ahead, a comprehensive public health approach is needed (Schoolwerth et al. 2006). A major component hereof will consist in the large-scale implementation of detection and prevention programs, such as screening for CKD. The leadership of nephrologists will prove a key factor in achieving this (Bello et al. 2005).

The problem of under-treatment and under-diagnosis is not merely attributable to the lack of a uniform application of simple tests for detection. There is also a problem of ‘under-education’. Diabetics and hypertensive patients are often unaware that they are at increased risk of developing CKD. Moreover, most CKD patients are oblivious of their condition (Schoolwerth et al. 2006). It is imperative to communicate the seriousness of CKD, its risk factors, and opportunities for screening to both health care providers and the general public. Educational materials, informing patients identified with CKD of the treatment regimens and benefits of therapy, should be drawn up (Schoolwerth et al. 2006). World Kidney Day, which aims to convey the common, harmful, and treatable nature of CKD to a broad range of stakeholders, represents a laudable educational initiative (Levey et al. 2009).

⁶⁹ A drug primarily used for the treatment of hypertension.

⁷⁰ Albuminuria is usually a symptom of kidney disease.

The success of a preventative approach to the CKD/ESRD burden hinges on a concerted effort from and collaboration between government agencies, lay organizations, health professionals, and professional societies. Moreover, an international collaborative response is needed. In the presence of a strong commitment to taking the necessary measures, a significant reduction in the societal impact of CKD/ESRD should be attainable within the next two decades (Alebiosu & Ayodele 2005).

6.5.2 Financial viability of preventative strategies

The easiest way of determining whether prevention represents a cheaper option than supply strategies is to assess the merit of both against the standard of the baseline scenario. The latter refers to the situation which obtains in the coming decades when neither preventative nor supply strategies are pursued. In short, it is the outcome that would be achieved if current policies for dealing with kidney scarcity were to be maintained. Below, we first assess whether, relative to the baseline scenario, preventative strategies produce cost savings and, if so, how substantial these are. Next, we do the same for supply strategies.

Preventative approaches to health care usually increase expenditures (Russell 2009). However, both primary and secondary prevention of CKD/ESRD constitute an exception to the rule, at least when specific high-risk populations are targeted. In a Dutch setting, administration of ACE inhibitors to newly diagnosed *type 2 diabetics* was cost-effective and reduced health care expenditures. This finding proved robust to a variety of different assumptions of uncertainty (Adarkwah et al. 2011). A major 5-year study, funded by the Australian National Health and Medical Research Council, evaluated 150 preventative health interventions. It demonstrated that screening for CKD in *diabetics* and subsequent treatment with ACE inhibitors has a large cost saving potential. In addition, such a preventative approach was shown to provide a greater health gain than dialysis and transplantation combined (Vos et al. 2010). Another Australian study researched the cost saving potential of screening for CKD in men and women *aged 50 years and older*. For every 20,000 people screened, a net cost saving of \$A 70,000 was obtained (Craig et al. 2002). In a French study, screening for CKD in patients with *type 2 diabetes and hypertension*, followed by adjusted therapy, resulted in a €4,812 reduction in ESRD-related costs per patient (Postma & de Zeeuw 2009). A similar result was achieved in a US setting (Postma & de Zeeuw 2009). Finally, a US study on screening for CKD in *diabetics* demonstrated cost savings of \$217 per person (Boulware et al. 2003).

As the above figures illustrate, the cost savings obtained through prevention vary according to the population screened. In the case of screening for CKD in diabetics, the projected number of diabetics in 2030 (around 36 million in the US), combined with the

abovementioned cost saving of \$217 per person, roughly suggest a \$8 billion reduction in costs, relative to the baseline scenario (Shaw et al. 2010). Similar to most research on screening for CKD, the study by Boulware et al. (2003) merely takes into account cost reductions obtained through averting new cases of *ESRD*. However, administration of ACE inhibitors subsequent to detection of CKD would also help avert cardiovascular disease (CVD) – a prevalent comorbidity in CKD patients (de Jong et al. 2008; Adarkwah et al. 2011). Costs related to treatment of CVD are high (Heidenreich et al. 2011). Thus, the \$8 billion finding substantially underestimates the cost saving potential of screening for CKD in diabetic patients.

It is impossible to reach a definitive verdict with regard to the cost saving potential, if any, of supply strategies, relative to the baseline scenario. There is a multitude of unknown variables, such as the exact cost of transplantation under radical supply strategies (and under a financial market in kidneys), the exact magnitude of the increase in kidney donors following implementation of conservative strategies, etc. Given these constraints, one can, at best, make an educated guess when assessing how supply strategies fare, relative to the baseline scenario. In doing so, we assume that the implementation of supply strategies will work out cheaper than the continued pursuit of current organ donation policies.⁷¹

The characteristics of supply strategies suggest that neither conservative nor radical interventions are likely to bring about *substantial* cost saving. As noted above, conservative strategies are likely to produce a negligible increase in donor kidneys. Therefore, relative to the baseline scenario, they avert only a minimal number of expensive dialysis cases. At first sight, the infinite supply of kidneys (i.e. the lack of need for *all* long-term dialysis) under radical strategies suggests that the latter produce substantial cost savings, relative to the baseline case. However, the high cost of xenotransplantation/transplantation of bioengineered kidneys suggests that, even if these modes of transplantation were to remain cheaper than dialysis, the difference in cost would only be marginal.

⁷¹ Note that conservative supply strategies (with the exception of a financial market) will most likely save costs, relative to the baseline scenario. After all, in increasing the kidney supply, conservative supply strategies ensure that a part of the group requiring dialysis under the baseline scenario now receive the cheaper mode of treatment. In contrast to conservative strategies, radical supply strategies do not necessarily reduce costs, relative to the baseline scenario. They will only do so if transplantation remains cheaper than dialysis. Thus, in assuming that radical supply strategies have cost saving potential, relative to the baseline scenario, we devise a line of reasoning based on the best case scenario.

In sum, relative to the baseline scenario, prevention is likely to produce greater cost savings than supply strategies. Consequently, compared to supply strategies (and the baseline scenario), a preventative approach to CKD/ESRD would better attenuate the need for rationing of dialysis and transplantation.

6.5.3 Prevention: a global solution to a global problem

Besides providing a more affordable and timely solution to the ESRD pandemic, prevention has yet another advantage. It is amenable to implementation, not only in developed, but also in developing countries.⁷² This is an important consideration, for 2 reasons. First, whereas ESRD mostly affects the elderly in the developed world, its prevalence generally peaks between the third and the fifth decade of life in developing countries. The latter disease pattern causes manpower shortage and economic waste (Alebiosu et al. 2005). Second, the prevalence of ESRD is also projected to rise significantly in developing countries. Although a high number of ESRD cases in developing countries is currently infection-related, diabetic nephropathy is becoming increasingly common due to changes in food intake and lifestyle. By 2025, diabetes prevalence is expected to reach 228 million, a 170% increase from current levels (Kaul et al. 2013).

Experience suggests that inexpensive, successful prevention programs are feasible in low-income settings. For example, in India, social health officers measured blood pressure and carried out simple urine tests in a rural community of 25,000. The screening identified 6% of the population as hypertensive and 4% as diabetic (Mani 2003). Using the cheapest preventative agents available, blood pressure lower than 140/90 mm Hg was achieved in 96% of hypertensive patients. In addition, a hemoglobin A1c level lower than 7% was obtained in 52% of the diabetics (Couser et al. 2011). The annual per-capita cost of the program was a mere \$0.27. A similar success story was

⁷² Obviously, there is little point in implementing supply strategies in developing countries. First, supply strategies which rely upon deceased donation would face religious and cultural opposition in many countries (Garcia-Garcia et al. 2012). Second, access to renal replacement therapy (RRT) is highly limited in developing countries. Many dialysis centers are located in urban areas and, therefore, require a long commute for most patients (Naicker 2013). The high costs of RRT services, the shortage of skilled personnel and inadequate facilities, funding and support further limit access to both dialysis and transplantation. For example, in Sub-Saharan Africa, only seven countries provide kidney transplantation (Naicker 2013). In India and Pakistan, a mere 5% of ESRD patients undergo transplantation. The high costs of hemodialysis compel most patients to cease treatment within the first three months (Schieppati et al. 2005).

recently observed in Nepal. A serum creatinine test⁷³ was performed in 1000 participants. 10.4% of the population was subsequently diagnosed with CKD. Cheap ACE inhibitors were administered to these patients in order to stabilize their proteinuria. Follow-up indicated regression or stabilization of proteinuria in 52% of patients (Kirby 2010).

Despite the abovementioned successes, challenges remain for the widespread implementation of preventative programs in developing countries. The lack of donor funds threatens to limit the long-term success of such programs. International donor funds earmarked for health tend to favor infectious diseases, at the detriment of chronic diseases, such as CKD and ESRD. Nevertheless, a slight turnaround in this tendency has recently been observed. For example, between 2004 and 2008, global donor funding for chronic diseases tripled (Nugent et al. 2011). The lack of donor funding, combined with the low priority assigned to CKD/ESRD prevention by local governments, render follow-up of patients a challenging task (Codreanu et al. 2006). The obtainment of government support will hinge on lobbying efforts from nongovernmental and charitable organizations (Bello et al. 2005).

The continuing 'brain drain' of health care workers from developing to developed countries represents an additional barrier to prevention. Whereas there are 16.7 nephrologists pmp in the United States, the numbers in Sub-Saharan Africa vary from 0.5 pmp in Kenya to 0.6 pmp in Nigeria, 0.7 pmp in Sudan, and 1.1 pmp in South Africa (Naicker 2013). Possible measures to address the 'brain drain' include a higher remuneration in the public health sector, penalization of departing professionals, and the establishment of compulsory service as a means of delaying departures. Another possible solution consists in training paramedics, whose skills would go unrecognized abroad, with a view to fulfilling roles otherwise performed by doctors. However, funding agencies also have an important role to play in tackling the 'brain drain' in that they can improve the educational services for health care professionals in developing countries (Pang et al. 2002).

⁷³ This test measures the level of creatinine in the blood. The latter, in turn, indicates how well the kidneys filter.

6.6 Conclusion

Currently, the burden of ESRD presents itself as a problem of commodity scarcity (i.e. scarcity of donor kidneys). For this reason, the solution is generally sought in increasing kidney supply. However, the increasing prevalence of ESRD, combined with the already high costs of renal replacement therapies (RRT), suggest that we are heading towards a situation wherein RRT faces both commodity scarcity and scarcity of financial resources. Supply strategies are shortsighted in that they are oblivious to the financial reality lying ahead. By contrast, a preventative approach provides a more financially viable and readily available solution. Moreover, it is implementable on a global scale.

We are not the first to promote a preventative approach to CKD/ESRD. The merit of the latter is increasingly being recognized by nephrologists. However, their advocacy makes no reference to (the flaws of) supply strategies. It merely consists in quoting the platitude that prevention is better than cure. The argumentative void wherein prevention is currently advocated allows the importance of a preventative approach to fall on deaf ears. In exposing supply strategies as dead-end solutions, we hope to incite the long overdue shift in the approach to ESRD.

6.7 References

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Background to chapters 7 and 8

Part two of this dissertation has, so far, largely concentrated on the implications of population aging for long-standing ‘coping mechanisms’ and ‘solutions’ in the context of kidney scarcity. Chapters 7 and 8 shift the focus away from population aging and kidney scarcity. Nevertheless, they continue along the same path as chapter 6 in that they provide an ethical analysis of currently proposed *solutions* to a *particular type of commodity scarcity* in health care. Chapter 7 focuses on the shortage of donor livers, whereas chapter 8 is devoted to the scarcity of human body material for research purposes. Recent amendments to the Belgian law in these two contexts motivate this shift away from kidney scarcity. We believe that an ethical analysis of supply-oriented proposals in the realm of commodity scarcity would not be complete without a discussion of these highly topical developments.

Chapter 7 relates to the tendency – described in the general introduction – towards an increased reliance upon living donation as a means of increasing organ supply. Donor eligibility criteria for living donation are becoming ever more lenient. A recent amendment of the Belgian transplantation law represents a radical move in the liberalization of these criteria in that it allows children as young as 12 to donate a liver segment or lobe to a sibling under certain circumstances. In chapter 7, we analyze whether living liver donation by minors is ethically acceptable.

Research on human biological material holds great promise for developing better means of preventing, diagnosing, and treating diseases. Biological material removed post mortem is a particularly valuable resource for research as some tissues only become available after death. In order to obtain such tissues more easily, Belgium has recently extended its presumed consent regime for post mortem removal of organs for *transplantation* to post mortem removal of body material for *research* purposes. In chapter 8, we examine whether this extension is ethically sound.

Chapter 7

Should minors be considered as potential living liver donors?

Based on published journal article:

Capitaine, L., Thys, K., Van Assche, K., Sterckx, S. and Pennings, G. (2013) "Should minors be considered as potential living liver donors?". *Liver Transplantation* 19: 649-655.

7.1 Introduction

Living donor liver transplantation was successfully introduced in 1989 as a response to the exceptionally high waiting list mortality for small children (Renz et al. 2003). Soon the procedure was expanded to large adolescents and adults and it has since become a widespread medical treatment for end-stage liver disease and genetic metabolic disorders. However, living liver donation involves a very complicated surgical procedure, with a significant risk of mortality and morbidity. In the absence of worldwide registration and mandatory reporting, exact estimation of donor mortality is extremely difficult. According to the most frequently cited estimates, mortality approaches 0.1% for left lobe donation and 0.5% for right lobe donation (Barr et al. 2006; Kousoulas et al. 2011; Otte 2003). As a result of widely diverging definitions, the incidence of donor morbidity is also of uncertain magnitude (Middleton et al. 2006; Gradiadei 2007). Apart from the risk of general anesthesia, potentially serious morbidities include surgical site infections, biliary complications, portal vein thrombosis, intra-abdominal bleeding, pulmonary embolus and incisional hernia. Studies focusing on such serious complications report an overall incidence rate of 15% to 20% (Kousoulas et al. 2011; Middleton et al. 2006; Dutkowski et al. 2010; Brown et al. 2003; Renz & Roberts 2003).

Confronted with these risks, the enormous benefit to the recipient is, presumably, the reason why living donor liver transplantation is still being performed. Obtaining an organ from a living donor may be the last resort for patients suffering from life-threatening liver disease. The need for a liver transplantation is often more urgent than for a kidney transplantation, as the annual mortality rate for patients awaiting a liver graft is almost double that recorded for patients awaiting a kidney. In addition, liver donation cannot be postponed in the same way as kidney donation since there is no substitute treatment similar to hemodialysis and peritoneal dialysis that can sustain functions until an organ becomes available (Weisberg & Brown 2007). Moreover, deceased liver donation has its technical limits. Admittedly, the practices of reduced-size and split-graft liver transplantation have increased the availability of donor grafts, yet these grafts may not be suitable for all patients.

Despite the availability of living donor liver transplantation as a lifesaving procedure, only a fairly small percentage of potential living donors may be suitable (Trotter et al. 2002). People suffering from common medical conditions such as cardiovascular disease, diabetes or hypertension will be ruled out, while smoking and obesity may also be considered relative contraindications to living donation. Sometimes, a minor may be the only suitable donor, especially in cases of acute liver failure (Ladd 2004). Although this

circumstance will be very rare, living liver donations by minors have been reported. Specifically, there have been 13 such cases in the US (OPTN 2012). Other countries, such as Japan and Brazil, have also recorded cases of minor living liver donors (Honda et al. 2009; Tannuri et al. 2011). When deemed to involve acceptable risks to the health of the donor, living liver donation by minors is allowed in several other countries, for example Ireland, Sweden and the UK. Moreover, in countries that currently allow minors to donate only hematopoietic stem cells, a tendency could be developing to interpret the possibility for minors to donate regenerative tissue/body material as also including liver segments or lobes. An indication hereof can be found in the August 2012 amendment of the Belgian transplantation law. The possibility for minors to donate regenerative tissue or organs/body material, which had previously been interpreted as only pertaining to hematopoietic stem cells, has now been reinterpreted as also referring to liver segments or lobes.⁷⁴ This law allows minors as young as 12 to donate to their brother or sister, on condition that they are capable of expressing their will and have given prior consent.

In the academic literature and professional guidelines, little attention is paid to developing a specific ethical framework for living liver donation by minors. The focus is frequently limited to donation of regenerative tissues and kidneys. However, due to the increased medical risks of liver donation and the lack of substitute therapies, the considerations that are relevant to this context may differ in important respects from those pertaining to kidney and regenerative tissue donation. Thus, there is an urgent need for more profound reflection on the ethical aspects of living liver donation by minors. In this chapter, we try to assess whether living liver donation by minors can be ethically appropriate. We occasionally refer to the new Belgian law as a starting point for our ethical reflection.

⁷⁴ The amendment of the Belgian transplantation law was published in the Official Journal of Belgium on 24 August 2012. Available at: http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=1986061337&table_name=wet (Dutch) and http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=1986061337&table_name=loi (French). [last accessed 14 October 2012].

7.2 Living liver donation and decisional capacity

The imposition of risks to the living liver donor may be warranted when the donor decides that they are worth taking. In other words, a potential living donor has a moral right to accept a considerable health risk in order to help a patient in need of an organ (Veatch 2000; Gutmann & Land 2008). However, the primacy of the donor's right to donate is not absolute. Most importantly, the decision to donate should be an autonomous one, implying that the potential donor demonstrates decisional capacity. One possesses this capacity when one is able to comprehend and to make a judgment about the information concerning a medical intervention, to intend a certain outcome, and to communicate freely one's wishes (Beauchamp & Childress 2009).

For subjects possessing decisional capacity, their prior, free and informed consent is a necessary condition of morally permissible living liver donation. 'Disclosure', 'understanding', and 'voluntariness' are generally recognized as the necessary components of informed consent (Beauchamp & Childress 2009). The 'disclosure' factor implies that complete, objective and intelligible information should be provided in order to allow the potential living liver donor to arrive at a well-reasoned conclusion. The 'understanding' component requires one to ensure that the potential donor has an accurate understanding of the purpose and nature of the procedure, the possible consequences to her health and emotional well-being, the expected health impact on the recipient and the availability and efficacy of possible alternative therapies. Finally, the 'voluntariness' element requires screening aimed at verifying that potential living liver donors are not influenced by undue pressure, deception or financial incentives (Veatch 2000; Gutmann & Land 2008).

Except for adults who have been judicially declared mentally incompetent, the law operates under the rebuttable presumption that adults are competent to make their own decisions about living liver donation. However, even when deemed sufficiently competent and free and informed consent to donate is obtained, the autonomy of the potential adult donor is still bound by legal restrictions and standards of reasonable medical practice. Donation will not be allowed when the transplant team is of the opinion that the overall risk-benefit balance of the procedure is clearly negative or that the absolute level of risk to the donor is too high. In addition, in most countries living liver donation is subject to additional requirements, such as authorization by an independent body and restriction to recipients with whom a close personal relationship exists. These provisions are intended to prevent undue pressure or improper inducement to donate (Veatch 2000; Gutmann & Land 2008).

If we are to determine whether minors should be allowed to donate a liver lobe, we must ascertain whether they possess sufficient capacity to make this decision. Therefore, in the following sections we take a closer look at minors' decision-making capacity. First, we discuss the (exceptional) circumstances under which minors are considered *legally* competent to make their own health care decisions. Next, we develop a *moral* framework which provides a means of distinguishing those health care decisions which minors (of a certain age) are capable of making from those which they are incapable of making. Finally, we apply this moral framework to the specific context of living liver donation.

7.2.1 Assessing minors' competence to consent to medical interventions

Legal framework

Minors are legally considered as incompetents, lacking the necessary capacity to make fully informed medical decisions (Boonstra & Nash 2000). There is a general, legal presumption that parents have their children's best interests at heart (Derish & Vanden Heuvel 2000). Parents, therefore, are granted the right to make health care decisions on their minor children's behalf.

The requirement for parental consent in the medical care of minors is subject to four possible exceptions. First, in emergency situations, when there is no time to obtain parental consent, medical personnel are allowed to treat a minor. The rationale behind this exception is the idea that parents, if present, would consent to treatment. In addition, the emergency exception serves to protect the physician from liability (Driggs 2001). Second, minors who are emancipated by marriage or other circumstances have the right to make decisions on their own behalf. Third, many jurisdictions explicitly authorize minors to consent to certain specific medical interventions, such as prenatal care, drug treatment, contraception, mental health care, and testing and treatment for sexually transmitted diseases. This authorization aims to encourage minors to seek care which, under a parental consent requirement, might not be sought for fear of parental punishment. As such, this third exception primarily constitutes a protective measure for minors (Boonstra & Nash 2000). A final exception to the parental consent requirement is the 'mature minor doctrine'. The latter permits a minor to consent to or refuse treatment provided that she has the capacity to understand the nature and consequences of the medical decision at hand. Many countries appear to have adopted a 'mature minor doctrine' of some sort (Stultiëns et al. 2007; Sancı et al. 2004). In the United States, however, only a few states have enacted statutes allowing mature minors to consent to their own medical treatment (Driggs 2001). In assessing a minor's level of

maturity, courts take into account the nature and gravity of the treatment. Adolescents are generally found competent to consent to or refuse low risk procedures (e.g. tonsillectomies, vaccinations, and treatments for back pain), whereas they are seldom deemed sufficiently mature to consent to high-risk or life-altering procedures (e.g. gender reassignment, sterilization) (Sanci et al. 2004). Moreover, with the exception of blood donation, courts do not generally sanction adolescent consent to non-therapeutic⁷⁵ procedures benefiting a third party, such as skin graft donations (Schlam & Wood 2000). Courts vary with regard to the standard of proof used for determining maturity. Some have favored a case-by-case approach. Others have applied the 'Rule of Sevens', a standard derived from English common law. Under this rule, children under age 7 do not have the capacity to consent, children aged 7 to 14 are presumed not to have this capacity (until proven otherwise in individual cases), and children aged 14 and above are presumed to have the capacity to make their own decisions, unless proven otherwise (Toner & Schwartz 2003).

Moral framework

According to Steinberg and Scott (2003), when discussing decisional capacity, we should distinguish cognitive maturity from its psychosocial counterpart. Studies suggest that adolescents beyond the age of 14 demonstrate a level of *cognitive* maturity similar to that of adults, i.e. they possess adult-like capacities for logical reasoning about moral, social, and interpersonal matters. For example, a study by Weithorn and Campbell (1982) showed that 14-year-olds did not differ significantly from 18- and 21-year-old adults with regard to their ability to reason or understand treatment information presented to them in medical dilemmas. Subsequent research into the development of *cognitive* capacities found similarly high levels of adolescent maturity (see, for example, Hale 1990; Belter & Grisso 1984). Those who advocate granting adolescents a higher degree of self-determination in medical decision-making often cite this type of research. The American Psychological Association, for example, has argued for a recognition of adolescents' right to consent to abortion on the basis of their having decision-making skills comparable to those of adults (Steinberg et al. 2009).

Whereas adolescents display cognitive capacities which come close to those of adults, they do not yet exhibit adult-like levels of *psychosocial* maturity. There are four psychosocial factors which are specifically relevant to decision-making outcomes (Steinberg et al. 2009).

⁷⁵ 'Non-therapeutic' refers to a procedure which does not provide a medical benefit to the *adolescent*.

A first factor is 'susceptibility to social coercion'. Research supports the common-sense view that adolescents are more susceptible to coercive influences than adults (Gardner & Steinberg 2005). In some contexts, adolescents' choices are made in response to *direct* peer pressure. However, adolescents' desire for peer approval or fear of rejection may also affect their choices *indirectly*, i.e. in the absence of direct coercion.

'Risk perception' constitutes a second psychosocial factor. Relative to adults, adolescents place less weight on risk, in relation to reward (Pontoon 1997). They often consider themselves invulnerable to harm (Schlam 2000). This factor, for example, explains why adolescents engage in unprotected sex more often than adults. The fact that adolescents demonstrate adult-like *cognitive* capacities implies that they are fully *aware* of and *understand* the potential risks involved. However, as a result of their distorted risk-reward calculus, they see the potential benefits of unprotected sex as outweighing the potential risks (Cauffman & Steinberg 2000).

A third psychosocial factor is known as 'future orientation', a term which refers to the extent to which one anticipates future consequences. Adolescents tend to focus mainly on short-term consequences – both risks and benefits – of their choices, whereas adults also take into account long-term impacts (see, for example, Halpern-Felsher & Cauffman 2001). The limited life experience of adolescents may account for their greater inclination to discount the future: a consequence 10 years away from now is likely to appear more remote the shorter one's experienced lifespan (Larson et al. 1980).

A final psychosocial factor relates to 'impulsivity'. Research indicates that adolescents are prone to more extreme mood swings and have more difficulty in controlling their impulses and behavior (see, for example, Farrington 2003).

The distinction between cognitive and psychosocial maturity provides us with a standard for identifying the type of decision to which the 'mature minor doctrine' should be held applicable. In sum, it tells us which decisions we may allow adolescents to consent to or refuse. The established cognitive maturity of adolescents suggests that we should regard them as having sufficient decisional capacity to make health care decisions which are generally *not strongly* influenced by any of the abovementioned psychosocial factors. By contrast, their psychosocial immaturity implies that we ought to consider them as lacking the decisional capacity to make health care decisions with a strong psychosocial component, i.e. decisions which *typically* elicit impulsivity, involve high levels of social coercion or significant immediate risks/long term consequences. Note that it will not always be clear-cut whether one is dealing with a health care decision of the former or the latter type.

One might argue that our approach is problematic in that it is based on findings of (in)sufficient decisional capacity in the *average* adolescent, thereby ignoring possible deviations from the average. Admittedly, our approach runs the risk of assuming cognitive maturity where there is none, and vice versa for psychosocial maturity.

However, we currently lack the instruments to reliably assess maturity on an individualized basis (Wendler 2006). In the absence of such instruments, it seems unproblematic to presume that sufficient decisional capacity is present in the case of health care decisions where psychosocial factors are not strongly at play. The latter, after all, tend to be low-risk decisions. In the same vein, the typically high-risk nature of health care decisions with a strong psychosocial component suggests that, in such cases, we do well to err on the side of insufficient decisional capacity.

7.2.2 Assessing minors' capacity to consent to living liver donation

If we are to determine whether we should consider adolescents as having the capacity to consent to living liver donation, we must identify the type of decision-making process involved. Therefore, this section will examine, for each of the psychosocial factors, the extent to which they are relevant to the context of living liver donation by minors.

With regard to 'susceptibility to social coercion', it should be noted that the context of living donation exhibits certain features which increase the chances of coercive pressures occurring. One such feature is that donation typically takes place between family members. In the case of living *liver* donation, there is the added element of the lack of any substitute therapy. Parents, regardless of whether they themselves or one of their children are in need of a liver, may pressurize their minor child into donation. The minor is likely to succumb to such pressure given that she is socially dependent on her parents. If the candidate recipient is a sibling, the latter may exert an additional source of coercion, especially if she is an adult.

The psychosocial factor 'risk perception' is also highly relevant to the context of living liver donation by minors. As noted earlier on, living liver donation involves a significant risk of mortality and morbidity. Data concerning morbidity and mortality risks, however, generally focus on adult donors. Due to the extremely small number of cases involving minor donors, very little is known about the risks for this specific population. Thus, we cannot, at present, exclude the possibility of the risks being still higher for minor donors.

'Future orientation', the third psychosocial factor, also comes into play in living liver donation by minors. Although the regenerative capacity of the liver is often invoked as a reason for dismissing the possibility of any significant *future* health risks to the donor, such dismissal, at present, seems highly premature. First, living liver donation is too recent a practice for long-term data to have been established. Second, whereas the

donor's liver regains normal metabolic function within a matter of weeks after donation, it only regenerates to about 89% of its preoperative volume (Middleton et al. 2006; Haga et al. 2008). Therefore, we cannot exclude the possibility of the incomplete restoration of initial liver volume having serious long-term consequences (Pomfret 2003). Where little is known about the long-term consequences for adult living liver donors, still less is known about the more recent (and extremely small scale) practice of using minors as living donors. In any case, however, minors are likely to suffer more from any adverse long-term effects as they have a greater number of life years ahead of them.

Most often, 'impulsivity' will not be a salient psychosocial feature of an adolescent's decision to consent to living liver donation. However, in exceptional circumstances, impulsivity might come into play. For example, if the candidate recipient suffers from acute liver failure, she might have a life expectancy of less than a week without transplantation (Stravitz & Kramer 2009). Under such time pressure, there is an increased chance of the adolescent's impulses getting the upper hand over deliberative, reasoned decision-making.

Based upon the above analysis, we may reasonably conclude that many, if not all, of the psychosocial factors feature in the living liver donation decision. We should, therefore, subject this decision to a heightened standard of decisional capacity, i.e. one requiring the presence of psychosocial maturity in addition to cognitive maturity. In demanding such a high level of decisional capacity, our proposal satisfies the widely accepted 'proportionality requirement'. The latter refers to a sliding scale, implying that the level of decisional capacity required ought to increase in accordance with the level of risk involved in the decision (Doig & Burgess 2000).

As a result of their psychosocial immaturity, adolescents considering living liver donation run the risk of giving in to coercive pressures as well as placing too little weight on possible immediate and long-term risks. Moreover, under circumstances requiring expedited transplantation, adolescents' decisions are more likely to be rash, rather than well-thought through. Adolescents should, therefore, be considered incapable of consenting to living liver donation. Thus, in presuming that minors as young as 12 are able to consent to such a procedure, the Belgian transplantation law is far too permissive.

7.3 Is living liver donation in the best interests of minors?

Given a minor's insufficient decisional capacity to consent to living liver donation, the harm involved in such a procedure cannot be justified on the basis of her autonomous decision. However, the acceptability of living liver donation by minors need not necessarily be ruled out. As noted earlier, parents are generally granted the right to make health care decisions on their minor children's behalf. Whereas this practice of proxy consent is generally undisputed in cases where the decision relates to the minor's own health, it is less clear whether it should extend to interventions on minors for the benefit of a third party (Schenberg 2007). In sum, there may, in the case of living liver donation, still be grounds to allow parents (or other surrogate decision makers) to give proxy consent.

Those advocating the right of surrogate decision makers to consent to living donation on a minor's behalf disagree as to which party is best suited to act as a proxy. While some argue that the proxy decision should be left to the parents' discretion, others believe that parents might have a conflict of interest. The latter, therefore, recommend transferring the decision making right to either a judge, the minor's physician, or an ethics committee (Nygren 2006).

When making medical decisions for their ward, surrogates are bound by certain standards. There are two widely used standards for making decisions on the part of incompetents: 'the substituted judgment' standard and the 'best interests' standard. The former standard dictates that the surrogate act in the way the patient would do if competent to make the decision. Use of the 'substituted judgment' standard is restricted to those cases where there is reliable evidence as to the patient's preferences for treatment under the circumstances (Nygren 2006). We inevitably lack such evidence when dealing with patients who have never been competent, such as minors. The 'best interests' standard governs surrogate decision-making for this category of incompetents. It requires that the surrogate "determine the highest net benefit among the available options, assigning different weights to interests the patient has in each option and discounting or subtracting inherent risks or costs" (Beauchamp & Childress 2009, 138).

As the above suggests, the 'best interests of the incompetent person' is the appropriate decision-making standard in the context of living liver donation by minors. Thus, if we grant surrogate decision makers the right to issue proxy consent to donation, their decision must be based on an analysis of the risks and benefits incurred by the minor donor. However, the question remains as to whether we *ought* to grant surrogate

decision makers this right. After all, it would be foolish to do so, and thus to allow living liver donation by minors, if we have ample reason to believe that this type of donation is *generally* not in a minor's best interests. Therefore, we now proceed to assess whether, generally speaking, living liver donation is in a minor's best interests.

Although living donor liver transplantation provides no therapeutic benefit to the donor and carries a high risk of morbidity and mortality, it can still be in the donor's overall best interests if she is likely to expect significant *psychological benefits*. Living organ donors have reported heightened self-esteem, enhanced feelings of autonomy, renewed meaning in life and other positive feelings associated with important altruistic acts (Johnson et al. 1999; Patenaude 1990). Combined with the emotional benefits that are more immediately derived from preventing the loss of a loved one, these elements may encourage donation even when considerable health risks are involved. The same type of risk-benefit calculation has been applied to kidney donation by minors to family members. It is argued that minors may already experience the positive effects of altruism and will clearly benefit from the continued companionship of the recipient and from growing up in a family untouched by tragic loss (see *Hart v Brown* 1972; *Little v Little* 1979).

However, this risk-benefit calculation is problematic when applied to minors. For instance, it remains unclear to what extent minors can indeed experience these psychological benefits, especially when their cognitive and emotional capacities are still developing (Schenberg 2007; Crouch & Elliott 1999). Furthermore, donation may also have severe negative psychological effects, such as lower self-esteem, feelings of abuse, a strained relationship with the recipient, a sense of neglect and lack of appreciation and, where the transplantation fails, feelings of anger, guilt, and blame (Cheyette 2000; Packman et al. 1997). Specifically in liver donation, additional psychological problems have been reported, including cosmetic issues due to significant scar formation, anxiety regarding one's future health and, remarkably, a significantly higher rate of psychiatric complications (Barr et al. 2006; Renz & Roberts 2000; Cipe et al. 2011; Erim et al. 2006; Trotter et al. 2007). Finally, there is yet another sense in which a living liver donor might experience adverse psychological effects. As minors have generally not yet started a family of their own, they may, later on in life, come to regret their decision to donate. After all, despite its regenerative capacity, a liver lobe can only be donated once in a lifetime, pre-empting the opportunity of subsequent donation to people with whom a more intimate bond might exist (Holm 2004).

In view of the high mortality and morbidity risk, rather speculative psychological benefits and potentially important psychological risks, we may conclude that living liver donation is *generally* not in a minor's best interests. Thus, we have no grounds to

grant surrogate decision makers the right to consent to living liver donation on a minor's behalf. This, in turn, suggests that we ought to prohibit living liver donation by minors.

The best interests standard has been criticized for its narrow construal of interests. This criticism draws upon the distinction between self-regarding interests and other-regarding interests. The former category includes those interests which bear *exclusively* upon the agent's own well-being. Other-regarding interests refer to an agent's desire for another's well-being. Whereas the fulfillment of this desire may partly serve as a means to the agent's own well-being, the agent generally also pursues the other's well-being as an end in itself (Crouch & Elliott 1999). In focusing exclusively on the *donor's* well-being, the best interests standard, it is argued, wrongly presumes that agents are motivated merely by self-regarding interests. This disregard for altruistic motives is said to be especially problematic in the family context – a context which is obviously highly relevant to living donation. According to these critics, the depiction of donors as mere self-interest maximizers fundamentally misconstrues the nature of familial relationships (Morley 2002). They stress that family members cherish each other simply for each other's sake. We do things for family members which we would not do for 'outsiders' (Crouch & Elliott 1999). Stronger still, we have a moral obligation to make sacrifices for our family. In acting as if incompetents should not be called upon to do so, the best interests standard is said to disregard their integral role within the family (Morley 2002). A true recognition of the reality of family life and of the moral obligations it entails, according to these critics, suggests that parents should base their decision to issue proxy consent on the interests of the family as a whole. Thus, it is precisely on the basis of furthering this family interest that these critics justify living liver donation by minors.

The above criticism of the best interests standard is problematic, however, for several reasons. First, while familial relationships may entail certain moral obligations, it is not clear why these should give rise to the specific obligation to donate an organ (Steinberg 2004). An argument should be put forward in defense of the existence of the latter type of obligation. Second, even if a solid basis could be provided in support of a moral duty to rescue family members, its scope would likely be limited to a very specific type of familial relationship. Parents may well have such a duty towards their children. However, it is less clear whether the child-to-parent and the sibling relationship are subject to the same obligation (Griner 1993). Third, even if minors were to have a moral duty to rescue, it is hard to imagine the latter extending to living liver donation. As Dwyer and Vig (1995) suggest, the degree of risk one should be expected to undergo, varies according to the type of familial relationship. Whereas one may expect parents to take significant risks for their children, the child-to-parent and the sibling relationship

could, at most, justify an exposure to moderate risks. As mentioned above, liver donation does not fit this description.

Although the above criticism of the best interests standard is unconvincing, it may force us to somewhat qualify our proposal of a blanket prohibition on living liver donation by minors. We have conceded that parents may have a moral obligation to donate an organ to their child. In any case, regardless of whether or not parents *actually have* such an obligation, research indicates that they *experience* such a feeling of moral indebtedness. Adult parents often describe the decision to donate to their own child as natural and self-evident, emanating from the moral imperative to place the interests of their child before their own. Parents who are not accepted as suitable living donors for their own children often report negative feelings, such as disappointment and anger (Zeiler et al. 2010).

The same feelings and experiences are also likely to occur in minor parents. The exceptional nature of the parent-child relationship suggests that a minor parent donating to his or her child will most probably experience a substantial psychological benefit – substantial enough to outweigh any negative effects. A uniform prohibition on living liver donation by minors may impede minor parents in exercising what they regard as an essential part of their parental responsibility. Thus, minor parent-to-child living liver donation merits consideration as a possible exception to our blanket prohibition. In this respect, it deserves mentioning that in several US states, minors are generally deemed unacceptable liver donors, except if the intended recipient is their own child (Brown 2008). Donation requests from minor parents would always require ad hoc consideration. The specifics of how to deal with such requests, however, lie outside the scope of this dissertation.

7.4 Concluding remarks

Living liver donation entails an invasive procedure with a fairly high morbidity and mortality risk. Donation by minors is only acceptable when the procedure is the result of an informed, well-considered and autonomous consent of the potential minor donor, or when it is in the minor's best interests. We have argued that minors should not be regarded as having sufficient decisional capacity to consent to living liver donation. Although adolescents possess sufficient *cognitive* maturity, they lack sufficient *psychosocial* maturity to resist family pressure and impulsivity and to fully take into account possible immediate and long-term risks. In addition, living liver donation by minors cannot be justified on the basis of the best interests of the minor, as current

knowledge regarding the psychological benefits of living liver donation by minors is inadequate. Moreover - presuming that a minor may experience psychological benefits as a consequence of living liver donation - these benefits are unlikely to outweigh the medical and psychological risks and burdens of the procedure. It is only in the case of a minor parent donating to her child, that the benefits are likely to outweigh the risks. Therefore, we conclude that, with the possible exception of minor parents donating to their child, minors should not be considered as potential living liver donors.

7.5 References

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Chapter 8

Governing the post mortem procurement of human body material for research: comments from an ethical perspective

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8.1 Introduction

This chapter swaps the heretofore dominant focus on organ shortage for an analysis of the broader category of scarcity of human biological material. Moreover, it shifts away from donation for therapeutic purposes to donation for research purposes. Human biological material is increasingly being used for research purposes. In combination with associated health-related data, research on human biological material allows researchers to investigate the effects of genetic predisposition, life-style and exposure to environmental factors. In this way, research on human biological material holds great promise for the development of diagnostic and therapeutic tools and disease-preventing strategies.

Biological material may be procured not only from living persons but also from the dead. Biological material removed post mortem is a particularly valuable resource for research, especially because some tissues generally only become available after death (e.g. brains, hearts, and metastasized tumors). Considering the enormous efforts that are currently being made to study the biochemical processes and possible genetic causes that underlie cancer and cardiovascular and neurodegenerative diseases, it is likely that biological material removed post mortem will continue to gain in importance.

The removal and storage of biological material from the deceased raises specific ethical concerns. As has recently been highlighted in various post mortem organ retention scandals in England, Wales, Scotland and Australia, severe ethical problems arise when proper consent is not sought (English & Sommerville 2003; Thomas 2002). In the wake of the outrage caused by the scandals in the Bristol Royal Infirmary and Liverpool's Alder Hey Hospital,⁷⁶ the Human Tissue Act 2004 and Human Tissue (Scotland) Act 2006 came into force in the UK. Subject to criminal sanctions, the post mortem removal of human biological material for research is now only allowed in the UK after so-called 'appropriate consent' is given. If the deceased person had not given explicit consent, that consent must be obtained from a 'nominated representative' or, in the absence of such, from a person who stood in a qualifying relationship with the deceased.⁷⁷

⁷⁶ The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995. (2001) Available at http://www.bristol-inquiry.org.uk/final_report/the_report.pdf and Royal Liverpool Children's Inquiry Report. (2001) Available at <http://www.rlcinquiry.org.uk/download/index.htm> [last accessed 18 March 2013].

⁷⁷ Human Tissue Act 2004, Part I, 2-5.

In countries operating an explicit consent or so-called ‘opt-in’ system for post mortem organ donation, similar provisions apply to post mortem removal of body material for research. Likewise, some countries operating a presumed consent or so-called ‘opt-out’ system for post mortem organ donation for transplantation have recently *extended* the presumed consent system to post mortem removal of human body material for research. This has happened in Spain, France and Belgium. It has resulted in a *twofold extension of the presumed consent regime* that governs cadaveric organ transplantation: *first*, an extension from post mortem removal of *organs* to post mortem removal of *any* human body material that falls under the scope of the applicable law on human body material, and *secondly*, an extension from post mortem removal for *transplantation* purposes to post mortem removal for *research* purposes.

In Spain, this extension was introduced by the Royal Decree of 18 November 2011.⁷⁸ The Decree allows removal of body material after death for research purposes when the deceased person had expressed consent or at least had not indicated opposition. In the latter case, efforts must be made to gather information about the wishes of the deceased person, by exploring the existence of advance directives or, in the absence of these, by consulting the next-of-kin and health care professionals involved in the treatment of the person concerned. If there is no indication of the deceased person’s wishes, removal is allowed unless the next-of-kin provide reasonable objections. Removal is only permitted if it is performed within the framework of a research protocol that has been approved by a Research Ethics Committee.

In France, a presumed consent system for post mortem removal of human body material for research was introduced by the Law N° 2004-800 on Bioethics of 6 August 2004.⁷⁹ The Law amended the Health Act in a way that allows post mortem removal of body material for research if the person concerned had not indicated refusal. The opportunity is offered to register refusal in a special national registry. In the absence of registered refusal, the next-of-kin must be consulted about the wishes which the deceased might have expressed in this regard. If there is no indication of the deceased person’s wishes, the removal will be permitted. The next-of-kin should be duly informed about the purpose of the removal and have the right to be informed about what body material has been removed. The Agency of Biomedicine has to grant prior approval of the research protocol and needs to be informed prior to any removal.

⁷⁸ Real Decreto 1716/2011, de 18 de noviembre, por el que se establecen los requisitos básicos de autorización y funcionamiento de los biobancos con fines de investigación biomédica y del tratamiento de las muestras biológicas de origen humano, y se regula el funcionamiento y organización del Registro Nacional de Biobancos para investigación biomédica, Art. 26

⁷⁹ Loi n° 2004-800 du 6 août 2004 relative à la bioéthique.

Whereas specific protective measures are in place in both the Spanish and French regulations, this is not the case in Belgium. Concerning post mortem removal of human body material for research, the Belgian law on human body material of 19 December 2008⁸⁰ simply refers to the provisions regarding presumed consent in the Organ Transplantation Law of 13 June 1986.⁸¹

The Belgian law of 2008 equates the absence of any registered objection to post mortem removal of organs for transplantation with the absence of any objection to post mortem removal of any body material for any purpose. Thus, the law permits post mortem removal of body material from any corpse, unless the deceased person has objected to post mortem removal of organs for transplantation. No separate ‘opt-out’ register has been put in place for registering objections to post mortem uses of body material for research. However, the Belgian population is unaware of this law. Neither the government nor any other organization has made any effort whatsoever to inform the public of this new legal regime for the post mortem procurement of body material. As a result, any citizen who objects to post mortem removal of her body material for research will obviously fail to register this objection.

Thus, *in practice*, the new Belgian presumed consent system amounts to *a routine removal or ‘conscriptio’ of body material after death* whenever a clinician or researcher: (1) finds a specific post mortem removal useful for research; (2) has access to a dead body; and (3) neither the deceased nor the next-of-kin object(ed) to post mortem removal of organs for transplantation.

In this chapter, we attempt to determine which consent regime should govern the post mortem procurement of body material for research. Given that, in practice, the Belgian system boils down to conscription, we first analyze whether a regime of conscription or routine removal is ethically acceptable. We will assess the various arguments that could be put forward in support of a duty to make body material available for research purposes after death. Our analysis suggests that such a duty can be substantiated on at least two grounds (a duty to refrain from free-riding and a duty to contribute to the maintenance of public goods) and possibly also on a third ground (a duty of easy rescue, depending on how such a duty is interpreted), but that this duty is always conditional. We conclude that this duty could support conscription but *only* as a last resort and *only*

⁸⁰ Wet inzake het verkrijgen en het gebruik van menselijk lichaamsmateriaal met het oog op de geneeskundige toepassing op de mens of het wetenschappelijk onderzoek/Loi relative à l'obtention et à l'utilisation de matériel corporel humain destiné à des applications médicales humaines ou à des fins de recherche scientifique, Article 12. Official versions of the law exist only in Dutch and French.

⁸¹ Wet betreffende het wegnemen en transplanteren van organen/Loi sur le prélèvement et la transplantation d'organes, Articles 10-13. Official versions of the law exist only in Dutch and French.

if a way were found to guarantee that two conditions that attach to the duty would be met. Since neither of these two criteria is currently fulfilled, conscription must be rejected. We conclude, however, that the duty to make body material available for research purposes after death is sufficiently strong to defend a policy of presumed rather than explicit consent.

8.2 Arguments in support of a duty to make body material available for research after death

A duty to make body material available for research after death could be advocated on the basis of two more fundamental duties: a *duty of fairness* towards research participants for having benefited from the results of research and a *duty of beneficence*, on the assumption that this type of contribution to research will prevent harm and does not imply a significant sacrifice. In this section, we will examine these arguments and indicate to what extent, if at all, they could support a duty to make one's body material available for research after death.

8.2.1 Duty of Fairness

It could be argued that people have a duty to make their body material available for research purposes after they die, out of fairness for having benefited from the results of biomedical research throughout their life. Following Rawls' (1971) principles of justice, the duty of fairness implies that people who benefit from participating in cooperative social schemes have duties towards each other to assume, when called upon, the risks and burdens which accompany the involvement in such social schemes. On the basis of such a duty, several prominent bioethicists have argued for a general duty to participate in biomedical research which, it is implied, could also require persons to allow research to be performed on their remains (Caplan 1984; Harris 2005; Rhodes 2008). The duty of fairness can be split up into two more specific duties: a *duty to refrain from free-riding* and a *duty to contribute to the maintenance of public goods*. In the following two subsections, we analyze each of these duties and argue that they both support a *conditional* duty to make body material available for research after death.

8.2.1.1 Duty to refrain from free-riding

Some bioethicists argue that people who do not take part in biomedical research, while at the same time accepting its benefits, are free-riding on the backs of those who do participate (Evans 2004; Harris 2005; Orentlicher 2005; Rhodes 2005). As we all (at least in industrialized countries) gain from the results of biomedical research, they argue, non-participants have an outstanding moral debt which implies a duty to also participate in biomedical research.

Free-riding occurs when a person obtains a benefit resulting from the efforts of others and this person refuses to assume part of the burdens involved in bringing about the benefit (Schaefer et al. 2009). It could be argued that, although a moral debt will result from gaining from biomedical research in general, this moral debt can be made up for in other ways than participation in biomedical research. From this perspective, it is overly simplistic to label as free-riders those who benefit from biomedical research without themselves having participated. After all, almost all people already pay – via taxes, insurance policies or out of their own pockets – for almost every medical benefit they enjoy (Brassington 2011; de Melo-Martin 2008). In addition, they often also indirectly support – through taxes – biomedical research projects. However, according to this line of reasoning, it may be asserted that the small minority of individuals who do not financially support biomedical research can still be accused of free-riding and may fairly be expected to make up for their moral debt by participating in person. In response, it can be pointed out that the likely unfairness that leaves persons in a position of not being able to contribute financially may override obligations stemming from being free-riders.⁸²

By contrast, if the focus is shifted to the moral debt arising from benefiting from specific knowledge resulting from biomedical research on body material, the conclusion that non-participation amounts to free-riding is much harder to escape. After all, specific biomedical research cannot be carried out on the basis of financial contributions alone (Chan & Harris 2009; Stjernschantz et al. 2013). It could therefore be argued that a moral obligation exists to allow post mortem removal of one's body material for research. However, this duty is conditional in that it will not attach to persons who have already donated samples while alive. Furthermore, it will only extend to types of research similar to the ones from which these persons had actually benefited.

⁸² We thank one of the anonymous reviewers for pointing this out.

8.2.1.2 Duty to contribute to the maintenance of public goods

A second argument put forward in support of a general duty to participate in biomedical research invokes the concept of ‘public goods’. A public good exhibits the characteristics of ‘non-rivalry’ and ‘non-excludability’. Non-rivalry implies that a person can use the good without diminishing the amount available for others. Non-excludability refers to the impossibility of excluding anyone from enjoying the benefits of the good, even if they contributed nothing to its provision (Clark et al. 2003). Some claim that the knowledge resulting from biomedical research represents a public good. Given that we all benefit from generalizable biomedical knowledge, it is argued, we have a duty to contribute to the advancement of such knowledge by participating in biomedical research (Schaefer et al. 2009). Again, this implicitly could require persons to allow post mortem removal of their body material for research.

The abovementioned argument has encountered major resistance. A first criticism challenges the public good status attributed to biomedical knowledge on the grounds that disadvantaged groups have no (or limited) access to health care (de Melo-Martin 2008). It is rightly stressed that in the industrialized world, access to the results of biomedical research also depends on factors such as one’s financial situation (health insurance), the availability of preventative health care and the extent to which information concerning medical solutions and developments is conveyed. In response, however, it can be pointed out that this argument does not seem generally applicable to countries operating welfare states where, at least in principle, access to basic health care is also provided for otherwise disadvantaged groups.⁸³ Moreover, lack of access to health care does not preclude other ways of benefiting from biomedical knowledge. For example, people who do not have access to a vaccine will benefit from herd immunity as long as a substantial number of other persons are vaccinated. To mention another example, research conducted at the beginning of the last century demonstrated an inverse relationship between higher fluoride concentration of the drinking water and lower levels of dental caries experience (Ripa 1993). Based upon this finding, numerous countries have adjusted the water fluoride concentration to a level expected to promote dental health. Up until today, both the rich and the poor in those countries benefit from this practice.

A second line of criticism argues that many biomedical research projects do not result in a public good. In this regard, three types of arguments are put forward. First, it is stressed that many research projects do not yield any relevant results and thereby fail

⁸³ We thank one of the anonymous reviewers for pointing this out.

to produce a public good (Holm et al. 2009). Second, it is pointed out that a lot of research is carried out in a way that hampers other researchers from obtaining useful results in the same field and, thereby, hinders the development of public goods. Typical measures include the refusal to publicly report findings and the use of patenting and licensing practices, which may stall subsequent research and the development of diagnostic and therapeutic tools (Sterckx 2011; Cockbain & Sterckx 2011). Third, it is observed that biomedical research projects may also be harmful to the participants. Even in the absence of physical harm, there is a possibility of researchers exploiting research participants by viewing them merely as a means to achieving prestige and/or wealth, as in the cases of, for example, the late John Moore (see *Moore v. Regents of University of California* 1990) and the members of the Havasupai tribe in the United States (Van Assche et al. 2013) Furthermore, research results may, for example in the case of genetic research, also be used for insurance or employment discrimination or be stigmatizing for the research participant or the wider group (Ashburn et al. 2000). However, these arguments miss the point since they do not refute the public good status of biomedical knowledge but merely emphasize that research should be carried out in a proper way.

A final group of critics acknowledges the public good status of biomedical knowledge, but disputes the claim that research participation is required in order to discharge the duty to contribute to the maintenance of the public good. However, as we have argued in the context of free-riding, biomedical research cannot be carried out on the basis of financial contributions alone. It could therefore be argued that, to the extent that biomedical knowledge can only be attained by direct participation of individuals, the duty to maintain the public good will result in a duty to participate.

On this basis, a duty may be said to exist to contribute to the maintenance of biomedical knowledge by post mortem donation of body material for research purposes. However, it should be stressed that this duty is conditional. Following the general principle of fairness, persons who have donated body material whilst alive will already have done their fair share. Moreover, the duty will only extend to research projects that will result in biomedical knowledge constituting a public good.

8.2.2 Duty of Beneficence

An additional argument that could be invoked to substantiate a duty to make one's body material available for research purposes after death does not focus on the duty of fairness but on the duty of beneficence. The latter implies that we have to act in ways that prevent or remove harm or that confer benefit (Beauchamp & Childress 2009). According to some commentators, given that biomedical research represents a

necessary tool for alleviating the plight of patients, we have a moral duty to participate in biomedical research (see, for example, Harris 2005). If such a duty were to be established, this could require people to allow post mortem removal of their body material for research. In this respect, a distinction needs to be made between the general duty of beneficence and the more specific duty of easy rescue. In the following subsections both duties will be analyzed and it will be argued that the duty of easy rescue can only support a *conditional* duty to make body material available for research after death.

8.2.2.1 General duty of beneficence

While the duty of non-maleficence (i.e. the duty to refrain from causing harm) can be considered as a perfect duty, the general duty of beneficence is merely an imperfect duty (Shapshay & Pimple 2007). The assumption of a *perfect* moral duty to help others is untenable, for at least two reasons. First, such a duty would require too great an effort because it would command people to continuously engage in a wide range of actions of benefit to society (Murphy 2000). Second, a perfect moral duty of beneficence would also undermine our moral integrity. Given that there are many ways in which harm to others can be limited, we would be obliged to spend most of our time, energy and resources on combating poverty, hunger, and wars, rather than on projects which minimize harm to others to a lesser extent. As Williams has convincingly argued, a perfect moral duty of beneficence would reduce an individual to a 'harm-minimizing instrument' lacking any integrity. After all, her actions would not correspond to her convictions and life projects (Williams 1990).

An *imperfect* duty to help others implies that we ought to view the happiness of others as an end in itself. However, at the same time we are given great leeway in achieving this goal. We are allowed to weigh up this end against other (possibly private) ends. Thus, the pursuit of others' happiness need not always be prioritized (Hill 1992). If we acknowledge the existence of an imperfect moral duty to help others, the question arises as to why this duty would entail obligatory participation in biomedical research, including making our body material available for research after death (Shapshay & Pimple 2007; Wachbroit & Wasserman 2005).

The duty of beneficence requires us to support our fellow-man. There are various ways of achieving this end, however, many of which are much more effective than participation in biomedical research (de Melo-Martin 2008). Even if the fight against disease were our primary task, it is not clear why participation in research is the only or even the best way of achieving this. Biomedical research (especially in its current form) may not represent the best means of reducing the global burden of disease. Given the

close link between poverty and disease, fighting poverty would probably constitute a much more efficient means of combating disease (Woolf et al. 2007; Pogge 2002).

In sum, if we consider the question at issue here from the perspective of a general duty of beneficence, the conclusion seems to be that, whereas people may have very good reasons to make their body material available for research after death, they are not required to do so. It is up to them to decide whether and, if so, under what conditions, they want to fulfill their duty of beneficence by engaging in precisely this type of act.

8.2.2.2 Duty of easy rescue

However, under certain specific circumstances the duty of beneficence may be a *perfect* duty, in which case the discretion normally allowed by beneficence is eliminated. This is frequently referred to as the ‘duty of easy rescue’. The duty of easy rescue was first elaborated by Thomas Aquinas and has been introduced in bioethics by ethicists like Peter Singer and Michael Slote. In a relatively old, but still very influential article concerning famine and ethics, Peter Singer (1972) argued, on the basis of his famous thought experiment about a child drowning in a pond, that we are morally obliged to prevent harm whenever we are able to do so without having to sacrifice anything of comparable moral significance. Similarly, Michael Slote (1977) endorses the view that we have a duty to prevent serious harm whenever we are able to do so without interfering with our own life plan and without incurring serious harm.

According to Beauchamp and Childress (2013, 206-209), there is an obligation to rescue if five cumulative conditions are fulfilled: (1) someone is at risk of significant loss of or damage to life, health or another basic interest; (2) another person’s action is required in order to prevent this loss or damage; (3) this action will probably prevent the loss or damage; (4) this action involves no important risks, costs or burdens for the other person; and (5) the expected gain for the person in need outweighs any likely harms, costs or burdens for the other person.

The duty of easy rescue is frequently used to justify an obligation of post mortem *organ* donation for transplantation, even to the point of advocating a system of conscription (Fabre 2006; Hester 2006; Snyder 2009; Spital & Taylor 2007). However, even if an obligation to donate one’s organs for transplantation after death could be established on the basis of a duty of easy rescue, a similar obligation to make one’s *body material* available for *research* purposes after death seems harder to substantiate.

In the case at hand the first two conditions seem to be met since many individuals at significant (future) health risk will arguably substantially benefit from other people’s post mortem donation of body material for research. With regard to the third condition, discussion may arise as to how likely it needs to be that the post mortem donation of

body material by a third person will prevent the health loss of the other person. In addition, uncertainty may exist as to how obvious the causal link between the contribution and the health benefit has to be. On the one hand, it can be argued that, even if a high probability of success and a clear causal relationship can be difficult to demonstrate, a duty of easy rescue may be defended if one factors in that this kind of health relief can only be achieved by collective and sustained action. On the other hand, the stock examples of easy rescue presented in the literature (e.g. assistance from bystanders which does not put them in harm's way; post mortem organ donation) seem to suggest that, at the time of the required action, both the rescuer and the person in peril have to be clearly identified and that the action of one and only one person is required to help the person in need (James 2007; Smith 1990). In view of these considerations regarding the third condition of easy rescue, it seems clear that the applicability of a duty of easy rescue can neither be easily substantiated nor simply discarded for the topic at issue here, i.e. making body material available after death for research purposes.

Taking into account the fourth condition, a duty of rescue will only apply where the action that is required does not represent significant risks, costs or burdens to the person concerned (otherwise the rescue would not be 'easy'). However, although this is frequently assumed, it is not at all obvious that the type of biomedical research at issue here – research on human body material – cannot involve important harms and wrongs. Some people may conscientiously object to the removal itself because of beliefs that the body should be buried as a whole. For these persons the costs incurred may be substantial and even disproportionate when compared to the expected benefits of their contribution.

Even for people who do not find the removal in itself objectionable, a lot could be at stake. As has already been highlighted, research on human body material may involve severe infringements upon the privacy, autonomy, or moral integrity of the research participants. Indeed, body material may be used in a way that is incompatible with the moral values of the person concerned. In this context it should be noted that, following Ronald Dworkin's (1993) terminology, so-called 'critical interests' may be at stake.⁸⁴ Such interests are bound in the projects, plans and choices that persons have made and that give meaning to their life. When meaningful life plans are made, it is important for the individual that others respect them and do not take actions that will critically impact on them in a negative way. From this perspective, people are entitled to their

⁸⁴ 'Critical interests' need to be distinguished from so-called 'experiential interests' which are related to the pursuit of pleasurable experiences. Contrary to 'critical interests', the setback of experiential interests will be temporarily frustrating at most (Dworkin 1993).

body material being used in a manner that corresponds to their life story, character, and values.⁸⁵ Failure to respect this would amount to instrumentalization.⁸⁶ As bioethicist Julian Savulescu has put it:

Each mature person should be the author of his or her own life. Each person has values, plans, aspirations, and feelings about how that life should go. People have values which may collide with research goals [...].

To ask a person's permission to do something to that person is to involve her actively and to give her the opportunity to make the project a part of her plans. When we involve people in our projects without their consent we use them as a means to our own ends. (Savulescu 2002, 648-649)

In the literature, it is sometimes quickly assumed that dead individuals cannot be harmed by posthumous events. Proponents of this view argue that, as the deceased have no interests, there are no interests which can be harmed by the posthumous use of their body material (Spital & Erin 2002). By contrast, defenders of the concept of 'posthumous interests' argue that people do have critical interests that survive their death and may thus be harmed when these interests are violated (see, for example, Belliotti 2012).

Although this debate is highly fascinating, we cannot elaborate on it here and we shall suffice to say that we agree with those commentators who claim that we should respect the wishes of people also after their death, yet not out of a concern for harming them through posthumous events but *for the sake of the living* (Hamer & Rivlin 2003; Partridge 1981; Wicclair 2002). Generally, one can draw great reassurance and comfort, while alive, from the knowledge that one's preferences and values will be respected after death. Conversely, the expectation that one's preferences and values will be disregarded

⁸⁵ As the US National Bioethics Advisory Commission already observed in 1999, anonymization of the body material cannot invalidate this claim: "It is incorrect to assume that because the sources cannot be identified they cannot be harmed or wronged. [...] Individuals have an interest in avoiding uses of their tissues they regard as morally impermissible or objectionable. Thus, were their materials to be used in research that they would consider objectionable, it is possible that some individuals could be wronged, if not harmed" (NBAC 1999,61). At most, anonymization might offer protection with regard to privacy, although several recent studies suggest that even this cannot be guaranteed (McGuire & Gibbs 2006; Schmidt & Callier 2012; Lowrance & Collins 2007).

⁸⁶ We are not suggesting here that the instrumentalization argument holds generally, i.e. that it is never permissible to do something to a competent person that does not correspond to their life story, values and character. In exceptional cases coercion might be permissible (e.g. mandatory immunization; coerced placement and treatment) but these interventions find their justification in averting a *grave and direct* danger to the person concerned, third parties or society at large. These conditions do not apply to (post mortem) removal of body material for research.

after death is likely to result in considerable anxiety and distress among the living (Wicclair 2002). As a result, the living have an interest in respecting the wishes of the deceased because in doing so they will strengthen the traditions that will protect their own interests in having posthumous influence (Partridge 1981).

Therefore, we would conclude that, even if the first three requirements for easy rescue would be fulfilled, no obligation to make one's body material available for research after death could be established on the basis of a duty of easy rescue when that research would disregard important values and wishes of the deceased. Put differently, samples should only be removed after death if such removal and subsequent research would be compatible with the critical interests of the pre mortem person. Hence a duty of easy rescue can only be a conditional duty in the context at issue here, and it cannot be sufficient to justify a conscription regime. This leads us to the question as to how people's wishes with regard to research uses of their body material should be ascertained, or, put differently, what kind of consent regime should apply.

8.3 Consent regimes revisited

We have reviewed several arguments that could be put forward in support of a duty to participate in biomedical research that could extend to a duty to donate body material for research after death. We found that such a duty could be substantiated on the basis of a least two grounds (a duty to refrain from free-riding and a duty to contribute to the maintenance of public goods) and possibly a third ground (easy rescue, depending on how the conditions for an easy rescue are specified). However, since, as explained above, in each of these cases important conditions need to be fulfilled before the duty to donate body material for research after death would be triggered, this duty is always conditional. What does this imply with regard to the question as to which regime should govern the post mortem procurement of body material for research?

8.3.1 No consent: Conscription

Can a conditional duty to donate body material for research after death commit us to accept a policy of conscription? Analyzing paradigmatic cases of conscription (e.g. military conscription; jury service; compulsory vaccination), Holm et al. conclude that conscription is only justified if its purpose cannot be achieved on a voluntary basis (Holm et al. 2009). However, in the context of post mortem removal of body material the claim that conscription is necessary is not plausible, for other, less coercive ways exist

to achieve a sufficient supply of body material. Even with regard to research that relies heavily on body material which only becomes available after death, there does not seem to be a need to resort to compulsory removal before other strategies have been actively pursued.

If insufficient body material would be collected by resorting only to non-compulsory ways of post mortem removal, a policy of conscription could be justified on the basis of a duty to donate body material for research after death. However, in that case, the system of conscription would still need to comply with the conditions that attach to the duty. It could, for instance, be argued that, on the basis of a duty to contribute to the maintenance of public goods, samples from persons who did not donate body material while alive may be conscripted after death if access to these samples would be limited to research projects which focus on obtaining biomedical knowledge that would unquestionably qualify as a public good. It has been proposed that this could be the case for research that is entirely uncontroversial and is likely to result in benefits that would be made available to everybody and would contribute to leveling social differences (Christensen 2009). However, in our view, these and similar suggestions raise overly challenging and arguably insurmountable problems related to the implementation and monitoring of the system of conscription. It would, for instance, be unclear who in each instance would decide whether conscription to a specific research project would be justified and what characteristics this project would need to have in order to be compatible with the conditional duty to make one's body material available for research after death.

We can conclude that, in the current state of affairs, since the claim of necessity is not fulfilled and major problems of implementation and monitoring would arise, a system of post mortem conscription of body material for research cannot be substantiated on the basis of a duty to donate body material for research after death.

8.3.2 Presumed consent rather than explicit consent

By contrast, we would argue that the duty to donate body material for research after death is clearly strong enough to defend a system of presumed consent to post mortem removal of body material for research, rather than a regime of explicit consent which is the default option for participation in biomedical research. As we have seen, there are two and possibly three grounds to expect that individuals make their body material available for research after death. Yet, since the resulting duty will always be a conditional one, it is reasonable to leave it to the persons concerned to decide for themselves if they do not wish to donate and to expect them to take the necessary steps to opt out if they wish.

Indeed, it has been pointed out that a presumed consent system does not in any way restrict a person's right to self-determination, as long as the person was aware of the system and the implications of action or inaction, had a reasonable time period in which to object, and was offered adequate and accessible means of formally recording objections (Den Hartogh 2008). Furthermore, for many people the cost of contributing more than strictly required by duty are low.⁸⁷ It may, for instance, be assumed that a lot of individuals do not have deep seated objections to the removal of body material after death, even in the absence of guarantees that the research will comply with the conditions governing their duty (e.g. that the research will indeed result in knowledge constituting a public good).

However, in order to minimize the chance that body material would be removed after death from persons to whom no duty applied (e.g. because the intended research project is incompatible with their pre mortem values, implying that the fourth and fifth condition for the existence of a duty of easy rescue would not be met) and who did not want to go beyond the call of duty, several requirements would need to be fulfilled. First, awareness-raising campaigns should be launched to inform the public about the possibility of post mortem removal of body material for research purposes, the possible research uses and the consent regime in place. Second, procedures should be established to allow potential participants to register their unwillingness to make their body material available for research after death.⁸⁸ Third, in the absence of a registered refusal, the next-of-kin must be consulted regarding the deceased person's wishes. Finally, it is conceivable that some people are unwilling to donate body material for certain types of research uses, while willing to do so for other research purposes. Therefore, besides the possibility for a blanket opt-out, it would seem to be advisable to also enable one to opt-out for certain generic categories of research uses.⁸⁹

Admittedly, a system of presumed consent would imply the possibility that some people may opt out of making their body material available for research after death without having discharged their moral duty even though the conditions for the applicability of

⁸⁷ We thank one of the anonymous reviewers for pointing this out.

⁸⁸ In other words, post mortem donation of body material and donation of organs should be governed by separate registers.

⁸⁹ Admittedly, it is impossible to compose an exhaustive list of such categories. Nevertheless, one could envisage a system wherein a limited number of categories are listed, followed by a text-box in which the person can write down any other research uses that she deems unacceptable. Further analysis is necessary to underpin more specific proposals in this regard; our focus here is on highlighting the reasons why, for the case of post mortem uses of body material for research, it is ethically permissible to depart from the default regime for participation in biomedical research, i.e. explicit consent, and to adopt a regime of presumed consent with proper safeguards.

the duty were met. However, as noted earlier, there is no reason to legally enforce this moral duty as long as a sufficient supply of body material can be obtained by non-compulsory methods.

8.4 Conclusion

On the basis of a critical examination of various arguments invoked in the literature, we found that a duty to make one's body material available for research after death could be established on the basis of the duty to refrain from free-riding, the duty to contribute to the maintenance of public goods and, depending on the interpretation, possibly also the duty of easy rescue, although the latter ground applies less straightforwardly to the case under discussion here.

However, we also found that in each instance the duty to make one's body material available for research after death is a conditional one, hence this moral duty is not sufficient to justify the general adoption of a regime of post mortem conscription of body material for research purposes (and a conditional adoption would face massive monitoring problems). Moreover, we argued that a conscription regime, whether generalized or not, cannot be supported because it is unacceptable to resort to compulsory removal before other strategies to promote donation have been actively pursued and have been found to result in an insufficient supply of body material for research.

By contrast, we found that the duty to make body material available for research after death is strong enough to depart from explicit consent, i.e. the default option for participation in biomedical research, and to support a system of presumed consent. Finally, we made a number of suggestions to improve existing systems of presumed consent so as to minimize the likelihood that body material would be removed after death if this would go against the wishes of individuals regarding the use of body material after their death. Indeed, we wish to strongly emphasize the necessity of putting in place various safeguards in order to prevent a regime for governing the procurement of post mortem body material for research from *being labeled a presumed consent regime whilst in practice boiling down to a regime of general conscription*, as is alarmingly the case in Belgium today.

8.5 References

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Conclusion

9.1 Research questions

The research questions for this dissertation were:

9.1.1 Financial scarcity in health care

1. Are proposals to curb spending on health care in the elderly an effective means of addressing the health care cost crisis?
 - 1.1. Is age-based rationing of life-extending care an effective means of addressing the health care cost crisis?
 - 1.2. Is the biogerontological approach to healthy aging an effective means of addressing the health care cost crisis?

9.1.2 Commodity scarcity in health care

‘Coping mechanisms’

2. Are there acceptable moral grounds to use recipient age in the allocation of kidneys?
 - 2.1. Are there acceptable moral grounds to deprioritize the elderly in the allocation of kidneys?
 - 2.2. Are there acceptable moral grounds to prioritize pediatric patients in the allocation of kidneys?

‘Solutions’

3. Are the currently proposed solutions to the kidney shortage well-suited to accommodate the projected surge in demand related to population aging?
4. What are some of the recently proposed solutions to commodity scarcity in health care in Belgium and are these ethically sound?

Below, we bring together our research findings with regard to each of these questions. This will allow us to make explicit some important similarities between financial and commodity scarcity in health care. We end this conclusion with some recommendations for further research.

9.2 Research question 1

Proposals for addressing the health care cost crisis frequently take the form of a plea for curbing health care expenditures on the elderly. In this dissertation, we have examined two such proposals: age-based rationing and the biogerontological approach to healthy aging. Instead of using traditional ways of assessing these, we opted for a more unconventional focus on their effectiveness. The rationale behind this was twofold. First, whether or not age-based rationing and the biogerontological approach to healthy aging are effective cost containment tools ought to be an important consideration in any assessment of their moral acceptability. Second, as we have repeatedly stressed throughout this dissertation, the adverse effects of the health care cost crisis are already taking their toll. It is, therefore, imperative that we not postpone the examination of the effectiveness of the two relevant proposals as a cost containment tool. We simply cannot afford to pursue dead-end solutions to the problem at hand.

Age-based rationing proposals rest on the assumption that population aging is an important driver of rising health care costs. Proponents of age-based rationing claim that, in denying the elderly life-extending treatment, we can severely reduce the adverse effects of population aging on health care expenditures. However, as we have seen, population aging is only a minor driver of rising health care costs. Medical technology is the root cause of the health care cost crisis. Recall that technological innovations often increase health care expenditures because of their tendency to produce a complementarity effect, i.e. they have a way of substantially increasing the reliance upon already available health care services and products.

Of course, in denying the elderly life-extending treatment, age-based rationing proposals unintentionally address the problem of medical technology. However, the reliance upon medical technology is evenly distributed among the young and the old. Given that age-based rationing proposals merely address (some forms of) technology use in the elderly, the savings hereby obtained will be of a temporary nature only. As long as the use of technology remains uncontrolled in the young, health care costs will soon resume their rise once we have cut out expensive forms of technology in the elderly.

As we have repeatedly stressed, it is highly unethical to deny the elderly treatment when the practice of doing so defeats its object, i.e. the goal of providing a solution to the health care cost crisis. This consideration illustrates how great a role the (in)effectiveness of a cost containment proposal can play in shaping our views on its moral acceptability. As such, it reinforces the importance, from a moral point of view, of examining the effectiveness of this type of proposal.

As a proposed solution to the health care cost crisis, the biogerontological approach to healthy aging fares even worse than age-based rationing. It makes a mistake similar to age-based rationing in that it aims to address population aging, rather than the root cause of the health care cost crisis. However, whereas age-based rationing at least has the merit of partially and inadvertently tackling the rising costs of medical technology, the same cannot be said of the biogerontological approach to healthy aging. The latter is likely to increase, rather than reduce, the use of expensive medical technology, for two reasons.

First, a significantly expanded healthspan and lifespan will most likely be achieved through the application of a combination of innovative technologies, such as stem cell treatments, pharmaceuticals, and genetic consultations. Moreover, these technologies will probably need to be administered periodically from an early age until the final stages of one's significantly expanded lifespan.

Second, besides introducing a whole range of novel technologies, the biogerontological approach to healthy aging is also likely to lead to the complementarity effect described above, i.e. it is likely to result in an intensified use of already existing medical technologies. After all, a significantly extended lifespan (even if free of age-related diseases) implies an increase in the number of years during which one can 'consume' such technologies.

As we mentioned in the general introduction, age-based rationing and the biogerontological approach to healthy aging are not the only cost containment proposals which operate under the assumption that population aging is a major driver of rising health care costs. Other proposals of this kind include the WHO approach to healthy aging and Medicare privatization. If successful, these proposals would reduce *demand* for health care in the elderly. In this dissertation, we have not explicitly addressed whether these proposals represent an effective solution to the health care cost crisis. Nevertheless, we need only draw on our assessment of age-based rationing and biogerontology to conclude that they share the same flaws. Medicare privatization and the WHO approach to healthy aging are also oblivious to the root cause of the health care cost crisis. In reducing demand for health care in the elderly, they will, similar to age-based rationing, inadvertently address the use of expensive technology in the elderly. However, once again, technology use in other age groups remains uncontrolled. Contrary to biogerontology, Medicare privatization and the WHO approach to healthy aging do not exacerbate the root cause of the health care cost crisis in that they do not rely on the development and use of sophisticated technology. In short, there is reason to believe that they will have an effect similar to age-based rationing, i.e. they will succeed at most in temporarily attenuating the trend of rising health care costs.

We have criticized age-based rationing, Medicare privatization and the healthy aging approach for their failure to provide a viable solution to the health care cost crisis. However, despite this criticism, we would like to stress that these proposals nevertheless deserve some praise. They have the merit of at least recognizing the problematic nature of rising health care costs. As we have seen, there is a minority who label the trend of increasing health care expenditures as laudable. These seem to believe that, in investing ever more financial resources in health care, we can come increasingly closer to fulfilling all our health care needs. The ensuing health benefits, they claim, outweigh the downsides of rising health care costs. Throughout this dissertation, we have encountered two arguments which undermine this line of reasoning.

First, growing health care expenditures imply that ever smaller amounts are available for other public spending priorities, such as education and employment. The latter's effect on health is greater than that of access to and use of health care services. Therefore, if one views health as the summum bonum – as those denying the problematic nature of rising health care costs clearly do – it makes little sense to invest ever greater amounts in health care at the detriment of more important determinants of health.

Second, it is an illusion to think that we can come ever closer to meeting all our health care needs. Human wants and needs are inherently infinite. This is the so-called internal aspect of scarcity described in the general introduction. In other words, our current needs, once met, will soon be replaced by new needs. Upon the fulfillment of the latter, further needs and wants will, once again, develop. In this sense, our medical achievements always remain one step behind our needs. Due to their inevitably limited nature, our financial resources cannot possibly keep pace with our unlimited wants and needs. Although an inherent trait of humans, our urge to continuously upgrade our needs is also fed by medical technology. The latter, as was illustrated in chapter 6, can create new needs by broadening the definition of disease.

Financial scarcity: directions for the future

Evidently, we cannot make progress in addressing the health care cost crisis if we hold onto misguided strategies. Thus, in drawing attention to the flaws of current cost containment proposals, we have set the stage for a much more productive approach to the problem at hand. At the same time, however, our research merely represents a first step in the right direction. A next step consists in formulating and implementing measures which substantially reduce our expenditure upon medical technology. We did not embark upon this task in this dissertation as it is more suited to health technology experts and health economists. Nevertheless, our research findings point towards a series of recommendations which come in handy in the search for measures aimed at limiting the use of medical technology. We can distinguish two types of

recommendation. The first set lays out the necessary groundwork for developing the relevant measures, whereas the second pertains to the basic characteristics which such measures ought to display if they are to be successful.

First set of recommendations

If we are to create an environment that is conducive to the development of successful policies aimed at limiting the use of medical technology, we must take at least the following two measures.

First, we must dispel the myth that population aging is the most important driver of rising health care costs. This myth has its origin in the 1980s, when age-based rationing proposals first emerged. The fact that it is still alive and flourishing bears testimony to its relentless nature.

Second, we must bring about a change in attitude. The modern, deeply engrained addiction to medical technology ought to make room for an awareness of the many downsides attached to rising health care costs. The most promising way of conveying this message consists in stressing that ever increasing financial expenditures on health care are not necessarily the most effective route to a better health status.

Second set of recommendations

Our research findings suggest that, in order to be successful, measures to reduce the reliance upon medical technology ought to satisfy at least the following three requirements.

First, as mentioned in the general introduction, a viable solution to the health care cost crisis consists of more than the mere elimination of waste (i.e. ineffective treatments). Thus, measures aimed at decreasing our uptake of expensive medical technology will need to tackle both ineffective and effective technologies.

Second, as we have repeatedly stressed, such measures ought to address the use of technology across all age groups.

Finally, these measures will have to improve upon currently employed methods of technology assessment. The latter, after all, have so far not succeeded in reducing the growth of health care spending to below the level of GDP growth. Our discussion of the relation between medical technology and rising health care expenditures hints at a possible way of making the current health technology assessment criteria more stringent. As repeated earlier, a factor which causes medical technologies to drive up costs is their tendency to produce a complementarity effect. Thus, when assessing new technologies, it will be important to take into account, not only their unit cost, but also their probability of increasing the reliance upon already existing health care services and products. It will not always be easy to predict whether or not complementarity will

occur, let alone the extent of the effect. As discussed in chapter 1, for example, innovations in treating coronary artery disease led to an increased incidence of ESRD and, thus, to a greater reliance upon dialysis. However, it was arguably impossible to foresee such an effect at the time these innovations were introduced. Besides attempting to predict complementarity, we also face the challenge of achieving substantial cost savings while at the same time ensuring that medical progress is not stifled. This issue was discussed in chapter 2.

9.3 Research question 2

The aging of the kidney transplant waiting list is increasingly perceived as a threat to the availability of kidneys for younger patients. In the US, this concern recently initiated an overhaul of the longstanding kidney allocation policy in favor of a system which deprioritizes the elderly. As the waiting list further ages and the adverse effects on the young become increasingly apparent, we may very well witness similar changes to allocation policies in other countries. Thus, the question as to whether there are acceptable moral grounds for deprioritizing the elderly will only gain in importance.

In this dissertation, we have developed one argument which could potentially serve to support a lower priority level for the elderly. Our argument rests on a concern for minimizing harm. Following Feinberg, we defined harm as a setback to one's interests. The basic interest at stake in organ transplantation is the interest in either continued life (lifesaving transplants) or a reasonable quality of life (non-lifesaving transplants). As we argued, this interest boils down to an interest in life projects. Thus, if we are to allocate organs so as to minimize harm, we ought to prioritize those who, in the absence of a transplant, experience the greatest setback to their interests in life projects. We identified the age group between mid/late 20s and mid 50s as satisfying this criterion. The rationale behind the inclusion of those in their mid/late 20s is that these people have the strongest interest in unstarted life projects. This is due to their being closest to initiating a whole range of projects. The inclusion of those in their early 30s to mid 50s in the age group eligible for prioritization rests on two grounds. First, their interests in started life projects are of the greatest strength level. Second, upon transplantation, their interests can be sustained at this strength level throughout the whole duration of the graft.

Our harm minimizing model has important implications at both the beginning and end of the lifespan, i.e. it deprioritizes pediatric patients as well as the middle aged (55+) and

the elderly (65+). Concerning the effect at the end of the lifespan, it is the deprioritization of the elderly (rather than that of the middle aged) which is of greatest interest to us here. After all, the question we set out to answer in developing our model pertains precisely to the appropriate priority level for the elderly. From a harm minimizing perspective, there are two arguments for deprioritizing the elderly. First, they have no unstarted life projects and, thus, no corresponding interests in these. Second, whereas they have started life projects similar to those in the early 30s-mid 50s age group, the elderly's interests in these projects are much weaker.

In this dissertation, we have discussed age-based rationing, both as a proposed solution to the health care cost crisis and as a coping mechanism in the context of commodity (organ) scarcity. It is, therefore, interesting to compare how it fares in each of these settings.

When analyzing age-based rationing as a proposed cost containment tool, we merely focused on its effectiveness. We did not consider the more traditional question relating to its moral acceptability, i.e. whether age-based rationing amounts to age discrimination. The main reason for this omission was that this question is rendered practically irrelevant by the finding that age-based rationing is an ineffective cost containment tool. As we have frequently stressed, this ineffectiveness in and of itself renders age-based rationing a morally unacceptable means of addressing the health care cost crisis. Nevertheless, as we pointed out in chapter 1, it may still be of theoretical interest to consider whether age-based rationing, as a proposed solution to the health care cost crisis, constitutes age discrimination. Although we did not explicitly address this question, our harm minimizing framework indirectly suggests that the answer to it is negative. After all, this framework, although developed with commodity scarcity in mind, can easily be extrapolated to the context of financial scarcity. We briefly hinted at this possibility of extrapolation in chapter 4. There, we stated that the interest in life projects in an instance of the more general interest in continued life. In other words, *all* denial of life-extending treatment, whether as a means of addressing the health care cost crisis or as a coping mechanism for organ scarcity, invariably sets back one's interests in life projects. Thus, if the elderly's weaker interest in life projects is a moral ground for deprioritizing them in the allocation of organs, then so is it a morally relevant reason for denying the elderly life-extending treatment as a means of containing costs. Nevertheless, we cannot stress enough that its non-discriminatory nature does not render age-based rationing a morally acceptable means of addressing the health care cost crisis. Its ineffectiveness as a cost containment tool outweighs any argument in support of age-based rationing.

In this respect, age-based rationing as a cost containment tool differs from its counterpart in the context of commodity (organ) scarcity. In the latter setting, effectiveness is not an issue. As we have seen, simulations suggest that a

deprioritization of the elderly would attain its ultimate goal, i.e. shifting organs from older to younger transplant candidate recipients. Thus, if our harm minimizing framework is convincing, then age-based rationing is morally acceptable in the context of commodity (organ) scarcity.

Besides granting the elderly a lower priority level, our harm minimizing framework also deprioritizes pediatric patients. Children have relatively few started life projects and thus, few corresponding interests. Moreover, despite having many unstarted life projects, their interests in the latter are rather weak due to the initiation of these projects lying in the relatively distant future. Both factors combined suggest that the magnitude of the harm experienced upon being denied a transplant is small for pediatric patients, relative to those in the mid/late 20s-mid 50s age group.

In chapter 5, we analyzed whether this framework supporting pediatric deprioritization could stand its ground against the various arguments put forward in defense of pediatric priority. We identified five such arguments: the growth and development argument, the life expectancy argument, the cost argument, the fair innings argument and the minority argument.

The growth and development argument exaggerates the adverse effects of delayed transplantation on children. Deficits in growth and development do not adversely affect pediatric patients' quality of life. In addition, the growth and development argument overlooks the fact that children are not alone in facing complications while on long-term dialysis. Adults with ESRD experience sexual dysfunctions, impairments of reproductive function and high rates of unemployment.

The argument which attributes pediatric patients priority on the basis of their greater life expectancy also fails. As we have shown, the benefit of transplantation does not amount to restoration of life expectancy.

With regard to the cost argument, we showed that pediatric priority is unlikely to represent the best route to achieving *social welfare* cost savings given that adult ESRD patients more heavily burden the system. In addition, we argued that *health care* cost savings are unlikely to occur as a result of prioritizing pediatric patients for the qualitatively better organs. This type of prioritization may reduce the need for retransplantation and duration of dialysis in pediatric patients. However, this reduction is likely to be offset by a corresponding increase in adults. This priority rule, after all, shifts the qualitatively worse organs to adults.

Both versions of the fair innings argument are problematic. The first version wrongly assumes that children stand alone in needing a long lasting graft (i.e. a qualitatively better kidney) in order to attain their fair innings. The second version argues that children have enjoyed fewer life years and, thus, fewer opportunities for medical well-

being than adults. We have shown, however, that age is too unreliable a predictor of such opportunities.

The minority argument was also found wanting. In determining their chance of obtaining a kidney, this argument wrongly considers children as a 'group entity', rather than as individuals. From an individual perspective, children are not disadvantaged in the competition for a kidney.

In addition to analyzing the arguments put forward in support of pediatric priority, we also pointed out some potential adverse effects of this policy. In reducing the reliance upon living donation in pediatric transplant candidates, pediatric priority policies may in the long run shorten children's graft survival. In addition, the policy's effect of decreasing the degree of HLA matching may reduce children's chances of finding a compatible graft when in need of a retransplant.

Our harm minimizing framework, when combined with the failure of the arguments put forward in support of pediatric priority rules, implies that there are strong reasons to doubt the legitimacy of such policies.

With the exception of our own analysis, the legitimacy of pediatric priority has so far not been scrutinized. It is merely taken for granted that this practice rests on a sound basis. This observation, combined with the fact that our research findings were often met with indignation, suggests that it is taboo to question the legitimacy of pediatric priority. Our research findings contravene the deeply engrained intuition that children ought to be granted special consideration at all times. The remarkable weakness of the arguments put forward in support of pediatric priority renders it plausible that the institution of this policy was largely informed by this intuition, rather than by efforts to test this hunch against the standard of rational reasoning. In short, these arguments appear to be an attempt at post hoc rationalization of the relevant intuition. The fact that the policy's potential adverse effects on children has so far failed to ring any alarm bells bears further testimony to the lack of rational argumentation in the issue of pediatric priority. It is, to us, the height of irrationality to introduce a policy with the aim of protecting children, while at the same time ignoring its potential counterproductive effects. We hope that our analysis of the issue can provide the necessary impetus for a more reasoned approach.

9.4 Research question 3

Proposed solutions to the current organ scarcity tend to focus on means of increasing supply. In chapter 6, we argued that supply-oriented strategies are shortsighted as they fail to satisfactorily address the projected surge in kidney demand related to population aging and the obesity epidemic. We identified two reasons for the failure of these strategies.

First, it is doubtful that supply-oriented strategies can be implemented in time to accommodate the 2030 peak in demand. Both scientific and ethical barriers hinder the timely implementation of so-called radical supply strategies. Conservative supply strategies, in turn, are met with great resistance, both from laymen and expert committees. This lack of public support is a strong contraindication to the implementation of the latter type of strategies as it significantly undermines the likelihood of their success.

Second, supply-oriented strategies pose a considerable financial burden. The increase in supply, generated by conservative strategies, would fall significantly short of meeting the projected surge in demand for kidneys. As a result, these strategies would be accompanied by a substantial demand for dialysis. Given that dialysis expenditures are already heading along an unsustainable path, an increase in demand for dialysis of this magnitude would be financially catastrophic. Radical supply strategies fare no better than their conservative counterparts in terms of financial viability. We further discuss our findings concerning the cost implications of radical strategies in the section below. This will allow us to make explicit some of the important similarities between financial and commodity scarcity in health care that we have encountered throughout this dissertation.

Similarities between financial and commodity scarcity

In this dissertation, we have discussed financial and commodity scarcity in two separate sections. Contrary to what this 'segregation' suggests, both types of scarcity have much in common. We have already encountered one similarity, i.e. the fact that the argument for the moral relevance of age in kidney allocation most likely lends itself to extrapolation to the context of financial scarcity. However, the similarities run much deeper than this. In this respect, chapter 6 is key. It illustrates how the central problem affecting the context of financial scarcity – the relentless pursuit of medical technology and its cost implications – also permeates the issue of commodity scarcity.

The hope vested in xenotransplantation and kidney bioengineering as a means of solving the organ shortage epitomizes the modern attachment to medical technology. Both strategies fail to escape the main feature of medical technology, i.e. its high cost.

Xenotransplantation and kidney bioengineering are likely to be subject, not only to a high unit cost, but also to the complementarity effect. They would intensify the reliance upon existing medical technology (transplantation in this case) by providing a virtually limitless kidney supply. The number of patients in need of a kidney transplant is estimated to reach approximately 2 million in the US by 2030. As explained in chapter 6, proponents of xenotransplantation and kidney bioengineering would, in the face of an unlimited kidney supply, be committed to transplanting all of these patients. A virtually limitless kidney supply would most probably also broaden the definition of ESRD so as to include the late stages of CKD, thereby further increasing the reliance upon transplantation.

The high unit cost of xenotransplantation and kidney bioengineering, combined with this substantial increase in demand, suggests that it would be financially prohibitive to meet all needs for transplantation under these radical strategies. Thus, despite an unlimited supply, kidneys would still need to be rationed. The only difference with the current need for rationing is that the latter presents itself because of constraints on the number of available organs, as opposed to financial limitations. In other words, rather than eradicating the kidney shortage, xenotransplantation and kidney bioengineering would merely transform the problem from one of commodity scarcity to one of financial scarcity. The potential for this type of transformation illustrates, once again, how closely intertwined the issues of financial and commodity scarcity are. In taking us back to financial scarcity, the starting point of our dissertation, chapter 6 completes the circle.

9.5 Research question 4

In chapters 7 and 8, we analyzed recent attempts by Belgian policy makers to address two specific types of commodity scarcity in health care. The first type relates to scarcity of donor livers, whereas the second pertains to the shortage of body material for research purposes. We concluded that neither of these attempts are ethically sound.

In response to the observation that a minor may sometimes be the only suitable donor, the Belgian transplantation law was recently amended so as to allow minors as young as 12 to donate a liver segment or lobe to a sibling (on condition that they are capable of expressing their will and have given prior consent). We identified various problems with this amendment. First, the law fails to take into account that minors only exhibit cognitive maturity from the age of 14 onwards. Second, minors do not possess the psychosocial maturity required to be able to consent to living liver donation. Finally, although there may be exceptions to these rules, we currently lack the instruments to

reliably assess maturity on an individualized basis. Consequently, we do well to err on the side of assuming immaturity in minors.

Belgium recently instituted a presumed consent regime for the post mortem removal of body material for research purposes in a bid to increase the latter's supply. However, in practice the change in the law amounts to conscription. Such a regime of routine removal is problematic for two reasons. First, it is unjustifiable to resort to compulsory removal before having actively pursued other strategies for increasing the supply of body material for research. Second, as the duty to donate body material for research purposes after death is a conditional one, conscription would need to be limited to those who are subject to this duty. However, such a conditional form of conscription would pose enormous problems in terms of implementation and monitoring. As we argued in chapter 8, this conditional duty is sufficiently strong to support presumed consent. If the latter is not to coincide with conscription, we must at least inform the public of its existence and put in place an opt-out register separate to the one employed for organ donation for transplantation.

9.6 Recommendations for further research

As mentioned at the start of this dissertation, scarcity in health care is a vast subject matter. We have limited ourselves to a discussion of specific issues arising in a selected number of medical settings. Thus, some of our findings inevitably beg the question as to whether they hold in other settings. However, questions for further research also arise when staying within the confines of the settings analyzed here. Below, we provide a non-exhaustive overview of questions of either type.

Our harm minimizing framework, developed in chapter 4, has its limitations. As already mentioned, we have not yet tested whether it can stand its ground against various existing criticisms of age-based rationing. One such criticism claims that, due to their higher life expectancy, women lose out more and, thus, are discriminated against under age-based rationing schemes. It must, therefore, be examined whether this criticism is valid. If it is, it raises the further question as to whether the harm hereby experienced by women outweighs the harm incurred by young patients upon being denied a transplant.

Our harm minimizing framework serves to support the new UNOS kidney allocation policy. The latter, which governs the allocation of kidneys in *adults*, deprioritizes the elderly in favor of young adults. One of the criticisms invoked against this policy is that it runs the risk of significantly decreasing young adults' reliance on living donation.

This, in turn, it is claimed, could adversely affect average graft survival. It will, thus, be important to conduct empirical research into the effects of the new policy on living donation rates.

The abovementioned concern regarding decreased reliance on living donation in young adults is based on the observation that Share 35, the US's pediatric priority policy, has significantly reduced adult-to-child living donation rates. As mentioned in chapter 5, only a few transplant centers have examined the effect of this reduction on pediatric graft survival rates. The limited evidence base points towards a negative impact. As this could undermine the legitimacy of Share 35, it is imperative that further research be conducted on the matter. In addition, it is important to examine to what extent the decreased degree of HLA matching, resulting from Share 35, affects children's chances of obtaining a compatible graft the second time around.

To our knowledge, no empirical research has been conducted into the impact of Eurotransplant's pediatric priority policy on adult-to-child living donation rates. The importance of filling this lacuna extends beyond the potential implications for the legitimacy of this policy. If it turns out that living donation rates have not declined within Eurotransplant, this may provide us with clues as to how to 'undo' the trend observed in the US.

Besides empirical matters, the issue of pediatric priority also potentially opens up avenues for further philosophical research. It would be interesting to investigate whether a pediatric priority policy is in place for organs other than kidneys and, if so, whether it rests on a more solid basis than its counterpart in the setting of kidney transplantation.

In chapter 7, we developed a moral framework which provides guidance in distinguishing those categories of health care decisions which minors (of a certain age) are capable of making from those which they are incapable of making. We applied this framework to the setting of living liver donation by minors and concluded that minors do not possess the psychosocial maturity required for this specific type of decision making. It would be interesting to determine how living kidney donation by minors fares against the standard of this framework. However, it would also be worthwhile to examine what this framework has to say about pediatric decision making in health care settings outside of organ donation. Examples include participation in clinical trials and euthanasia. The latter is particularly interesting, given that Belgium has very recently extended the right to euthanasia to minors.

A final recommendation for future research pertains to the issue of post mortem donation of body material for research purposes. In chapter 8, we made the case for a 'true' presumed consent regime, i.e. one that does not boil down to conscription. As

noted in chapter 6, the effectiveness or success of a consent regime governing the procurement of body material is, to a great extent, dependent on the presence of a large constituency in favor of it. It is, therefore, crucial to conduct research gauging the public's attitudes towards post mortem donation of body material for research and the possible consent regimes to govern it. This is all the more important given the lack of an evidence base on this matter and the increasing importance of research on human body material.

English summary

Scarcity obtains whenever there is less of a good or resource available than needed to fulfill human wants and needs. Such situations compel us to decide how to use and allocate scarce services and goods. In short, scarcity entails the need to trade off various goods against others.

Scarcity is omnipresent in health care. Intensive care beds, high-tech scanners, organs, and oocytes are but a few examples of scarce health care resources. For ease of reference, we introduce a distinction between 'financial' and 'commodity' scarcity in health care in this dissertation. We use the latter as an umbrella term for those goods which are inherently in short supply, i.e. goods which are, by nature, scarce. Organs and oocytes are typical instances of commodity scarcity. Financial scarcity, by contrast, refers to those resources which are theoretically abundant, but nevertheless provided in limited amount (or not at all) due to financial constraints or considerations. Intensive care beds and high-tech scanners fall into this category of scarcity.

Even when narrowed down to health care, scarcity represents a vast topic of research. For example, it is the *raison d'être* of all issues pertaining to distributive justice in health care. Evidently, then, it is impossible to present an exhaustive analysis of any subset of issues relating to scarcity in health care, let alone to cover all the ground. In this dissertation, we mainly limit ourselves to a selection of ethical issues ensuing from the impact of population aging on scarcity. Population aging is increasingly being perceived as a grave threat, both in the realm of 'financial' and 'commodity' scarcity. More specifically, this demographic phenomenon raises concerns with regard to the sustainability of customary approaches to making the necessary trade-offs among scarce goods. The main aim of this dissertation is to present some of the most prominent, newly proposed alternatives to the current trade-offs and assess their ethical soundness. Part one of this dissertation addresses the alternatives put forward in the context of financial scarcity, whereas part two analyzes the proposals made in the realm of commodity scarcity.

Financial scarcity in health care

For over three decades, health care expenditure in OECD countries has grown at rates exceeding the economy's growth rate. This trend is unsustainable. The cause of rising health care expenditures is often attributed to population aging. As a result, solutions to the health care cost crisis frequently target the elderly. One such proposal is to deny the elderly all forms of life-extending care (age-based rationing). Another strategy is to invest more in biogerontology - research into the biology of aging. The idea is that such research will enable us to tackle age-related diseases simultaneously, thereby ensuring that the elderly enjoy an increased healthspan (i.e. that they enjoy an increase in the number of years spent in a disease-free state). This, in turn, it is believed, will reduce the pressure on the health care system.

As health care costs continue to rise, the aforementioned proposals to curb spending on health care in the elderly are likely to further gain ground. It is, therefore, important to ask ourselves whether they represent a morally acceptable solution to the health care cost crisis. Their ethical soundness is, in part, dependent on whether they are likely to actually achieve their ultimate aim, i.e. whether they will succeed in reducing spending growth in health care to the level of overall GDP growth. It would, for example, be highly unethical to deny the elderly life-extending care if this practice offered little prospect of substantially controlling health care expenditures. The effectiveness of proposals to curb health care spending in the elderly has seldom or never been addressed in the literature. This is lamentable. After all, the adverse effects of the health care cost crisis have already started to materialize. Therefore, we cannot afford to adopt a trial and error approach to the problem.

Part 1 of this dissertation examines whether proposals to curb health care spending in the elderly represent an efficacious means of containing costs. It does so by analyzing the extent to which these proposals tackle the root cause of the health care cost crisis. We conclude that both age-based rationing and biogerontology provide, at best, temporary relief from the trend of rising health care costs. The failure of both proposals points towards the need for developing cost containment policies which target both the young and the old.

Commodity scarcity in health care

Part two of this dissertation is devoted to a discussion of ethical issues ensuing from population aging in the realm of commodity scarcity. We predominantly focus on the stock example of commodity scarcity in health care, i.e. the shortage of donor organs for transplantation. Within this context, we mainly limit the scope of our discussion to kidney transplantation, given that the scarcity of this type of organ is most pronounced.

With respect to methods for dealing with the problem of kidney scarcity (and organ scarcity in general), it is useful to distinguish between ‘coping mechanisms’ and ‘solutions’. We introduce the former concept to refer to strategies which are *not* aimed at diminishing the magnitude of the kidney scarcity, but merely attempt to make the best of the shortage. In other words, the term ‘coping mechanisms’ denotes the activity of devising criteria for the allocation of kidneys in a way which strikes a balance between the goals of fairness and efficiency. By contrast, ‘solutions’ are strategies which endeavor to lessen the kidney scarcity, either by reducing demand for or increasing the supply of donor kidneys.

Part two of this dissertation is divided into two sections. Whereas the first section addresses ‘coping mechanisms’, the second is devoted to ‘solutions’.

Coping mechanisms

Population aging is increasingly being perceived as jeopardizing the availability of kidneys for the non-elderly under current allocation systems. This observation has incentivized UNOS to formulate a new kidney allocation policy which deprioritizes the elderly. The new policy, the implementation of which will take place at the end of this year, has elicited a series of criticisms. The most frequently cited concern is that age is morally irrelevant in kidney allocation. UNOS/OPTN policy makers have failed to seriously address this criticism. They have settled for ‘easy point scoring’, i.e. they merely make a hasty, uncritical reference to arguments that are commonly put forward in support of age-based rationing in the context of financial scarcity. This response is disconcerting. Criticisms of the organ allocation system should not be treated lightly. The perception that the new kidney allocation policy is based on an irrelevant criterion may, if widespread, damage public trust in organ exchange organizations. This, in turn, could have serious consequences, such as a decreased willingness to register as an organ donor. It is, therefore, important that the transplant community provide the public with a solid argument for the moral relevance of age. The fact that other countries are already considering a policy change similar to the one recently approved by UNOS only adds urgency to this task. The first section of part two of this dissertation is, therefore, devoted to the search for a more satisfactory account of the moral relevance of age than the one so far put forward by UNOS officials. We examine the moral relevance of age at both ends of the spectrum, i.e. at both the beginning and the end of life. To this end, we develop a framework grounded in a concern for minimizing harm. We conclude that the new UNOS policy, when assessed against this framework, is not far reaching enough. In addition to penalizing the elderly, a concern for minimizing harm also calls for deprioritizing pediatric patients.

Solutions

The most commonly pursued strategy to reduce the gap between supply of and demand for renal allografts is to increase the supply of donor kidneys, both from living and deceased sources. Proposals to increase the kidney supply have mainly been developed with the *current* extent of the kidney shortage in mind. Unfortunately, however, the effects of population aging and the obesity epidemic on the prevalence of end-stage renal disease (ESRD) are yet to fully materialize. In other words, the kidney shortage has far from reached its peak. Projections suggest that, by 2020, the prevalence of ESRD patients in the United States will approach 785,000, an increase of more than 60% from 2005 levels. By 2030, the expected peaking point of population aging, the US ESRD population could reach 2 million.

Population aging and its effects have fuelled a recognition among policy makers that the traditional kidney allocation systems (i.e. traditional '*coping mechanisms*') are no longer viable. Surprisingly, however, when it comes to devising *solutions* to the kidney shortage, the implications of population aging have gone largely unnoticed. In short, little or no thought has been given to the question of whether the currently proposed solutions are well-suited to accommodate an ever aging kidney transplant waiting list and the accompanying, projected surge in demand. Given that we are quickly approaching the peak of population aging, an examination of this question is long overdue. In the second section of part two of this dissertation, we address this lacuna in the research on the merit of currently proposed solutions. We argue that strategies aimed at increasing the kidney supply are shortsighted in that they merely transform what is, at present, largely a problem of commodity scarcity into a problem of financial scarcity. We make the case for a preventative approach.

Nederlandse samenvatting

Schaarste ontstaat overal waar er van een goed of middel ('resource') minder beschikbaar is dan wat nodig is om aan de wensen en behoeften van de mensen te voldoen. Dergelijke situaties nopen ons ertoe keuzes te maken over hoe schaarse goederen en diensten worden gebruikt en toegewezen. Kortom, schaarste maakt het noodzakelijk verschillende goederen tegen elkaar af te wegen.

Schaarste is alomtegenwoordig in de gezondheidszorg. Intensive care bedden, hightech scanners, organen en eicellen zijn maar een paar voorbeelden van schaarse middelen in de gezondheidszorg. Gemakshalve maken we in dit proefschrift een onderscheid tussen 'financiële' en 'goederenschaarste' in de gezondheidszorg. We gebruiken goederenschaarste als een verzamelterm voor goederen waaraan inherent een tekort bestaat, d.i. goederen die door hun aard schaars zijn. Organen en eicellen zijn typische voorbeelden van goederenschaarste. Financiële schaarste daarentegen verwijst naar middelen die in theorie in overvloed voorhanden zijn, maar niettemin slechts in beperkte mate (of helemaal niet) ter beschikking worden gesteld wegens financiële beperkingen of overwegingen. Intensive care bedden en hightech scanners behoren tot deze schaarstecategorie.

Ook als het verengd wordt tot de gezondheidszorg, is schaarste een breed onderzoeksonderwerp. Het is bijvoorbeeld de bestaansreden van alle kwesties in verband met verdelende rechtvaardigheid in de gezondheidszorg. Het is dan ook onmogelijk om een exhaustieve analyse te bieden van een specifieke set van problemen met betrekking tot schaarste in de gezondheidszorg, laat staan het thema volledig te behandelen. In dit proefschrift beperken we ons grotendeels tot een selectie ethische kwesties die ontstaan door de impact van de vergrijzing op schaarste. De vergrijzing wordt steeds meer gezien als een grote bedreiging op het gebied van zowel de 'financiële' als de 'goederenschaarste'.

Meer specifiek leidt dit demografisch verschijnsel tot bezorgdheid over de houdbaarheid van de gebruikelijke manieren waarop de noodzakelijke afwegingen tussen schaarse goederen worden gemaakt. Het voornaamste doel van dit proefschrift is sommige van de meest opvallende alternatieven voor de huidige afwegingen voor te stellen en hun ethische verantwoordheid te toetsen. Deel één van dit proefschrift gaat over de alternatieven die naar voor worden geschoven op het gebied van financiële

schaarste, terwijl in deel twee de voorstellen worden geanalyseerd die in verband met goederenschaarste worden gedaan.

Financiële schaarste in de gezondheidszorg

Al meer dan drie decennia stijgen de uitgaven voor gezondheidszorg in de OESO-landen sneller dan de economische groei. Dit is een onhoudbare trend. Als oorzaak van de stijgende uitgaven voor gezondheidszorg wordt vaak de vergrijzing genoemd. Met als gevolg dat in oplossingen voor de kosten crisis in de gezondheidszorg geregeld de ouderen in het vizier worden genomen. Een van de voorgestelde oplossingen is ouderen alle vormen van levensverlengende zorg te ontzeggen (rantsoenering op basis van leeftijd). Een andere strategie is meer investeren in biogerontologie – onderzoek naar de biologie van het ouder worden. Het idee is dat dergelijk onderzoek ons in staat zal stellen om leeftijdsgebonden ziekten tegelijkertijd aan te pakken, waarbij ervoor wordt gezorgd dat de ouderen langer gezond leven (d.w.z. dat ze meer jaren vrij van ziekte kunnen leven). Dat zal dan op zijn beurt, zo wordt aangenomen, de druk op het gezondheidszorgsysteem verminderen.

Aangezien de kosten van de gezondheidszorg blijven stijgen, zullen voormelde voorstellen om de zorguitgaven voor ouderen in de hand te houden waarschijnlijk verder terrein winnen. Daarom is het belangrijk dat we onszelf afvragen of ze een moreel aanvaardbare oplossing voor de kosten crisis in de gezondheidszorg bieden. Hun ethische verantwoordelijkheid hangt deels af van het feit of ze hun uiteindelijke doel effectief kunnen bereiken, m.a.w. of ze er zullen in slagen de groei van de uitgaven in de gezondheidszorg terug te brengen tot het niveau van de algemene BBP-groei. Het zou bijvoorbeeld erg onethisch zijn de ouderen levensverlengende zorg te ontzeggen als deze praktijk weinig uitzicht biedt op een significante beheersing van de uitgaven in de gezondheidszorg. De effectiviteit van voorstellen om de zorguitgaven voor ouderen te beteugelen is in de literatuur zelden of nooit aan bod gekomen. Dat is jammer. De negatieve effecten van de kosten crisis in de gezondheidszorg beginnen immers al zichtbaar te worden. We kunnen het bijgevolg niet maken om dit probleem met een trial-and-error-aanpak te behandelen.

In deel één van dit proefschrift gaan we na of voorstellen om de zorguitgaven voor ouderen te beperken een afdoend middel zijn om de kosten in de hand te houden. Dat doen we door na te gaan in hoeverre deze voorstellen de grondoorzaak van de kosten crisis aanpakken. We komen tot de conclusie dat zowel leeftijdgebaseerde rantsoenering als biogerontologie, in het beste geval, slechts tijdelijk soelaas brengen voor de trend van de oplopende zorgkosten. Dat beide voorstellen geen oplossing bieden, wijst erop dat er

nood is aan een kostenbeperkend beleid dat op zowel de jongeren als de ouderen is gericht.

Goederenschaarste in de gezondheidszorg

Deel twee van dit proefschrift is gewijd aan een bespreking van ethische kwesties die een gevolg zijn van de vergrijzing op het vlak van goederenschaarste. Wij focussen grotendeels op het typevoorbeeld van goederenschaarste in de gezondheidszorg, namelijk het gebrek aan donororganen voor transplantatie. In dit verband beperken we de scope van onze bespreking hoofdzakelijk tot niertransplantaties aangezien de schaarste van dit soort orgaan het meest uitgesproken is.

Met betrekking tot methoden om het probleem van nierschaarste (en orgaanschaarste in het algemeen) aan te pakken is het nuttig een onderscheid te maken tussen ‘copingmechanismen’ en ‘oplossingen’. We voeren eerstgenoemd concept in dat verwijst naar strategieën die *niet* bedoeld zijn om de omvang van de nierschaarste te verminderen, maar enkel proberen het beste te maken van het tekort. Met andere woorden, de term ‘copingmechanismen’ wijst op de activiteit die erin bestaat criteria voor nierallocatie te bedenken op een manier dat een evenwicht wordt gevonden tussen het gelijkheids- en utiliteitsbeginsel. ‘Oplossingen’ daarentegen zijn strategieën die de nierschaarste trachten te verminderen door ofwel de vraag naar donornieren te beperken ofwel het aanbod ervan te verhogen.

In deel twee van dit proefschrift bespreken we eerst ‘copingmechanismen’ en daarna ‘oplossingen’.

Copingmechanismen

De vergrijzing wordt in toenemende mate gezien als een bedreiging voor de beschikbaarheid van nieren voor jonge mensen bij toepassing van de huidige allocatiesystemen. Deze vaststelling heeft UNOS (United Network for Organ Sharing) ertoe aangezet een nieuw beleid voor nierallocatie te formuleren dat ouderen deprioriteert. Dit nieuwe beleid, dat eind dit jaar in de praktijk zal worden gebracht, heeft heel wat kritiek uitgelokt. Het meest aangehaalde bezwaar is dat leeftijd moreel irrelevant is voor de toewijzing van donornieren. De wijze waarop de beleidsmakers van UNOS/OPTN deze kritiek beantwoorden, is onbevredigend. Ze stellen zich tevreden met het scoren van een makkelijk punt, ze verwijzen gewoon snel en kritiekloos naar argumenten die doorgaans worden aangevoerd ten gunste van leeftijdgebaseerde rantsoenering in de context van financiële schaarste. Dit antwoord is verontrustend. Met kritiek op het orgaanallocatiesysteem mag niet lichtzinnig worden omgegaan. De perceptie dat het nieuwe beleid voor toewijzing van donornieren op basis van leeftijd ongegrond is, kan, als ze wijd verspreid geraakt, het vertrouwen van het publiek in

organisaties voor orgaantoewijzing ondermijnen. En dat zou op zijn beurt zware gevolgen kunnen hebben, zoals een verminderde bereidheid bij het publiek om zich als orgaandonor te registreren. Het is daarom belangrijk dat de transplantatiegemeenschap het publiek een stevig argument voor de morele relevantie van leeftijd kan voorleggen. Het feit dat andere landen al een beleidswijziging overwogen zoals die welke UNOS onlangs goedkeurde, maakt dit alleen maar dringender. De eerste sectie van deel twee van dit proefschrift is daarom gewijd aan de zoektocht naar een meer bevredigende verantwoording van de morele relevantie van leeftijd dan die welke door de beleidsmakers van UNOS is gegeven. We gaan na wat de morele relevantie van leeftijd is aan beide uiteinden van het spectrum, namelijk zowel bij het begin als op het einde van het leven. Daartoe ontwikkelen we een kader dat als doel heeft schade te minimaliseren. We komen tot de conclusie dat het nieuwe UNOS-beleid, als het aan dit kader wordt getoetst, niet verregaand genoeg is. Naast het feit dat ouderen worden gepenaliseerd, vraagt het criterium 'minimalisering van schade' ook dat pediatrische patiënten worden gedeprioriteerd.

Oplossingen

De strategie die veelal wordt gevolgd om de kloof tussen vraag en aanbod met betrekking tot niertransplantaties te verkleinen, is het aanbod van donornieren van zowel levenden als overledenen te verhogen. Voorstellen om het aanbod te vergroten zijn hoofdzakelijk uitgewerkt met de *huidige* omvang van het tekort aan nieren voor ogen. Maar jammer genoeg beginnen de gevolgen van de vergrijzing en de obesitasepidemie op de prevalentie van end-stage-renal-disease (ESRD) of eindstadium nierziekte nu pas ten volle voelbaar te worden. Met andere woorden, het tekort aan nieren heeft zijn piek nog lang niet bereikt. Projecties geven aan dat tegen 2020 de prevalentie van ESRD-patiënten in de Verenigde Staten zal oplopen tot 785.000, wat ruim 60% meer is dan in 2005. Tegen 2030, de datum waarop de vergrijzing naar verwachting zal pieken, zouden de Verenigde Staten twee miljoen ESRD-patiënten tellen.

De vergrijzing en de effecten daarvan hebben de beleidsmakers doen onderkennen dat de traditionele systemen voor nierallocatie (d.w.z. traditionele '*copingmechanismen*') niet langer leefbaar zijn. Maar wanneer het erom gaat *oplossingen* voor het tekort aan nieren te bedenken, dan wordt aan de implicaties van de vergrijzing verrassend genoeg weinig aandacht besteed. Kortom, er is weinig of niet nagedacht over de vraag of de thans voorgestelde oplossingen geschikt zijn om het hoofd te bieden aan een wachtlijst met aldoor ouder wordende kandidaten en de hiermee gepaard gaande stijging van de vraag naar donornieren. Gelet op het feit dat de piek in de vergrijzing snel dichterbij komt, had een bespreking van deze kwestie al lang moeten plaatsvinden. In de tweede sectie van deel twee van dit proefschrift bekijken we deze leemte in het onderzoek naar de verdiensten van de momenteel voorgestelde oplossingen. We argumenteren dat de

strategieën om het aanbod van nieren te verhogen kortzichtig zijn omdat ze wat nu grotendeels een probleem van goederenschaarste is omvormen tot een probleem van financiële schaarste. Wij pleiten voor een preventieve aanpak.