Preface

In most OECD countries, health care spending is outpacing economic growth, witness the fact that it amounted to an average 7 percent of the gross domestic product in 2002 versus 9 percent in 2008; further rise was expected in 2009.\footnote{OECD, Health: Key Tables from OECD, OECD 2011 (accessed on April 13, 2011).} This phenomenon is largely ascribed to innovation in health care technologies and ageing of the population claiming medical care. Both factors will continue to push up health spending in the near future. Under these circumstances, health care rationing is (expected to be) the central policy issue. So, the “R” word has cropped up again – although one may claim that the item has never disappeared from the policy agenda since the introduction of the famous ‘Oregon Health Plan (1989).’\footnote{The essence of the Oregon rationing approach was based on budget control through explicit rationing of services. It represented a striking contrast both to the well-established practice of implicitly rationing medical care in the United States by income and insurance coverage, and to the somewhat less visible resource allocation decisions made by health policy makers and professionals in other countries. See L Jacobs, Th Marmor, J Oberlander, ‘The Oregon Health Plan and the Political Paradox of Rationing: What Advocates and Critics Have Claimed and What Oregon Did’ (1999) 1 JHPPL 162.} Healthcare rationing has never disappeared from the policy agenda. Others, however, would perhaps claim that rationing is no policy or clinical issue, at least not in their country.\footnote{Ja Califano, ‘Rationing’ Health Care: The Unnecessary Solution’ (1992) 5 University of Pennsylvania Law Review 1592-38.}

Part of the rationing problem is disagreement about its meaning. How to define health care rationing? Traditionally, the term ‘rationing’ refers to the distribution of scarce resources during wartime, but in fact the term applies to any time a scarce good or service will be denied or delayed. Still, there are many notions of health care rationing, which differ in several ways.\footnote{PA Ubel, SD Gold, ‘Rationing’ Health Care, Not all definitions are created equal, Commentary 158 (1998) Feb 9 Arch. Intern Med 210.} First, they may differ according to whether the rationing is explicit or not, as it is argued that rationing includes only conscious decisions taken at an administrative level that make a service unavailable to some people.\footnote{RH Brook, KN Lohr, ‘Will we need to ration effective health care?’, (1986) Fall Issues Sci Tech 68-77, quoted by Ubel (note 4) 210.} Or – in contrast – non-explicit mechanisms, such as allocating goods by the free market, may be classified as rationing.\footnote{MA Hall, The problems with rule-based rationing 19 J Med Philos 1994:315-332.} Second, they may differ as to the scarcity of resources. Some maintain that a resource must be absolutely scarce for its distribution to qualify as rationing (e.g., organs); whereas others think that rationing also includes the allocation of non-scarce resources (e.g., expensive medicines).\footnote{ibid note 2.} Third, they may differ on whether rationing involves only limits on medical necessary services, or involves limits on any beneficial services.\footnote{DC Hadorn, RH Brook, ‘The health care resources allocation debate: defining our terms’ (1991) 266 JAMA: 3328-3331; AS Relman, Is rationing inevitable? (1990) 322 N Engl J Med (NEJM) 1809-1810.} In our view
Reinhardt’s broad notion of health care rationing is the most adequate: the use of any mechanism – price or non-price – to deny individuals access to beneficial health care. The use of such a selection mechanism implies painful choices of scarce goods and services, emphasizing the “moral significance” of these decisions, which notion is absent from the general phrase “allocation or distribution of resources”. The painful outcomes of rationing decisions cause controversy in society and therefore, rationing has a negative connotation. We would like to argue that rationing can even be perceived as fair, provided the decision-making process is fully transparent and public, and the arguments are rationally explained to those who are denied health care. These requirements give rationing its moral legitimacy, or what Fleck describes as the process of “rational democratic deliberation”.

‘The Importance of being Earnest’

In the rationing debate, most authors favour explicit rationing for reasons of accountability (e.g., Newdick, Syrett and Flood), or transparency and democratic decision-making (Fleck). In contrast, implicit rationing on a micro level occurs in a sub rosa world: decisions are based on imperfect information, distorted interpretations of evidence on effectiveness, and hidden cost concerns. From a legal perspective, implicit rationing can also be rejected since it violates a basic notion of health law: the principle of informed consent. Traditionally, consent has been interpreted as a moral and legal condition to legitimize any medical intervention. Patients are expected to give consent on the basis of objective information from the responsible health professional prior to treatment. Absent or insufficient information makes consent invalid and can be considered as a violation of the fundamental right of bodily integrity and the autonomy principle. Moreover, in international law, providing informed consent is fundamental to a person’s right to health care, i.e. informed decision-making on the available and accessible health care services of good quality.

---

10 Fleck (note 4) 211. Nonetheless, we agree with Ubel that also allocation decisions involve tragic choices, and can be just or unjust like rationing.
11 Fleck (note 9) ch. 5.
13 The doctrine of informed consent is historically rooted in both common law and civil law countries, and developed by landmark cases such as Canterbury v. Spence, Circuit Court of Appeals for DC (US 1972) setting the “reasonable man” standard for informed consent; ECtHR Keenan v. the United Kingdom, no. 27229/95; ECtHR Herzogfahy v Austria, no. 10533/83.
15 United Nations, Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. ‘Right to everyone to the enjoyment of the highest attainable standard of physical and mental health’, UN General Assembly Doc A/64/272. 10 August 2009: 6.
As a general rule, the duty to inform covers information about the purpose and nature of treatment or research, (side) effects, possible risks, and alternative treatment options. The scope of information may vary by patient, however, depending on characteristics such as age, co-occurring diseases, high or low risk intervention, language skills, etcetera. To conclude, respecting informed consent therefore requires full information about all treatment options “in order to weigh up the necessity or usefulness of the medical intervention against its risk and the discomfort or pain it will cause”. The less knowledgeable, docile patient is withheld this information in the case of implicit rationing. In the legal doctrine, withholding information can only be justified in the so-called ‘therapeutic exception’, i.e. when it is in the patient’s health interest. But courts are unlikely to accept such a claim in case information is withheld for non-therapeutic reasons. Consequently, nondisclosure of a beneficial treatment option based on economic rather than strictly medical grounds may increase the risk of medical disciplinary and malpractice litigation.

Rationing at the Court

Nonetheless, fear of litigation in case of explicit rationing is not unfounded. On several occasions applicants have successfully challenged the denial of necessary medicines or treatment by local health trusts or health financiers, for example the refusal to provide Herceptin in Rogers v Swindon NHS Primary Care Trust (UK), and the refusal to fund in vitro fertilization treatment in Cameron v Nova Scotia (Canada). But in general, the judiciary has been reluctant to overturn rulings of decision-making bodies on health care rationing, therefore accepting their margin of appreciation. Instead of considering the substance of the decision, courts have been more comfortable in challenging the decision-making procedure.

This is a procedure that requires the highest degree of transparency of decision-making, or ‘clarity about how priorities are set’. Since adequate rationales

---

17 Though in practice, no such malpractice cases have been found. Some reasonable speculations are possible such as the patient remains simply unaware of alternative treatment options, and when it concerns low-income and less knowledgeable patients the high costs of malpractice litigation.
18 As discussed by Keith Syrett in his contribution ‘NICE and the problem of ‘postcode prescribing’ in the English National Health Service, chapter 7.
20 Flood and Essajee ibid, also C Newdick, ‘Re-balancing the Rationing Debate: Tackling the tensions between individual and community rights’, chapter 8.
21 Daniels and Sabin, chapter 1.
for the political priorities are absent, there is the danger of arbitrariness, which is the main reason to initiate lawsuits.

Towards fair and just rationing decisions

According to Fleck, the focus on procedural justice – thus the plea for explaining rationing decision-making based on evidence, reasons and principles – is in itself not sufficient. Democratic deliberation in health care rationing and priority-setting is need to make fair and just rationing decisions, as Fleck argues.22 Whereas Daniels thinks the deliberate process of independent ‘citizens panels’ is futile, Fleck strongly believes it is essential to “having an outcome that is self-constructed and self-imposed by the deliberative group”. This would help ensure the outcome is just and legitimate.23 Given that we are critical about the practical implications, we nevertheless support Fleck’s idea of broad public deliberation organized by a NICE-like entity creating a broad range of rationing protocols.

Triggering the rationing debate, ‘Rationing Health Care – Hard Choices and Unavoidable Trade-offs’ is aimed at achieving fair and just rationing decisions. The debate remains unresolved – but the strength of the book is that each chapter analyses the rationing debate from a different perspective in search of a reasonable solution.

Rotterdam, 2012
André den Exter
Martin Buijsen

22 Fleck, ‘Just caring: In defense of the role of democratic deliberation in health care rationing and priority-setting’, chapter 2.
23 ibid.