

With the support of the
Erasmus+ Programme
of the European Union



Journal of Medical Law and Ethics

The Journal of Medical Law and Ethics (JMLE) aims to publish excellent quality peer-reviewed articles, reports, case notes and essays in the field of medical law and ethics, which is a very exciting and controversial area of law. This journal aims to focus in particular on the legal and ethical aspects of medicine. This is an opportunity for the increasing number of academics and practitioners alike to discuss the most controversial areas of medical law, to present research, to analyse and criticise the law, and hopefully aim to improve the way that medical care is provided.

Chief Editor & Creator:

Lisa Cherkassky, Law School, The University of Derby
L.Cherkassky@derby.ac.uk

Deputy Editor:

Professor Eduard Verhagen, Faculty of Medical Sciences,
University Medical Centre Groningen, a.a.e.verhagen@umcg.nl

International Editorial Board:

Professor Melodie Nothling Slabbert, University of South Africa
Professor Grant Gillett, University of Otago
Dr Leigh Rich, Armstrong Atlantic State University
Dr Andrew McGee, Queensland University of Technology
Nisha Parikh, University of Hawaii
Suhayfa Bhamjee, University of Kwazulu-Natal
Dr Darius Whelan, University College Cork
Professor Bernice Elger, University of Basel
Dr Patricia Zapf, John Jay College of Criminal Justice
Professor Emma Cave, Durham University
Dr Janne Rothmar Herrmann, University of Copenhagen
Professor Michael Pepper, University of Pretoria
Professor Rebecca Bennett, The University of Manchester
Dr Kartina A. Choong, University of Central Lancashire
Mr Kevin Bampton, The University of Derby

Other reviewers:

Professor Jean McHale, The University of Birmingham
Dr Atina Krajewska, The University of Birmingham
Dr Jonathan Ives, The University of Birmingham
Roy Gilbar, The University of Leicester
Pamela Ferguson, The University of Dundee
Genevra Richardson, Kings College Law

Ann Macaskill, Sheffield Hallam University
Judy Laing (part time), The University of Bristol
Therese Callus, The University of Reading
Nicky Priaulx, Cardiff University
Seamus Burns, Sheffield Hallam University
Rob Heywood, The University of East Anglia
Richard Huxtable, The University of Bristol
Laura Machin, Lancaster University
Jose Miola, The University of Leicester
Michelle Robson, Northumbria University
Kristina Swift, Northumbria University
Professor Matthew Weait, Birkbeck College, London
Anthony Wrigley, Keele University
Jonathan Hughes, Keele University
Shawn Harmon, The University of Edinburgh
Kirsty Horsey, The University of Kent
Dr Tracey Elliott, University of Leicester

This Journal may be cited as [2019/2] JMLE
ISSN 2213-5405 (print); 2214-5354 (online)
www.jmle-online.com

Submissions:

We invite papers for this scholarly, peer-reviewed publication of original articles and analysis of current developments in the field. Prospective authors should contact any of the editors with their proposals (300-500 words).

Subscription and Pricing Information:

Paris Legal Publishers, PO Box 4083,
7200 BB Zutphen, The Netherlands
info@parislegalpublishers.com

© 2019, Paris Legal Publishers

All rights reserved. No part of this publication may be reproduced or transmitted, in any form of by any means, or stored in any retrieval system of any nature, without the written permission of the publisher. Application for permission for use of copyright material shall be made to the publisher.

mvw
media voor vak
& wetenschap

Guest editorial Why age-based rationing is not necessarily evil	227
--	-----

Why health care rationing is not acceptable in the USA and Russia	
<i>Vasiliy V. Vlassov, Sergey V. Shishkin, Alla E. Chirikova and Anna V. Vlasova</i>	231

Introduction	232
Methods	232
Rationing agenda in the USA and the RF	233
The practice of rationing in the RF	235
How do Russian physicians do it?	237
Conclusion	239
References	239

Personal responsibility for health: the impact of digitalisation	
<i>Andrea Martani and Georg Starke</i>	241

1. Introduction	241
2. Personal responsibility for health as a rationing criterion: a practical problem	244
3. The challenge of <i>practical enforceability</i> : two policy examples	247
4. The impact of digitalisation: responsibility becoming enforceable?	250
5. Digitalisation and causal responsibility	253
6. Enforcing personal responsibility: the best way of using digitalisation to improve resource allocation?	256
7. Concluding remarks	258
8. Abbreviations	258
9. Acknowledgments	258

Health care rationing in Italy: right to health vs. budget constraints in a regional-based health system	
<i>Alceste Santuari</i>	259

1. Introduction	259
2. A short description of the Italian national health system	260
3. Health care rationing and the right to health	265
4. Social enterprises as the result of health care rationing?	266
5. Concluding remarks	268

Rationing in the English NHS and the Tension between Patient Choice and Solidarity

269

1.	Introduction: The Backdrop to Solidarity and Choice in the NHS	269
2.	Rationing in a Comprehensive Health care Service	272
		275
2.1	Rationing and Patient Choice: Individual Funding Requests	275
2.2	The Definition of Exceptionality Criteria	276
2.3	Relevant Principles in the Decision-Making Framework	279
3.	Judicial Review Challenges: Patient Choice versus Solidarity	282
4.	Conclusion	285

Guest editorial Why age-based rationing is not necessarily evil¹

Confronted with a rapidly ageing population in need of medical care, and the drive for technological innovations in health care (e.g. diagnostic devices, therapy options and medicines), the need for rationing health care is unavoidable. For this reason, the National School of Public Health (ENSP in Lisbon) organised a multidisciplinary conference: 'Health care rationing in Europe: The past, present and future'. Speakers with different backgrounds from European countries addressed the controversial 'R-word'. Emerging rationing questions discussed were: who is responsible for rationing (the market, governments, bureaucrats, physicians or others); how does it function (explicit or implicit); what are relevant and acceptable selection criteria; to what extent is current rationing just and what can be done to make it more just; and, how will health care rationing affect equal access to health care?

Health care rationing is generally defined as setting limits to the basket of care that will result in the denial of, or delay in specific medical interventions; exclusion of necessary health care for other than medical – read financial – reasons. When alternatives to containing the costs of health care have failed, or appeared inadequate (efficiency measures, co-payments, etc.), more drastic cost saving measures such as rationing health care become a reality.

Nowadays, most health care systems are familiar with some kind of rationing, either explicitly or implicitly. Ideally, choices in health care are made explicitly, based on transparent, democratic and participatory decision-making procedures, valuing verifiable reasons or criteria known in advance. Except for the National Institute for Health and Care Excellence (NICE) – responsible for the appraisal of new technologies based on clinical and economic evaluations – such a deliberate and explicit process is unknown in most countries.

More common is implicit rationing decided by clinicians at the bedside. Neither the decision, nor the basis for that decision is clear. It happens in secrecy, 'behind the scenes', and lacks public scrutiny.² As a result, implicit rationing has been criticised since physicians fail to inform patients about the real reason for the denial of a necessary treatment, primarily to prevent distress or being put in an uncomfortable position. Nowadays, implicit rationing has been generally rejected,³ but persists. An illustration is the situation in Russia as described by Vlassov et al. where leading physicians, acting as heads of de-

¹ DOI 10.7590/221354020X15815920230960 2213-5405 2020 Journal of Medical Law and Ethics

² E.g., S. Huster and others, 'Implizite Rationierung als Rechtsproblem', 25 *MedR* (2007):703-706; V. Vlassov and others, 'An idea alien to both worlds: why health care rationing is not acceptable in the USA and Russia', *JMLE*, 3: 2020.

³ E.g. G. Oei, 'Explicit versus implicit rationing: Let's be honest', 7 *American J Bioethics* (2016):68-70; F. Breyer, 'Implizite versus Explizite Rationierung von Gesundheitsleistungen', *Bundesgesetzblatt* 55 (2012):652-659.

partments, deny costly interventions not covered by insurance, although here the reason is given as ‘controlling proper use’, rather than rationing.⁴

Rationing comes in a variety of forms. At the macro level, NHS England and the Clinical Commissioning Groups (CCGs) – succeeding the commissioners’ role on the Primary Care Trusts (PCTs) – have a mandate to decide which treatments are available and which are restricted because of limited resources.⁵ As mentioned, these decisions of both NHS England and the CCGs are guided by NICE appraisal guidelines. In exceptional cases, by submitting an individual funding request, patients will be granted a treatment or procedure not generally available in the NHS (*Sheppard*). This is somewhat different from NHS-like systems, such as Italy’s *Servizio Sanitario Nazionale* (SSN) which is more regionally based, as described by *Santuari*.⁶

In social health insurance (SHI) systems, the ‘package of care’ decision-making has been institutionalised by federal or national bodies, with a wide range of regulatory powers. These decisions, ‘listing or delisting’ services on/from a benefit catalogue are based on evaluation of evidence-based reports. So far, these evaluation studies have focused primarily on the cost-effectiveness of new medicines. Initiatives at European level, such as establishing an EU-wide network for Health Technology Assessment (HTA) and the Commission’s proposal of a Regulation on HTA might help to improve the evaluation process, while increasing transparency in the appraisal decision-making process.⁷ But overall, an explicit rationing mechanism or cost-effectiveness threshold is absent in most SHI systems.⁸

Probably the most difficult question is, which selection criteria should be used? *Martiani* and *Starke* argue that *personal responsibility* could be a feasible rationing criterion. But a system of reward and punishment based on personal responsibility has encountered the problem of ‘practical enforceability’. The authors claim to have overcome that hurdle by means of the digital monitoring of medication-taking behaviour (‘datafying health and making patients transparent’).⁹ An interesting but also controversial and worrying consequence of digitalisation in health.

4 Vlassov, op.cit.

5 M. Sheppard, ‘Rationing in the English NHS and the Tension between Patient Choice and Solidarity’, *JMLE*, 3: 2020)

6 A. Santuari, ‘Health care rationing in Italy: right to health vs. budget constraints in a regional-based health system’, *JMLE* 3:2020.

7 See the HTA Core Model of EUnetHTA (www.EUnetHTA.eu) and the Proposal for a Regulation on health technology assessment and amending Directive 2011/24/EU, 31 January 2018, COM(2018)51 final.

8 It was suggested to apply a bandwidth with a median value of €40,000 per added life-year (QALY), CPB Document no. 152, 10 (in Dutch), see: www.zorginstituutnederland.nl.

9 A. Martani and G. Starke, ‘Personal responsibility for health: the impact of digitalization’, *JMLE* 3: 2020

Apart from the clinical and cost-effectiveness thresholds, could age be considered as an acceptable criterion for rationing health care, or is that ageist and thus discriminatory? On other occasions, health ethicists have argued that certain forms of age-based rationing can be accepted with the 'fair innings' argument.¹⁰ Elaborated by Fleck, age-based rationing does not generally advocate the withholding of all medical treatment from the elderly, but only limited to high-cost life-extending care, taking into account relevant circumstances such as, type of disease, survival prospects, and degree of effectiveness or benefits (subtle age rationing).¹¹ Also from a human rights perspective, I have argued that subtle age rationing is not necessarily discriminatory.¹² Taking into account the General Comment 20, which clarifies the understanding of non-discrimination in socio-economic rights, some forms of differential treatment may be permissible,¹³ but only when complying with the Committee on Economic, Social and Cultural Rights' conditions.

Such a controversial measure will be compatible with the Convention rights, assuming that the aim and effects of age-based rationing 'promote general welfare' (sustainability), while respecting the elderly's health needs, except for life-sustaining treatment. Secondly, defining a maximum age for age-based rationing is considered an objective standard, to be defined by state parties, allowing (groups of) individuals the right to participate actively in the decision-making process over the selection of such a criterion ('democratic deliberation').¹⁴ This approach then requires access to and disclosure of all relevant information, a transparent and participatory decision-making process, regulated by law and the mechanisms for legal redress when rights have been violated. In this way, such a fair and accountable procedure combines both substantive and procedural principles, echoing the accountability for reasonableness standards advocated by Daniels and Sabin.¹⁵

Although the fair-innings argument in age-based rationing has certain weaknesses, it is the least worst of the selection criteria. Alternative criteria (gender, socio-economic status, religion, disability, cost-effectiveness thresholds,

¹⁰ J. Harris, *The Value of Life. An Introduction to Medical Ethics* ([PLACE OF PUBLICATION???]: Routledge 1991):91-94; elaborated by L. Fleck, *Just caring: Health Care Rationing and Democratic Deliberation* (New York: OUP, 2009).

¹¹ Fleck, *Ibid.* ch.9.

¹² 'Access to new health technologies and age-based rationing', in: A. Taylor, S. Negri, *Legal, Ethical and Social Implications of Ageing* (OUP in press).

¹³ CESCR, General Comment (GC) no. 20 'Non-discrimination in economic, social and cultural rights', E/C12/GC/20, 2 July 2009, para. 13.

¹⁴ Also argued by Fleck, *op.cit.*, ch. 5.

¹⁵ AfR: this is the idea that the reasons or rationales for important limit-setting decisions should be publicly available. In addition, these reasons must be ones that 'fair-minded' people can agree are relevant to pursuing appropriate patient care under necessary resource restrictions (N. Daniels and J. Sabin, *Setting limits fairly: Can we learn to share medical resources?* ch. 4, ebook).

random lottery) appear arbitrary and are therefore rejected. When other cost-curbing measures have failed, then limited age-based rationing remains the least onerous, but most necessary, option to cope with an imminent public health threat.

André den Exter

Jean Monnet Chair EU Health Law
Erasmus University Rotterdam
Universidade Nova de Lisboa, ENSP
André den Exter <denexter@law.eur.nl>

Prof. Paula Lobato de Faria

Escola Nacional de Saude Publica

An idea alien to both worlds: why health care rationing is not acceptable in the USA and Russia

MD Vasiliy V. Vlassov*

National Research University Higher School of Economics, Moscow, Russia

PhD Sergey V. Shishkin

National Research University Higher School of Economics, Moscow, Russia

PhD Alla E. Chirikova

National Research University Higher School of Economics, Moscow, Russia

MD Anna V. Vlasova

I.M. Sechenov First Moscow State Medical University, Moscow, Russia

Abstract

The simple idea of rationing appears unacceptable both for the relatively poor “socialist” health care in Russia and for the most expensive USA health care. In Russia the idea of rationing is unacceptable, because the Constitution promises free and unlimited medical care. Therefore, discussion is blocked from the top. In the USA the idea is unacceptable, because citizens are understood as having the right to free choice of legal access to any care, without intervention of a ‘death jury’.

We analyse the similarities and differences in the arguments rejecting explicit rationing in health care in the USA and Russia. We describe the legal framework in Russia related to rationing, and the results of a qualitative study of the understanding of the concept of rationing by Russian doctors and of the practices in Russian health care organizations to limit the use of expensive diagnostic and treatment options.

While the Russian Constitution promises free medical care, unlimited, legally there are limits imposed by the quota of specific treatments, limited access to care abroad, and problematic access to drugs not included on the essential drug list for inpatient care. Explicit rationing is not rejected by society or by the medical profession. In medical organizations the more explicit techniques are a second opinion by a committee (physicians’ commission), especially in the case of prescription of drugs and diagnostic tests. Physicians tend to behave as medical professionals do: provide more care to people in greater need.

* DOI 10.7590/221354020X15815920230924 2213-5405 2020 Journal of Medical Law and Ethics

Introduction

The health care systems in the Russian Federation (RF) and the United States (US) are strikingly different. While the US system is based on the rights of the person and his/her ability to pay for care, the RF system is nominally egalitarian, promising in the Constitution equal access to health care based on need only. The US libertarian approach is softened by the moral obligation to help those in need. In the RF the unlimited promise of health care is limited by the provision of drugs only in hospital care and some other lower level regulations constructed to channel the demand for expensive care.

At the very different levels of funding for health care, both systems are under pressure to control costs. In the US, reform addresses both health care coverage and skyrocketing costs. There is no health care reform in the RF, but number of national scale projects initiated over the last 20 years to upgrade some sectors and services without significant changes to the system, and keeping the cost of the system low.¹ In both countries, resource-centred rationing is practised, as it is everywhere. It is simple, because it is not connected to a comparison of individual patients; e.g. aesthetic surgery and tattoo removal is not covered. Individual level rationing –rationing based on the qualities of the individual patient and his needs – is more complicated² and its application is the litmus test for the acceptance of rationing.

Methods

We systematically review the literature related to rationing both in the US and the RF. We searched MEDLINE using the query: “rationing AND (russia*[ti] or russia*[ab] or russia[mh] OR united states[mh] OR america*[ti] or america*[ab]) AND 2000:2018[dp] NOT latin”. A total of 607 items were found and screened for relevance and 24 included in the review. Additional articles were included through snowballing.

We use the semi-structured in-depth interview to study the opinions and decision making by doctors in the RF. We interviewed physicians (internal medicine, gynaecology), junior and senior, and physicians in top managerial positions in hospitals in 2017. Interviewees were selected in an affluent region (Moscow) and in the less affluent provincial region in the European part of the

¹ ‘Why is there no reform of the Russian health care system?’ [Rus] in E.G. Yassin (ed), *XVI April International scientific conference on the problems of the development of the economy and society*, vol 4 (Higher School of Economics) <<https://www.hse.ru/mirror/pubs/lib/data/access/ram/ticket/85/152524462241f47b9fiobe143331d86c895ab2444d/XVI%20%D0%9A%D0%BE%D0%BD%D1%84.%D0%9A%D0%BD.4.pdf>>

² ‘How should we use age to ration health care? Lessons from the case of kidney transplantation’, 58 *Journal of the American Geriatrics Society* 1980

RF. We did work in two organizations in Moscow (outpatient polyclinic and acute care hospital) and in three organizations in the region (outpatient polyclinic, city hospital, small city hospital). A total of 28 interviews were summarized for this analysis.

Rationing agenda in the USA and the RF

In general, both in the US and in the RF, rationing is not a subject of open debate, nor of systematic judicious practice. The only large exception in the USA is the Oregon Health Plan – an exemplary project of explicit rationing.³ Over 30 years it attracted enormous attention and ignited a great deal of discussion, but it still is the only well-designed plan built on the principles of evidence-based selection of the services covered.⁴ It is an example of the effort to achieve rationing, not as the limits to care imposed by a physician, but as a citizens' agreement on the use of public resources.⁵

The exceptional position of the Oregon Health Plan does not mean that elements of rationing do not exist elsewhere in the US. Under the pressure of rising health care costs, managed care and capitated care are the prevailing responses intended to help with rising costs. By design, these forms of care as well as gatekeeping by primary care physicians have elements of rationing.⁶ All benefit packages are incomplete, and what is not listed, may be deemed implicitly rationed. It became obvious when patients went to court complaining that they had not received the care required. At its extreme, proponents of rationing include as rationing any case when a person has been refused treatment because of the high cost of the treatment. The proportion of people in the US who somehow miss out on health care due to cost is 17%.⁷ The pessimistic view is that unless resources for health care face an actual shortage, US society will not embrace rationing.⁸

When the US public is polled about health care reform, most are displeased with the current state of the system, and most agree that universal coverage is

³ 'The Oregon Health Plan: to cover all diagnostic visits', 268, *JAMA : The Journal of the American Medical Association*, 790

⁴ 'Rationing medical care: rhetoric and reality in the Oregon Health Plan', 164, *CMAJ : Canadian Medical Association Journal = Journal de l'Association medicale canadienne*, 1583

⁵ 'Should physicians be gatekeepers of medical resources?' [BMJ Group], 27 *Journal of Medical Ethics*, 268

⁶ 'Rationing: a transatlantic perspective', 46, *The British Journal of General Practice : The Journal of the Royal College of General Practitioners*, 543

⁷ 'Who can't pay for health care?' [Blackwell Science Inc], 20, *Journal of General Internal Medicine*, 504

⁸ 'Rationing health care and the need for credible scarcity: why Americans can't say no', 85 *American Journal of Public Health*, 1439

needed, but when rationing and managed access by queuing are mentioned, support for such variants is low.⁹ Many physicians in the USA reject the possibility of rationing, and a majority declares that they provide all beneficial therapies without regard to cost.¹⁰ In a poll of a sample of US physicians, 67% supported cost containment, but 54% objected to the use of cost-effectiveness in clinical decisions.¹¹ This last large proportion should not surprise us, because the question was not about cost-effectiveness reasoning in the design of the coverage plan, but about the use of 'cost-effectiveness data to determine which treatment will be offered to patients'. This split of opinion by US physicians reflects the split in US society. A large number of US citizens believe that health care is a service to purchase and inequality in access to health care is normal. The other large number tend to think that healthcare is a social good and must be available for people on roughly equal terms. Discussion of cost containment, and reduction in the use of low value care is difficult because it 'easily oversteps the bounds of political correctness in a nation whose media ... convey political debates on public policy in terms of sound bites'.¹²

It was the hope that 'comparative effectiveness research' would smooth the way to acceptance of health technology.¹³ Unfortunately, this did not happen. This does not mean that US physicians do not somehow prioritize care. Even more: primary care physicians in the US believe that their patients receive too much care, and the cost of care may be reduced without rationing necessary care.¹⁴ This understanding led to the initiatives "less is more" and "choosing wisely" encouraging the voluntary cancelling of unnecessary/low value care by physicians.¹⁵ , ¹⁶ The reduction of potentially ineffective care is a major theme

⁹ 'Americans' views of health care costs, access, and quality' [Blackwell Publishing Inc], 84, *The Milbank Quarterly*, 623

¹⁰ 'The ethics and reality of rationing in medicine' [American College of Chest Physicians], 140, *Chest*, 1625

¹¹ 'The moral psychology of rationing among physicians: the role of harm and fairness intuitions in physician objections to cost-effectiveness and cost-containment' [BioMed Central], 8, *Philosophy, Ethics, and Humanities in Medicine: PEHM* 13

¹² 'Health reform in america' [Engage Healthcare Communications, LLC], 1, American Health & Drug Benefits, 8

¹³ 'Comparative effectiveness research: a cornerstone of healthcare reform?' [American Clinical and Climatological Association] 121 *Transactions of the American Clinical and Climatological Association* 141

¹⁴ 'Too Little? Too Much? Primary care physicians' views on US health care: a brief report', 171, *Archives of Internal Medicine*, 1582

¹⁵ 'Less is More: Modern Neonatology' [Rambam Health Care Campus], 9, *Rambam Maimonides Medical Journal*, e0023

¹⁶ 'Beyond the "Choosing wisely": a possible attempt' [BioMed Central], 42, *Italian Journal of Pediatrics*, 55

in US medicine, but there has been no progress in achieving it during the current health care reform.¹⁷

Most difficult questions arise in relation to expensive cancer care, potentially lifesaving. It is clear that no one health care system provides equal and unlimited access to this type of care. The fragmented US system provides patients with more expensive drugs, but the ‘socialized’ UK system is fairer.¹⁸ Access to low value expensive cancer drugs is explicitly limited in UK, and in the US access to the most expensive drugs is painted as a major attractive element of the system.¹⁹

In the RF, funding for health care is insufficient, but health care access is declared to be unlimited and there is no discussion in professional or lay media about balancing the budget through exclusion of low value interventions. In the comparative study, RF physicians are more prone to provide life-extending care to dying elderly dementia patients than their European colleagues.²⁰ This may reflect the strong demand by RF law to provide life-supporting care in all circumstances. This demand does not mean the banning of rationing. In practice, when providing health care through scarce resources, physicians tend to provide it to nice patients, who ‘deserve’ it.²¹

The practice of rationing in the RF

The Soviet health care system was large and poor. Modern technology was supplied only to a small number of Moscow’s exemplary centres. Most physicians in the USSR had no idea about what was available and had no possibility to refer patients to these centres. The decision to hospitalize a patient at such a centre belonged to the staff of the centre and was regulated by internal documents. Party bosses were treated in special well-equipped hospitals, and had access to all the technology available in the country. The inequality of access to health care was a major source of discontent during last Soviet years, though some steps towards equality of access had been taken during Perestroika. The situation was mainly restored in the mid-1990s by the creation of the “Kremlin hospital”. While the selection of technologies for their cost-effectiveness was not legally possible, numerous practices and solutions are in essence rationing

¹⁷ ‘Potentially ineffective care: time for earnest reexamination’ [Hindawi Publishing Corporation], 2014, *Critical Care Research and Practice* 134198,

¹⁸ ‘Expensive cancer drugs: a comparison between the United States and the United Kingdom’ [Blackwell Publishing Inc], 87, *The Milbank Quarterly*, 789

¹⁹ ‘UK drug appraisal process is restricting access to cancer drugs, say charities’, 354, *BMJ*, i4465

²⁰ ‘Doctors’ authoritarianism in end-of-life treatment decisions. A comparison between Russia, Sweden and Germany’ [BMJ Group], 27, *Journal of Medical Ethics*, 186

²¹ ‘Systemic barriers accessing HIV treatment among people who inject drugs in Russia: a qualitative study’ [Oxford University Press], 28, *Health Policy and Planning* 681

practices or may be viewed as rationing. It appears that Russian society as well as the medical professionals accept the practice of rationing despite it not being named and not being described as a system.

In efforts to protect the best medical centres from degradation in the difficult 1990s, the RF Government created a special line of funding of “high technology”/expensive care. It took 10 years before the mechanism of regulating access mostly to Moscow located “high technology” centres for patients from every region was introduced in 2005. These “quotas” for hospitalization were distributed centrally to serve the needs of the regions. The number of quotas was (and still is) insufficient for patients from all around the country, as well as for the participating hospitals, because of limited funding. To get access to quota care, a patient has to go through a chain of selection procedures, the last one taking place in the participating speciality hospital. It is in essence a process of rationing based on the need, age and predicted results of the treatment for a specific patient.

A variant of expensive care – transplantology. The Ministry of Health provides quotas for transplantology to selected hospitals, and these hospitals select the patients and manage the queue themselves. Despite the absence of national statistics, we believe that most patients in the queue do not survive to transplantation, as well as the fact that many are not included in the queue.

Some interventions are not available in the RF. For serving patients who cannot receive the necessary care some funding is reserved in the national health care budget. Again, there is a commission assembled from representatives of the specialist hospitals. The commission decides whether a specific patient is eligible for getting access to these limited funds, or whether the treatment mode available in the national centre is sufficient. Every year these limited funds do not get used in full. Again, people accept this way of distributing limited resources.

A major restriction in RF health care is the non-provision of drug therapy in outpatient care. Free drugs are provided only for inpatient care and in outpatient care as part of social subsistence. There is a list of “life-saving and important” drugs by generic name, which limits drug provision in hospitals. The access to other drugs, not included on the list, is possible, but limited by the obligatory second opinion of the colleagues’ commission. These limits, imposed on access to drugs, are quietly accepted by patients and physicians, probably because they are very similar to the limits of the Soviet period. The methods for preparing this drug list were approved by the Government in 2014²² and this regulation is the only one mentioning a cost-effectiveness evaluation of the drugs and evaluation of their influence on the budget. It is notable, because no one federal

²² *On approval of the regulation for preparation of the lists of the medicines and minimal assortment of medicines needed for health care [Rus]* (Government of the Russian Federation)

law contains a provision of a drug or any other intervention depending on its cost.

If access to drugs is limited, what kind of treatment is recommended by the Russian guidelines? Traditionally, medical associations draft their guidelines according to the best recent documents approved by international medical associations. The Russian guidelines may recommend treatments that are not provided free and not affordable for the totality of patients. The guidelines rarely offer advice to physicians on how to limit the range of patients who may benefit from treatment. A good example is the expensive antiviral drugs for treatment of hepatitis C. While in the US guidelines limit the use of a therapy, unaffordable according to the budget, to a specific subgroup of patients, in the RF the guidelines just contain information about an effective therapy. Some of the Russian guidelines vaguely advise that a treatment option should be selected taking accessibility into account. When the US, Spanish and some other medical associations and health care systems more or less openly advise on how to limit access, the RF guidelines advise physicians simply to deliberate.

National health care law in the RF introduced a special type of prescriptive document – standards. The standard for the management of a condition is a table describing the interventions, the proportion of patients receiving it, and the number of doses/applications. Care should be provided in agreement with these standards. The medical organization receiving payment from an insurance company should treat patients in agreement with the standards.²³

How do Russian physicians do it?

Most practices of rationing in Russian hospitals are institutionalized in some way. The prevailing form is the approval of expensive treatment or diagnostic test by the commission of leading hospital specialists chaired by the hospital chief physician. In a large organization, additional steps of control exist – by a department head, or a leading specialist. Officially, this practice is introduced for control of the appropriateness of interventions, not for rationing. The positive outcome is more or less obvious to physicians: without such a control physicians tend to respond to patients' demands by increasing testing and prescription with the obvious result –overloading, long queues and exhaustion of funds. Commissions cancel up to 30% of requests from attending physicians using the argument that the test or treatment is not indicated, not necessary in the case presented. Talking about the limits imposed, whether

²³ 'Russian experience and perspectives of quality assurance in healthcare through standards of care' [Elsevier], 5, *Health Policy and Technology*, 5

permanent or temporary, physicians underscore that if the test is really needed, it will be approved by the commission and provided for the patient.

At the same time, physicians complain that there is a massive burden of paperwork and consultation accompanying the arrangement of access to the expensive/limited test, service or treatment. Another outcome of these barriers, reported by some physicians in the outpatient setting, is the feeling that you belong to a team playing against the patient, putting an unnecessary burden on the patient and his physician.

In Moscow hospitals, the control commissions check a sample of patients' records to control compliance with the standards and to fine physicians for unnecessary tests and treatments. Paraclinical departments provide information on the overuse of expensive tests and impose limits on the number of tests for the department per period. Hospital managers tend to describe physicians, who order more tests, as having lower qualifications.

Another specialist with a role in saving resources, correcting prescriptions and advising physicians in Moscow is the clinical pharmacologist. Surgeons interviewed are very positive in relation to correction of drug therapies by pharmacologists, leading to better efficacy and saving resources.

Moscow physicians in general are very positive towards the idea and practice of saving resources by limiting access to unnecessary or less necessary interventions. Many physicians, especially surgeons, approve treatment by protocols of the majority of patients for the sake of quality and rational use of resources. Some outpatient physicians, especially in Moscow, underscore that standards of treatment help and protect them from over-demanding patients. Other physicians comment that standards at the same time impose unnecessary tests and treatments, thus increasing the workload and the costs. A major line of tension is that a treatment prescribed by the standards is not adequately funded.

In provincial hospitals the processes of cost control are less formal; more decisions depend on a chain of command, and the pressure of costs originated from services bought from outside the hospital is higher. The standards prescribing the content of care should be met somehow, otherwise cases may be not paid for by the insurance companies. Collegial decisions are described by physicians as a positive experience, as a way of providing the care required, as they understand it. It appears that the less formal cost control in provincial organizations is less effective, than in Moscow, but the problem may be another one – provincial hospitals have fewer resources. They have many doctor and nurse positions vacant, old and unreliable equipment. As a result, their work is an everyday struggle to limit care for the sake of having sufficient resources for those who need it most. Physicians list the patients who are preferred: severe cases, mothers with children, compliant patients, bosses and other people recommended by the hospital chief or colleagues. Older patients are mentioned only to contrast the preferred others. The physicians interviewed were usually reluctant to describe these preferences.

In general, in Moscow and in the provinces, physicians understand their practice not as a practice of rationing, but as an everyday service to patients, to overcome the limits imposed. Only some of the physicians interviewed protested against the limits imposed by the standards or drug lists.

Conclusion

While in the US, a significant proportion of the population is negative in relation to health care rationing, a not negligible proportion of physicians are ready to embrace it. The health care system – insurers and providers – employs elements of care organization, provision and coverage, which are rationing in essence.

In the RF the rationing debate is suppressed, and the corpus of national legislation explicitly bans the rationalization of health care spending based on cost. At the same time, the health care system has a number of elements designed to lower the cost of care and suppress the use of expensive services. Physicians accept these elements of the system and work with them, trying to trick the system in order to provide better care.

References

- *On approval of the regulation for preparation of the lists of the medicines and minimal assortment of medicines needed for health care [Rus]* (Government of the Russian Federation 2014)
- Vlassov V, 'Why there is no reform of Russian health care system? [Rus]' in Yassin EG (ed), *XVI April international scientific conference on the problems of the development of the economy and society*, vol 4 (Higher School of Economics 2016) <<https://www.hse.ru/mirror/pubs/lib/data/access/ram/ticket/85/152524462241f47b9f0be143331d86c895ab2444d/XVI%20%D0%9A%D0%BE%D0%BD%D1%84.%D0%9A%D0%BD.4.pdf>>
- Antiel RM and others, 'The moral psychology of rationing among physicians: the role of harm and fairness intuitions in physician objections to cost-effectiveness and cost-containment' [BioMed Central] 8 Philosophy, ethics, and humanities in medicine : PEHM 13
- Bernardini R and others, 'Beyond the "Choosing wisely": a possible attempt' [BioMed Central] 42 Italian journal of pediatrics 55
- Blendon RJ and others, 'Americans' views of health care costs, access, and quality' [Blackwell Publishing Inc] 84 The Milbank quarterly 623
- Faden RR and others, 'Expensive cancer drugs: a comparison between the United States and the United Kingdom' [Blackwell Publishing Inc] 87 The Milbank Quarterly 789

- Jackson WL, Jr. and Sales JF, ‘Potentially ineffective care: time for earnest reexamination’ [Hindawi Publishing Corporation] 2014 Critical care research and practice 134198
- Kugelman A and others, ‘Less is More: Modern Neonatology’ [Rambam Health Care Campus] 9 Rambam Maimonides medical journal e0023
- Mariner WK, ‘Rationing health care and the need for credible scarcity: why Americans can't say no’ 85 American journal of public health 1439
- Mushlin AI and Ghomrawi HMK, ‘Comparative effectiveness research: a cornerstone of healthcare reform?’ [American Clinical and Climatological Association] 121 Transactions of the American Clinical and Climatological Association 141
- Oberlander J, Marmor T and Jacobs L, ‘Rationing medical care: rhetoric and reality in the Oregon Health Plan’ 164 CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne 1583
- Purdy S, ‘Rationing: a transatlantic perspective’ 46 The British journal of general practice : the journal of the Royal College of General Practitioners 543
- Reese PP and others, ‘How should we use age to ration health care? Lessons from the case of kidney transplantation’ 58 Journal of the American Geriatrics Society 1980
- Reinhardt U, ‘Health reform in america’ [Engage Healthcare Communications, LLC] 1 American health & drug benefits 8
- Richter J, Eisemann M and Zgonnikova E, ‘Doctors' authoritarianism in end-of-life treatment decisions. A comparison between Russia, Sweden and Germany’ [BMJ Group] 27 Journal of medical ethics 186
- Sarang A, Rhodes T and Sheon N, ‘Systemic barriers accessing HIV treatment among people who inject drugs in Russia: a qualitative study’ [Oxford University Press] 28 Health policy and planning 681
- Scheunemann LP and White DB, ‘The ethics and reality of rationing in medicine’ [American College of Chest Physicians] 140 Chest 1625
- Sirovich BE, Woloshin S and Schwartz LM, ‘Too Little? Too Much? Primary care physicians' views on US health care: a brief report’ 171 Archives of internal medicine 1582
- Vlassov VV, ‘Russian experience and perspectives of quality assurance in healthcare through standards of care’ [Elsevier] 5 Health Policy and Technology 5
- Weinick RM, Byron SC and Bierman AS, ‘Who can't pay for health care?’ [Blackwell Science Inc] 20 Journal of general internal medicine 504
- Weinstein MC, ‘Should physicians be gatekeepers of medical resources?’ [BMJ Group] 27 Journal of medical ethics 268
- Wise J, ‘UK drug appraisal process is restricting access to cancer drugs, say charities’ 354 BMJ 14465
- Wopat RC, ‘The Oregon Health Plan: to cover all diagnostic visits’ 268 JAMA : the journal of the American Medical Association 790

Personal responsibility for health: the impact of digitalisation

Andrea Martani*

Institute for Biomedical Ethics, University of Basel, Basel, Switzerland

Georg Starke

Institute for Biomedical Ethics, University of Basel, Basel, Switzerland

Abstract

Fostering the personal responsibility of patients is often considered a potential remedy for the problem of resource allocation in health care systems. In political and ethical debates, systems of rewards and punishments based on personal responsibility have proved very divisive. However, regardless of the controversies it has sparked, the implementation of personal responsibility in concrete policies has always encountered the problem of practical enforceability, i.e. how causally relevant behaviour can be tracked, allowing policies of this kind to be applied in a fine-grained, economically viable and accurate fashion. In this paper, we show how this hurdle can be seemingly overcome with the advent of digitalisation in health and delineate the potential impact of digitalisation on personal responsibility for health. We discuss how digitalisation – by datafying health and making patients transparent – promises to close the loophole of practical enforceability by allowing to trace health-related lifestyle choices of individuals as well as their exposure to avoidable risk factors. Digitalisation in health care thereby reinforces what Gerald Dworkin has called the causal aspect of personal responsibility and strengthens the implicit syllogism that – since exposure to risk factors happens at the individual level – responsibility for health should be ascribed to the individual. We conclude by addressing the limitations of this approach and suggest that there are other ways in which the potential of digitalisation can help with the allocation of resources in health care.

I. Introduction

Should people who contribute to their own poor health be held accountable for it? The question whether enhancing personal responsibility for health is a just policy-choice enjoys a prominent role in the political as

* DOI 10.7590/221354020X15815920230933 2213-5405 2020 Journal of Medical Law and Ethics

well as the scientific debates concerning the allocation of health care resources.¹ The increasing importance that this argument has acquired in recent decades can be related to several factors. First, with the population ageing and the incidence of non-communicable diseases increasing, health care services struggle to keep up with the populations' health needs. Second, with scarcity of resources hitting many health care systems – albeit to different extents – there is an increasing need for socially accepted criteria to allocate the available money. Third, the advancements of medicine raise popular expectations of receiving effective treatment with respect to an increasing number of conditions regardless of their cost – especially when those illnesses are life-threatening and affect children.² Fourth, research is showing that for common non-communicable diseases whose treatment significantly contributes to health expenditure – such as cardiovascular diseases, diabetes and even cancer – a few changes in lifestyle would reduce the occurrence of many of these illnesses.³

In this context, it is easy to understand the appeal of the idea that people who contribute to their own poor health should be personally and financially responsible for it. In England, for example, some local Clinical Commissioning Groups (the public body responsible for the planning and commissioning of health care services in England's National Health Service) have been contemplating plans to restrict free⁴ elective surgery for smokers and obese patients.⁵ Similarly, individual co-payments for health problems resulting from medically unnecessary cosmetic surgery, tattoo or piercing were increased in Germany,

¹ See, for example, M. Minkler, 'Personal Responsibility for Health? A Review of the Arguments and the Evidence at Century's End', *Health Education & Behavior* 26 (1999):121-140; A.M. Buyx, 'Personal responsibility for health as a rationing criterion: why we don't like it and why maybe we should', *Journal of Medical Ethics* 34 (2008):871-874; K. Sharkey & L. Gillam, 'Should patients with self-inflicted illness receive lower priority in access to healthcare resources? Mapping out the debate', *Journal of Medical Ethics* 36 (2010):661-665; A.M. Baker & L.M. Hunt, 'Counterproductive Consequences of a Conservative Ideology: Medicaid Expansion and Personal Responsibility Requirements', *American Journal of Public Health* 106 (2016):1181-1187.

² See, with respect to this point, the literature on the "rule of rescue", e.g. Bettina Schöne-Seifert: 'The "rule of rescue" in medical priority setting: Ethical plausibilities and implausibilities', *Perspectives in Moral Science* (2009):421-430.

³ See e.g. S. Barquera, A. Pedroza-Tobías, C. Medina, L. Hernández-Barrera, K. Bibbins-Domingo, R. Lozano & A.E. Moran, 'Global overview of the epidemiology of atherosclerotic cardiovascular disease', *Archives of medical research* 46 (2015):328-38.; I. Soerjomataram, E. de Vries, E. Pukkala & J.W. Coebergh, 'Excess of cancers in Europe: A study of eleven major cancers amenable to lifestyle change', *Int. J. Cancer* 120 (2007):1336-1343; I. Soerjomataram, K. Shield, C. Marant-Micallef, J. Vignat, C. Hill, A. Rogel, G. Menvielle, L. Dossus, J.N. Ormsby, J. Rehm & L. Rushton, 'Cancers related to lifestyle and environmental factors in France in 2015', *European Journal of Cancer* 105 (2018):103-113; Y. Zheng, S.H. Ley & F.B. Hu, 'Global aetiology and epidemiology of type 2 diabetes mellitus and its complications', *Nature Reviews Endocrinology* 14 (2018):88.

⁴ Free at the point of use.

⁵ V. Pillutla, H. Maslen & J. Savulescu, 'Rationing elective surgery for smokers and obese patients: responsibility or prognosis?' *BMC Medical Ethics* 19 (2018), 28.

based on the Competition Reinforcement Law passed in 2007.⁶ Even in Switzerland, a country where ‘there is little explicit rationing of services [...] [and] cost is a concern, but there has been no cost explosion’,⁷ rising insurance premiums and out-of-pocket spending have reinforced calls to increase personal responsibility for health. In a recent editorial of the *Schweizerische Ärztezeitung*, the author expressed this point strongly:

People without personal responsibility are overweight, smoke and sit in front of their screen instead of doing exercise. They eat too much sugar, too much fat and few vegetables. They ignore the suggestions of the professionals and run to the doctor when they feel ill, without any second thought. And we – the slim, fit and sporty non-smokers – co-pay for that. We – the ones who take personal responsibility seriously – will be punished with ever higher insurance premiums.⁸

The success of the idea of enhancing personal responsibility for health lies in its intuitive appeal. Holding people accountable (e.g. through requiring higher co-payments) depending on their behaviour is profoundly rooted in a certain interpretation of the liberal principle ‘that the liberty of the individual must be thus far limited; he must not make himself a nuisance to other people.’⁹ Following John Stuart Mill, one could thus conclude that – by voluntarily choosing an un-healthy behaviour – the individual is damaging the community who, as a consequence, is allowed to withdraw the support normally provided to them according to the solidarity principle. In such instances, withdrawal of support would allegedly be justified if it concerned only guilty risk-takers (such as those who do not eat healthily), since they are not allowed to pass on to their fellow citizens the negative externalities produced by their voluntarily-assumed behaviours, and not a risk-carrier, such as people with a genetic predisposition.¹⁰

⁶ S. Huster, ‘Individual Responsibility and Paternalism in Health Law’, in *New Perspectives on Paternalism and Health Care*, ed. T. Schramme (Switzerland: Springer International Publishing Switzerland, 2015), 221.

⁷ N. Biller-Andorno & T. Zeltner, ‘Individual responsibility and community solidarity -The Swiss Health Care system’, *New England Journal of Medicine* 373 (2015):2194.

⁸ A. Sax, ‘Eigenverantwortung’, *Schweiz Ärzteztg* 98 (2017):174. Translation from the German version. The original reads “Leute ohne Eigenverantwortung sind übergewichtig, rauchen und sitzen vor dem Bildschirm, statt sich zu bewegen. Sie essen zu viel Zucker, zu viel Fett und zu wenig Gemüse. Sie füttern sich um die Empfehlungen der Fachleute und rennen, wenn sie sich krank fühlen, ohne nachzudenken, zum Arzt. Und wir, die schlanken, fitten, sportbewussten Nichtraucherinnen, zahlen mit. Wir, die wir unsere Eigenverantwortung wahrnehmen, werden mit immer höheren Krankenkassenprämien bestraft”.

⁹ J.S. Mill, ‘On Liberty’, in J. S. Mill, *Utilitarianism. Liberty and Representative Government*, Introduction by A. D. Lindsay, (London: J. M. Dent & Sons Ltd, 1947), 114.

¹⁰ I. Van Hoyweghen, K. Horstman & R. Schepers, ‘Genetic ‘risk carriers’ and lifestyle ‘risk takers’. Which risks deserve our legal protection in insurance?’, *Health Care Analysis* 15 (2007):179-193

Despite the many doubts that have been cast on such reasoning, the question whether it is appropriate to create policies reinforcing personal responsibility for health has enjoyed ongoing popularity, both inside academia and in the political domain.

In this paper, however, we do not primarily address the theoretical issue of whether it is legitimate to use personal responsibility as a rationing criterion in general. Instead, we focus on the interplay between the principle of personal responsibility for health and the phenomenon of digitalisation in health care. First, we outline how – aside from theoretical arguments for or against this principle – implementing policies based on a strict interpretation of personal responsibility has always encountered the hurdle of *practical enforceability*. We also provide two policy examples to root the debate on a more practical level. In the following section, we show how digitalisation supposedly offers a remedy to circumvent this hurdle since it allows closely and accurately to monitor individual behaviour, thus allegedly opening up the possibility to strengthen personal responsibility for health. Based on these considerations, we then analyse the influence of this shift on the conception of personal responsibility and argue that digitalisation stresses the *causal* aspect of this principle. Having highlighted the conceptual and practical limits of such digitally-supported inferences regarding personal responsibility, we finally plead that, beyond a mere focus on the individual, there are more promising alternatives as to how digitalisation can improve resources allocation in health care.

2. Personal responsibility for health as a rationing criterion: a practical problem

Using personal responsibility as a criterion for allocating resources in health care remains a contentious idea. On the one side, arguments in favour of more personal responsibility for health underline that de-prioritising patients who contribute to their own poor health is justified on several accounts. It is argued that these patients (1) are more likely to have poor health outcomes following treatment, (2) take away limited resources from patients who are more careful about their health, (3) lack incentives to change their behaviour and (4), if not held to account, may even disincentivise other people to contribute to the financing of health care.¹¹ On the other side, opponents of the use of personal responsibility as a rationing criterion have argued that ascribing responsibility generates stigma and does not necessarily improve health-related

¹¹ Sharkey & Gillam (note 1).

behaviour, therapeutic outcomes or public finances.¹² Apart from arguments at these two extremes, many authors have tried to find some middle ground. For instance, it has been argued that whether responsibility is prospective (i.e. a commitment to the future) or retrospective (i.e. accountability for the past) should determine its legitimacy.¹³ As an alternative criterion, Harald Schmidt¹⁴ has suggested that the degree of consequences (e.g. higher co-payment vs higher co-payment plus lower priority on the waiting list) assigned to the individual would affect a policy's adequacy.

Whilst the theoretical debate concerning the legitimacy of increasing the use of personal responsibility for health as a rationing criterion has flourished, the concrete issues that implementing this principle would entail at a practical level have not received the same attention. It seems clear, though, that using personal responsibility in the rationing of health care would encounter two sets of challenges. On the one hand, it would be necessary to agree upon a list of facts, acts and situations for which responsibility can be demanded and then set the consequences for the individual when those facts, actions or situations occur. Taking the example from Germany quoted above, the policy listed unnecessary cosmetic surgery, piercing and tattoo as triggering actions, and higher co-payment as consequence. On the other hand, it would be necessary to ensure the accuracy and correctness in the concrete operationalisation of such a list. We will refer to these two set of challenges as – respectively – the macro- and micro-level.

At a macro-level, the challenge consists in drafting an evidence-based and socially accepted list of actions for which personal responsibility can be demanded. This entails several questions for policymakers. First, they would need to determine which facts or actions produce a negative outcome *per se* (e.g. does smoking lead to COPD?), or – as Alena Buyx put it – ‘we want to be sure that we know exactly what actions or behaviours lead to a certain condition before holding patients responsible for the consequences.’¹⁵ In this respect, it has been suggested that there are two categories of facts and actions for which people could be held accountable.¹⁶ On the one hand, there are traditional health-related

¹² P. Friesen, ‘Personal responsibility within health policy: unethical and ineffective’, *Journal of Medical Ethics* 44(2018):53-58.

¹³ E. Feiring, ‘Lifestyle, responsibility and justice’, *Journal of Medical Ethics* 34 (2008):33-36. The exact terminology used by Feiring is “forward-looking” and “backward-looking”. However, the use of “prospective” and “retrospective” is more established in the literature. For a more in-depth definition, see G. Marckmann, M. Möhrle & A. Blum, ‘Gesundheitliche Eigenverantwortung’, *Der Hautarzt* 55 (2004):715-20.

¹⁴ H. Schmidt, ‘Personal responsibility in the NHS Constitution and the social determinants of health approach: competitive or complementary?’, *Health Economics, Policy and Law* 4 (2009):129-138.

¹⁵ Buyx (note 1), 873.

¹⁶ J. Savulescu, ‘Golden opportunity, reasonable risk and personal responsibility for health’, *Journal of Medical Ethics* 44 (2018):59-61.

behaviours like smoking, drinking, and unhealthy eating habits. On the other hand, there are risky behaviours such as practicing extreme sports, opting for elective surgery and driving motorcycles. Furthermore, it would be necessary to determine if those facts and actions truly determine negative consequences for the rest of the society. This would entail both purely economic considerations – e.g. are smokers really compromising public finances?¹⁷ – and moral ones – e.g. would it be socially accepted, in a given society, to require higher co-payments for emergency health care services for drivers?¹⁸ Lastly and more importantly, one would need to determine objective measurements for holding people responsible for a certain fact or action. Is one cigarette a week enough to warrant higher co-payments for health care services? Which health care services exactly will be affected? Only those related to the risk-taking behaviour, e.g. lung cancer treatment for smokers? Or more generally all services, e.g. by requiring smokers to pay higher health-insurance premiums?

Even more complicated are the challenges at the micro-level. In this respect, implementing personal responsibility for health as a rationing criterion would require to ‘single out the one decisive causal factor when it comes to individual patients’.¹⁹ Even when a list of actions and facts and their consequences in terms of responsibility were compiled at a macro-level, the fact would remain that in single cases it would be necessary to distinguish between those individuals where health care services can be rationed due to their behaviour and those where it cannot. Let us consider the example of a rule establishing higher co-payments for treating a multifactorial disease such as type II Diabetes when it is caused by unhealthy habits like exercising too little. Enforcing such a measure as a general policy would require considerable effort to distinguish between those patients who should be held accountable (e.g. because their condition is causally related to specific eating habits) and those with whom society should

¹⁷ This aspect might seem a trivial one but cannot be underestimated. For example, it is a common assumption that smokers’ poorer health outcomes generate a higher consumption of health care resources, which would supposedly justify reducing their health care benefits or increasing their co-payments. However, this assumption is often incorrect, from a purely economic perspective. Smokers are often “cheaper” to society because their higher mortality contributes to saving the money that they would have cost the health care and social system had they lived longer, the so-called ‘survivor consumption costs’, see e.g. D.R. Rappange, W.B. Brouwer, F.F. Rutten & P.H. van Baal, ‘Lifestyle intervention: from cost savings to value for money’, *Journal of Public Health* 32 (2009):440-447; L.B. Russell, ‘Preventing chronic disease: an important investment, but don’t count on cost savings’, *Health Affairs* 28 (2009):42-45. Of course, such purely economic considerations ought not to be dominant – e.g. the higher mortality of smokers should not be considered acceptable just because society saves money on their forgone pensions. It is, however, important to consider such aspects before surrendering to the intuitive assumption that it is easy to select those behaviours for which personal and financial responsibility can be demanded.

¹⁸ This aspect is also very important, and it is related to the societal determination of what is considered an acceptable risk-taking behaviour.

¹⁹ Buyx (note 1), 873.

be supportive (e.g. because the illness has occurred due to genetic predisposition). These micro-level challenges concerning the accurate operationalisation of personal responsibility for health as a rationing criterion have been a crucial deterrent to the implementation of policies of this kind. Indeed, an accurate and impartial operationalisation might often prove difficult and especially expensive, thus undermining one of the main objectives why personal responsibility for health would be reinforced (i.e. to save costs). As one author put it, attempts to practically implement policies based on the reinforcement of personal responsibility for health would be largely impractical because of ‘the extensive time and resources that would be required to assess each individual's responsibility for a given condition.’²⁰ For example, with regard to cost-sharing schemes based on personal responsibility in some US states’ publicly-funded Medicaid programme, it has been argued that the additional administrative costs incurred by tracking patients would likely exceed expected savings, rendering the implementation financially inefficient.²¹ On the same line, other authors have emphasised that, from a concrete policy perspective, ‘not all risky activities are taxable (e.g. sitting on the couch all day) since they are not *administratively* controllable.’²² From now on, we will refer to this set of issues as the problem of *practically enforcing* personal responsibility for health.

3. The challenge of *practical enforceability*: two policy examples

The challenges of *practically enforcing* personal responsibility for health as a rationing criterion become even more evident when far-reaching – in terms of people impacted and money affected – policy-questions in the context of rationing are considered. To substantiate this claim, we provide two hypothetical policies: the first one concerning sub-optimal medication adherence, the second one concerning liver transplantation.

Poor medication adherence – i.e. the habit of *not* taking medication as prescribed – has been widely identified as one of the most impactful health-related behaviours – both in terms of health outcomes and financial burden to health

²⁰ Friesen (note 11), 53.

²¹ J.B. Wishner, J. Holahan, D. Upadhyay & M. McGrath. Medicaid expansion, the private option, and personal responsibility requirements: the use of Section 1115 waivers to implement Medicaid expansion under the ACA’, *Urban Institute*, (2015), <http://www.urban.org/sites/default/files/alfresco/publication-pdfs/2000235-Medicaid-Expansion-The-Private-Option-and-Personal-Responsibility-Requirements.pdf> (accessed September 10 2019). Retrieved in Baker & Hunt (note 1).

²² K. Bærøe & C. Cappelen, ‘Phase-dependent justification: the role of personal responsibility in fair healthcare’, *Journal of Medical Ethics* 41 (2015):839 (emphasis added).

care systems. In a famous report by the WHO of 2003,²³ it was estimated that 50% of patients worldwide do not take medications as prescribed. As a result, not only are health outcomes worse, but also considerable amounts of health care resources are wasted. Estimates put the cost of hospitalisations due to poor medication adherence in the range of hundreds of billions of dollars – in the US alone.²⁴ A putative policy to help tackle this problem could be that of strengthening personal responsibility. If individuals choose not to adhere to the prescribed treatment plan, personal responsibility for such a decision would come into play. One putative policy might require, for example, higher costs for follow-up treatments when individuals incur poor health outcomes as a result of sub-optimal medication adherence. Alternatively, patients could be required to stick to their medication plan as an initial and future-oriented requirement to have their costs covered by the health care system. Assuming that it were possible to define a threshold where patients would be considered non-adherent and assuming that the policy were socially accepted, the problem of *practical enforceability* would remain. In fact, it would often prove difficult to show – when the policy needs to be applied – which patients adhered to their medication plan as prescribed and which did not, thus becoming accountable for the poor treatment outcome. Relying on self-reporting by patients would arguably not represent a fair and feasible solution: with health coverage at stake, lying would be encouraged and honesty punished. An alternative may be checks by medical professionals or administrative personnel verifying the correctness of medication-taking behaviour, e.g. by blood or urine testing. However, this would not only be highly impractical (especially in the outpatient setting) but also financially counterproductive, if the objective of the policy were to save costs.

Another example showing the difficulty of *practically enforcing* personal responsibility is that of liver transplantation. Already in 1991, Moss and Siegler suggested that ‘patients who develop ESLD [end stage liver disease] through no fault of their own (e.g., those with congenital biliary atresia or primary biliary cirrhosis) should enjoy higher priority in receiving a liver transplant than those whose liver disease results from failure to obtain treatment for alcoholism.’²⁵ According to the authors’ proposal, general guidelines for physicians should not entail an outright ban on liver transplant for people who fail to obtain treatment for alcoholism but simply move them down in the waiting list for transplantation. Their reasoning sparked controversial debates about organ

²³ E. Sabaté (ed), *Adherence to long-term therapies: evidence for action* (World Health Organization, 2003).

²⁴ L. Osterberg & T. Blaschke, ‘Adherence to Medication’, *New England Journal of Medicine* 353 (2005):487-497.

²⁵ A.H. Moss & M. Siegler, ‘Should alcoholics compete equally for liver transplantation?’, *Jama* 265 (1991):1295-1298.

donation and substance abuse, with many subscribing to the intuition that ‘entitlements to health care for a diseased condition are inversely proportional to control and responsibility’²⁶ – a preference that has also been corroborated by empirical research.²⁷ More recently, Daniel Brudney has argued in a similar vein that substance abusers are less deserving of liver transplants if they are aware of the consequences, including the fact that they may deprive someone else of a necessary organ transplant.²⁸ Apart from any considerations about the ethical merit of such proposals, even here the question would remain of how to *practically enforce* this policy in individual cases. As has been pointed out, it is not clear how physicians could ‘distinguish those among this group who could and should have taken steps to prevent liver failure from those who may have had no reason to suspect that their drinking would lead to liver failure.’²⁹ Whether the reason to ascribe responsibility is rooted in the awareness of the patient (i.e. she is informed about the potential consequences of her actions) or in the presence of a specific link between drinking habits and liver failure, the problem remains that both are difficult to verify. It seems that the only option would be to ‘undertake intrusive investigations into the private lives of patients.’³⁰ If responsibility were to be ascribed on the basis of the patient’s awareness of his risky conduct, medical personnel would have to collect evidence to determine such awareness. If, on the contrary, responsibility were to be ascribed on the basis of a specific link between drinking habits and liver failure, doctors would have to impose additional medical examinations (e.g. carbohydrate deficient transferrin (CDT) levels), which would be both expensive and ethically troubling (since they would not promote the welfare of the patients). In either case, this would be a problem, not only by compromising the role of and trust in medical personnel but especially because – at a practical level – it ‘would be a very intensive and time-consuming job to determine the *real* measure of responsibility for a patient’s disease.’³¹

These two examples demonstrate how *practical enforceability* would remain an obstacle to the implementation of this principle in concrete policies. This is because ‘on *practical* grounds, it seems very difficult, if not impossible, to

²⁶ W. Glannon, ‘Responsibility, alcoholism, and liver transplantation’, *The Journal of Medicine and Philosophy* 23 (1998):35.

²⁷ P.A. Ubel, C. Jepson, J. Baron, T. Mohr, S. McMorow & D.A. Asch, ‘Allocation of transplantable organs: do people want to punish patients for causing their illness?’, *Liver Transplantation* 7 (2001):600-607.

²⁸ D. Brudney, ‘Are alcoholics less deserving of liver transplants?’, *Hastings Center Report* 37 (2007):41-47.

²⁹ M. Benjamin, ‘Transplantation for alcoholic liver disease: the ethical issues’, *Liver Transplantation and Surgery* 3 (1997):337-342.

³⁰ *Ibid.*, 339.

³¹ W. Martens, ‘Do alcoholic liver transplantation candidates merit lower medical priority than non-alcoholic candidates?’, *Transplant International* 14 (2001):172 (emphasis added).

measure out and determine the exact scope of people's individual freedom and responsibility'.³² Even if theoretical and political issues concerning the appropriateness of using personal responsibility for health as a rationing criterion were set aside, far-reaching policies would always face a thorny dilemma. Either they have to accept approximation and potential errors in those cases where it may be impossible or unreliable to verify the actual adoption of the specific health-related choices to which responsibility is linked (e.g. poor medication adherence, or drinking). Or they require a complex and often costly (especially if needed on a large scale) effort to retrospectively or prospectively check – for example through the presence of specific markers – that individuals have taken the course of action that justifies a different allocation of health care resources.

4. The impact of digitalisation: responsibility becoming enforceable?

Whilst the debate concerning the personal responsibility for health has become increasingly stagnant and repetitive,³³ health care has drastically changed, undergoing a profound digital revolution. Digital health has been defined as 'the development of technological solutions to monitor, process and integrate vast amounts of data at the individual and population levels'.³⁴ At the core of the digital revolution in health care is a more extensive use of different types of health-related data, which can be divided into three main categories.³⁵ First, there is traditional patients' information – such as doctor's notes, hospital records and health care bills – which can be collected in electronic form and are therefore often more easily shareable and linkable. In this sense, digitalisation has mainly impacted collection and transit of information, rather than the nature of the information collected. Second, there is the category of data belonging to so called "–omics data streams", which includes genomic and proteomics data now also collectable through direct-to-consumer tests. Third, there is health-related behavioural data traceable through new technological solutions (e.g. mobile sensors on phones, fitness devices or digital therapeutics).

Digitalisation, in other words, has been conveying a true 'datafication of health'.³⁶ This has fostered views of patients – and individuals more generally

³² Schmidt (note 13), 130 (emphasis added).

³³ Sharkey & Gillam (note 1).

³⁴ 'Medicine in the digital age', *Nature Medicine* 25 (2019):1.

³⁵ M. Swan, 'The quantified self: Fundamental disruption in big data science and biological discovery', *Big data* 1(2013):85-99.

³⁶ M. Ruckenstein & N.D. Schüll, 'The datafication of health', *Annual Review of Anthropology* 46 (2017):261-278.

– as quantifiable entities that can be defined by the electronic information that is collected from and about them. In the medical literature, it is no minority position to claim that ‘just about everything that makes a human tick can now be quantified like never before, by means of sensors, sequencing, laboratory tests and scans.’³⁷ At the same time, digitalisation of health care also largely facilitates access to medical data, making patients increasingly transparent. Through electronic health records, wearable devices and other e-health tools, information concerning a patients’ health status – from their medical history and test results to data collected directly through apps and wearables – becomes much more accessible and monitorable. Unsurprisingly, this vision has also been endorsed by a large part of the industry active in the e-health sector.³⁸ In the most optimistic accounts, digitalisation promises ‘to prevent and mitigate the physical and financial burdens of “lifestyle diseases” such as obesity, diabetes, and cardiovascular disease—conditions that derive from daily behaviours of overeating, underexercising, and smoking—by shifting their management away from hospitals and doctors and into the hands of empowered patients.’³⁹

More importantly, with the datafication of health and patients becoming increasingly transparent, digitalisation seems to offer the missing link necessary to *practically enforcing* personal responsibility for health. Indeed, the problem of *practical enforceability* gets drastically downsized, since patients’ health status and their health-related behaviours become easily measurable and accessible through digital means. For example, the European Union has recently funded the MyHealthAvatar project, consisting of an internet-platform where citizens can upload their behavioural data (e.g. number of steps), medical records and also allow linkage to their twitter profiles, so that information can be analysed to facilitate the prediction of some non-communicable diseases.⁴⁰ Similarly, at the end of 2017, the United States approved the first pill combined with an ingestible sensor that monitors – automatically and in real-time – whether patients take their medications correctly.⁴¹ With the rapid increase of tools of this kind, not only is it possible to ‘deliver a more efficient and effective healthcare system.’⁴² but also to effectively monitor patients’ behaviour.

³⁷ L.J. Kish & E.J. Topol, ‘Unpatients—why patients should own their medical data’, *Nature biotechnology* 33(2015):921.

³⁸ N.D. Schüll, ‘Data for life: Wearable technology and the design of self-care’, *BioSocieties* 11 (2016):317-333.

³⁹ Ruckenstein and Schüll (note 35), 262.

⁴⁰ European Commission, ‘MyHealthAvatar: your digital health status through an app’, <https://ec.europa.eu/digital-single-market/en/news/myhealthavatar-your-digital-health-status-through-app>, (accessed 10 September 2019).

⁴¹ FDA - Food and Drug Administration, ‘FDA approves pill with sensor that digitally tracks if patients have ingested their medication’, <https://www.fda.gov/newsevents/newsroom/press-announcements/ucm584933.htm>, (accessed 10 September 20189).

⁴² E. Rich & A. Miah, ‘Mobile, wearable and ingestible health technologies: towards a critical research agenda’, *Health Sociology Review* 26 (2017):85.

Indeed, digitalisation makes it much more appealing to implement policies demanding personal responsibility for health because many risk factors such as a lack of exercise or an unhealthy diet can be easily, extensively and pervasively documented. In a sense, digitalisation has the potential to shift the burden of proof concerning responsibility from society to the individual. If individual-level data is available suggesting that one patient has taken poor health-related choices, this could be used as justification to demand responsibility and, more importantly, as an instrument to make it practically enforceable. The assumption is that the collected data is correct and complete and that the single person – if she wants to avoid responsibility – must prove herself that her poor lifestyle choices cannot be ascribed to her in the single case. When evidence thereof is not provided, rationing health care services covered by the community might become the default option. In the case of medication adherence, for example, patients could be asked to digitally monitor their medication-taking behaviour and, if results show that they miss certain doses, reimbursement of the cost of their medications could be curtailed. In the case of liver transplantation, patients could be asked to prove that they have not been purchasing large amounts of alcoholic beverages or that they have not been frequent visitors to the pub.

The claim that digitalisation provides the means to *practically enforce* personal responsibility as a rationing criterion is not purely hypothetical. Although official policies and regulation of this kind do not exist yet, private actors are already deploying digital health solutions as tools to *practically enforce* personal responsibility for health. In Switzerland, for example, some major health insurance companies are offering customers the possibility to pay cheaper premiums for basic insurance – either directly through discounts or indirectly through monetary rewards – if they demonstrate achievement of daily challenges in terms of steps or other relevant health-related behaviours.⁴³ Users simply have to link their fitness trackers to an app provided by the insurance company and, then, those customers who are more active end up paying less for the same insurance coverage that other customers have who are not as fit.

The appeal of using digital tools to *practically enforce* personal responsibility for health is fostered by the logic of personalised medicine. Although its exact definition may vary, the term ‘personalised medicine’ generally refers to ‘a medical model using characterisation of individuals’ phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention.’⁴⁴

⁴³ A. Martani, D. Shaw & B.S. Elger, ‘Stay fit or get bit-ethical issues in sharing health data with insurers’ apps’, *Swiss medical weekly* (2019), 149.

⁴⁴ Council conclusions on personalised medicine for patients, 2015/C 421/03, <https://op.europa.eu/en/publication-detail/-/publication/f416ce37-a48c-11e5-b528-01aa75ed71a1> (accessed 10 September 2019).

In other words, the movement of personalised medicine contends that individual health-related data should be routinely used to improve the care of patients at the individual level by making care more tailored and precise. The same logic could be extended to the use of data at the societal level to personalise and individualise resource allocation in the health care sector. As has been argued, ‘it is assumed that more information necessarily will lead to better healthcare and economic efficiencies, both by encouraging patient engagement and self-responsibility for their health and providing healthcare services with the data they need to improve medical care and service delivery.’⁴⁵ Beyond promising to solve the practical problem of enforceability, such reasoning also affects the way personal responsibility in health care is construed on a conceptual level.

5. Digitalisation and causal responsibility

As digitalisation promises to make personal responsibility for health *practically enforceable*, it is important to reflect on the consequences that this can have on the conception of personal responsibility and its use as a criterion to allocate health care resources.

Throughout the debates about personal responsibility for health care rationing, several attempts have been made to disentangle its different conceptual facets. Gerald Dworkin⁴⁶, for example, distinguished between three interrelated aspects of the concept of personal responsibility, namely role-responsibility, causal-responsibility and liability-responsibility. With regard to health, role-responsibility could roughly be said to refer to a person’s responsibility for her health precisely because it’s *her* body, of which she has an obligation to take care. In comparison, causal responsibility describes an individual bringing about a certain health impairment as a consequence of her very behaviour. As Walter Glannon put it: ‘To the extent that a person has causal control over the events that determine his healthy or diseased condition, he is causally responsible for these events as well as for this condition.’⁴⁷ Finally, liability responsibility describes the aspect of holding a person materially accountable for her actions’ consequences, such as paying for her own treatment.

While the other two aspects stay largely constant, it seems that increased traceability due to digitalisation in health care mainly affects causal responsibility. It focusses on voluntarily assumed risks and ‘implicates [that] the individual’s choices and actions with regard to diet, exercise, and so forth [help] to determine

⁴⁵ D. Lupton, ‘The digitally engaged patient: Self-monitoring and self-care in the digital health era’, *Social Theory & Health* 11 (2013):260.

⁴⁶ G. Dworkin, ‘Voluntary Health Risks and Public Policy’, *The Hastings Center Report* 11 (1981):26-31.

⁴⁷ Glannon (note 25), 33.

his or her health status'.⁴⁸ In other words, causal responsibility aims to trace factual relations between individual behaviour and its consequences, allowing to hold patients accountable for them. Traditionally, it is particularly this aspect of personal responsibility that has often been subject to moralisation.⁴⁹ This is because the underlying claim of causal responsibility is that every individual needs 'to change his personal bad habits or quit complaining. He can either remain the problem or become the solution to it.'⁵⁰ From this perspective, linking causal responsibility to culpability, *unhealthy behaviour* equals *bad behaviour*, a problem for which people should be held accountable.

Digitalisation seems to be closely linked to this aspect of personal responsibility and it further extends its scope. By making individual behaviours ever more traceable, digitalisation emphasises the importance of choices with respect to health outcomes – is the patient compliant with her medication regime? Does she eat, sleep and drink well? Has she sought medical treatment at the appropriate time? At the same time, digitalisation advances an allegedly value-neutral conception of responsibility, according to which individuals can be held accountable when objective data confirms they have causally contributed to their poor health. In this perspective, accessible and shareable information concerning the life – both inside and outside the health care sector – of a patient offers a supposedly *objective* benchmark that can be used to define and treat the patient herself. Health-related data is thought of as a repository of all the events and choices that patients have taken and that can have a – direct or indirect – influence on their health.

When the causal aspect of responsibility is emphasised, patients' data can be framed as a useful tool not only to find the most apt treatment for single patients, but also to single out patients for whom health care resources can be used most effectively. As others have argued, there is a – potentially unconscious or implicit – connection between notions such as personalised or individualised health care and responsabilisation in health care policy.⁵¹ Given the wide-spread optimism regarding the objectivity of data and algorithmic decision making,⁵² allocating resources based on vast individually and longitudinally collected personal data can be presented as objective, unbiased and therefore even just.⁵³

⁴⁸ Minkler (note 1), 122.

⁴⁹ R.C. Brown, 'Resisting Moralisation in Health Promotion', *Ethical Theory and Moral Practice* 21 (2018):997-1011.

⁵⁰ J. Knowles (ed.), *Doing Better and Feeling Worse: Health in the United States* (New York: Norton, 1997). Retrieved in Minkler (note 1).

⁵¹ R.C. Brown, 'Moral responsibility for (un) healthy behaviour', *Journal of Medical Ethics* 39 (2013):695-698.

⁵² P.L., Galison, 'Algorists Dream of Objectivity', in *Possible Minds: 25 Ways of Looking at AI*, ed. J. Brockman (New York, Penguin Publishing Group, 2019), 231 et seq.

⁵³ In the literature supporting the use of personal responsibility as a rationing criterion, this includes roughly two elements: 1) the idea that only actions which produce a relevant health-related outcome (either positive or negative) would be used to ascribe responsibility; 2) that only those individuals who have autonomously chosen those actions would be held responsible.

This is consistent with the view that ‘digitisation of the welfare state and e-health services is an advancement based on the assumption that more access to information is better for citizens, patients and consumers,’⁵⁴ When choices and behaviour are documented through an extensive data-collection effort, holding individuals accountable for those choices and behaviours becomes a seemingly obvious consequence.

The focus on causal responsibility within the interplay between personal responsibility and digitalisation seems to have two further implications. On the one hand, tracking causally relevant health-related behaviour before the onset of a disease further extends the reach of the medical paradigm into the ordinary life of the healthy, in line with the broader phenomenon of medicalisation. In fact, the advent of the new category of ‘unpatients’ – defined as ‘neither patients in the usual sense of being under treatment, nor nonpatients, in the sense of being [totally] free of a medically relevant condition’⁵⁵ – had already been prognosticated at the dawn of the genomics era. With digitalisation, the datafication of medicine and the possibility of using data to predict future health status, the ‘sense that some, perhaps all, persons though existentially healthy are actually asymptotically or pre-symptomatically ill’⁵⁶ has advanced. Secondly – and more importantly – the reinforcement of the *behavioural* side of personal responsibility caters for a conception of health that is markedly atomistic. The public health dimension of health tends to get lost, and the latter is rather seen as the product of a series of choices by single self-caring individuals. In this perspective, persons are positioned as ‘ready and willing to actively engage in their own healthcare and promote their own health, in the attempt to shift such responsibilities from the state to the individual.’⁵⁷ If it is mainly dependent on behaviour, health belongs to the domain of the individual-consumer, with the corresponding need for the (welfare) state to back-off.⁵⁸ Indeed, a transition is happening from the idea that ‘[m]y health is the responsibility of my physician [and my health care system]’ to the new thinking that ‘[m]y health is my responsibility, and I have the tools to manage it.’⁵⁹ As a consequence, if ‘health is mostly a function of how individuals choose to behave, then medical care is less important.’⁶⁰

⁵⁴ A. Fotopoulou & K. O’Riordan, ‘Training to self-care: fitness tracking, biopedagogy and the healthy consumer’, *Health Sociology Review* 26 (2017):65.

⁵⁵ A.R. Jonsen, S.J. Durfy, W. Burke & A.G. Motulsky, ‘The advent of the “unpatients”’, *Nature medicine* 2 (1996):623.

⁵⁶ N. Rose, *The Politics of Life Itself: Biomedicine, Power, And Subjectivity in The Twenty-First Century* (Princeton, NJ: Princeton University Press, 2007). Retrieved in Schüll (note 37).

⁵⁷ Lupton (note 44), 266.

⁵⁸ Schüll (note 37).

⁵⁹ M. Swan, ‘Health 2050: The realization of personalized medicine through crowdsourcing, the quantified self, and the participatory biocitizen’, *Journal of personalized medicine* 2 (2012):108.

⁶⁰ D. Wikler, ‘Who should be blamed for being sick?’, *Health Education Quarterly* 14 (1987):17.

6. Enforcing personal responsibility: the best way of using digitalisation to improve resource allocation?

In the previous paragraphs, we have explored some of the limitations that the practical implementation of policies using personal responsibility for health as a rationing criterion has traditionally encountered. We have shown how digitalisation promises to close the loophole of *practical enforceability* by offering tools for monitoring exposure to individual risk factors, thus allowing to hold people accountable for successive negative health outcomes. In this sense, digitalisation corroborates the often-implicit syllogism that, since many risk factors can be tracked on an individual level and correlate with behaviour, responsibility for health should be ascribed to individuals and their choices. This narrative is in line with the twofold promise of personalised health care which aims at being ‘a stone that kills two birds: its effectiveness is tantamount to its cost-efficiency.’⁶¹ The emphasis on the individual, his behaviour and his own personal responsibility is thus seen as ‘an important contribution to diminishing the burden of disease and financial cost.’⁶² From this perspective, even population health is not seen primarily as a collective concern, but as the arithmetical sum of the effort by single citizens to self-manage their own individual health.

However, even if digitalisation seemingly allows the creation of the conditions to use personal responsibility as a criterion to allocate resources, there are several limitations to this proposition. The first problem concerns accuracy. Although digital tools in health care allow monitoring patients (and prospective patients) in a much more granular way, measurement of individual behaviours is still an infant science, frequently rendering the quality of the measured data problematic. Some medical devices – especially wearables – are often commercialised without proper scientific validation, thus raising the question whether ‘it make[s] sense—and is it ethically defensible—to collect and analyse data of questionable accuracy,’⁶³ especially if such data is then used to determine access to socially funded health care. While if studies on the accuracy and validity of data produced by health monitoring tools have recently picked up,⁶⁴ for now, caution concerning data quality is certainly warranted. The second challenge

⁶¹ T. Sharon, ‘Self-tracking for health and the quantified self: Re-articulating autonomy, solidarity, and authenticity in an age of personalized healthcare’, *Philosophy & Technology* 30 (2017):100.

⁶² *Ibid.*, 100.

⁶³ B. Sperlich, H. Holmberg, ‘Wearable, yes, but able...?: it is time for evidence-based marketing claims!’ *British Journal of Sports Medicine* (2017):51:1240.

⁶⁴ See e.g. E.A. Chowdhury, M.J. Western, T.E. Nightingale, O.J. Peacock & D. Thompson, ‘Assessment of laboratory and daily energy expenditure estimates from consumer multi-sensor physical activity monitors’, *PloS one* 12 (2017); M.A. Case, H.A. Burwick, K.G. Volpp, & M. Patel, ‘Accuracy of smartphone applications and wearable devices for tracking physical activity data’, *Jama* 313 (2015):625-626.

concerns determining causal relations. On a conceptual level, inferences from human behaviour to health outcome remain challenging and often spurious – not least given the complexities of health-related behaviour and the multifactorial aetiologies of many common diseases. The two policy examples discussed in this paper are cases in point. With regard to alcoholism, debates about the culpability of addicted individuals in the light of their socio-economic circumstances, personal history and biological disposition are long-standing and have even featured in a controversial ruling of the US Supreme Court.⁶⁵ Even concerning the supposedly easier case of medication adherence, research shows that medication adherence is as much a function of patient-doctor interaction and the structures of a health care system as it is the responsibility of individual patients. A comprehensive literature review on the topic thus concluded that '[b]elieving that medication nonadherence is the "fault" of the patient is an uninformed and destructive model that is best abandoned'.⁶⁶ Third, even if accuracy and causality issues can be surmounted in specific instances, the question remains whether we believe allocation based on personal responsibility to be adequate and ethically justified – especially from the point of view of justice. While it is beyond this paper's scope to take a general stance here, it seems clear that any answer to this question would need to take the actual consequences of implementing such policies into account.

So, is enforcing personal responsibility for health the best use of digitalization for allocating scarce resources? While digital monitoring of risk factors such as leading a sedentary life happens at the individual level, this does not necessarily entail that assigning responsibility to the individual is an appropriate or effective strategy to improve health outcomes – or reduce overall costs. Indeed, alternative approaches for using the potential of digitalization may be better suited to improving resource allocation. Digitalisation allows, for example, to collect data of large cohorts to scale-up epidemiological studies, improve our understanding of the impact of environmental factors on health and study how to 'make avoidance of behavioural risk factors easier'.⁶⁷ Digital tools can also be used to conduct Phase IV post-marketing studies of newly approved drugs, to then decide whether it is appropriate and safe to publicly reimburse their costs or recommend their use. Finally, digitalisation can offer the tools to better target public health interventions that extend beyond the individual level such as tailoring suitable limits for pollutants.

⁶⁵ Traynor and McKelvey vs. Turnage. (1988). 108 S. Ct. 1372. Retrieved in Glannon (note 25), 39.

⁶⁶ M. Brown & J. Bussell, 'Medication Adherence: WHO Cares?', *Mayo Clinic Proceedings* 86 (2011):312.

⁶⁷ R.C. Brown, H. Maslen & J. Savulescu, 'Responsibility, prudence and health promotion', *Journal of Public Health* 41 (2018):563.

7. Concluding remarks

Allocation of resources is an intricate matter and developing strategies to cope with scarcity remains a constant challenge for health care systems. In this respect, tackling individual risk-factors that contribute to non-communicable diseases constitutes an important milestone in this respect. Digitalization can indeed support this process. With appeal to personal responsibility, digitalization may be used to monitor individual behavior to single out the allegedly “undeserving”, whose health care expenditures should not be covered by public means. However, this does not imply that digitalization should be used in this way. We are aware that neither of the alternative uses of digitalization we have suggested will definitely settle the problem of resource allocation. But holding individuals accountable for their digitally monitored health most likely won’t either. Ethicists, policymakers and society at large should thus revisit old debates about distributive justice in health care and carefully think about the way new technologies are used for resource allocation.

8. Abbreviations

COPD= Chronic Obstructive Pulmonary Disease

FDA= Food and Drug Administration

CDT= carbohydrate deficient transferrin

9. Acknowledgments

A preliminary version of this work was presented by AM during the Autumn Academy 2019 by the Academia Engelberg. AM would thus like to thank all the participants to the Academy for their precious feedback and inputs. The authors would also like to thank Christopher Poppe and Maddalena Favaretto for their comments on previous versions of the paper.

Health care rationing in Italy: right to health vs. budget constraints in a regional-based health system

Alceste Santuari*

Department of Sociology and Business Law – University of Bologna

Abstract

After the enactment of the 2001 Constitutional Reform Act, the Italian health system consists of as many as 21 regional health systems. The central government retains the public task of ensuring that all citizens, regardless of their territorial residence, may access the same universal and equitable health services and provisions.

After the economic crisis of 2007/2008, as has been the case in many other EU MSs, the Italian central government has decreased public expenditure on health care. Not only has such an approach undermined citizens' fundamental right to health. It has also triggered a fierce confrontation between regional governments and the State, which has also been the object of some rulings of the Italian Supreme Court.

Against this background, the paper aims to analyse the impacts that health care rationing has on the organisation of health and care services and on the evolution of social enterprises as health providers.

I. Introduction

The Italian national health system represents a good example of a long-lasting and sometimes controversial debate between market forces and State intervention. During the drafting of the Italian Constitution back in 1946 there were two main political options through which to organise the health care system. On the one side, there were those MPs who wanted to keep the role of public authorities as integrating the main action of private initiative. In contrast, on the other side, there were those MPs who supported the idea that protection of health would be far better ensured by robust and direct action on the part of public agencies. According to this latter approach, national and, later, regional authorities would take on responsibility for the organisation, management and supply of health care services.

At the end of the discussion in Parliament, the Constitution included a clear recognition of the right to health (s. 32), of the duty of public authorities to remove all the obstacles that may hinder such a right (s. 3) as well as the recognition of civil society and also business organisations to deliver health care services (sections 2 and 41).

* DOI 10.7590/221354020X15815920230942 2213-5405 2020 Journal of Medical Law and Ethics

The 2001 Constitutional Reform Act has provided for a regional-based health care system: currently, there are as many as 20 regional health care systems, corresponding to the regions of Italy.

The international economic and financial crisis that broke out in 2007/2008 also brought with it heavy health care rationing, which has inevitably had a major impact on the organisation of health care services and, accordingly, on the protection of the right to health.

Against this background, the Italian Supreme Court has had to strike a (difficult) balance between health budgets and individual rights. Not only has the Constitutional Court had to rule in a legal context in which health care activities are largely and solely entrusted to regional and local governments. It has also had to take into account the progressive pressure of European and international laws.

In the light of the foregoing, this paper is aimed at analysing how health care rationing has influenced the Italian health system and if it can somehow explain the development of social enterprises as health care providers.

2. A short description of the Italian national health system

Marketisation,¹ globalisation,² health budget constraints as well as the increase in the demand for health care services and the progressive ageing of the population appear to undermine individuals' right to health. Sometimes, it seems as though the obligation on the part of governments and public authorities to ensure citizens' fundamental rights is no longer an essential dimension of modern welfare states. There are also views of certain political and economic players who consider social (and perhaps also health) policies as a burden on growth and competitiveness.³

Added to this is the progressive and long-lasting devolution process of powers from central governments to regional and local levels,⁴ which too may endanger the actual enforcement of the right to health. Such a condition is peculiar to

¹ See C. Newdick, 'From Hippocrates to commodities: three models of NHS governance', in *Medical Law Review*, Vol. 22, No. 2 (Spring 2014): 162-179.

² Globalisation 'has significantly affected the law and economics approach, causing a re-thinking of the mechanisms of balance and un-balance between economic freedoms and individual rights. Accordingly, new systems of regulation are required to adequately and effectively match new social and economic needs.' M.A. Stefanelli, *Prefazione*, in M.A. Stefanelli (ed.), *Dopo la globalizzazione: sfide alla società e al diritto*, Giappichelli, Torino (2017):2.

³ B. Vanherke, S. Sabato and D. Bouget (eds.), *Conclusions. Social policy in the EU: high hopes but low yields, Social policy in the European Union: state of play 2017*, European Social Observatory (OSE):201.

⁴ See A. Rico, S. Leòn, *Health care devolution in Europe: trends and prospects*, Health Organisation Research Norway – Horn, Working paper (2005):1.

those legal and health systems, such as Italy, in which central and local governments share some provinces as to the organisation and supply of health care services. Whereas the central government retains the power of setting forth the general guidelines and principles of law, regional and local governments are entrusted with and are in charge of the organisation of health care services at the community level. In accomplishing this task, regional and local governments exhibit different models and patterns, which may even weaken the free, universal and fair access to health care services, which is to be ensured at the national level.

But what are the reasons why powers in the health care sector have been and still are devolved from central to regional/local governments? What effects does such a devolution process have on health care provisions? Are we facing an era of re-centralisation of powers? Is there any way to make national and regional systems work together?

In health care, devolution constitutes the key governance mechanism mainly in tax-funded countries, where the public sector performs the roles of financing, purchasing and providing care. This means that in all European tax-funded health care systems devolution has been a key reform issue.⁵ There are two main reasons for the devolution of powers, in general, and in health care in particular. The first reason has to do with policy: devolving powers from the central to local levels is expected to strengthen local democracy. This end is supposed to improve the capacity of welfare systems to respond more effectively to citizens' needs. Public policies and finances are then implemented to enhance building government capacity and service accountability at the local level. The second reason is fiscal accountability, that is, the financial risk is on the part of local governments, which are accordingly held responsible for public services. The combination of these two reasons in health care has forced national welfare systems to be divided into as many health regional systems as the national territories have been organised into. Such a division may cause some significant territorial inequalities or "patchwork quilt", since the actual enforcement of health care rights heavily depends on the organisation of the regional welfare systems. The rich areas would then tend to offer better and more effective health care services than the poor ones.⁶

These patterns, if any, changed dramatically after the outbreak of the international financial and economic crisis in 2007/2008. The crisis has reshaped

⁵ See Srinivasa Vittal Katikireddi, Katherine E. Smith, David Stuckler, Martin McKee, Devolution of power, revolution in public health? In *Journal of Public Health*, Volume 39, Issue 2 (1 June 2017):241–247.

⁶ In Italy, due to the great economic and social divide between the North and the South, there is a significant health tourism of patients moving from Sicily, Campania and Calabria to be treated in hospitals and clinics up north. It is noteworthy that such a movement is largely funded by the Southern local health authorities, which causes a rise in health expenditure.

the agenda of public policies regarding health and social care. National welfare systems have been confronting with a relatively new need, namely, to provide health care services with universal coverage but on a selective basis.⁷ Such a turning point has been caused by the budget constraints that have progressively affected national and regional health policies. Doubtless, one of the challenges of modern welfare systems is to ensure citizens' fundamental rights *vis-a-vis* the financial sustainability of health care systems.⁸

To ensure citizens' right to health means that both central and regional governments have to come to terms with two different dimensions, namely, the programming and organisation function and the financial sustainability of their systems, respectively. The programming function implies the necessity of regarding the organisation of health care services as the positive answer by modern welfare states. They are responsible for both the quality of the services delivered and the organisational models that are considered to be the most adequate to supply those services. Whilst in the past, health care services used to be mainly supplied by public agencies, since late 1980s these services have also been delivered also by private organisations, especially non-profit. Both governments, at the central and also local level, as well as non-profit organisations are then entrusted with ensuring citizens' fundamental rights.

Through programming, the activities and actions are coordinated so as to accomplish public purposes. Planning and programming are essential functions in the health care sector given the importance of protecting and ensuring the right to health. First and foremost planning and programming imply the recognition of the major role that public institutions play in organising health care provisions. In this respect, the duty of solidarity and universal access to health care services ought to be interpreted according to an approach aimed at defining the scope and the extent of the intervention of public agencies in organising and supplying services of general interest.

7 The so-called "selective universal health coverage" has been regarded as 'a contradiction in terms; rather an oxymoron'. See P. Carrozza, *Riforme istituzionali e sistemi di welfare*, in M. Campedelli, P. Carrozza, L. Pepino (ed.), *Diritto di welfare*, Bologna: [PUBLISHER??] (2010):220.

8 I do agree with those legal scholars who support the idea that 'a welfare system is necessary to modern societies, though it needs re-arranging and modernisation, especially to improve the quality of services provided.' G. Iperata, *Intervento pubblico, concorrenza e integrazione nel sistema delle prestazioni sanitarie e sociali*, in C. Bottari (ed.), *Terzo settore e servizi socio-sanitari: tra gare pubbliche e accreditamento*, Torino: [PUBLISHER??] (2013):90. On the same topic, see also L. Torchia, *Premessa*, in L. Torchia (ed.), *Welfare e federalismo*, Bologna: [PUBLISHER??] (2005):8ff.

Although at times there have been some attempts to reverse the current devolved health care systems,⁹ it is difficult, if not impossible to some extent, to turn back the clock of recent history.¹⁰ Citizens and patients seem to be quite satisfied with services and provisions that can access near their homes. Indeed, in some cases, citizens and local governments have struck back against the decisions of regional political powers to close down country hospitals, even if these are regarded as dangerous for public health or underperforming.

Are we therefore bound to live with regional and local health systems that are national-proof? Do we have to raise our hands in the face of progressive and apparently unstoppable social and health inequalities within the same national legal systems? Do we have to get used to fragmentation amongst services and territorial areas? Alternatively, is there any possibility of combining national guidelines with regional and local implementation of health care services?

In those legal systems, in which either Constitutions or statutes provide for a clear, though not always easy to perform, responsibility on the part of public authorities to ensure services of general interest, central governments retain some general regulatory and monitoring powers. Generally, Secretaries for Health Care exert their powers by getting regional and local governments involved in the decision-making process concerning important issues, such as migration, health risks, setting of quality standards and the like. Regional and county governments are then free to implement health policies according to their economic, social and demographic dimensions. In times of economic crisis, Supreme Courts may take action to compel regional governments to respect European financial and budget constraints, which then may serve as a kind of life-jacket to uphold central governments' powers.¹¹

At any rate, except for a few cases in which the decisions and policies of regional governments can be appealed before national Supreme Courts, regional and county authorities are free to implement the actions and policies they consider more effective and sustainable for their own areas.¹² Such an approach can be harmonised through coordination meetings at the national level, in which regional and local governments share with central governments their

⁹ Some scholars have written that 'regional differentiation is by no means synonym of waste and inefficiencies.. See M. Bertolissi, *Tutela della salute: esigenze di eguaglianza e modelli organizzativi differenziati (con spunti di comparazione)*, in Tronconi (ed.), op. cit.:82.

¹⁰ On 4th December 2016, the majority of Italian citizens voted "No" in a referendum that, amongst other things, intended to re-centralise some powers, including health care services.

¹¹ M. Belletti, *Percorsi di ricentralizzazione del regionalismo italiano nella giurisprudenza costituzionale, tra tutela di valori fondamentali, esigenze strategiche e di coordinamento della finanza pubblica*, Roma: Aracne (2012):124-125.

¹² In this perspective, it is noteworthy that some regions belonging to neighbouring countries can also programme and plan cross-border health care services.

own views, projects and prospects. In their turn, central governments may propose to provide regional and local governments with funds, not according to their expenditure history, but according to standard costs incurred in providing health care services.

The right to health can be ensured and protected only by combining public policies that tend to promote solidarity, equality and financial sustainability. In this respect, regional and central governments are called upon to construe individuals' "health citizenship". In particular, the principal task of central governments is to co-ordinate and guide the actual implementation of the right to health at the regional and county levels. These levels should remain independent to some extent to better match individual's needs. Differences amongst regional systems do not necessarily imply negative consequences for the organisation and provision of health care services. Rather, if possible, devolution of powers brings about a higher level of responsibility and accountability of local health authorities. Responsibility and accountability serve then as prerequisites for striking a balance between de-centralisation of powers and the necessity of ensuring equal, universal and homogeneous rights to welfare and health care services. Any national health system faces such a "dilemma": how to recognise regional and territorial independence while the central governments take actions as to the financing of the services and their enforceability.

A way to overcome the difficulties of reconciling the national with the local levels of health care services could be to plan for "place-based" systems of care.¹³ These systems, which consist of both public entities and private organisations, especially non-profit ones, represent the legal and institutional frameworks through which to deliver health care services and to ensure the enforcement of the right to health. Legal, territorial and organisational models all significantly affect the way health care services are managed and supplied, as well as the possibility of effectively enforcing the right to health.¹⁴ In this perspective, new actors can be set up and some important changes in the organisation of traditional players can be introduced.¹⁵

¹³ C. Ham, H. Alderwick, *Place-based systems of care. A way forward for the NHS in England*, The King's Fund (November 2015).

¹⁴ See R. Pessi, *Tornando su adeguatezza e solidarietà nel welfare*, in *Rivista del Diritto della Sicurezza Sociale*, Issue 4 (December 2016):594ff.; M. Cinelli, *L'effettività delle tutele sociali tra utopia e prassi*, in *Rivista del Diritto della Sicurezza Sociale*, anno XVI, n. 1 (2016):21ff; L. Rampa, *Pater-nalismo, autonomia e diritti sociali: una rilettura in termini di analisi economica*, in *Politica del Diritto*, (3/2016), a. XLVII:305-336.

¹⁵ On this issue, see IBM Institute for Business Value, *La sanità e l'assistenza sanitaria nel 2015. Evoluzione dei modelli di erogazione dei servizi sanitari*.

Given the complexity of the current social and health care systems, it is recommended that public regulation may offer a set of tools to govern processes whereby local welfare systems are enabled to match individuals' needs. Within a legal framework in which regional and local authorities are entrusted with organising health care services, the regional level is expected to outline guidelines that support local welfare actions and projects.¹⁶ It is at the local level that coordination plays its own strategic role, since the different public responsibilities are challenged and compared locally. In this respect, the regional programming function is supposed to provide health authorities and local municipalities with integrated, efficient and effective responses, including health rationing and organisational re-arrangements.

3. Health care rationing and the right to health

In Italy, health care rationing is not an outcome deriving from the international and financial crisis of 2007/2008. In fact, it dates back to the early 1990s, when the Italian government started to inventory the health basket by connecting to it the necessary economic resources. In other words, the 1992 Health Reform Act attempted to ensure the protection of the right to health and to cap the resources that were intended to implement that right. This legal approach did not quite make it clear whether resources were to be regarded as constrained or as a proper objective to be achieved. Such a doubt was indeed the reason why many regional governments appealed to the Supreme Court against the Reform Act.¹⁷

The subsequent rulings of the Supreme Court, together with the 2001 Constitutional Reform Act, which has designed the regional health system as well as defined the duty of the central Government to ensure all citizens equal and universal access to health, have confirmed that financial rationing can by no means win the upper hand over the right to health. In other words, the Italian legal and health care systems do recognise that the right to health consists of an irreducible core.

Yet the recognition of the right to health has been heavily challenged by a recent Constitutional provision that provides for stringent and accurate financial constraints on the part of both central and local governments.¹⁸ In this perspective, the Italian Constitution, which has been founded on a clear concept of the "Welfare State", no longer allows public authorities to go into debt. Such an obligation has triggered a fierce debate concerning the possibility of disregarding

¹⁶ See C. Ham, H. Alderwick, *op. cit.*

¹⁷ See ruling No. 355 of 1993.

¹⁸ See Section 81 of the Italian Constitution, as amended in 2012.

this provision when it comes to health care services, which are aimed at ensuring citizens' right to health.

In my opinion, the financial balance that Section 81 has introduced into the Italian legal and health care system should always be inconsistent with a constitutional setting according to which citizens, especially the most vulnerable people, are expected to be granted social and health rights only insofar as the economic or financial circumstances allow for them.

In other words, it is necessary to avoid financial and budget constraints being regarded as more important than the right to health.¹⁹ Such a recognition is all the more significant in a contemporary context in which both European and national economic bonds seem to prevail over community solidarity and social cohesion.

4. Social enterprises as the result of health care rationing?

In many EU jurisdictions, social enterprises have long been engaged in the delivery of services of general interest, especially health care services. Their legal and organisational features largely depend on the individual Member States' legal systems. However, social enterprises may commonly be regarded as non-profit organisations whose social aims can be achieved through the carrying out of economic activities. In most welfare systems, social enterprises, along with public authorities, ensure citizens' right to health.

This implies a special role for social enterprises: they serve as adequate and effective legal forms through which to provide health care services.²⁰ Since social enterprises pursue the same goals as the services of general application and since they present specific legal and organisational patterns, not only are they suitable for delivering services of general interest;²¹ in supplying health care services, they also actively contribute to ensuring citizens' right to health.

This role of social enterprises is consistent with the legal provisions included in the Charter of the Fundamental Rights of the European Union²² that encompass the possibility for all EU citizens of accessing a relatively wide range of

¹⁹ See E. Furno, *Pareggio di bilancio e diritti sociali: la ridefinizione dei confini nella recente giurisprudenza costituzionale in tema di diritto all'istruzione dei disabili*, in *Nomos* (1-2017):22.

²⁰ Recital No. 71, Directive 123/2006.

²¹ See Recital No. 36 and Article 20 of Directive 2014/24/EU relating to public procurement and repealing Directive 2004/18/EC.

²² The Charter was adopted in December 2000 in the framework of the Treaty of Nice. See S. Peers, T. Hervey, J. Kenner, A. Ward (eds.), *The EU Charter of Fundamental Rights: A Commentary*, Oxford: Hart Publishing (2014):951-952.

services.²³ In this respect, Article 35 of the Charter provides for a general right to health, which all individuals are to benefit from.²⁴ The circumstance that the right to health falls under the broad definition of human rights, makes it part of EU policy and no longer the obligation of the single Member States only. EU law then provides for a general obligation not to violate fundamental rights (negative approach). At the same time, it also encourages both governments and non-profit organisations to be committed to promoting the implementation of those rights according to the European Charter (positive approach).²⁵ In this perspective, the right to health aims to enhance social equity and solidarity within the European national, public and universal social security systems.

The accomplishment of this aim is entrusted to a system of procedural rights, in which health authorities keep a certain degree of autonomy and power.²⁶ However, their power is subject to the scrutiny of the courts, which, in their turn, determine whether a decision taken by a public authority concerning the right to health is in accordance with national and EU laws.²⁷ This is the space in which social enterprises deliver their services and their public interest obligations. Within this legal framework social enterprises carry out their activities to fulfil the principles that are set forth in the EU Charter of Fundamental Rights. In this respect, social enterprises are regarded as essential partners in performing and implementing all those welfare services, including health care services, which are necessary to ensure that the right to health is fully accomplished. This task accounts for a different approach towards the supply of health care services. It has progressively shifted from a mere technical procedure whereby these services are outsourced through a regulatory framework according to which social enterprises deliver their services on the basis of their specific legal nature. However, social enterprises are not limited to this scope: local and health authorities also call upon them to take part in the programming of the services to be supplied.

²³ See, G.M. Caruso, *Diritti sociali, risorse e istituzioni: automatismi economici e determinismo politico di un sistema complesso*, in *www.federalismi.it*, (n. 4/2016):12. See also S. Gambino, *Livello di protezione dei diritti fondamentali (fra diritto dell'Unione, convenzioni internazionali, costituzioni degli Stati membri) e dialogo fra le Corti. Effetti politici nel costituzionalismo interno ed europeo*, in *www.federalismi.it*, (n. 13/2014, 25 giugno 2014):2.

²⁴ 'Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.'

²⁵ See, G. Palmisano (ed.), *Making the Charter of Fundamental Rights a Living Instrument*, Leiden-Boston: [PUBLISHER??] (2014).

²⁶ See Article 41, para. 1 of the EU Charter of Fundamental Rights. See also Court of Justice of the European Union, case C-617/10, *Åklagaren v Hans Åkerberg Fransson*, 26 February 2013, especially para. 21.

²⁷ C. Newdick, *Citizenship, Free Movement and Health Care: cementing individual rights by corroding social solidarity*, in *Common Market Law Review* (2006):43, 1653.

The legal and organisational structure of social enterprises, their specific goals, as well as their capacity for funding make these non-profit organisations particularly suitable to bridge the gap between citizens' needs and the lack of public resources. In times of austerity, in which it is all the more difficult for the MS's welfare systems to ensure equitable access to health care services, social enterprises are actually a legal and organisational tool which public authorities and citizens may count on to deliver health care services. Accordingly, social enterprises appear to be less the result of health care rationing than one of the responses to it. Due to their characters, social enterprises become "agents" of social innovation, whose action is consistent with the programming background of a given local community. Such a responsible engagement of social enterprises in the delivery of health care services seems to respect both public responsibilities and the ideal dimensions as well as their legal nature. Social enterprises also define social and health projects for the benefit of the community by contributing with their own financial resources.

5. Concluding remarks

The paper has endeavoured to prove that the right to health cannot be disregarded because of health care rationing. This needs to be balanced with the setting of priorities, which social enterprises can also be summoned and called upon to contribute to.

In this perspective, social enterprises are then engaged in the provision of health care services also "on behalf" of public authorities. This allows these organisations to propose new and innovative services, which are rightly needed with respect to citizens' health demands.

Since budget constraints on health care are not likely to decrease in the near future, the action and activities of social enterprises become all the more essential to the overall national health care system.

Ultimately, it is not a matter of the supremacy of public authorities or denial of the role of social enterprises. Rather, it is a question of how the health care system is arranged and organised: the more it is centred on co-operation and partnerships, the better.

Rationing in the English NHS and the Tension between Patient Choice and Solidarity

Abstract

Solidarity is a principle that underlies the English National Health Service (NHS). While intended to be comprehensive, since its inception financial constraints meant that limits have been placed on the availability of NHS health care. Health care has been rationed in a number of ways but English law demands that any such rationing policies by public bodies must allow for exceptions in special cases. When a patient makes an individual funding request (IFR) for such a treatment it is a question for the health authority to decide on the merits of the IFR whereas in any subsequent judicial review proceedings the court considers that decision in terms of its legitimacy, procedural propriety and reasonableness. To avoid judicial review of decisions health authorities are often inclined to accede to patients' requests because litigation, apart from being costly and time-consuming for the authority, also sets new precedents. This has led to suggestions that solidarity is being eroded in the NHS since resources that are spent on such requests by patients mean disinvestment from other areas of the NHS. This paper argues that enabling individual choice may in effect support a collective commitment to a solidaristic health care system. Rather than encroaching on the principle of solidarity (intended) litigation by patients destabilises the health care system and leads to much needed change and reform. Not only do the potential ramifications of (intended) litigation go beyond the immediate consequences for the parties to the action, but the need to account for rationing decisions by the health authority in public makes the system accessible to broader interests. Patient treatment choice can thus be seen as an affirmation of a commitment to solidarity that is also supported by the increased emphasis on patients taking responsibility for their own health with the aim of reducing NHS costs.

I. Introduction: The Backdrop to Solidarity and Choice in the NHS

Much academic work exists which discusses the values underlying the English National Health Service (NHS).¹ Although the National Health Service Act 1946 which established the NHS, did not mention the founding

¹ B. New, *A Good Enough Service – Values Trade-offs and the NHS* (London: Institute for Public Policy Research, 1999); D. Seedhouse, *Fortress NHS: A Philosophical Review of the Health Service* (Chichester: John Wiley & Sons, 1995); C. Webster, *The National Health Service: A Political History*, 2nd ed. (Oxford: OUP, 2002), 24.

values of the English NHS, from various government documents² and the latest edition of the NHS Constitution³ it is possible to condense these values to four; comprehensiveness, universality, equity of access, and a service free at the point of delivery. These are abstract values, and as abstract values they not only allow competing interpretations but are also in tension with each other.⁴ It has been asserted that these values constitute a ‘political fudge’, which in turn enables universal support.⁵ Not mentioned as one of these founding values, but nevertheless an overriding principle that can be gleaned from the wartime Beveridge Report⁶ and which underlies the foundation of the NHS is that of solidarity.

The Nuffield Council on Bioethics in its report on solidarity defines this term, which is criticised as being vague, as signifying ‘shared practices reflecting a collective commitment to carry “costs” (financial, social, emotional, or otherwise) to assist others.’⁷ Solidarity as a manifestation of both an *individual* willingness or a *collective* commitment to carry costs to assist others, comes arguably close to subsume the two NHS values of universality and equity. Thus, universality was referred to by Bevan, the architect of the NHS and its first Health Minister, as one of the purposes of the NHS: ‘to provide the people of Great Britain, no matter where they may be, with the same level of service.’⁸ ‘Everyone – rich or poor, man, woman or child’⁹ was to be covered.¹⁰ Equity on the other hand, as Dixon and others point out, rarely misses in any academic study regarding the values underlying the NHS.¹¹ It is often described as the belief that ‘the health service should be for all the British people equally.’¹² However, it is often not clear what equity in terms of health care implies, whether it refers,

² See e.g. Department of Health, *The NHS Improvement Plan: Putting People at the Heart of Public Services* (London: HMSO, 2004); Department of Health, *Equity and Excellence: Liberating the NHS* (London: HMSO, 2010).

³ Department of Health, *NHS Constitution for England* (London: HMSO, 2015).

⁴ R. Klein, ‘Values Talk in the (English) NHS’, in *Devolving Policy, Diverging Values: The Values of the United Kingdom’s National Health Services*, ed. S.L. Greer and D. Rowland (London: Nuffield Trust, 2007) 22–23.

⁵ D. Seedhouse, *Fortress NHS* (note 1), 12–13.

⁶ W. Beveridge, *Social Insurance and Allied Services*, Beveridge Report, Cmd 6404 (London: HMSO, 1942).

⁷ B. Prainsack and A. Buyx, *Solidarity: Reflections on an Emerging Concept in Bioethics* (London: Nuffield Trust, 2011), xiv and 29–30.

⁸ R. Klein, *The New Politics of the NHS: From Creation to Reinvention*, 6th ed. (Abingdon, Oxon: Radcliffe Publishing, 2010), 19.

⁹ C. Webster, *The National Health Service* (note 1), 24.

¹⁰ M. Foot, *Aneurin Bevan – A Biography*, vol 1 (London: MacGibbon & Kee, 1962), 105.

¹¹ A. Dixon et al., ‘Is the NHS Equitable? A Review of the Evidence’, paper no. 11 (London: LSE Health and Social Care, 2003), 5.

¹² D. Seedhouse, *Fortress NHS* (note 1), 61 citing C. Ham, *Health Policy in Britain* (London: Macmillan, 1982).

for example, to equity of access or equity according to need and whether need is to be assessed according to the level or degree of ill-health, the capacity to benefit, time waiting for treatment, social factors or age. Necessarily, the lack of consensus regarding the interpretation of *need* makes it difficult to realise a fair or equitable health care system.¹³ While closely related to universality, which provides reassurance of the availability of health care in times of need, equity, unlike universality, is more concerned with the distribution of benefits in society and deals with the fairness of distribution. Universality, therefore, will allow people to avail themselves of the health service whether or not they are able to pay for it, whereas equity of access is concerned with the fairness of distribution.¹⁴ The concept of solidarity could be viewed as combining these two values within it, namely that of cohesion and togetherness, and of security and reassurance, achieved by ensuring that everyone is covered by the health care system.¹⁵

Solidarity both in terms of universality and in terms of equity appears, at least in a narrow definition, to be anathema to individualism or individualistic patient choice,¹⁶ another concept that has gained prominence in the NHS. Choice linked with the notion of rights as a liberal value, or with the concept of the individualistic consumer in the market, exchanging money for the desired goods or services seems to question our concern for social citizenship in which we share common interests in a community of others.¹⁷ It is therefore not surprising that choice only appeared later on as a concept in the NHS, namely with the establishment of the internal health care market in 1989 in the White Paper *Working for Patients*.¹⁸ Patient choice became an important policy of the NHS with the introduction of the NHS Plan in 2000.¹⁹ Successive Department of Health Papers confirmed the government's vision of patient choice with free choice of any hospital for treatment, including private hospitals,²⁰ and choice of treatment options for patients with long-term conditions.²¹ *Liberating the*

¹³ B. New, *A Good Enough Service* (note 1), 28.

¹⁴ *Ibid.*, 28.

¹⁵ *Ibid.*, 27.

¹⁶ B. Prainsack and A. Buyx, *Solidarity* (note 7), 29–30.

¹⁷ C. Newdick, 'The European Court of Justice, Trans-National Health Care and Social Citizenship—Accidental Death of a Concept?', *Wisconsin International Law Journal* 26, Issue 3 (2009), 844.

¹⁸ Department of Health, *Working for Patients* (London: HMSO, 1989).

¹⁹ Department of Health, *NHS Plan: A Plan for Investment, A Plan for Reform* (London: HMSO, 2000); I. Greener, 'Towards a History of Choice in UK Health Policy', *Sociology of Health and Illness*, 31 (2009), 318.

²⁰ Department of Health, *Choice Matters: Putting Patient in Control* (London: HMSO, 2007), 6–8.

²¹ Department of Health, *NHS Choices: Delivering for the NHS* (London: HMSO, 2008), 14.

NHS, the White Paper published by the coalition government in 2010,²² was to enable choice ‘through an information revolution’ where patients were to have the choice of any qualified provider, choice of a consultant-led team, choice of GP practice, choice of care for long-term conditions and choice of treatment. Patient choice is also enshrined in the new edition of the NHS Constitution for England²³ and the Health and Social Care Act 2012.²⁴ Furthermore, choice of treatment for the patient has been linked with the notion of personalised health care in which patients are given a more tailored service.²⁵ Choice is also the theme in the recent NHS publication ‘*Universal Personalised Care: Implementing the Comprehensive Model*’ with personalised care being defined as ‘people hav[ing] choice and control over the way their care is planned and delivered, based on “what matters” to them and their individual strengths, needs and preferences.’²⁶ It is supposed to give people ‘the same choice and control over their mental and physical health’ that they expect in every other aspect of their life.²⁷

2. Rationing in a Comprehensive Health care Service

It has been noted that the founding value of the comprehensiveness of the NHS could not been guaranteed, even from its inception.²⁸ Although rationing and priority-setting were not contemplated when the NHS was created, as it was expected that the demand for health services would gradually decrease once the unmet need had been satisfied, the opposite happened: the demand for medical services exceeded all expectations.²⁹ It was recognised early on that the NHS was not self-limiting in that its contribution to national health did not limit the demands upon it to a volume that could be fully met.³⁰ Thus, financial constraints have always meant that limits are placed on health care so that it is affordable; and cost containment has therefore become a necessary policy goal.

²² Department of Health, *Equity and Excellence*, (note 2).

²³ Department of Health, NHS Constitution, (note 3).

²⁴ See further Health and Social Care Act 2012, s. 20(1)(2)c and s. 131.

²⁵ See e.g. Department of Health, *High Quality Care for All: NHS Next Stage Review: Final Report* (London: HMSO, 2008); Department of Health, *Personal Health Budgets: First Steps* (London: HMSO, 2009).

²⁶ NHS England, *Universal Personalised Care: Implementing the Comprehensive Model*, page 6, www.england.nhs.uk/publication/universal-personalised-care-implementing-the-comprehensive-model/, 31 January 2019.

²⁷ *Ibid.*, 2

²⁸ C. Webster, *The National Health Service* (note 1), 22.

²⁹ *Ibid.*, 29–30; D. Seedhouse, *Fortress NHS* (note 1), 14.

³⁰ R. Klein, *The New Politics of the NHS* (note 8), 29.

In health care that subscribes to the principle of solidarity there should of course be a commitment to a common cause including the need for cost restriction in the NHS. In the words of Beveridge solidarity is an exhortation of ‘men stand[ing] together with their fellows’ and the ‘pooling of risks’.³¹ Such cost containment can be achieved in a variety of ways³² but in the form of explicit rationing, such as the exclusion of treatment by denial of specific interventions or by delay of treatment, it has not commanded universal support.³³ In particular, the greater visibility of explicit treatment denial in the past 25 years³⁴ has brought the issue of rationing into the public consciousness³⁵ particularly since rationing appears to stand in contradiction to policy-makers’ use of the patient choice mantra. It has therefore been argued that solidarity is being challenged by the new emphasis on patient choice³⁶ and that demanding treatment not generally available to the community of patients can be regarded as acting contrary to the underlying values of the NHS of equality and universality. In this context Pollock, for example, claims that the new ‘NHS plc’ with its new policy goal of patient choice has abandoned the founding principles of the NHS of comprehensiveness, universality and equity.³⁷

Leaving comprehensiveness aside, health care rationing is also indispensable when there are competing demands on the public purse, that is on the monies allocated to health care from taxation. In England, it is NHS England and the Clinical Commissioning Groups (CCGs) that have the unenviable task of deciding which treatments are available and which are restricted because of finite annual financial allocations.³⁸ This is despite the fact that NHS England has concurrent responsibility with the Secretary of State for Health for the discharge of the overarching duty to continue to *promote a comprehensive* health service in England.³⁹ Its duties lie in arranging for the nationwide provision of certain specialist services, to such extent as it considers *necessary* to meet all reasonable

³¹ Beveridge Report (note 6), 849.

³² R. Klein, *The New Politics of the NHS* (note 8), 28 referring to the introduction of prescription charges; A. Pollock, *NHS plc: The Privatisation of Our Healthcare* (London: Verso, 2005), 41 referring to the drive to increase efficiency by the introduction of managers to replace hospital consultants from 1989 onwards.

³³ R. Klein, ‘Values Talk in the (English) NHS’ (note 4), 22.

³⁴ K. Syrett, *Law, Legitimacy and the Rationing of Healthcare* (Cambridge: CUP, 2007), 159 pointing out that there were very few legal challenges to resource allocation decisions before the case of *R v. Cambridge Health Authority, ex parte B* [1995] 1 WLR 898.

³⁵ N. Daniels and J. Sabin, *Setting Limits Fairly* (Oxford: OUP, 2008), 160.

³⁶ J. Clarke, J. Newman & L. Westmarland, ‘The Antagonisms of Choice: New Labour and the Reform of Public Services’, *Social Policy and Society* 7, Issue 2 (2008), 250.

³⁷ A. Pollock, *NHS plc*, (note 32), 78–79.

³⁸ National Health Service Act 2006 as amended by the Health and Social Care Act 2012, s. 223H.

³⁹ *Ibid.*, Ch. 7 s.1.

requirements. In contrast, the Clinical Commissioning Groups (CCGs) established under the Health and Social Care Act 2012 to take over as commissioners from the previous Primary Care Trusts (PCTs), are responsible for the commissioning of health services only for their local area.⁴⁰

In their decision-making both NHS England and the CCGs are guided by the National Institute for Health and Care Excellence (NICE), originally established as National Institute for Clinical Excellence, to increase consistency in local decision-making.⁴¹ NICE undertakes technology appraisals of new drugs and treatments to establish clinical and cost effectiveness, and CCGs and NHS England are under a legal obligation to make available, within a period of 3 months, health technology appraisals recommended by NICE.⁴² As the NHS cannot possibly fund every health care treatment for every patient, the duty of these public bodies to balance their budgets is an important one. There are inevitable funding implications when mandatory technology appraisal recommendations have to be covered from existing budgets.⁴³ Not all guidance by NICE is mandatory, however, but public bodies do need to take note of its guidance. They can adopt, in effect, their own priorities for other health care expenditure providing they avoid a breach of legal duties and a possible legal challenge in the courts.⁴⁴

Because of the role of NICE and NHS England there is at least some consistency on a national level over funded treatment.⁴⁵ However, for their local areas the different CCGs have developed their own lists of treatments and procedures they do not routinely fund.⁴⁶ Such exclusion may be on the grounds that these treatments and procedures are of low value, that they are either relatively ineffective or that more cost-effective alternatives are available, or on the grounds that they are of low priority such as procedures relieving pain or discomfort or

⁴⁰ Health and Social Care Act 2012, s. 13(3)(1A).

⁴¹ NHS England and Wales, The National Institute for Clinical Excellence (Establishment and Constitution) Order (S.I.1999/220), www.legislation.gov.uk/uk-si/1999/220/pdfs/uk-si_19990220_en.pdf.

⁴² The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 Sch. I, 259 part I s. 7.

⁴³ K. Syrett, *Law, Legitimacy and Rationing*, (note 34), 31 writing in the context of Primary Care Trusts.

⁴⁴ C. Newdick, *Who should we treat?* 2nd ed. (Oxford: OUP, 2005), 94.

⁴⁵ NHS England, *Conditions for which over the Counter Items should not Routinely be Prescribed in Primary Care: Guidance for CCGs*, www.england.nhs.uk/wp-content/uploads/2018/03/otc-guidance-for-cggs.pdf, 29 March 2018, which aims to produce a consistent, national framework for CCGs to use.

⁴⁶ J. Maybin and R. Klein, *Thinking about Rationing* (London: King's Fund, 2012), 21 stating that more than a third of PCTs had expanded the number of treatments for which they were withholding funding in 2011.

procedures which might affect people's major life events.⁴⁷ Examples of these range from specific drugs, surgery for varicose veins, cosmetic surgery, tattoo removal, vasectomy, bariatric surgery, surgery for lower back pain, knee arthroscopy, IVF to complementary alternative medicine.⁴⁸ Even if the decisions as to which treatments and procedures are generally not funded are supplemented by guidance from NICE and NHS England⁴⁹ they will continue to attract controversy. Unsurprisingly, refusal of their preferred treatment by health authorities has led many disgruntled patients taking recourse to the law to have the decision reviewed by the court but as will be explained below, judicial remedies in these cases have their limitations.

2.1 Rationing and Patient Choice: Individual Funding Requests

The expression of choice by patients who request a treatment or procedure not generally available in the NHS can be seen as underlying individual funding requests (IFRs). These are made by the patient with the support of the medical practitioner and can be for a treatment not routinely offered by NHS England or the patient's CCG. Patients will generally only succeed if they can show exceptional circumstances. This is because as a general principle of administrative law and despite public bodies' wide discretionary power regarding allocative priorities such exceptional cases to any general policy on treatment funding must be admitted. Auld LJ stated the law in the case of *A, D and G*:

The precise allocation and weighting of priorities is clearly a matter of judgment for each Authority, keeping well in mind its statutory obligations to meet the reasonable requirements of all those within its area for which it is responsible. It makes sense to have a policy for the purpose – indeed, it might well be irrational not to have one – ...It is proper for an authority to adopt a general policy for the exercise of such an administrative discretion, to allow for exceptions from it in “exceptional circumstances”...⁵⁰

Individual funding requests are significant, not only because they define what the NHS will fund but also because refused IFRs can come to the courts for judicial review where the decision of the health authority is exposed to legal and public scrutiny.⁵¹ In adjudicating, the role of the court is not to assess the

⁴⁷ Audit Commission, *Reducing Spending on Low Clinical Value Treatments* (London: Audit Commission, 2010), 2 referring to the Croydon List; N. Edwards, H. Crump & M. Dayan, *Rationing in the NHS* (London: Nuffield Council on Bioethics, 2015), 6-7.

⁴⁸ Audit Commission, *Reducing Spending*, (note 47), appendix 1.

⁴⁹ NHS England, *Guidance for CCGs*, (note 45).

⁵⁰ *R v. North West Lancashire Health Authority, ex parte A, D and G* [1999] Lloyd's Rep Med 399, 412.

⁵¹ J. Russel and T. Greenhalgh, 'Affordability as a discursive accomplishment in a changing National Health Service', *Social Science & Medicine* 75, Issue 12 (2012), 7.

merits of the patient's claim but to oversee the legitimacy, procedural propriety and reasonableness of the decision by the public body regarding the patient's exceptional circumstances. In any case, judicial challenges to resource allocation decisions have not been easy to win by patients.⁵² This is because of the nature of judicial review, which sets limits to challenging the substance of policy decisions. Even where a challenge is successful, the court will not usually invalidate the decision but refer the matter back to the authority for re-consideration in the light of the court's observations⁵³ and as long as the defects in the original decision-making process are remedied, the public body is entitled to come to the same decision.⁵⁴

2.2 The Definition of Exceptionality Criteria

Subject to these described public law grounds, as long as their policies allow for 'exceptions' public bodies are unfettered in their allocation of resources and priority-setting.⁵⁵ Exceptionality does not refer to the patient's exceptional illness but means that the patient's exceptional circumstances are such that he or she will derive significant benefit from the requested treatment, not routinely offered by the NHS. While it is not necessary to define the specific exceptional circumstances it has to be possible to envisage there being exceptions, such as the possibility of there being an overriding clinical need, since 'if it is not possible to envisage such circumstances the policy would in practice be a complete refusal.'⁵⁶ It may of course be difficult to determine exceptional circumstances in advance but 'to leave the circumstances undefined presents a considerable challenge for public bodies and results in their decisions being vulnerable to legal dispute.'⁵⁷

The volume of litigation in the courts since the decision in *A, D and G* in 1999 is evidence of this problematic. Thus, a whole series of judicial review cases have come before the courts demonstrating the difficulty encountered by many commissioning bodies in formulating a definition of what constitutes

⁵² K. Syrett, *Law, Legitimacy and Rationing*, (note 32), 132-133; B. Sheldrick, 'Judicial Review and the Allocation of Healthcare Resources in Canada and the United Kingdom', *Journal of Comparative Policy Analysis* 5, Issue 2-3 (2003), 151.

⁵³ C. Newdick, 'Accountability for Rationing – Theory into Practice', *J. Law Med & Ethics* 33, Issue 4 (2005), 661; cf C. Newdick, 'Can Judges Ration with Compassion? A Priority-Setting Matrix', *Health and Human Rights* 20, Issue 1 (2018), 115 where the author argues that the procedural response by the court in practice is often a substantive response.

⁵⁴ B. Sheldrick, (note 52), 152.

⁵⁵ *R v. North West Lancashire*, (note 50), 412 (Auld LJ).

⁵⁶ *Ibid.*; *R (Rogers) v. Swindon NHS Primary Care Trust and Secretary of State for Health* [2006] EWC Civ 392 (Admin)[62] (Sir Anthony Clarke MR).

⁵⁷ A. Ford, 'The Concept of Exceptionality: A Legal Farce?', *Med Law Rev.* 20, Issue 4 (2012), 317.

‘exceptional circumstances’. Thus, in *Ac*, the Berkshire West PCT having refused the prosthetic breast enlargement by a male-to-female transgender patient described their policy as considering cases that are significantly outside the normal range by comparing the patient with the cohort of patients with the same condition.⁵⁸ There needs to be a comparator for something to be exceptional against, with the baseline or comparator being the cohort of people with the condition.

If the patient is one of the eligible group but cannot show relevant clinical circumstances by comparison with others in the group, then the case is not exceptional.⁵⁹ To define exceptional as requiring some unusual or unique clinical factor was, however, held to be unlawful in the case of *Ross*,⁶⁰ a case of a patient with multiple myeloma who had suffered serious drug side effects and requested a different drug treatment not made generally available by the health authority. Such definitions of exceptionality would disqualify any person automatically as long as he can be likened to another rather than being merely exceptional.⁶¹ Exceptionality was to be interpreted in its dictionary sense of being ‘out of the ordinary course’ or ‘unusual’ or ‘special’ rather than in the sense of being unique.⁶²

In view of these judicial pronouncements the ambiguity of the term exceptionality persists, as it will of course always be possible for other patients to emerge who are appropriately comparable. It will depend on how wide the group label is drawn and it will be more difficult to show exceptionality if the cohort is a large heterogeneous group of people.⁶³ Many questions remain unanswered by the case law. Thus, how unusual or special does a patient wanting to avail himself of NHS treatment or NHS procedures have to be to qualify? What is an exceptional case to qualify for treatment not generally available? Are requests by more than one patient for a particular treatment always automatically excluded from consideration for an individual funding request? Must there be a possible exceptional case for every treatment?⁶⁴ Moreover, are non-clinical factors to be regarded as irrelevant in the determination of exceptional or is there an overlap between clinical and non-clinical factors?

The case of *Condliff*⁶⁵ considered the relevance of social factors in the determination of exceptionality for obtaining bariatric surgery. The patient had dia-

⁵⁸ *AC v. Berkshire Primary Care Trust* [2010] EWHC 1162 (Admin) [31].

⁵⁹ *Rogers*, (note 56), [65] and [82].

⁶⁰ *R (Ross) v. West Sussex Primary Care Trust* [2008] EWHC 1908 [28].

⁶¹ *Ross*, (note 60), [79].

⁶² A. Ford, ‘The Concept of Exceptionality’, (note 57), 319.

⁶³ *Rogers*, (note 56), [42].

⁶⁴ A. Ford, ‘The Concept of Exceptionality’, (note 57), 330-221.

⁶⁵ *R (Condliff) v North Staffordshire Primary Care Trust* (2011) EWHC 872 (Admin).

betes and a number of other health problems such as renal impairment, hypertension and obstructive sleep apnoea. An attempt at weight loss using standard methods had been unsuccessful but for the health authority concerned the patient's BMI had not reached the threshold for routine funding and his case was therefore not considered exceptional. Mr Condliff applied for judicial review regarding the criteria set by the PCT for determining exceptionality that excluded social factors⁶⁶ arguing they contravened Article 8 of the European Convention of Human Rights (ECHR). The court held that the Social Factors Exclusion policy of the PCT did not violate Article 8, as it did not create a positive obligation in the context of an individual funding request.⁶⁷ The judge, however, did consider the possibility of social factors that had direct clinical implications, in contrast to non-clinical social factors.⁶⁸ However, the case does not clarify what factors would constitute clinical social factors, although the judge cited the IFR non-discrimination policy to include factors such as a person's religion, lifestyle, social position, family or financial status, or intelligence as possibly relevant to the clinical effectiveness of an intervention and the capacity of an individual to benefit. Therefore, one might ask whether it is not just a question of when a social factor takes on clinical significance.⁶⁹

Health authorities therefore often grapple with the difficult question of what constitutes exceptionality in a given case while at the same time having to strike a fair balance between the interests and choices of the individual and the community of patients.⁷⁰ Both, CCGs or NHS England, are of course entitled to set an IFR policy that reflects what they reasonably consider the fairest way of treating patients claiming exceptionality. However, since there is no overall *national* list of excluded low value or low priority treatments or procedures, some patients are receiving treatments in one CCG but not in another, the so-called post-code lottery.⁷¹ It should be apparent that different lists and the different application of exceptionality criteria make for a lack of equitable distribution of health care both in terms of a lack of geographical equity and of equity according to need.

⁶⁶ *Ibid.*, [14].

⁶⁷ *Ibid.*, [52] and [54].

⁶⁸ *Ibid.*, [20] and [23].

⁶⁹ A. Ford, 'The Concept of Exceptionality', (note 57), 320; C. Newdick, 'Resource Allocation in the National Health Service', *American Journal Law & Med* 23, Issue 2-3 (1997), 309.

⁷⁰ See further NHS England, *Individual Funding Requests of Specialised Services, a Guide for Patients*, www.england.nhs.uk/wp-content/uploads/2017/11/ifr-patient-guide.pdf, 20 November 2017.

⁷¹ Audit Commission, *Reducing spending*, (note 47), 2.

2.3 Relevant Principles in the Decision-Making Framework

Individual funding requests not only pertain to the consideration of the exceptional circumstances of a patient but CCGs need to consider a number of further criteria in arriving at the decision whether a particular treatment is to be paid for and how to reduce spending in a particular area. Although NHS England has developed guidance in this respect,⁷² different CCGs have developed their own framework of further principles and their definitions, in order to enable fair, consistent, and transparent decisions and decision-making. This framework includes factors such as equity, capacity to benefit, health care need, cost of the treatment, cost effectiveness, evidence of clinical effectiveness and any national policy guidance.⁷³

It is not surprising that as in *Condliff* the assessment of some of the more subjective notions such as a patient's health care need and a patient's capacity to benefit from treatment have given rise to difficulties in the determination of whether a patient's treatment request is granted. The different assessment of these factors and decision-making frameworks adopted by CCGs renders achieving an equitable health care system, subject to equity of access and to equity in terms of need, problematic. The analysis of need is dependent on the definition of its proxies, such as the severity of ill-health, social factors, age or time waiting for treatment as well as the patient's capacity to benefit.⁷⁴ These proxies are in turn open to subjective interpretations. Capacity to benefit, for example, apart from taking into account the likely response of a patient to treatment, is necessarily subjective and must take into account other elements such as age, clinical factors and clinical social factors. Besides, defining need in terms of capacity to benefit depends on whether one considers the stage of the illness at which the patient presents or the degree of ill-health. If one uses the former qualification then clearly patients presenting at an earlier stage of their illness have a greater chance of a better treatment outcome than patients presenting with more advanced disease. If need is defined in terms of a person's health status or degree of ill-health, then the later presenter has greater need than the early presenter.⁷⁵

While the interpretation of some of these factors for decision-making may be ambiguous, it is difficult to understand why there is so little agreement on

⁷² NHS England, *Items which Should not be Routinely Prescribed in Primary Care: Guidance for CCGs*, www.england.nhs.uk/publication/items-which-should-not-be-routinely-prescribed-in-primary-care-guidance-for-ccgs/, 30 November 2017.

⁷³ C. Newdick, 'Can Judges Ration with Compassion?', (note 53), 111.

⁷⁴ B. New, (note 13)

⁷⁵ A. Dixon et al., 'Is the NHS Equitable?', (note 11), 7.

criteria that seem much less open to interpretation. An example of the latter is the criterion of treatment effectiveness. A number of IFRs have been litigated in the courts on the question of effectiveness. In the recent case of *SB v. NHS England*,⁷⁶ a child with phenylketonuria and autism applied for treatment with the drug Kuvan to reduce the high phenylalanine levels in his blood, which were likely to lead to significant intellectual impairment. Because of his autism, these levels could not be controlled sufficiently by standard dietary treatment. Although there was overwhelming evidence of the clinical effectiveness of Kuvan in about 20% of patients, namely treatment sensitive patients, the CCG panel rejected the request without giving any reason for their conclusion. Andrews J found for the claimant on the grounds of irrationality of the decision and referred the case back for reconsideration by the health authority suggesting that the panel ought to take into consideration the prospective financial burden to the NHS were the child to suffer irreversible brain damage due to the ineffectiveness of dietary control.⁷⁷

Judicial review cases where the assessment and relevance of effectiveness are the issue are not unusual. To give some examples of court rulings where the criterion of effectiveness in the IFR consideration by the health authority was challenged:-

- In reaching a decision, the health authority should consider the nature and seriousness of each type of illness and the effectiveness of various forms of treatment.⁷⁸
- A decision, which seriously affects the citizen's health, will require substantial consideration and will be subject to careful scrutiny by the court.⁷⁹
- A health authority cannot simply determine that the procedure has no proven clinical benefit while giving no indication of why it considers that is so.⁸⁰
- A health authority may not simply dismiss responsible medical opinion, even if there are differing opinions on the effectiveness of a treatment. Such opinion is relevant and must be given proper weight.⁸¹
- The health authority needs to understand the clinical efficacy data and the quality of the evidence.⁸²

⁷⁶ *SB v. NHS England* [2017] EWHC 2000 (Admin).

⁷⁷ *Ibid.*, [91].

⁷⁸ *R v. North West Lancashire HA*, (note 50), 413; *Ross* (note 60), [34] and *SB v. NHS England*, (note 76), [90].

⁷⁹ *R v. North West Lancashire HA*, (note 50), 412 and *Ross* (note 60), [39].

⁸⁰ *SB v. NHS England*, (note 76).

⁸¹ *R v. North West Lancashire HA*, (note 50), 412.

⁸² *Ross*, (note 60), [84] and [85].

- Where there are differing opinions on clinical effectiveness and the health authority's conclusions are not irrational, the court will not decide which opinion is right.⁸³

These judicial pronouncements demonstrate that for CCGs the effectiveness criteria have not always been an absolute notion with scientific evidence sometimes insufficient to provide clear conclusions as to the benefits of a particular treatment.⁸⁴

Case law further demonstrates that the problem of equity of access to health care in England with variations in the allocation of health care by different CCGs in England is quite common.⁸⁵ Differences between health authorities are apparent regarding the availability of elective surgery, as in *Condliff*, and of interventions and treatments where effectiveness is contested or has not been established.⁸⁶ These differences exist because of the absence of clear national lists of treatments excluded from public funding, of unambiguous exceptionality criteria and because of the divergent decision-making frameworks in different CCGs. Thus, health authorities will continue to be exposed to the risk of legal action. Disgruntled patients will continue to challenge the refusal of their individual funding requests by applying for judicial review of the decision by the health authority. After all, patients are often aware of the NICE guidelines for their requested treatment or the assessment criteria in neighbouring health authorities and if they are not, their doctors will be. Thus, Mr. Condliff's North Staffordshire PCT did not follow the NICE guidance on bariatric surgery to provide surgery for patients with a body mass index of 40, or 35 in the presence of other illnesses such as diabetes, but also differed in its decision-making framework from that of two neighbouring PCTs.⁸⁷

From the point of view of the health authority, judicial review proceedings involve considerable expenditure in terms of finances and staff time devoted to the case.⁸⁸ It is therefore often the case that health authorities concede indi-

⁸³ *R. (Gordon) v. Bromley NHS Primary Care Trust* [2006] EWHC 2462 [31], *Ross*, (note 60), [36], *R (Murphy) v. Salford Primary Care Trust* [2008] EWHC 1908 (Admin) [6] and *AC v. Berkshire Primary Care Trust*, (note 58), [22] and [23].

⁸⁴ C. Newdick, 'Resource Allocation in the NHS', (note 69), 313 stressing that evidence may be incomplete, ambiguous or uncertain; A. Ford, 'The Concept of Exceptionality', (note 57), 331 and note 138; see also generally R. Veatch, *Patient, Heal Thyself: How the New Medicine Puts the Patient in Charge* (Oxford: OUP, 2009), ch. 3.

⁸⁵ J. Maybin and R. Klein, *Rationing*, (note 46), 37 give the example of a 38-fold variation in the rate of bariatric surgery between the populations of different health authorities.

⁸⁶ *Ibid.*, 37.

⁸⁷ A. Owen-Smith et al., 'A NICE example? Variation in the provision of bariatric surgery', *BMJ* 346 (2013), 2453, www.bmj.com/bmj/section-pdf/187908?path=/bmj/346/7909/Analysis.full.pdf, 25 May 2013.

⁸⁸ A. Ford, 'The Concept of Exceptionality', (note 57), 332.

vidual funding requests, which do not involve major treatment costs, simply to avoid the expense of court proceedings, the possibility of a negative outcome for the CCG and the risk of setting a precedent encouraging more potential claims.⁸⁹ According to data collected from a freedom of information request by the British Medical Journal 73,900 IFRs were made to CCGs in 2016-17, a 47% rise from 2013-14 when 50,2000 were made, while compared to 2015-16 the increase was 20% from

60,400 IFRs. In 2016-17, over half of the IFRs were approved.⁹⁰ No overall figures are available for 2017-18 but as regards the approval of IFRs specifically for knee replacement and for hip surgery there was a drop in the numbers approved but this may have been due to a considerable increase in the number of requests.⁹¹

3. Judicial Review Challenges: Patient Choice versus Solidarity

One might assume that a health care system where such large numbers of individual funding requests are being made for treatment that is not generally available is a system where the principle of solidarity in face of rationing has been discarded. A solidarity-based approach in a severely cash-strapped health care system with a finite budget would mandate that the approval of IFRs is kept to a minimum and that unwarranted geographical variations are reduced. This is because such individualist demands for treatments as an expression of patient choice might be challenged as being in tension with health care, which aims to be universal and equitable.⁹²

However, this may be an erroneous conclusion. Solidarity should not simply be viewed in juxtaposition to individualist patient choice where exceptional cases represent an opportunity cost with fewer resources available for all other patients. Rather individual funding requests and judicial reviews of refused requests have a role to play in ensuring that health authorities have to provide reasons when making resource allocation decisions and their decision-making is transparent. Moreover, the effects of judicial review do not only extend to the patient litigating but judicial review has an impact on the quality of decision-

⁸⁹ *Ibid.*, 25.

⁹⁰ G. Iacobucci, 'Surge in exceptional funding requests', *BMJ* 358 (2017), j3188, https://www.bmj.com/bmj/section-pdf/947166?path=/bmj/358/8113/This_Week.full.pdf, 8 July 2017.

⁹¹ G Iacobucci, 'Nearly 1700 requests for knee and hip surgery were rejected in England last year', *BMJ* 362 (2018), k3002, www.bmj.com/content/362/bmj.k3002, 18 July 2018.

⁹² B. New, *A Good Enough Service*, (note 1), 44.

making by health care authorities. Furthermore, as Bondy et al. claim, judicial review generally makes a substantive contribution to the outcome of disputes between claimants and public bodies because outcomes are not symbolic or formal but because public bodies engage with the issues raised and reconsider their decisions rather than merely correct them.⁹³

There are therefore tangible and intangible benefits from IFR cases even if they are rarely won by patients. However, even when they lose their case patients often feel more empowered and have greater confidence in the legal system.⁹⁴ Moreover, judicial review challenges can be viewed as a means of bringing pressure on health care institutions in their future rationing decisions. It follows that judicial review has major policy and reform consequences enabling improvements in the quality of the public decision-making and of the services by public bodies.⁹⁵ In this light, Sabel and Simon, for example, maintain that the implications of public law litigation go beyond the immediate parties to the action, that they have a destabilising effect on the status quo and on the entire health care system.⁹⁶ The need for transparency by the health authorities and the media interest in judicial review litigation opens the system to broader interests and voices and can be a means of bringing pressure on public institutions.⁹⁷ Thus, actual or threatened public law litigation destabilises, leads to public engagement, deliberation and negotiation, and may lead to a restructuring of practices and of health care institutions in the long term.⁹⁸ Platt et al. also found in the context of judicial review of local authority decisions that an increased level of challenge appears to lead to improvements in levels of performance and is therefore helpful to authorities, rather than a hindrance.⁹⁹ Rather than considering the actual or intended judicial review solely in terms of an individual's claim or grievance, public law litigation should therefore be seen as an incentive to change and expand the parameters governing the implementation of policies.¹⁰⁰ Consequently, patient choice, rather than solely benefiting the individual, can have positive effects on a much wider scale.¹⁰¹

⁹³ V. Bondy, L. Platt & M. Sunkin, *The Value and Effects of Judicial Review: The Nature of Claims, their Outcomes and Consequences* (London: Public Law Project, 2015) 2.

⁹⁴ *Ibid.*, 62.

⁹⁵ *Ibid.*, 46.

⁹⁶ C. Sabel and W. Simon, 'Destabilisation Rights: How Public Law Litigation Succeeds', *Harvard Law Review* 117, Issue 4 (2003), 1017.

⁹⁷ B. Sheldrick, (note 52), 155–56.

⁹⁸ C. Sabel and W. Simon, (note 96), 1017.

⁹⁹ L. Platt, M. Sunkin & K. Calvo, 'Judicial Review Litigation as an Incentive to Change in Local Authority Public Services in England and Wales', *J Public Adm Res Theory* 20, Issue suppl 2 (2010), 1252.

¹⁰⁰ B. Sheldrick, (note 52), 156.

¹⁰¹ M.K. Sheppard, 'Fallacy or Functionality: Law and Policy of Patient Treatment Choice in the NHS', *Health Care Analysis* 24 (2016), 279.

The apparent conflict between individualistic choice and solidarity, between individualist and collectivist values, is ameliorated further by policy-makers linking choice with people taking responsibility. The NHS where patients can make individual funding requests for treatment not generally on offer expects patients to become more active and more involved in their own care.¹⁰² Individuals are asked to take responsibility for their lifestyle choices in relation to health. A considerable number of government White Papers refer to the notion of responsibilisation. Thus, *High Quality Care for All* speaks of patients who are empowered by choice being more likely to take responsibility.¹⁰³ Similarly in *Personal Health Budgets: First Steps* references are made to people having independence and choice but also responsibility,¹⁰⁴ and people exercising their choice around support for self-care.¹⁰⁵ The White Paper *Equity and Excellence: Liberating the NHS* suggests that patients, in return for greater choice and control, should accept responsibility for the choices they make¹⁰⁶ and the need for increasing self-care.¹⁰⁷ Likewise *Liberating the NHS: Greater Choice and Control* addresses responsibilisation as patients taking more responsibility for their health and treatment choices¹⁰⁸ and building ownership of, and a shared responsibility for, managing their conditions, especially where lifestyle changes may be needed.¹⁰⁹ Patients are therefore positioned not only as conscious choosers of possible treatments but also as choosers of their lifestyle, and must therefore take greater responsibility for making healthy choices.¹¹⁰ The current NHS publication *Personalised Care: Implementing the Comprehensive Model* speaks of better self-care.¹¹¹ The emphasis on the individual to assume responsibility for the management of her own health and health care is also encapsulated in the NHS Constitution: 'Please recognise that you can make a significant contribution to your own, and your family's, good health and wellbeing, and take personal responsibility for it.'¹¹²

¹⁰² C. Needham, 'Interpreting Personalization in England's National Health Service: A Textual Analysis', *Critical Policy Studies* 3, Issue 2 (2009), 207.

¹⁰³ Department of Health, *High Quality Care for All*, (note 25), 33.

¹⁰⁴ Department of Health, *Personal Health Budgets*, (note 25), 38.

¹⁰⁵ *Ibid.*, 30.

¹⁰⁶ Department of Health, *Equity and Excellence*, (note 2), 16.

¹⁰⁷ *Ibid.*, 46.

¹⁰⁸ Department of Health, *Liberating the NHS: Greater Choice and Control, a Consultation on Proposals* (HMSO 2010) 23.

¹⁰⁹ *Ibid.*, 4.

¹¹⁰ I. Greener, 'Towards a History of Choice', (note 19), 322.

¹¹¹ NHS England, *Universal Personalised Care*, (note 26), 14.

¹¹² Department of Health, *NHS Constitution*, (note 3), 11.

It is expected that making patients become more active and assuming responsibility for their health by encouraging self-care and self-management might lead to resource savings overall. Linking this responsabilisation of the patient to the traditional values of the NHS, one can take it a step further and interpret it as a commitment to the value of solidarity. The shift to patients taking more control reduces their dependence on the NHS. Taking responsibility for one's health and health care is particularly relevant in respect of the increasing number of people living with chronic conditions.¹¹³ Teaching individuals to identify challenges and to solve problems associated with their illness and enabling self-management represents a promising strategy. Self-management also shows potential by establishing a pattern for health early in life and providing strategies for mitigating illness and managing it in later life.¹¹⁴ Thus, the policy of patient responsabilisation has the potential benefit of reducing the costs of publicly funded health care¹¹⁵ while at the same time deepening the commitment to the value of solidarity.¹¹⁶

4. Conclusion

It is known that health authorities often accede to patients' IFRs because of the risk of costly and time-consuming litigation and the risk of setting new precedents creating further individualistic demands. They therefore spend resources on these rationed treatments, which, in turn, leads to disinvestment from other areas leading to the conclusion that individualistic patient choice erodes the solidarity-base of the NHS. However, as has been shown, patient demands for treatment and procedures not generally on offer by the NHS need to be considered in a much broader light. Not only are public bodies not at liberty simply to deny treatment requests but English law demands that the rationing policies of health authorities allow for exceptions in special cases and that health authorities account for the legitimacy, procedural propriety and reasonableness of their decisions. While judicial review imposes costs on public bodies, as Bondy et al. conclude, judicial review has much wider consequences. It enables improvements in the quality of public administrative decision-making and assists public bodies to meet their legal obligations. Apart from its effect on the nature and quality of decision-making, intended or actual

¹¹³ M.K. Sheppard, (note 101), 279-300.

¹¹⁴ P.A. Grady and L.L. Gough, 'Self-Management: A Comprehensive Approach to Management of Chronic Conditions', *Am J Public Health* 104, Issue 8 (2014), e25-e31.

¹¹⁵ K. Veitch, 'The Government of Health Care and the Politics of Patient Empowerment: New Labour and the NHS Reform Agenda in England', *Law & Policy* 32, Issue 3 (2010), 320.

¹¹⁶ C Needham, 'Interpreting Personalization', (note 102), 213 referring to New Labour's avowed aim to use personalisation in order to deepen solidarity and equity within the NHS.

litigation by patients demanding a specific treatment choice has further secondary effects. Thus, Simon and Sabel suggest that intended or actual litigation destabilises the health care system and leads to change and reform of the health care system.

Thus while it has been claimed that with its emphasis on patient choice the NHS has abandoned the founding principles of NHS comprehensiveness, universality and equity, this view may be too intransigent. Patient choice does not necessarily trump the principle of solidarity of the NHS as the potential ramifications of (intended) judicial review challenges of IFRs go beyond the parties to the action. Health authorities have to account for their rationing decisions in public but also actual or intended litigation makes the health care system accessible to broader interests leading to change and improvements. Furthermore, as has been argued, patient choice is not a free-standing concept but is linked by policy-makers and public bodies with an emphasis on patients taking responsibility for their own health. The NHS enables individualistic choice including IFRs but expects patients to become more involved in their own care with the avowed aim of reducing overall health care costs. Thus, it is possible to draw the conclusion that patient choice is an affirmation of a commitment to solidarity rather than its negation.