Institution: University of Reading

Unit of Assessment: 20 Law

Title of case study: *NHS treatment rationing and priority-setting: Improving ethical decision-making amongst UK healthcare providers*

1. Summary of the impact

Research carried out by Professor Christopher Newdick in the School of Law, University of Reading, explored the ways in which individualistic 'rights-based' models of healthcare cause problems within areas of finite public resources, such as NHS treatment rationing and priority-setting. By developing a new ethical model to help settle individual competing rights claims, the research produced impact by changing the policies and practices of a series of NHS Primary Care Trusts (PCTs) who implemented new Ethical Frameworks informed by Newdick's findings. By reframing the treatment rationing debate, and working directly with PCTs, his research produced a new, more robust and defensible way of balancing individual and collective interests within NHS decision-making.

2. Underpinning research

Between 1995 and 2012, as Reader (1995-2007) and then Professor (2007-) in the School of Law at Reading, Newdick undertook a long-running programme of research into the theory and practice of medical rationing and priority-setting within the NHS and other health systems. The approach he puts forward was developed in his book *Who Should We Treat? – Rights, Rationing and Resources in the NHS* 2nd ed. (Oxford: Oxford University Press. 2005), and journal article 'Citizenship, Free Movement and Health Care: Cementing Individual Rights by Corroding Social Solidarity', *Common Market Law Review* (2006), among other publications.

Newdick's work combined the legal principles developed by the courts (which promote notions of 'procedural justice') with the practical needs of NHS priorities committees in order to produce a reasonable and ethical process by which difficult decisions can be reached in ways that ought to satisfy critical scrutiny. The demand for care is rising, resources are being squeezed, medical developments offer more choice and hope for treatment, and individuals are more litigious and possess increased rights under domestic and EU law. Within this context, governments offer little guidance on resource allocation, and so health commissioners are left to develop their own processes for doing so. Newdick's research asked: if hard choices have to be made, should we focus more on acute care to make people better, chronic care to make them more comfortable, or preventative care to stop people becoming sick in the first place? Do we need more clinicians, more medicines or more hospitals? If hard choices are unavoidable, who should make them: clinicians, local NHS managers, the community or government?' As he stated in his 2005 book, there is *'*no simple solution' (p1) and since 2011, within a climate of public-service austerity, these decisions have become even more difficult.

Newdick's research into the procedural realities of NHS resource allocation and the role of the actors involved in it identified that decisions were often made on a case-by-case basis, as a matter of 'solving' discrete problems, and without a coherent frame of understanding. By drawing on theoretical insights from communitarian social and political theory, and the jurisprudence of UK and EU courts, Newdick was able to devise a framework for decision-making that was both procedurally fair and capable of taking into account collective interests such as the cost of treatment, the needs of the community, and the need for equity. His model applied communitarian theory so as to allow hard choices to be made with finite NHS resources in ways which treat patients transparently and consistently, even in the face of substantial pressures on priority-setting mechanisms; as he notes: *'*as the pressures upon resources become more intense, the pretence that rationing is someone else's fault is no longer sustainable. If rationing is a fact of life, it should take place within the framework of equality, fairness and consistency between patients' (2005, p48). His model entails using reflexive processes (rather than concrete principles) that recognise individual rights as relative, not absolute, to guide decision-making. This original research was thus of

huge significance for the NHS in underpinning the subsequent development of Ethical Frameworks to enable resource allocation in a rational and transparent manner that should reassure decision-makers, patients and the public. Priority-setting exposes the NHS to the risk of judicial review; Ethical Frameworks enable decision-makers to withstand this sort of legal challenge.

3. References to the research

1. Newdick, C. (2005) *Who Should We Treat? – Rights, Rationing and Resources in the NHS* 2nd ed. (Oxford: Oxford University Press), 298pp., ISBN: 978-0199264186.

This book-length research text, published by the leading UK academic publisher for law, is recognised as 'the standard reference on the law of the National Health Service' (*Journal of Medical Ethics,* 2007, 33: 185). A copy of this publication is available from the HEI on request.

2. Newdick, C. (2006), 'Citizenship, Free Movement and Health Care: Cementing Individual Rights by Corroding Social Solidarity', *Common Market Law Review,* 43/6: 1645-1668 (http://www.kluwerlawonline.com/document.php?id=COLA2006123).

This output was published in a respected peer-reviewed international academic journal, with an impact factor of 2.422 and an ISI Journal Citation Reports Ranking: 2011: 13/136 (for Law). A copy is available from the HEI on request.

Both outputs have been internally assessed as of at least 2* quality.

4. Details of the impact

Newdick's research was used in the development of an Ethical Framework for use by NHS organisations and Primary Care Trusts (PCTs) to assist decision-making about the allocation of finite resources. His work moved both practice and policy-level debate around NHS resource allocations in these organisations away from a dialogue focused on individual rights (micro-level decisions on a case-by-case basis) and towards one more rooted in collective interests (macro-level considerations referencing communitarian ethics).

Newdick became an invited member of the Berkshire NHS Priorities Committee in 1999 on the basis of his research expertise in this field. In this role, he developed an Ethical Framework for resource allocation that was guided by the needs of that organisation and informed by the principles developed in his research outputs. This document emphasises a number of fundamental principles, and is written with a lay readership in mind so as to guide NHS resource allocators ("commissioners") and patients through the decision-making process. It reflected the approach developed in Newdick's work in that it explicitly recognised the role of collective considerations, like the cost of treatment and needs of the community, as relevant elements in resource-allocation decisions. The Framework was adopted for use in the Berkshire PCT, one of the first health authorities to respond to the need for consistency in this area, in 2005, and was subsequently adopted for use across the nine PCTs of the South Central NHS Region (East Berkshire, West Berkshire, Buckinghamshire, Hampshire, Isle of Wight, Milton Keynes, Oxfordshire, Portsmouth and Southampton) in 2007 (Corroborating Source 1). This process was iterative and collaborative, involving the sharing of expertise across an NHS region, and was underpinned in part via Newdick's role as an Honorary Consultant and Special Advisor on Law to the NHS South Central Priorities Committee.

The primary impact of Newdick's work (post-2007) took the form of a change of policy and practice by a series of public bodies (the PCTs who have implemented Ethical Frameworks as a result of his findings). The significance of this impact derives from the research's widespread and pervasive use within these organisations to guide all subsequent resource-allocation decisions. Newdick's exemplar developed for Berkshire/South Central Region PCTs provides a pertinent demonstration of this, and there are many examples from elsewhere in the country of PCTs – such as East Lancashire in 2008 (Corroborating

Source 2) and Wolverhampton City in 2009 (Corroborating Source 3) –which have explicitly based their practices and policies on the initial model..

Newdick was also invited to contribute guidance materials based on his research for the National Prescribing Centre (NPC), the central Government body that informs resource decisions across the NHS (Corroborating Source 4), and the NHS Confederation published a report by Newdick recommending this approach to other PCTs (Corroborating Source 5). These publications disseminated a more robust and defensible way of balancing individual and collective interests within NHS decision-making to a wider audience of PCTs and NHS user bodies, illustrating the considerable reach of this impact. As a result, decisions across the NHS are likely to be i) different than they might otherwise be; ii) fairer in the way that they account for collective and individual interests; and iii) less susceptible to judicial challenge. Newdick's research (Output Two) was cited by the Advocate-General of the European Court of Justice in a case concerning inter-State resource allocation (Corroborating Source 6), and the South Central Ethical Framework was endorsed in a 2011 UK Court of Appeal decision involving the rights of transgender patients to cosmetic surgery. A decision made under the auspices of the Ethical Framework was challenged in judicial review, and was held to be lawful (Corroborating Source 7).

The impact of Newdick's work can also be understood in terms of a redefinition of wider practice within the NHS and elsewhere. Newdick was called to give evidence as an expert witness to the second inquiry into the Mid Staffordshire NHS Foundation Trust on the organisation and structure of NHS decision-making processes (Corroborating Source 8), which referenced his insights on institutional decision-making in its final report (Corresponding Source 9, paragraph. 20.92), while in 2010 he was invited to give expert evidence to NHS Scotland to assist in the production of their report on priority-setting policy, *Making Difficult Decisions in NHS Boards in Scotland* (Corroborating Source 10). This impact has even extended overseas: in December 2012, Newdick led a two-day conference with Brazilian judges in the Federal University of Fluminense, Rio de Janeiro, considering the extent to which his Ethical Framework could resolve comparable judicial challenges in Brazil. In April 2013, legislative changes replaced PCTs with CCGs (clinical commissioning groups); in May 2013, Newdick joined an NHS priorities committee to assist local CCG commissioners to respond to the legal duties imposed upon them and this role is likely to develop.

5. Sources to corroborate the impact

1. Ethical Framework: The updated *Ethical Framework for Priority-Setting* as adopted across the nine Primary Care Trusts of the South Central Region of the NHS: (http://www.oxfordshireccg.nhs.uk/wp-content/uploads/2013/03/Ethical-Framework.pdf).

2. Ethical Framework: The *Ethical Framework for Decision Making* adopted for use by East Lancashire Primary Care Trust, and explanatory narrative highlighting the influence of the South Central Region example: (http://www.elmmb.nhs.uk/making-a-request-for-a-medicine-overview/requesting-a-policy-decision-for-medicines/).

3. Ethical Framework: The *Policy for Funding of Treatments Outside Commissioned Services* adopted for use by Wolverhampton City Primary Care Trust, with appendix 1 (pp18-20) highlighting the influence of the South Central Region example: (http://www.medlaw.eu/pdf/Wolverhampton.PCT.IFR.23.11.10.pdf).

4. E-learning documents: Prepared by Newdick for the National Prescribing Centre on: *Developing and Using an Ethical Framework in Practice: The South Central Ethical Framework: A Case Study* (http://www.npc.nhs.uk/local_decision_making/case_legal.php); and *Legal and Ethical Aspects of Local Decision-making About Medicines and Treatments* (http://www.npc.nhs.uk/local_decision_making/resources/ethical_script_web.pdf).

5. Policy guidance: Prepared by Newdick for the NHS Confederation on *Priority Setting: Legal*

Considerations (http://www.nhsconfed.org/Publications/Pages/Prioritysettinglegal.aspx).

6. Judicial Proceeding: Opinion of Advocate-General Sharpston in the case of *European Commission v French Republic* (2010) Case C-512/08 (particularly note 3) (http://curia.europa.eu/juris/document/document.jsf?text=&docid=78674&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=1480073).

7. Judicial Proceeding: *AC v Berkshire West PCT and the EHRC* (2010) 116 BMLR 125 (High Court) and (2011) 119 BMLR 135 Civ 247 (Court of Appeal); PDF attached.

8. Inquiry Evidence: A copy of the report submitted to the second inquiry into the Mid Staffordshire NHS Foundation Trust on the organisation and structure of the NHS, 15-16/10/2010 (www.midstaffspublicinquiry.com/hearings/s/120/week-two-15-18-nov-2010); and a transcript of the oral evidence given: (http://www.midstaffspublicinquiry.com/hearings/s/120/week-two-15-18-nov-2010).

9. Report: The Mid Staffordshire NHS Foundation Trust Public Inquiry (2013) *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry: Volume 3: Present and Future Annexes* (London: HMSO); (http://www.midstaffspublicinquiry.com/sites/default/files/report/Volume%203.pdf).

10. Policy guidance: Health Improvement in Scotland Report, *Making Difficult Decisions in NHS Boards in Scotland* (http://www.healthcareimprovementscotland.org/previous_resources/policy_and_strategy/making_difficult_decisions_in.aspx).