

Impact case study (REF3)

Institution: University of Reading		
Unit of Assessment: UoA18 Law		
Title of case study: Reforming NHS Policy on Individual Patient Funding Requests		
Period when the underpinning research was undertaken: 2000 - 16		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Chris Newdick	Reader Professor	01/10/1995 – present
Period when the claimed impact occurred: 2017–20		
Is this case study continued from a case study submitted in 2014? No		
<p>1. Summary of the impact</p> <p>NHS Individual Patient Funding Requests (IPFRs) are applications submitted by clinicians on behalf of individual patients for medicines and treatments not routinely purchased by the NHS. Previously the IPFR criteria for funding required clinicians to demonstrate that patients were <i>exceptional</i>. In Wales, patient groups petitioned the Welsh Assembly for a review on the grounds that the “exceptionality” test was unclear and unfair. In 2016 Newdick was appointed to an independent panel tasked with reviewing the IPFR process for NHS Wales. Following Newdick’s research on ethical frameworks, clinicians in Wales are now required to demonstrate the <i>potential significant clinical benefit</i> of a treatment. Recognising the changes in terms of improved fairness and transparency, four clinical Commissioning Groups across the Thames Valley have adopted a similar policy change.</p>		
<p>2. Underpinning research</p> <p>The research underpinning this submission asked how we can develop an acceptable response to the tensions created by NHS rationing [Section 3, Ref 1]. Many would acknowledge that (a) demand for health care exceeds the resources available to the NHS and that hard choices are unavoidable; and (b) government is reluctant to propose solutions to resolve the dilemmas these questions present. Since this difficult and sensitive area is left to local NHS commissioners to manage, postcode rationing is likely, and patients may feel aggrieved when similar cases are not treated alike. For example, should more care be invested in paediatrics, elderly patients, cancer or mental health? What priority should be given to “last chance” treatments for terminal illness, when the cost is high, evidence of clinical efficacy is incomplete, and they may serve to extend a patient’s life by a relatively short period only? Should resources be diverted into acute care to make patients better, or public health to prevent people becoming ill in the first place? What can be done when each claim is legitimate, yet not all can be achieved?</p> <p>The solutions suggested by Newdick to these questions lie mainly in the application of <i>procedural</i> law, modified where appropriate by substantive patient rights [Ref 5]. His research enabled him to develop an Ethical Framework [Refs 3 and 4] at the macro-level to assist NHS resource-allocators to promote fairness, consistency and transparency in this process. Since 1999, he has been a member of NHS Priorities Committees advising NHS commissioners (previously Primary Care Trusts – PCTs, and now Clinical Commissioning Groups – CCGs). Newdick’s Ethical Framework was adopted first by Berkshire PCT, then South Central PCT and, most recently, all the CCGs who subscribe to the Thames Valley Priorities Committee.</p> <p>This work responds to the challenges of NHS priority-setting at the community level. It combines knowledge of legal and ethical theory with an awareness of the realities of NHS rationing. The Ethical Framework is based on communitarian values, procedural justice and the guidance of case-law, and promotes a consistent reference point even in the face of considerable resource</p>		

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pressure. Rather than identifying particular patients, groups or treatments as meriting a special response, the framework combines a series of explicit values on which decisions should be based. As with most other public health systems, it cannot always guarantee access to care, but it will balance competing claims and the interests of the community in ways that are reasonable, consistent and transparent.

The Ethical Framework research [Refs 3 and 4] provides background to this current submission. It provides a macro-tool for resource allocation, whilst also addressing the position of the patient (micro-level) in the form of assessing exceptionality (see below). This time, rather than developing responses to NHS rationing at the macro-level of communities (work which he had undertaken for health authorities in the south of England previously), Newdick was invited to advise the Minister of State for Wales on how these mechanisms translate into solutions at the micro-level of individual patients.

A compassionate NHS must also be responsive to the needs of individual patients [Ref 2]. Even if a general policy recommends that a particular treatment is not funded, the NHS must be sensitive to “exceptional” patients for whom the treatment will provide significant clinical benefit. It is with respect to this latter concern that subsequent NHS Wales research was undertaken. Historically, many patients felt considerable discomfort about the term “exceptionality” and it was in response to this disquiet that Newdick was asked by the Minister for Health and Social Services (National Assembly for Wales) to join the committee conducting the Independent Review of the Individual Patient Funding Requests Process in Wales in September 2016. Newdick co-designed and conducted 10 workshops across Wales for the purpose of understanding the concern around the “exceptionality” test. The workshops garnered a large body of qualitative data directly from patients, relatives, Assembly Members, health authorities and patient groups, and provided a unique insight into the strengths and weaknesses of the crucial word, “exceptionality”. The word was understood in different ways by clinicians and patients and, as a result, policy was applied in an unclear and inconsistent manner. The Review’s findings [Ref 6] and recommendations were based on this body of research and led to a key change in the NHS Wales policy on IPFRs.

3. References to the research

1. Newdick, C. (2018) 'Can judges ration with compassion? A priority-setting rights matrix'. *Health and Human Rights Journal*, 20 (1). pp. 107–120.
2. Newdick, C. (2015) 'Bioethics through the telescope: institutional ethics in the NHS'. In: Ferguson, Pamela R. and Laurie, Graeme T. (eds) *Inspiring a Medico-legal Revolution: Essays in Honour of Sheila McLean*. Ashgate, Farnham, pp. 125–136.
3. Newdick, C. (2014) 'Health care rights and NHS rationing: turning theory into practice'. *Revista Portuguesa de Saúde Pública*, 32 (2). pp. 151–157.
doi: <https://doi.org/10.1016/j.rpsp.2014.07.001>
4. Newdick, C. (2012) 'Re-balancing the rationing debate: tackling the tensions between individual and community rights'. In: den Exter, Andre and Buijsen, Martin (eds) *Rationing Health Care: Hard Choices and Unavoidable Trade-offs*. Maklu, Antwerp, pp. 153–170.
5. Newdick, C. (2005) *Who Should We Treat? — Rights, Rationing and Resources in the NHS*, 2nd ed. (Oxford University Press).
doi:10.1093/acprof:oso/9780199264186.001.0001 This research monograph has been widely cited (155, Google Scholar) and is published by one of the top academic publishers internationally. These provide good support for it being 2* quality or above.
6. Blakeman, A., Littlejohns, P., Newdick, C., Routledge, P., Williams, I. and Cass, K. (2017) *Independent Review of the Individual Patient Funding Request Process in*

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Wales. Report. Welsh Government (Report for the Cabinet Secretary for Health, Wellbeing and Sport).

4. Details of the impact

Changing and improving NHS Wales policy on Independent Patient Funding Requests

The NHS Wales policy on IPFR was considered by patient groups to be unfair and in need of review. Newdick's research has underpinned a significant change in the IPFR policy by redefining the key criterion for funding. This means that the system is now fairer, more consistent and more transparent. Vaughan Gething, Minister for Health and Social Services, stated in October 2019 that, following the independent review, "patients and clinicians can have every confidence that IPFRs are being carried out to the highest standards".

An IPFR is a request to a health board or the Welsh Health Specialised Services Committee (WHSSC) to fund NHS health care for a patient who falls outside the range of services and treatments that an NHS organisation routinely provides. An IPFR can cover any type of health care, including a specific service, treatment, medicine, device or piece of equipment. Inevitably, in terms of budget and resource allocation, this creates a difficult balance between meeting the needs of the community as a whole and responding to individual patient need. Hence a policy is required which recognises the possibility that, notwithstanding macro-level commissioning policies, individuals may find themselves in *exceptional* circumstances and merit treatment. IPFRs often concern "last chance" treatments for terminal diseases which are expensive but supported by limited clinical evidence. They may involve children and young parents and attract significant public concern.

In Wales, despite a series of previous reports and recommendations, the experience of IPFRs was an unhappy one and the system continued to give rise to considerable disquiet. "*Exceptionality*" (as it came to be known) is unclear and potentially confusing; in one sense, every patient is exceptional. From an IPFR Panel Member's point of view, it took "a disproportionate amount of time to agree what exceptionality meant in relation to each individual case" [Source 7]. Patients frequently contacted Welsh Assembly Members to complain that the system failed to respond to their needs fairly and consistently, and there was a constant threat of litigation. Because of his experience with Thames Valley CCGs, and his research devising the Thames Valley Ethical Framework, Newdick was appointed in 2016 by Vaughan Gething to a Committee of Independent Review into IPFRs, tasked with making recommendations for reform.

The Independent Review of the Individual Patient Funding Request (IPFR) Process in Wales was established to recommend reform of the c.700 IPFRs submitted annually. The Committee of Inquiry held 10 public meetings across Wales and received qualitative evidence from individual patients, the public, patient groups, Assembly Members, local health boards and the pharmaceutical industry. Its conclusions were published in a January 2017 report [Source 1a]. The review discovered that different health boards used different criteria for assessing IPFRs and that postcode rationing was common. The same was true of the Welsh Health Specialised Services Committee (WHSSC), responsible for dealing with highly specialised treatments. The review found that patients had legitimate reasons for concern.

Newdick led on Chapter 2 of the report (pp. 28–40) which discussed the term in common use: "exceptionality". This was not well understood and had been applied inconsistently, with many patients mistakenly considering their circumstances "exceptional". He recommended that "exceptionality" should be replaced by the phrase "significant clinical benefit". This focuses attention purely on the extent to which the patient is likely to be clinically assisted by the treatment, which was what exceptionality was meant to be doing, but failed at because the wording was suggestive of wider social considerations. The recommendation from Chapter 2 was agreed by the other members of the committee and resulted in a major *substantive* change in funding criteria. The remaining chapters of the review dealt with the processes of applying for funding, quality assurance, sharing of good practice and training.

Implementation of recommendations

The report was submitted to the Minister in January 2017, and on 21 March 2017, Mr Gething accepted its recommendations in full. Recognising the review committee’s “commitment to tackling what is a highly complex area”, the Cabinet Secretary for Health, Wellbeing and Sport accepted all 27 recommendations in March 2017 and implemented them across all seven Welsh Health Boards [Sources 1a and 1b]. Furthermore, with regard to the change in policy from exceptionality to significant clinical benefit, the subsequent Welsh government’s response to the review report in 2018, stated that the NHS Wales Policy “Making Decisions on Individual Patient Funding Requests” had already incorporated these new criteria in May 2017 [Source 1b].

Further to the policy amendment, the All Wales Therapeutics and Toxicology Centre has worked with IPFR panels and the WHSSC to implement the 27 recommendations for strengthening and improving the IPFR process in Wales. As a result of the revised approach of significant clinical benefit, funding decisions are now better informed, fairer, more consistent and more transparent [Source 7]. Indeed, in addition to IPFR Panel Members reporting the changed approach making it easier to justify decision making, one IPFR Panel Member also reported that it “will have a positive impact on more patients who might otherwise miss out on the opportunity to benefit greatly from treatments” and “will have a positive impact on mental health as well as physical health” [Source 7]. Moreover, the process is supported by a new IPFR Quality Assurance Advisory Group [Source 4]; new policies and processes have included training of clinicians – to which Newdick also contributed at annual IPFR meetings – [Sources 3a and 3d] – and the publication of IPFR guidance notes [Source 2]. Furthermore, access to data on IPFR cases and outcomes has enabled all seven Health Boards and IPFR panels to make more informed and fairer decisions. These changes reflect best practice in NHS Wales and improve the clarity of local policy for doctors and patients [Source 3a]. The application process for clinicians is now online [Source 3c] and patients are better informed on how decisions are made (on the basis of clinical evidence) through a patient guide and video [Source 3b].

The number of IPFRs made has been falling since 2015 and the small number submitted in 2018–19 (358) means it would be difficult to generalise or draw definitive conclusions about the impact of the changes made to the IPFR process. Nonetheless, the approval rate for all IPFRs has been rising since 2016/17, reaching the highest level to date – 68% – in 2018/19. Similarly, the approval rate for medicine IPFRs has been increasing for the past four years, reaching the highest level to date – 71% – last year. The approval rate for non-medicine IPFRs has varied over time, but last year’s approval rate – 66% – was the highest to date. As well as IPFRs, in 2018/19, there were 34 continued funding requests, to fund extensions to original IPFRs. Of these, there were 28 for medicines and 6 for non-medicines. This suggests that patients are benefiting from improved clarity in the system [Source 5].

Further impact in the Thames Valley

Newdick’s work in Wales has now had further impact in England. In November 2018, Newdick hosted an annual review of priority-setting for the Thames Valley CCG at the University of Reading. The purpose was to reflect on the work in NHS Wales and reconsider Thames Valley CCGs’ expertise on managing IPFRs. As a result, the CCGs’ policy has been changed to amend the decision-making process to one of significant clinical benefit, making exceptionality the outcome rather than the decision-making principle. This underpins “a more comprehensible, transparent and defensible rationale for decision making in respect of individual patients” in the NHS Thames Valley CCG [Source 6]. This impact was a direct result of Newdick’s engagement as a Special Adviser in Health Law to the Thames Valley Priorities Committee (since 2000). The Priorities Committee acts as an advisory body for priority-setting to the four CCGs across the Thames Valley Region (encompassing Berkshire West, Buckinghamshire, East Berkshire and Oxfordshire CCGs, covering a population of over 1.5 million patients). Decisions on resource allocation are based on Newdick’s Ethical Framework [Source 6].

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In summary, Newdick's research on ethical frameworks has informed a significant change in NHS Wales IPFR policy, which was considered as an unfair system lacking in transparency. For those involved in making the requests (clinicians) and receiving funding or not (patients), the change has been profound, with a fairer and more transparent decision-making process. The reach has embraced the whole of Wales, with similar changes also introduced in the Thames Valley CCGs.

5. Sources to corroborate the impact

- [S1] *Independent Review of the Individual Patient Funding Request (IPFR) Process in Wales* (January 2017) (a) the IPFR Review Report and recommendations and (b) response to report from Cabinet Secretary.
- [S2] *NHS Wales Policy-Making Decisions on IPFR* (June 2017) (Explaining the policy position and setting out the changes to be implemented).
- [S3] *Welsh Health Specialised Services Committee: Updated IPRF information* (October 2018) (a) *General guidance on IPFRs*, (b) *IPFR Patient Leaflet*, (c) *Help with Requesting an IPFR Review* (d) *training*.
- [S4] [The new Quality Assurance Advisory Group](#)
- [S5] [Written Statement: Annual Individual Patient Funding Request \(IPFR\) Report, 2018–19 \(Oct. 2019\)](#)
- [S6] Thames Valley Priorities Committee (Testimonial).
- [S7] IPFR User Survey (2020)