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Emerald Article: Social values and health priority setting in England: "values" based decision making

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Social values and health priority setting in England: "values" based decision making

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Abstract

Purpose – The purpose of this paper is to provide an overview of the organisational and procedural arrangements for priority setting in England and Wales. It describes the role of social values in the decision-making process.

Design/methodology/approach – The processes and content of decisions made by the National Institute for Health and Clinical Excellence are analysed using the framework developed by Clark and Weale for identifying social values in health priority-setting.

Findings – While countries are seeking to achieve similar outcomes from their health prioritisation processes, each country has established different systems that reflect the social and legal framework underpinning their health systems. England is somewhat unique in being explicit about assessing "value for money" and using formal cost-effectiveness in developing policy.

Originality/value – Many countries are now considering the use of formal health economic methodologies to assess the value and prioritise health care interventions. However there is increasing recognition of the importance of values other than efficiency (cost effectiveness) in making acceptable decisions. This is manifest in the range of potential new approaches being developed including multiple criteria decision analysis.

Keywords England, Social values, Health care, Health priority setting, Resource allocation

Paper type General review

Introduction

Health technology assessment (HTA) has emerged as one of the ways of addressing the increasing tension faced by all health care systems when they are managing the introduction of new and often costly health technologies with finite healthcare budgets. HTA has been called "the bridge between evidence and policy-making", because it seeks to provide a range of stakeholders (typically those involved in funding, planning, purchasing, commissioning and investing in healthcare) with accessible, useable and evidence-based information that will guide decisions about technology and the efficient allocation of resources. It is a multidisciplinary activity that systematically examines the safety, clinical efficacy and effectiveness, cost-effectiveness, organisational implications, social consequences, legal and ethical considerations of the application of a health technology – usually a drug, medical device or clinical/surgical procedure.

In the UK a national Health Technology Assessment programme was established as part of the new NHS Research and Development initiative (Smith, 1993). In 1999 in order to increase the impact of the resulting reports the National Institute for Health

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and Clinical Excellence (NICE) was established (Littlejohns, 2001). One of the key roles of the institute was to put HTA reports through a process of "appraisal" in order to convert them into formal guidance for the NHS. Not only was guidance issued through its appraisal programme but NICE also established a broader clinical guidelines programme. The remit of NICE expanded in 2005 to include guidance for public health (Littlejohns and Kell, 2006), and in 2010 it established dedicated programmes to identify and promote innovative diagnostics and devices that provide a significant quality and efficiency improvements in patient care. "NHS Evidence", a web-based portal giving access to high quality evidence was also established at that time. The current coalition government has proposed expanding the institute's remit to include social care and using NICE's evaluations of cost-effectiveness to inform "value-based pricing" of pharmaceuticals.

As well as identifying what new inventions should be available on the NHS, NICE also provides guidance on what "low value" treatments" should be withdrawn (Garner and Littlejohns, 2011). In 2006, NICE was formally asked to help the NHS "reduce spending on treatments that do not improve patient care" by supporting disinvestment. NICE has improved the visibility of the disinvestment recommendations from its guidance by creating a database summarising all the published NICE guidance that recommends complete discontinuation or stopping routine use of clinical practices/interventions. The NICE "referral advice" recommendations database seeks to reduce the number of inappropriate referrals from primary to secondary care by collating all the relevant recommendations from NICE clinical guidelines, cancer service guidance and public health guidance. In addition through NHS Evidence NICE has developed a collection of case studies from the field and opportunities from Cochrane reviews that highlight improvements in quality of care and provide potential productivity savings for the NHS's Quality, Innovation, Productivity and Prevention (QIPP) programme (Garner *et al.*, 2012).

More recently NICE's remit has expanded do develop Quality Standards. The programme started in 2009 and aims to provide sets of "specific, concise statements that act as markers of high-quality, cost-effective patient care, covering the treatment and prevention of different diseases and conditions". The Institute intends to develop a library of 150 by 2015 (Sharma *et al.* 2011).

NICE has achieved its reputation in priority setting through the robustness of its technical analyses of clinical and cost effectiveness. However NICE is also aware that judgements of social value are required. (Rawlins and Culyer, 2004). Such values include justice, solidarity, respect for persons and dignity. Indeed, even scientific criteria such as clinical and cost effectiveness presuppose social values in the assessment of the quality of life that an intervention will deliver. Social values are also relevant to the policy processes by which priority-setting decisions are reached, since procedural values affect the perceived sense of legitimacy of decisions. Such procedural values include independence, transparency, inclusiveness, scientific rigour, contestability and timeliness (Faden and Chalkidou, 2011). Value for money in health care means social value for money in health care.

This paper sets out the structures, mechanisms and values of the decision-making process in England and Wales in light of a framework developed for collecting and sharing comparative data on the content and processes of health priority-setting (Clark and Weale, 2012).

Healthcare resource allocation for England and Wales: the contribution of the National Institute for Health and Clinical Excellence (NICE)

What follows is a description of how decisions on health priority setting are made by NICE, using the two overall dimensions of "process" and "content" of decision-making as outlined in Clark and Weale's framework for analysis of social values (ibid.).

Dimension 1: the processes of decision-making

A: the institution setting. The tax-funded National Health Service (NHS) covers the whole of the UK, and offers comprehensive and largely free healthcare at the point of use. However, through the devolved administrations, some of the detail varies between countries. In England The National Institute for Health and Clinical Excellence (NICE) was established in 1999 as a Special Health Authority (an independent organisation) within the NHS, to ensure equal access to medical treatments and to improve quality of care through evidence-based decisions regarding the effective use of NHS resources (Rawlins, 1999). NICE is responsible for providing guidance on the promotion of good health and the prevention and treatment of ill health for England. Some of NICE guidance also covers Scotland and Wales (NICE, 2011a).

Local health communities (including professionals) are expected to take the guidance fully into account when making health care decisions. When the Institute issues appraisal guidance that is supportive of the use of a technology then the local health community is required to make the funding available within three months of the guidance being issued.

NICE has evolved and expanded in response to the changes and demands in the NHS. It has been proposed that NICE will become a Non Departmental Public Body called the National Institute for Health and Care Excellence and cover social care from April 2013 (House of Commons, 2011).

B: rules of decision-making. The Secretary of State for Health sets the direction and the framework for the Institute to operate within. The current directions (Department of Health, 2005) permit NICE to exercise specific functions "in connection with the promotion of clinical excellence and the effective use of available resources in the health service".

NICE is also responsible for advising the Secretary of State regarding possible improvements in the provision of health services and provides information on medicines and prescribing through the National Prescribing Centre (NPC). In addition, NICE through NHS Evidence accredits guidance prepared by other bodies concerning the clinical benefits of health care interventions and good practice in the management of diseases and other conditions affecting health.

NICE is required to give due regard to the following factors in decision making:

- the broad balance of clinical benefits and costs;
- the degree of clinical need of patients with the condition or disease under consideration;
- any guidance issued to the NHS by the Secretary of State that is specifically drawn to the attention of the Institute by the Secretary of State and any guidance issued by the Secretary of State; and
- the potential for long term benefits to the NHS of innovation.

In practice at NICE guidance is developed in consultation with independent committees and experts and is underpinned by the need for transparency, collaboration and involvement of stakeholders. The Board and Senior Management Team set the strategic direction and oversee delivery. They also provide financial stewardship and ensure corporate governance (NICE, 2011b).

C: accountability for decisions. The Secretary of State for Health notifies NICE of all topics for consideration and they are all formally referred through the Department of Health (2005). All technology appraisal guidance and can be appealed on specific grounds (NICE, 2008a). When technology appraisal guidance is taken to Appeal, each appeal is considered by an appeal panel, the members of which are appointed from the Appeal Committee. Appeals must fall within one or more of the three grounds of appeal:

(1) *Ground 1*. The Instute has failed to act fairly.

(2) *Ground 2*. The Institute formulated guidance which cannot reasonably be justified in the light of the evidence submitted.

(3) *Ground 3*. The Institute has exceeded its powers.

If the appeal is valid, then the Appeal Panel will aim to hold an appeal hearing within eight weeks for oral hearings and ten weeks for written submissions (NICE, 2011c). All NICE guidance can also be subject to Judicial review.

D: participation in decision-making. NICE works with experts from the NHS, local authorities and others in the public, private, voluntary and community sectors – as well as patients and carers. The institute makes independent decisions in an open, transparent way, based on the best available evidence and including input from experts and interested parties (NICE, 2011b).

NICE's approach to patient and public involvement is based on two key principles that lay people, and organisations representing their interests, have the opportunity to contribute towards the development of NICE guidance and quality standards, as well as support their implementation and that through this contribution, NICE products are enhanced giving them a greater patient, carer or community focus and relevance (NICE, 2011d).

Dimension 2: the content of decision-making

A. Cost and clinical effectiveness. Consideration of a comprehensive evidence base is fundamental to the development of NICE guidance. It is essential that the evidence and analysis, and their interpretation, are of the highest standard and are transparent.

The evidence considered by the independent advisory bodies group should be:

- relevant to the issue under consideration in terms of relevant population groups, the comparators, perspective, outcomes and resource use as defined in the scope;
- balanced and not selected to support a specific case;
- inclusive of all study design information, such as the type of study, the circumstances of its undertaking and the selection of outcomes and costs; and
- fit for purpose, that is, in contributes to an overall assessment of benefit of the technology, including health-related quality of life and resource use.

The clinical/treatment effect of a technology can be summarised as the difference between the duration and state of health or health-related quality of life (including the impact of any adverse effects of treatment) that would be experienced on average by patients receiving the technology and that experienced by the same group were they to receive alternative (current NHS) care.

For all parameters (including effectiveness, valuation of health related quality of life and costs) a systematic consideration of possible data source is required, and the selection of sources to justify a particular outcome should be avoided (NICE, 2008a).

B. Social value judgements. NICE endeavours to make decisions based on the best available evidence of clinical and cost effectiveness, however, often it often requires judgements because the evidence is not always of good quality or complete. Although each type of NICE guidance is developed following different processes according to the nature of the guidance programme, all these processes share common features based on the key procedural principles – scientific rigour, inclusiveness, transparency, independency, challenge, review, support for implementation and timeliness.

In addition to making scientific judgements NICE advisory committee also, make social value judgements which are related to society rather than science. These are presented in a document signed off by the by NICE Board called "The Social Value Principles" (NICE, 2008b). The second edition contains eight social-value principles formulated with the advice of its lay advisory body, the Citizens Council, the experiences of its guidance advisory bodies and input from ethicists (see Appendix 1). The document "Social values judgements" forms the basis of NICE advice to its advisory bodies on how to apply social-value judgements when making decisions. Both the process and outcomes of appraisals are thus reflective of and receptive to contemporary values and ethical principles held by society. These include an obligation actively to consider health inequalities, such as those associated with age, and an explicit commitment to ensure interventions are only restricted to a particular subgroups (e.g. determined by age) when there is clear evidence about the increased effectiveness of the intervention in this context.

NICE reinforced the relevant social value principles (7 and 8) with an equality scheme in 2007 which fitted well with the UK Equality Act 2010 which added age as a protected (from discrimination) characteristic. Its equality scheme for the period 2010-2013, describes a process that enables it critically to assess the equality impact of its evaluation processes and decisions at key stages in the production of guidance and other products (Stevens *et al.*, 2012).

C. Cost-sharing. Cost-sharing has only a limited relevance to the NHS in England and Wales because of its free-of-charge at the point of health service delivery for eligible individuals in the NHS. However, NHS prescription charge has been gradually increased to £7.40 from its first introduction at the level of one shilling (equivalent to 5 pence) in 1952. There are comprehensive criteria established to protect people with low income and chronic conditions (NHS Choices). In 2008, the Department of Health lifted the ban on top-up fee for chemotherapy among people with cancer who were willing to pay for treatments not approved by NICE for the use in the NHS (Department of Health, 2008). The so called "top-up fee" is a form of co-payment, the first that has been introduced into the NHS since its foundation. Simultaneously, risk-sharing schemes such as patient-access schemes were also implemented in order to improve access to

medicine for people with cancer. See Appendix 2 for an example of the influence of the application of the social value principles to a NICE Technology Appraisal.

Conclusions

Since its inception the NHS in England has provided universal care free to all at point of entry, based on the patient's need for treatment. This value of solidarity remains as strong as ever. However with the number and costs of potential interventions increasingly inexorably there is also a general acceptance that choices have to be made. While the term "rationing" still remains difficult for politicians to articulate considerable effort and public resources are being expended in identifying the value of interventions as determined by their cost effectiveness. NICE has become the focus of this debate and is perceived by key stakeholders such as government, industry, academics, professionals, patients and the public as a successful model to implement evidence based medicine on a routine basis and provide a forum for stakeholders to debate and influence policy. However there remains unease when this approach results in total exclusion of a treatment from use in the NHS and a number of mechanisms have been (and are being) put in place to ameliorate the need for this, e.g. value based pricing.

The UK has been in the vanguard of addressing the challenge of being open and transparent in prioritising health care. This explicit approach to assessing "value for money" is only now beginning to be introduced in other European countries. For example in France Haute Autorité de Santé (HAS) was established in 2004 to evaluate drugs, medical devices and procedures scientifically, to authorise their reimbursement by health insurance, and to promote the use of best practice by health professionals. Economic evaluation was originally excluded from its activities, but new legislation in 2007 allowed its inclusion in the development of guidance and recommendations on the most effective strategies. One contribution to this approach has been the creation of the Economic and Public Health Specialist Committee. This committee comprises of 25 members including economists, social scientists and patient representatives as well as doctors. It gives advice, but final decisions are made by the minister of health. Reconciling science with economics has proved a struggle, because the prevailing view sees the two disciplines as in conflict. HAS has produced a guide to its methods of economic assessment. Its principles include: being transparent about assumptions and methodological choices; being explicit about the level of uncertainty and the robustness of results; justifying departures from standard cases and being explicit about the reasons for such departures; and reconsidering results when more evidence becomes available.

HAS is now trying to make social values more explicit. A recent example was the cost of expensive growth hormone treatment for a number of conditions, including infants who are small relative to gestational age. At present, he cost of treatment is fully covered in France. The benefits of treatment include achieving normal adult height and a better quality of life. But there are uncertainties about the efficacy of treatment, and the possibility of an increased risk of diabetes and cancer. The institutions involved in making the decisions in cases like this are Haute Autorité de Santé (HAS) and the Transparency Committee (the committee that agrees reimbursement for drugs), both accountable to the Ministry of Health which makes the final decision on reimbursement. The Ministry of Health often follows the

recommendations it is given, but does not have to. There is a debate in France over whether the ministry should be able to exercise this power. HAS's main responsibility is to establish the clinical effectiveness of the hormone and its cost, together with various other factors, none of which are explicit and are currently being debated. Social values not only inform the content of the decisions made, but have also influenced the way the process has been set up. For France this is a political rather than a technical decision – which is why the ministry is responsible for taking it. The process is relatively transparent by comparison with other systems in France. There is no public element in consideration of medical efficacy, but the broader assessment can include patients' views. There is also a period in which decisions can be contested. Decisions are informed by a consideration of the clinical benefits and a full cost utility analysis – though the definition of benefit in the case of growth hormones (number of centimetres of extra height) is the subject of disagreement. Is an extra 2 cm of height part of what it means to be a healthy person? And who should decide? There are social values being discussed here, but in the guise of judgements on effectiveness.

Comparison of the French with the English system shows the differences in the way that social values are institutionalised, and this European variation is highlighted further in the paper on the system in Germany by Kieslich (2012) and commented on in the editorial (Littlejohns *et al.*, 2012).

It will be interesting to see how all these European systems develop in the future as the financial crisis in Europe deepens and health care budgets become even tighter. Will there be increasing differences or harmonisation of approaches? Will this new age of austerity herald a more open debate about the "value" of health care or will the political will to be rational about rationing diminish even further. However it is evident whatever happens, that there is an urgent need to undertake empirical research into how different countries are currently applying values in their assessments and to understand if there are better ways of achieving a fair allocation of health resources.

References

Clark, S. and Weale, A. (2012), "Social values in health priority setting: a conceptual framework", *Journal of Health Management and Organisation*, Vol. 26 No. 3, pp. 293-316.

Department of Health (2005), "Directions and Consolidating Directions to the National Institute for Health and Clinical Excellence 2005", available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_4109216 (accessed 5 September 2011).

Department of Health (2008), "Improving access to medicines for NHS patients: a report for the Secretary of State for Health by Professor Mike Richards CBE", available at: www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_089952.pdf

Faden, R.R. and Chalkidou, K. (2011), "Determining the value of drugs – the evolving British experience", *New England Journal of Medicine*, Vol. 364 No. 14, pp. 1289-91.

Garner, S. *et al.* (2012), "Reducing ineffective practice: challenges in identifying low-value healthcare using systematic reviews", *The Journal of Health Services Research and Policy*, in press.

House of Commons (2011), *Health and Social Care Bill 221 2010-2012 (as amended, on re-committal, in public bill committee) Part 8 National Institute for Health and Clinical Excellence*, HMSO, London, July.

Littlejohns, P. (2001), "The relationship between NICE and the national R&D programme", in Baker, R. and Kirk, S. (Eds), *Research and Development for the NHS: Evidence, Evaluation and Effectiveness*, Radcliffe Press, Milton Keynes.

Littlejohns, P. and Kell, M. (2006), "The changing face of NICE: the same but different", *The Lancet*, Vol. 366 No. 9488, pp. 791-4.

Littlejohns, P., Weale, A., Chalkidou, K., Faden, R. and Teerawattananon, Y. (2012), "Social values and health policy: a new international research programme", *Journal of Health Organization and Management*, Vol. 26 No. 3, pp. 285-92.

Garner, S. and Littlejohns, P. (2011), "Disinvestment from low value clinical interventions: NICEly done?", *British Medical Journal*, 343(d4519, available at: www.bmj.com/content/343/bmj.d4519?tab=responses

Kieslich, K. (2012), "Social values and health priority setting in Germany", *Journal of Health Organization and Management*, Vol. 26 No. 3, pp. 372-81.

NICE (2008a), "Guide to the methods of technology appraisal", available at: www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf (accessed 7 September 2011).

NICE (2008b), *Social Value Judgements: Principles for the Development of NICE Guidance*, 2nd ed., National Institute for Health and Clinical Excellence, London, available at: www.nice.org.uk/media/C18/30/SVJ2PUBLICATION2008.pdf (accessed 7 September 2011).

NICE (2010), "Use of tumour necrosis factor alpha (TNF a) inhibitors (adalimumab, and infliximab [review]) for Crohn's disease (review of TA40)", Guidance No. TA187, National Institute for Health and Clinical Excellence, London, available at: http://guidance.nice.org.uk/TA187 (accessed 22 September 2011).

NICE (2011a), "Who we are", National Institute for Health and Clinical Excellence, London, available at: www.nice.org.uk/aboutnice/whoweare/who_we_are.jsp (accessed 5 September 2011).

NICE (2011b), "How we work", National Institute for Health and Clinical Excellence, London, available at: www.nice.org.uk/aboutnice/howwework/how_we_work.jsp (accessed 5 September 2011).

NICE (2011c), "Technology appraisals appeals", National Institute for Health and Clinical Excellence, London, available at: www.nice.org.uk/newsroom/publicmeetings/appeals/TechnologyAppraisalAppeals.jsp (accessed 5 September 2011).

NICE (2011d), "Patient and public involvement policy", National Institute for Health and Clinical Excellence, London, available at: www.nice.org.uk/getinvolved/patientandpublicinvolvement/patientandpublicinvolvementpolicy/patient_and_public_involvement_policy.jsp?domedia=1&mid=5D00F560-19B9-E0B5-D48225F724082ED8 (accessed 5 September 2011).

Rawlins, M. (1999), "In pursuit of quality: the National Institute for Clinical Excellence", *Lancet*, Vol. 353 No. 9158, pp. 1079-82.

Rawlins, M.D. and Culyer, A.J. (2004), "National Institute for Clinical Excellence and its value judgements", *BMJ*, Vol. 329, pp. 224-7.

Sharma, T., Doyle, N., Garner, S., Naidoo, B. and Littlejohns, P. (2011), "NICE supporting England and Wales through times of change", *Eurohealth*, Vol. 17 No. 2, pp. 3-4.

Smith, R. (1993), "Filling the lacuna between research and practice: an interview with Michael Peckham", *British Medical Journal*, Vol. 307 No. 6916, pp. 1403-7.

Stevens, A., Doyle, N., Littlejohns, P. and Doherty, M. (2012), "National Institute for Health and Clinical Excellence appraisal and ageism", *Journal of Medical Ethics*, published online first: 2 January 2012, doi:10.1136/medethics-2011-100129

Further reading

Richards, M. (2008), "Improving access to medicines for NHS patients: a report for the Secretary of State for Health", available at: www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_089952.pdf (accessed 7 September 2011).

UCL (2011), "Social values and health priority setting", UCL research project, University College London, available at: www.ucl.ac.uk/socialvalues/ (accessed 5 September 2011).

Appendix 1. The social value principles

Principle 1

NICE should not recommend an intervention (that is, a treatment, procedure, action or programme) if there is no evidence, or not enough evidence, on which to make a clear decision.

Principle 2

Those developing clinical guidelines, technology appraisals, or public-health guidance must take into account the relative costs and benefits of interventions (their cost-effectiveness) when deciding whether or not to recommend them.

Principle 3

Decisions about whether to recommend interventions should not be based on evidence of their relative costs and benefits alone. NICE must consider other factors when developing its guidance, including the need to distribute health resources in the fairest way within society as a whole.

Principle 4

NICE should explain its reasons when it decides that an intervention with an ICER below £20,000 per QALY gained is not cost effective; and when an intervention with an ICER of more than £20,000 to £30,000 per QALY gained is cost effective.

Principle 5

Although NICE accepts that individual NHS users will expect to receive treatments to which their condition will respond, this should not impose a requirement on NICE's advisory bodies to recommend interventions that are not effective, or are not cost effective enough to provide the best value to users of the NHS as a whole.

Principle 6

NICE should consider and respond to comments it receives about its draft guidance, and make changes where appropriate. But NICE and its advisory bodies must use their own judgement to ensure that what it recommends is cost effective and takes account of the need to distribute health resources in the fairest way within society as a whole.

Principle 7

NICE can recommend that use of an intervention is restricted to a particular group of people within the population (for example, people under or over a certain age, or for women only), but only in certain circumstances. There must be clear evidence about the increased effectiveness of the intervention in this subgroup, or other reasons relating to fairness for society as a whole, or a legal requirement to act in this way.

Principle 8
When choosing guidance topics, developing guidance and supporting those who put its guidance into practice, [NICE] should actively consider reducing health inequalities, such as those associated with sex, age, race, disability, and socioeconomic status

Appendix 2. Social values in practice

Social values in practice: example from Technology Appraisal 187 Crohn's disease – infliximab (review) and adalimumab [review of TA40] (NICE, 2010)

The Advisory Committee considered the clinical and cost-effectiveness evidence for this appraisal and also heard from the clinical and patient experts for this condition.

Both infliximab and adalimumab were licensed for the treatment of severe active Crohn's disease. However the trials included people with moderate to severe Crohn's disease and the results suggested that response to treatment did not differ between moderate and severe disease. There were no direct comparative studies, therefore the relative clinical effectiveness of infliximab and adalimumab could not be directly assessed. Despite several limitations with the evidence on the cost-effectiveness of infliximab and adalimumab, the Committee decided that the collective body of evidence was sufficient to inform their decision. For "*planned courses of treatment, the ICERs for adalimumab were lower than those for infliximab, when both were compared with standard care*". There was sufficient evidence that both "*infliximab and adalimumab appeared to be clinically and cost effective when used continuously for defined periods in people who responded to induction treatment*" but "*there was considerable uncertainty about the clinical and cost effectiveness of both drugs over periods longer than 1 year*".

Through the clinical experts it was established that "*majority of people with Crohn's disease were diagnosed under the age of 30, making this a chronic long-term condition, where the disease and its treatment (in particular corticosteroids) could severely impair growth in children and young people, especially during puberty*". They also considered it "*reasonable to review the need for biological treatment in patients who were in stable remission*". Patient representatives with Crohn's disease highlighted the difficulties of living with the condition, the "*substantial disruptive effects that relapses had on everyday activities and the major impact on quality of life in general*". They also stated that "*effective treatment and avoidance of relapses were of paramount importance*".

The use of infliximab for fistulising disease was considered separately (because of the lack of a long-term standard care cohort study) and on comparison of maintenance treatment with standard care, the ICER was £30,300 per QALY gained. "*Although this ICER was considered to be relatively high, the Committee considered the severity of the disease and noted that there were few treatment options available to these patients*". Therefore the Committee recommended the use of "*infliximab for the treatment of severe active or active fistulising Crohn's disease [. . .] Infliximab should now be given as a planned course of treatment until treatment failure (including the need for surgery) or for 12 months, whichever is shorter. Treatment should then only be continued if there is clear evidence of ongoing active disease. Adalimumab is now also recommended as another treatment option for people with severe active Crohn's disease*".

About the authors

Peter Littlejohns has recently joined King's College London from the National Institute for Health and Clinical Excellence (NICE) where he was the founding Clinical and Public Health Director for 12 years. He holds an MBBS degree from St George's Hospital Medical School and an MD and has a professorial chair at the University of London. Previous posts include Director of the NHS-funded Healthcare Evaluation Unit and Chief Scientist on the EU BIOMED II project, which developed the critical appraisal instrument for clinical guidelines (AGREE). He is a Fellow of the Royal College of Physicians, Fellow of the Royal College of General Practitioners and a Fellow of the Faculty of Public Health. His research interests are directed towards improving the cost

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