UNIVERSITY *of York*

This is a repository copy of *Rights, responsibilities and NICE: a rejoinder to Harris*.

White Rose Research Online URL for this paper:
http://eprints.whiterose.ac.uk/3412/

Article:

Claxton, Karl orcid.org/0000-0003-2002-4694 and Culyer, Anthony J. (2007) Rights, responsibilities and NICE: a rejoinder to Harris. Journal of Medical Ethics. 462. -. ISSN 0306-6800

https://doi.org/10.1136/jme.2006.018903

Reuse

Items deposited in White Rose Research Online are protected by copyright, with all rights reserved unless indicated otherwise. They may be downloaded and/or printed for private study, or other acts as permitted by national copyright laws. The publisher or other rights holders may allow further reproduction and re-use of the full text version. This is indicated by the licence information on the White Rose Research Online record for the item.

Takedown

If you consider content in White Rose Research Online to be in breach of UK law, please notify us by emailing eprints@whiterose.ac.uk including the URL of the record and the reason for the withdrawal request.

White Rose university consortium
Universities of Leeds, Sheffield & York

eprints@whiterose.ac.uk
https://eprints.whiterose.ac.uk/

promoting access to White Rose research papers

Universities of Leeds, Sheffield and York
http://eprints.whiterose.ac.uk/

This is an author produced version of a paper to be/subsequently published in **Journal of Medical Ethics**. (This paper has been peer-reviewed but does not include final publisher proof-corrections or journal pagination.)

White Rose Research Online URL for this paper:
http://eprints.whiterose.ac.uk/3412

Published paper
Claxton, K. and Culyer, A. J. (2007) Rights, responsibilities and NICE: a rejoinder to Harris. Journal of Medical Ethics, 33 (8). Art. No. 462.

White Rose Research Online
eprints@whiterose.ac.uk

Rights, responsibilities and NICE: a rejoinder to Harris

K Claxton, A J Culyer

Corresponding author: A J Culyer, Institute for Work & Health, Toronto, Ontario, M5G 2E9, Canada,

aculyer@iwh.on.ca

Tel: ++ 416 927-2027 Ext 2118

Fax: ++416 927-4167

Karl Claxton
Centre for Health Economics
University of York
Heslington
York
YO10 5DD
UK

Anthony Culyer
Institute for Work & Health
481 University Avenue
Toronto
Ontario
M5G 2E9
Canada

Key words: cost-effectiveness, Harris, NICE (National Institute for Health and Clinical Excellence), QALY

Word count: 2,013 (excluding abstract and references)

Abstract

Harris' reply to our defence of NICE's current cost-effectiveness procedures contains two further errors. First, he wrongly draws from the fact that NICE does not and cannot evaluate all possible uses of health care resources at any one time and generally cannot know which NHS activities will be displaced or which groups of patients will have to forgo health benefits the inference that no estimate is or can be made by NICE of the benefits to be forgone. This is a non sequitur. Second, he asserts that it is a flaw at the heart of the use of QALYs as an outcome measure that comparisons between people need to be made. Such comparisons do indeed have to be made but this is not a consequence of the choice of any particular outcome measure, whether the QALY or anything else.

Rights, responsibilities and NICE: a rejoinder to Harris

K Claxton, A J Culyer

We are heartened that Harris accepts our characterisation of the allocation problem in health care, whether the good of health is defined as health gain (measures by QALYs or other metric) or some other, as yet to be clearly defined, rights based measure. [1] The disagreement now only turns on two issues: one we believe to be an epistemological misunderstanding the other a more substantive and widely debated issue about the measure of the good of health care.

1. Absurdly abusive

Firstly, we have no comment make on the balance of corporate vs personal abuse within these recent exchanges. Our own view is that those responsible for corporate policy are also morally accountable for and personally answerable to criticisms and moral condemnation of such policies. Others may differ. We are content for readers of the exchange to come to their own view of the absurdity of our interpretation of the previous editorials and the distinctions offered - with or without the assistance of the Oxford English Dictionary. We also leave readers to judge whether NICE's attempts to follow their consciences and the instructions of the Secretary of State by having regard to citizens' values are fairly described as "populist".

2. Cost-effectiveness

Of more substance is the apparent confusion about how decisions of cost-effectiveness can be made in a health care system like the NHS. Harris suggests that our paper implies that, "no estimate is or can be made by NICE of the benefits to be forgone", and therefore, "NICE, in the expert opinion of Claxton and Culyer, cannot and is not making its decisions on the basis of cost-effectiveness."[1]

To support this Harris quotes and is referring to the following passage by us, "NICE does not and cannot evaluate all possible uses of health care resources at any one time and generally cannot know which NHS activities will be displaced or which groups of patients will have to forgo health benefits. Harris is certainly correct about this. But what may be inferred from this? Again it is not clear what he is arguing."[2] Our question was somewhat rhetorical. We continued, "The two obvious possibilities are:

- there will be no real costs because other activities will not be displaced and health benefits will not be forgone
- because the individuals bearing the cost are unidentified and unknown these health or lost opportunities to benefit are less important or of no consequence compared to the groups of patents under consideration who may benefit from treatment."[2]

Our point was that neither NICE nor any other decision making entity, including a practising physician at the bed side, can know precisely which NHS activities will be displaced by their guidance or prescribing decisions nor exactly who will forgo which specific health benefits. However, we do know there will be health forgone to real, albeit unidentified, patients and we maintain the value judgement that the

consequences for those unidentified individuals ought to be valued in the same way as the consequences for others who gain from the technology under consideration (or who are in the bed) and who are currently identified and known.

Harris seems to have taken the obvious fact that no institution or individual can know at any one point in time *precisely* who will forgo a health benefit to imply that we have no way of assessing whether “the health benefits that it is *estimated* could be gained from the technology are less than those *estimated* to be forgone by other patients.”[1, 2]

Such an estimate requires some knowledge of the health gained by some of the least productive (in health outcome terms) of the activities currently undertaken by the NHS. Therefore, to say we know nothing and have no estimate of the health forgone is to say we have no knowledge of the productivity of any NHS activities. This is absurd. NICE itself has generated substantial evidence of the cost-effectiveness of interventions currently undertaken (and not undertaken) within the NHS. There also a much wider body of evidence which can easily be accessed (e.g., the NHS Economic Evaluation Database). In addition NICE engages in a broad consultation process with all stakeholders, including the nation’s foremost clinical generalists, experts in the management of the diseases and treatments under examination, and the general public, to identify technologies for both investment and disinvestment. The proposals obtained through the consultation process are reviewed by two expert committees; the Advisory Committee on Topic Selection (ACTS) and the Joint Planning Group who bring their broad knowledge of the efficiency of a wide range of NHS interventions to the consideration of which therapies to put forward for review.

This approach usually embodies the seemingly reasonable assumption that, where NICE has not identified a concurrent disinvestment, local decision makers in the NHS will in general curtail activities which provide less rather than more health gain. If in general they do not and, for example, displace activities at random, then the forgone health will be even higher than when only the least productive activities are carefully identified and displaced. In these circumstances the estimate of the health forgone should be *higher* (reflecting the average rather than marginal productivity of health care) making it much *less* likely that interventions such as the drugs for Alzheimer’s disease or multiple cycles of IVF can be regarded as cost-effective. [3]

There is a substantial literature addressing how these decisions can be made in these common circumstances including the NICE methods guidance itself.[4, 5] Our mistake was to take this literature as read, which hardly amounts to a “fatal flaw”.

There is an important debate and a body of literature about how decision makers within a health care system can improve decision making at a national and local level when they are uncertain about the gains from technologies and the forgone health benefit elsewhere.[5] Harris may have intended to point out that greater precision than that provided by current estimates would be valuable. He may also believe that the central estimate of what will be displaced may be incorrect. If so, we agree on both counts: generating information to inform the Institute (or other decision making entities) whether the guidance issued might displace more health than it generates (or vs versa) is obviously very important. At present, given the funding for the NHS and the difficulties faced by local commissioners and clinical governance managers, the

estimates of forgone health may be too low. So far as we are aware, no informed commentator is suggesting it is too high. However, if this is his concern then, by all accounts, the provisional guidance to withhold treatment for Alzheimer's disease (a decision to which Harris objected and the origin of these exchanges) would have been more rather than less secure.

We find it hard to believe that that Harris really holds that it is impossible to *estimate* what may be forgone within the health care system on the grounds that one cannot be precise about identities or quantities. We therefore conclude that his objection is based on a misunderstanding and are content to let readers judge whether there is a "fatal flaw" in our argument or - much more importantly - in the methods used by NICE to make its inevitably difficult decisions about health care priorities in an explicit and transparent way.

3. The good of health care

Harris' imaginary example of the twin sisters raises again two matters that are inherent in nearly all resource allocation decisions and have been the subject to a large and venerable literature.[6] The first is that there are insufficient health care resources to permit all who may have Mars Jones' "unfinished business" to be able to conclude it. This may mean that *neither* of the twins may receive care from which it is conceivable they may benefit or that *both* may, or that *only one* may. Harris refuses to take responsibility for the unavoidable choice he has posed, "it is unethical to choose between them…there is no rational basis for so doing".[1] Abdication of responsibility for this decision does not mean it will not be made; instead both, neither or one will ultimately receive care based on some opaque and possibly arbitrary process and the cost in terms of lost lives (long or short) will be ignored.

The other matter is the question of which, if only one can receive care, ought to have it. This is a question of interpersonal comparisons that the QALY methodology has starkly raised. It is not a "flaw at the heart of the QALYs"[1][1] that comparisons between people need to be made. The question of how best to make interpersonal comparisons is not one that is in any way specific to QALYs; it arises in virtually all comparisons of future health, whether measured by QALYs or in some other way including the sorts of measure preferred by Harris that are invariant with respect to life expectation. We count it as a virtue of the QALY method that it highlights the question and has enabled its extensive discussion in the QALY-related literature to which we referred in our previous comment - which has many more dimensions to it than that the potential "ageism" to which Harris attaches such signal importance. God has not granted the hours but he may be said to have granted society the right to make choices and the duty of taking responsibility for them. Although exercising these choices implicitly and opaquely might provide some comfort to decision makers and commentators it will serve neither accountability nor democracy – nor, we conjecture, social justice.

It seems to us that the best way of handling such questions, once they have been identified and whatever evidence concerning them gathered and assessed, is by a deliberative process, despite the risk of being charged with "populism". This is what NICE has done in response to the requirements of the Secretary of State. On some

such matters it has consulted its Citizens' Council. Indeed NICE has recently consulted the Citizens Council on precisely the issues raised by Harris in his two examples.[7]

The Citizens' Council Report on the Rule of Rescue makes interesting reading.[7] They found precise and explicit definitions almost impossible and the trade-offs between 'immediate risk' and health gain to others even more difficult. All members rejected a clearly defined rule of rescue (an imperative to save life) and focused instead on the circumstances when exceptions to decisions based on health gain could be made. A minority of the Council rejected any exceptions based on rescue; a majority suggested that concerns for rescue should not be completely rejected but should only be applied in exceptional circumstances. These circumstances include a "good probability of increased life expectancy" and "a significant improvement in quality of life". However, the council was unable to define, "good probability", "increased life expectancy" or "significant improvement in quality". All agreed that any exceptions based on rescue should consider the opportunity costs (forgone health to others) but were unable to specify the trade off that should be made. One reason why the Citizens' Council found it so difficult to provide precise and explicit answers to these questions is that they took their duty to explore fully the implications of holding particular views seriously.

4. Rights and responsibilities

All society ought to have the right to comment on the processes, deliberations and recommendations made by NICE on behalf of the NHS but those who exercise that right, and whose wish is to engage and inform the decision makers, commonly take responsibility for fully exploring the implications - for the whole of society - of the positions they hold. However, commentators who choose to abdicate this responsibility face no such discipline. Their reward is the freedom of the nihilist, who has no duty to offer alternative solutions let alone any that are precise, explicit, or fully explored. The defence of academic freedom, sometimes combined with pedantry, is always available to those who choose such a course – and it should be recognised for what it is.

Competing interests

Claxton is a member of NICE's Appraisals Committee and was a member of the working party which recommended NICE's current methodology for the conduct of economic appraisals; Culyer was a member of the NICE Board which commissioned and accepted this work and, though no longer on the Board, remains a member of NICE's Research and Development Committee.

References

1. Harris J. Nice is not cost-effective. Journal of Medical Ethics, 2006; 32: 378-380.

2. Claxton K, Culyer AJ. Wickedness or folly? the ethics of NICE's decisions. Journal of Medical Ethics, 2006; 32: 373-377.

3. Harris J. It's not NICE to discriminate. Journal of Medical Ethics, 2005; 31: 373-375.

4. National Institute for Health and Clinical Excellence. *Guide to the Methods of Technology Appraisal*. NICE: London, 2003.

5. Culyer AJ, McCabe CJ, Briggs A, Claxton K, Buxton M, Akehurst R, Sculpher MJ and Brazier J. Searching for a threshold, not setting one: the role of the National Institute of Health and Clinical Excellence. Forthcoming 2007 Journal of Health Services Research and Policy.

6.Jonsen AR. Bentham in a box: Technology Assessment and Health care allocation. Law Medicine and Health Care; 1986;14:172-174

7. National Institute for Health and Clinical Excellence. *Citizens Council Report: the Rule of Rescue*. NICE: London, 2006.