Challenges for the new Cancer Drugs Fund

NHS England has just completed its consultation on the future of the Cancer Drugs Fund in England.[1] The proposal is to transform the Cancer Drugs Fund into a managed access fund for new cancer drugs that NHS England will run in collaboration with the National Institute for Health and Care Excellence (NICE). Under the proposed scheme, NICE would assess all new cancer drugs and make one of three recommendations: (1) the given drug should be made available through routine commissioning processes; (2) the given drug should not be made available; or (3) the given drug should be made available through the Cancer Drugs Fund for a pre-determined period during which additional evidence would be collected. This third recommendation is based on a judgment that the evidence to support or reject a recommendation for routine commissioning is insufficient at that time. NICE would then wait for additional evidence and do a short re-appraisal. At this point, NICE would either recommend the drug for routine commissioning or move it out of the Cancer Drug Fund, so that it would be available only on the basis of individual funding requests.[1]

This is a sensible response to the politically charged and increasingly financially unsustainable situation that the Fund has been in since its inception in 2010. However, it remains to be seen whether this response addresses the original problem that the Cancer Drugs Fund was established to rectify—namely, that NICE was rejecting new cancer drugs because their price did not reflect their value to patients and the NHS.

The consultation document addresses an aspect of NICE methodology that has been elusive during the 17 years of the Institute's existence. When (the original) NICE was established in 1999, its statutory instruments allowed it to offer the NHS one of three types of funding recommendation: (1) "yes", for routine use in the NHS; (2) "no", not for routine use; or (3) "only available as part of a research project".[2] The difficulty was that, in practice, "only in research" became a soft "no" because there were no systems or incentives to ensure that necessary research would be done, and the only in research option was rarely used.[3] The consultation document addresses these weaknesses by making the "only in research" decision a soft "yes". New cancer drugs would provisionally be funded by the Cancer Drug Fund, provided that companies agree to fund the collection of a pre-determined dataset that enables NICE to assess the drugs' effectiveness and cost-effectiveness within 24 months, and drug prices are affordable within the available Cancer Drugs Fund budget.[1] Effectively, this constitutes a temporary public–private partnership for research.

Despite this promising step, much needs to be done to achieve the Fund's aim of making the majority of new cancer drugs available at a price that reflects their value to patients and the NHS. Achieving this goal will require from all involved parties political maturity and adherence to NICE's methodological rigour and the core values of the NHS.[4] While observers were concerned that the creation of the Cancer Drugs Fund would undermine NICE's standing, the Institute's emergence as a key player in salvaging the Fund represents adroit political and organisational footwork. However, setting up the new Cancer Drugs Fund framework will mean adapting to significant changes to the way the Institute usually functions.

First, recommendations will not be signed off through the usual NICE processes, but agreed by a joint NICE–NHS England committee. The so-called Cancer Drugs Fund Investment Group will receive and make decisions on recommendations from NICE Appraisal Committees for drugs to enter the Cancer Drug Fund; determine the managed access agreement in each case; and monitor the use of the Fund to keep it within budget. It remains to be seen how the final criteria for sign-off will differ from NICE's social values framework which, among other things, does not give precedence to any particular condition per se.[5] Working with NHS England could be a welcome opportunity for NICE because, for the first time, the Institute's assessments would need to take into account the effect on budgets in an NHS in an unprecedented financial crisis. However, the consultation jargon suggests that NHS England might primarily see the Cancer Drugs Fund Investment Group as a way of promoting industry interests within the NHS, potentially weakening other important values for setting priorities in health care.

Second, there are several new initiatives in Europe exploring ways to more quickly access novel drugs, but these appear not to be fully integrated with the

Science Photo Library

Lancet Oncol 2016

Published Online
March 3, 2016
http://dx.doi.org/10.1016/S1470-2045(16)00100-5

Cancer Drugs Fund proposals. NICE already contributes to these initiatives: it will be important to use its enhanced role as a leader in health technology appraisal and priority-setting to ensure that adaptive licensing schemes are developed consistently with the ethical and social values underpinning the NHS.[4]

Third, NICE has to take full responsibility for the specification and design of the processes for data collection itself. Previously, when the Institute left it to others to organise data collection to assess drugs for multiple sclerosis, the result was a costly and embarrassing disaster.[6] Much work is being done on how to gain and interpret rapid, real-life data, and the NHS could become a world leader in this field. NICE has the academic and service links—including the Academic Health Sciences Centres and Networks and the National Institute for Health Research Collaborations for Leadership in Health and Care Research—to make this happen, as it has done by stimulating new methods in health economic analysis. At the same time, caution is required. The proposed model of managed access is not new, but a variant of "only in research" or "coverage with evidence development",[2,7] which has been explored internationally for many years. These models have proved challenging to implement because of difficulties in agreeing study designs and identifying responsibility for financing data collection, as well as practical obstacles to initiating and completing studies in complex health service environments. Some of these challenges seem to be addressed by the new proposals, but the requirement to gain meaningful new data within the proposed 24-month period may be unrealistic.

For NHS England, politicians, and ultimately the public, the main challenge will be the need to accept the inevitable rejections that will emerge from the new Cancer Drugs Fund. rejections are to be expected because evidence suggests the Cancer Drugs Fund did not speed up the process of adopting drugs that NICE positively assessed.[8] Moreover, the proposed criteria for drugs entering the Cancer Drugs Fund are similar to those that NICE uses in its appraisal process. So the only way that the "no" judgements can be avoided in the future is if the new process enables the NHS to negotiate more freely on price than they have in the past. If not, then the Cancer Drugs Fund will merely give cancer drugs a 2-year window of opportunity at the expense of the NHS. Moreover, there is a risk that decisions to discontinue the funding of unsuccessful drugs will be met with lobbying and legal challenge, and these drugs will be kept within the Cancer Drugs Fund for far longer than intended.

Finally, the Cancer Drugs Fund poses the well-recognised ethical challenge that it is exclusive to the needs of cancer patients: there is no Autism or Dementia Drugs Fund, for example. The point is not that we should not make an exception for cancer drugs when we allocate resources to different population groups, but that at present no robust justification has been given for why cancer should be given priority over other diseases—or, indeed, why cancer drugs ought to be prioritised over other treatments within oncology. For example, national coverage of the new cost-effective intensity modulated radiotherapy[9] has increased from 10% to 35% in the past 3 years after an additional investment of £23 million. It would have only taken a small proportion of the £968 million spent by the Cancer Drugs Fund on cost-ineffective interventions to have achieved equal access to this treatment for all.[10]

In the absence of a sound basis for treating cancer drugs differently from other treatments, justice—and the NHS Constitution[4]—demands that we treat them alike. If the proposed managed access scheme is successful, therefore, it should serve as a model for managing uncertainty around the effectiveness and cost-effectiveness for all new health technologies, both within oncology and in other diseases.

*Peter Littlejohns, Albert Weale, Katharina Kieslich, James Wilson, Benedict Rumbold, Catherine Max, *Annette Rid*
Department of Primary Care and Public Health Sciences (PL, KK), Department of Social Science, Health & Medicine (AR), King's College London, London WC2R 2LS, UK; Department of Political Sciences (AW), Department of Philosophy (JW, BR), University College London; and Catherine Max Consulting, London, UK (CM)
annette.rid@kcl.ac.uk

We are part of the Social Values and Health Priority-Setting Group (http://www.ucl.ac.uk/socialvalues) and are grateful to its members for stimulating discussions. Many thanks to Sir Iain Chalmers, Prof Kalipso Chalkidou, and Prof Steven Pearson for helpful comments on an earlier version of this paper. PL and KK are supported by the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care South London at King's College Hospital NHS Foundation Trust. The views expressed are those of the authors and not necessarily those of the NHS, the National Institute for Health Research, or the Department of Health. PL was the founding Clinical and Public Health Director of the National Institute of Health and Care Excellence (NICE) from 1999 to 2011. In this role, he designed the process and methods for the development of NICE guidelines and was the executive director responsible for the Citizens Council and the R&D programme. In a personal

capacity, CM was appointed (December 2015) Lay Chair of NHS England's new Specialised Commissioning Individual Funding Requests Panel. In a consultancy capacity (in 2014), she supported NICE's work with the Citizen's Council to inform the review of their Social Value Judgements. AR, JW, BR, KK, and AW declare no competing interests.

1 NHS England, Cancer Drugs Fund Consultation, November 2015: https://www.engage.england.nhs.uk/consultation/cdf-consultation (accessed Feb 1, 2016).

2 Littlejohns P, Barnett D, Longson C; UK National Institute for Clinical Excellence. The cancer technology appraisal programme of the UK's National Institute for Clinical Excellence. *Lancet Oncol* 2003; **4:** 242–50.

3 Chalkidou K, Lord J, Fischer A, Littlejohns P. Evidence-based decision making: when should we wait for more information? *Health Aff* 2008; **27:** 1642–53.

4 NHS. The NHS Constitution for England, 26 March 2013. http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/2013/the-nhs-constitution-for-england-2013.pdf (accessed Feb 1, 2016).

5 Rid A, Littlejohns P, Wilson J, Rumbold B, Kieslich K, Weale A. The importance of being NICE. *J R Soc Med* 2015; **108:** 385–89.

6 McCabe C, Chilcott J, Claxton K, et al. Continuing the multiple sclerosis risk sharing scheme is unjustified. *BMJ* 2010; **340:** c1786.

7 Tunis SR, Pearson SD. Coverage options for promising technologies: Medicare's 'coverage with evidence development'. *Health Aff* 2006; **25:** 1218–30.

8 Chamberlain C, Collin SM, Stephens P, Donovan J, Bahl A, Hollingworth W. Does the Cancer Drugs Fund lead to a faster uptake of cost-effective drugs? *Br J Cancer* 2014; **111:** 1693–702.

9 Yong JH, Beca J, O'Sullivan B, et al. Cost-effectiveness of intensity-modulated radiotherapy in oropharyngeal cancer. *Clin Oncol (R Coll Radiol)* 2012; **24:** 532–58.

10 NHS England. Improving Outcomes: A Strategy for Cancer, Fourth Annual Report, December 2014: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/388160/fourth_annual_report.pdf (accessed Feb 1, 2016).