

## Scientific, policy and ethical challenges for the Cancer Drugs Fund

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NHS England has just completed its consultation on the future of the Cancer Drugs Fund (CDF) in England.<sup>1</sup> It is proposed that, from 1<sup>st</sup> April 2016, the CDF should become a ‘managed access’ fund for new cancer drugs, with clear entry and exit criteria. The National Institute for Health and Care Excellence (NICE) is to assess all new cancer drugs, with 3 potential outcomes: (i) that a drug should be made available through routine commissioning processes within the NHS in England; (ii) that the drug should not be made available; and (iii) that there is insufficient evidence to support or reject a recommendation for routine commissioning. Drugs falling in the third category would be given a conditional recommendation by NICE and their use enabled by the CDF for a pre-determined period while additional evidence is collected. After a short NICE appraisal using this additional information, the drug would attract either a NICE positive recommendation, at which point it would move out of the CDF into routine commissioning, or a NICE negative recommendation, at which point it would move out of the CDF and become available only on the basis of individual funding requests.<sup>1</sup>

This is a sensible response to the politically charged and increasingly financially unsustainable “solution” that the CDF has become since its inception in 2010. However, it remains to be seen whether this response addresses the original “problem” that the CDF was established to rectify, namely, that NICE was saying ‘no’ to new cancer drugs because their price does 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: (i) ‘yes’, for routine use in the NHS; (ii) ‘no’, not for routine use; or (iii) ‘only available as part of a research project’ (OIR, for ‘only in research’).<sup>2</sup> The difficulty was

that, in practice, OIR became a soft ‘no’ because there were no systems or incentives to ensure that necessary research would be done, and the OIR option was rarely used.<sup>3</sup> The consultation document addresses these weaknesses by making the OIR decision a soft ‘yes’. New cancer drugs would provisionally be funded by the CDF, provided that companies agree to fund the collection of a pre-determined dataset that allows NICE to assess the drugs’ effectiveness and cost-effectiveness within 24 months, and drug prices are affordable within the available CDF budget.<sup>1</sup> Effectively, this constitutes a temporary public-private partnership for research.

### **Challenges for NICE**

Despite this promising step forward, much needs to be done to achieve the CDF’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 stakeholders political maturity and adherence to NICE’s methodological rigour and the core values of the NHS.<sup>4</sup> While observers were concerned that the creation of the CDF would undermine NICE’s standing,<sup>5</sup> the Institute’s emergence as a key player in salvaging the CDF represents adroit political and organisational footwork. However, working with setting up the new CDF 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 CDF Investment Group will receive and make decisions on recommendations from NICE Appraisal Committees for drugs to enter the CDF; determine the managed access agreement in each case; and monitor the use of the CDF 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*.<sup>5</sup> 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 budget impact on an NHS in unprecedented financial crisis.

However, the consultation jargon suggests that NHS England may primarily see the CDF Investment Group as a way of promoting industry interests within the NHS, potentially weakening other important values for priority-setting in healthcare.

Second, there are a number of new initiatives in Europe exploring ways to achieve quicker access to novel drugs,<sup>6</sup> but these appear not to be fully integrated with the CDF 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 being developed consistent with the ethical and social values underpinning the NHS.<sup>4</sup>

Third and most importantly, 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.<sup>7</sup> There is an emerging literature 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 thinking, but a variant of "only in research" or "coverage with evidence development"<sup>2, 8</sup> that has been explored internationally for many years. These models have proved challenging to implement because of difficulties in agreeing relevant study designs

and identifying responsibility for financing data collection, as well as practical obstacles to initiating and completing studies in today's complex health service environment. Some of this appears to be addressed by the new proposals, but the requirement to gain meaningful new data within the proposed 24-month period may be unrealistic.

### **Challenges for policy-makers and the public**

For NHS England, politicians, and ultimately the public, the main challenge will be the need to accept the inevitable 'nos' that will emerge from the new CDF. 'Nos' are to be expected because evidence suggests the CDF did not speed up the process of adopting drugs that NICE positively assessed.<sup>9</sup> Moreover, the proposed criteria for drugs entering the CDF are similar to those that NICE currently uses in its appraisal process. So the only way that the 'no' judgements can be avoided in the future is if the new process allows the NHS to negotiate more freely on price than they have in the past. If not then the CDF will merely give cancer drugs a 2-year window of opportunity at the expense of the NHS. Moreover, there is a real 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 CDF for far longer than intended.

### **Ethical Challenges**

The CDF poses the well-recognised ethical challenge that it is partial to the needs of cancer patients: there is no Autism or Dementia Drugs Fund, for example. To be clear, the point here 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

newer cost-effective Intensity Modulated Radiotherapy<sup>10</sup> has increased from 10% to 35% in the last 3 years after an additional investment of £23 million. It would have only taken a small proportion of the £968m spent by the CDF on cost-ineffective interventions to have achieved equal access to this treatment to all.<sup>11</sup>

In absence of a sound basis for treating cancer drugs differently from other treatments, justice—and the NHS Constitution<sup>4</sup>—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 disease areas.

### **Authors’ contributions**

PL conceived the idea for the paper based prior discussions with the other authors and wrote the first draft. AW, KK, JW, BR, CM and AR revised the paper critically for important intellectual content. All authors approved of the final version and agree to be accountable for all aspects of the work.

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## **Conflicts of interest**

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 report that they have no financial and personal relationships with other people or organisations that could inappropriately influence (bias) their work.

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