

Royal College of Nursing response to NHS England and NICE consultation on Proposals for a New Cancer Drugs Fund (CDF) Operating model from 1st April 2016

Introduction

With a membership of around 430,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. RCN members work in a variety of hospital and community settings in the NHS and the independent sector. The RCN promotes patient and nursing interests on a wide range of issues by working closely with the Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations.

Background

This consultation seeks views on the planning and consideration and future sustainability of the Cancer Drugs Fund (CDF) and the proposal for a new operating model of a new fund which is aligned with adapted NICE processes. The proposal is that the fund should become a “managed access” fund with criteria for entry and exit, including a provision for some drugs to be given “conditional approval” by NICE before all the evidence is collected to enable a final appraisal decision.

The RCN welcomes the opportunity to feed-in to this consultation, RCN members have a vital role in shaping cancer services and treatment, nurses provide expert clinical care and continuity from first diagnosis, and have a unique understanding of the whole patient pathway.

General comments

Many people’s lives are touched by cancer and the RCN welcomes the significant progress that has been made in improving cancer services in recent years and welcomes the government’s overall commitment to improving outcomes for cancer patients.

The RCN has previously called for a greater role of NICE in the Cancer Drugs Fund approval process and for greater transparency in how the Cancer Drugs Fund is accessed and how the money is spent. NICE is a widely respected organisation with a global reputation, NICE methodology has been developed over time to respond to the needs of society and ensuring access to new and innovative treatments and on the whole has successfully balanced this with public expectations for the NHS. Aligning the Cancer Drug’s Fund (CDF) with NICE appraisal processes presents an opportunity to collect the much needed data to help with future appraisals of drugs, particularly for rare cancers. Despite this strengthened role of NICE, the RCN is concerned that by maintaining NHS England as the governing body of the Cancer

Drugs Fund with NICE approval process, this offers only a partial solution that may lead to confusion for patients and public. It is vital that the new system does not cause delays for patients and their families.

The RCN continues to have concerns that the Cancer Drugs Fund results in public perception that individuals can automatically access any cancer drug that is licensed in the UK and available on the market. Health professionals, including nurses can potentially be placed under pressure from patients demanding treatment options that are not currently provided by the NHS or that may not be clinically effective in individual cases. Health professionals will often experience difficulties in explaining to a patient that they do not qualify for a drug available through a clinical trial as it is not fully available.

There is a continued need for further transparency in terms of how the Cancer Drugs Fund is accessed and where the money is spent and support to health professionals including specialist cancer nurses, to ensure that the fund will enable them to access drugs that are appropriate for their patients, without burdening them with rationing decisions and undermining patient relationships. Patients and their families ultimately want to survive a cancer diagnosis, and building knowledge of new and emerging drugs can be an important coping strategy for patients. Nurses and health professionals need clarity about how the new fund will operate so they can provide clear and consistent information to those they care for with cancer.

The RCN recognises that the NHS is constrained in terms of what it can provide based on resources available and hence difficult decisions must be made on funding. The way in which this tension is managed must be debated more widely. The RCN remains concerned that the Cancer Drugs Fund may not be an effective use of NHS resources. A cancer diagnosis is a life changing event and all kinds of support are needed and it is important to invest in wider support services including ensuring investment in the wider nursing workforce. Since the Fund's initiation in 2011, the numbers of specialist nurses have declined dramatically¹. Specialist cancer nurses answer clinical questions for patients and families, carry out procedures and advise on drugs. Specialist cancer nurses also provide emotional support, continuity of care and a presence at the end of the phone.

Investing in specialist cancer nurses now is crucial not just to patients but to reduce the costs to the NHS from unnecessary complications. They also deliver savings by enabling patients to be treated at home rather than in hospital.

Responses to specific questions

This response will now address selected consultation questions of relevance to the RCN.

1. Do you agree with the proposal that the CDF should become a 'managed access' fund for new cancer drugs, with clear entry and exit criteria?

¹ RCN (2014) *Frontline First: More Than Just a Number* <http://frontlinefirst.rcn.org.uk/>

The RCN agrees in principle with the proposal that the CDF becomes a 'managed access fund' but that there is a need for clear and transparent national criteria on which to base decisions. The role of NICE is critical to ensure processes are based on clear evidence.

2. Do you agree with the proposal that all new cancer drugs and significant new licensed cancer indications will be referred to NICE for appraisal?

Yes, the role of NICE is critical but the RCN is concerned that under the proposed changes there is a potential to create a two-tier system with an assessment process that almost duplicates NICE's own technology appraisal process. The RCN questions the rationale for establishing it outside the existing NICE appraisal process. The RCN believes that there is a need for a strong overall centralised process led and managed by NICE.

3. Do you agree with the proposal that the NICE Technology Appraisal Process, appropriately modified, will be used to evaluate all new licensed cancer drugs and significant licence extensions for existing drugs?

The RCN agrees in principle but there is a need for regular review and assessment

4. Do you agree with the proposal that a new category of NICE recommendations for cancer drugs is introduced, meaning that the outcome of the NICE Technology Appraisal Committee's evaluation would be a set of recommendations falling into one of the following three categories:

- i. Recommended for routine use;
- ii. Recommended for use within the Cancer Drugs Fund;
- iii. Not recommended.

The RCN has previously expressed concerns about the role of the Cancer Drugs Fund and some of our concerns remain. The new arrangements appear complex and could result in variation in decision making and could also result in confusion for individuals navigating the system. The RCN has reservations that an initial decision could be made and then overturned later causing significant distress and confusion for patients and families.

5. Do you agree with the proposal that "*patient population of 7000 or less within the accumulated population of patients described in the marketing authorisation*" be removed from the criteria for the higher cost effectiveness threshold to apply?

This needs to be fully risk assessed and the RCN would want to see further evidence on the implications of this for patients.

6. Do you agree with the proposal for draft NICE cancer drug guidance to be published before a drug receives its marketing authorisation?

The RCN believes that all drugs should go through the full NICE assessment process. The proposal for NICE to issue its recommendations before marketing authorisation of the drugs is at odds with the current appraisal process.

8. Do you agree with the proposal that all drugs that receive a draft NICE recommendation for routine use, or for conditional use within the CDF, receive interim funding from the point of marketing authorisation until the final appraisal decision, normally within 90 days of marketing authorisation?

Drugs should go through the full NICE authorisation process. There is a danger of a conditional recommendation being overturned and then causing distress, a clear and straightforward process for patients should be paramount.

9. What are your views on the alternative scenario set out at paragraph 38, to provide interim funding for drugs from the point of marketing authorisation if a NICE draft recommendation has not yet been produced, given that this would imply lower funding for other drugs in the CDF that have actually been assessed by NICE as worthwhile for CDF funding?

The RCN believes that all drugs should be taken through the full NICE assessment process.

12. Do you consider that the investment control arrangements suggested are appropriate for achieving transparency, equity of access, fair treatment for manufacturers and operational effectiveness, while also containing the budget? Are there any alternative mechanisms which you consider would be more effective in achieving those aims?

The RCN notes the comments provided by the National Audit Office² that increased pressures meant that the Cancer Drugs Fund was no longer sustainable in current form, we note that there is an existing cap on the fund, but this will inevitably be exceeded despite the investment control arrangements and will lead to frustration for individuals seeking to access treatment.

14. Do you agree that, on balance, the new CDF arrangements are preferable to existing arrangements, given the current pressures the CDF is facing?

The RCN welcomes the greater involvement of NICE but believes that the proposed new arrangements have the potential to cause even greater complexity and confusion. It is crucial that a full impact assessment of the new operating model is conducted throughout the process including intended and unintended consequences of the change.

**Policy and International Department
Royal College of Nursing
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² Public Finance (17 September 2015) *NAO: Spiralling Costs Make Cancer Drugs Fund Unsustainable*
www.publicfinance.co.uk