Where next for the Cancer Drugs Fund?

The Cancer Drugs Fund is a unique national fund that supports new therapies for malignant disease that would normally be unavailable through usual funding mechanisms. This article looks at the origins, the effectiveness and the future of the fund.

The Cancer Drugs Fund was announced in 2010 by the then new Conservative government and became fully established in 2011. The intention was to provide additional funding for cancer therapies (including those for malignant haematology) until a new value-based drug pricing scheme would be introduced in 2014.

Since this time numerous patients with cancer have been able to avail of drug therapies that were either not yet assessed by the National Institute for Clinical Excellence (NICE) or previously assessed but for which new evidence was available. The annual sum available is £200 million across England.

So what was the rationale of this programme? Why was it restricted to cancer and has it been of benefit to patients, to society or to the management of the health service? The question that is being asked most now by patients and oncologists is what will happen in 2014?

Background

Modern medicine is dominated by the development of ever more sophisticated and specifically targeted therapies. These carry large development costs that pharmaceutical companies seek to recover, with profit, within the duration of the initial patent. Very often, by the nature of the science behind these products, they are applicable for relatively small sub-populations of patients. In cancer, for example, this is less than 10% of non-small-cell lung cancers in the case of gefitinib or 20% of breast cancers in the case of trastuzumab.

Clearly the smaller the number of patients who will benefit from a costly development programme, the more is required per patient to deliver acceptable financial returns to pharmaceutical companies.

Through the 1990s there was clear evidence, and concern, that new therapies were being introduced in a haphazard fashion with funding agreed through local mechanisms that varied widely across the nation, leading to the so-called 'postcode lottery'.

NICE was established in 1999. A major part of its role is in the assessment of the effectiveness of new technologies including cancer therapies. NICE has sought to deliver this by establishing a level playing field in which any new technology needs to demonstrate an equivalent benefit to patients and to society that can be benchmarked against other technologies in competition for NHS funding. NICE established this process based on formulae that derive a cost per quality-adjusted life year gained. By comparing a new intervention with care without that intervention the cost of the benefit of the new treatment can be expressed as cost per quality-adjusted life year gained (National Institute for Health and Clinical Excellence, 2010). The initial amount considered to be of value was less than £20 000, but this was increased to £30 000 and in 2008 the secretary for health suggested that this ceiling be increased further for some cancer treatments (Boseley and Sparrow, 2008).

The introduction of NICE assessments led to a process that was in part transparent but which could never keep pace with the rapidly changing landscape of new drugs and new evidence on existing drugs that might have already been assessed. The inability of NICE to review and to re-review drugs rapidly led to a number of actions by patients, doctors and the pharmaceutical industry.

Challenges were made to NICE on the basis of incomplete analysis of available evidence or that available evidence had been excluded. Doctors in some areas lobbied for funding of drugs which were not yet NICE approved or which had efficacy for some patients that was considered too costly on the basis of the NICE quality-adjusted life year standards. Applications were made either on a population basis or through individual exception applications to primary care trusts. More recently some drugs have been approved by NICE subject to pharmaceutical support through the development of access programmes where costs are reduced or refunded by the manufacturers, for example, for non-responding patients.

Patient lobbying groups, particularly in breast cancer, became very active and there was general consensus that the playing field was again unequal and that the access of patients to new therapies appeared to be inferior to peers in other developed countries.

Under the last government it also became apparent that a gulf was widening between those patients limited to the NHS and those who could afford or who had insurance cover for private health care. In most cases private insurers would cover any licensed treatment whether or not it was approved by NICE, and many

Dr Johnathan Joffe *is Chair of the Association of Cancer Physicians and Macmillan Consultant in Medical Oncology in the Department of Oncology, Huddersfield Royal Infirmary, Calderdale & Huddersfield NHS Foundation Trust, Huddersfield HD3 3EA (jk.joffe@cht.nhs.uk)*

doctors in the private setting were prepared to offer therapies here that they could not offer within their NHS practices. The adverse publicity over this was never worse than in the case of trastuzumab (Herceptin) where, 'pre NICE', there were highly publicized examples of patients remortgaging or selling their homes to fund private care.

The government response in 2008, following a report on access to medicines in the NHS (Department of Health, 2008), was the development of the highly controversial 'top-up' scheme where patients under the care of the NHS could apply directly to their provider trust and pay the additional costs of drugs that were not normally funded by the NHS so long as this did not lead to any additional costs to the trust. This required complex governance arrangements such that the patients were managed as quasi private patients within any trust that provided this service with the intention that they should receive treatment separately from any NHS patients who were unable to afford or were unaware of the benefits of top-up. Insurance policies also became available that would support this type of treatment.

Improving access to medicines for NHS patients (Department of Health, 2008) also recommended that the Department of Health should urgently undertake further work to investigate the extent and causes of international variations in drug usage.

Members of the 2009 Pharmaceutical Price Regulation Scheme agreed to work with the Department of Health to look at ways in which uptake of new medicines could be benchmarked across the EU and Sir Mike Richards, the National Cancer Director and author of the 2008 report, was asked to lead this work looking at patient access to new and existing drug therapies through a number of peer health systems, including the NHS and, specifically, at NICE-assessed technologies within the UK.

The scope of this assessment was not restricted to cancer but included a number of major therapeutic areas and aimed to compare access to therapies in five large European countries (Spain, Italy, France, Germany and England), five smaller European countries (Austria, Denmark, Norway, Sweden, Switzerland) and four other countries with comparable gross domestic product and health spend as a proportion of gross domestic product (Australia, New Zealand, Canada and USA).

The report (Department of Health, 2010a) ranked each country by the access and use of a number of drugs in each therapeutic area. It was clear that access compared to peers varied significantly between therapeutic areas within the UK which was ranked within the top four, for example, in access to cardiovascular drugs, in the middle group for example for cancer-related endocrine therapies and cancer therapies launched between 6 and 10 years ago, but in the bottom four for a number of areas including newer cancer drugs (*Table 1*).

Outcomes from the Eurocare-4 project (Berrino et al, 2009) were also publicized at this time demonstrating that, although survival from cancers was improving year by year, significant international differences in cancer cause-specific survival could be seen for all cancers and in the majority of cancer types survival was lowest in the UK and in Denmark.

The landscape was, therefore, one in which there was evidence for under-spends on cancer therapy compared to peers, variation in access to new drugs and also poorer outcomes in terms of survival from cancer within the UK. It was considered likely that the worse outcomes related in part to under-use of systemic therapies, although the other main focus was to become delay in diagnosis.

The incoming Conservative government promised to address this and in July 2010 the health secretary, Andrew Lansley, announced the immediate availability of an interim fund of £50 million for cancer drugs, pending establishment of the Cancer Drugs Fund following full consultation, stating that: 'I promised that I would help patients in England get cancer drugs that are readily available in the rest of Europe. It's a scandal that we are strong in cancer research and participation in clinical trials in the UK, yet NHS patients aren't always seeing the benefits from the research swiftly enough.' (Department of Health, 2010b).

Table 1. Ranking of the UK in access to drugs in different therapeutic areas

Position	Therapy indication	UK rank out of 14 countries
Top four nations	Statins	2
	Acute myocardial infarction	2
	Respiratory distress syndrome	4
Middle four nations	Hormonal drugs for cancer	5
	Wet age-related macular degeneration	5
	Osteoporosis	6
	Stroke	6
	Respiratory syncytial virus	8
	Cancer drugs launched in the last 6–10 years	9
Bottom four nations	Rheumatoid arthritis	10
	Cancer drugs launched over 10 years ago	10
	Dementia	11
	Second generation antipsychotics	11
	Cancer drugs launched in the last 5 years	12
	Multiple sclerosis	13
	Hepatitis C	13

From Department of Health (2010)

The full Cancer Drugs Fund, worth £200 million per year for 3 years, was introduced from 31 March 2011 (Department of Health, 2011) and came with a comprehensive guide to how the fund was to be set up, accessed and monitored: Cancer Drugs Fund monies would be allocated to each regional strategic health authority and in each region a separate mechanism would be established to both administer the fund and to decide which drugs would be available. Local 'clinically-led panels' would determine what drug needs were of most value to their local populations and continuously review evidence to update the list, both agreeing to fund individual therapies and agreeing not to do so in other cases.

The introduction of the fund was hailed by patient support groups and by cancer charities and was generally embraced with caution by the oncological community and commissioners.

By August 2012 18 500 cancer patients who would not otherwise have been able to access new innovative therapies had 'benefited' from the fund (Department of Health, 2012). However, there are no national data on the rates of clinically meaningful tumour response.

Has the fund delivered equitable access to therapies?

It is acknowledged that only patients with malignant disease have been able to benefit. There is no doubt that there are equally deserving therapies within other therapeutic areas that remain unavailable, and some of those therapeutic areas were demonstrated to be equally under-funded by international benchmarking (Department of Health, 2010a). To the author's knowledge, this discrepancy has not been addressed by the Department of Health or secretary of state. However, the evidence on poor survival compared to peers (Berrino et al, 2009), as well as the very strong national lobbies from some cancer support groups and charities, will have been of significant influence on the decision to restrict the fund to cancer.

The regional structure of the fund's administration has led to wide variation in process of drug selection across the country. In some areas the introduction of the fund across a large strategic health authority region uncovered huge differences in funding of many existing therapies. Consequently there was a need for some health economies to play catch-up with neighbours where those drugs were already commissioned as part of standard therapy. In that respect, at least, the Cancer Drugs Fund had a levelling effect in some regions. However, it became obvious early on that very different drugs had been made available within different regions, a return, in part, to the pre-NICE postcode lottery. According to unpublished data from the National Commissioning Board, the number of drugs funded in at least one region of the country is greater than 50 within over 180 indications; in the author's region there are 29 drugs in over 50 indications.

In April 2012 data were published in the *Daily Mail* (Hope, 2012) demonstrating significant variations in Cancer Drugs Fund spend between regions, with some regions under-spending by as much as 60%. At the same time the health minister Lord Howe announced that an improved mechanism would be introduced to access the Cancer Drugs Fund.

This was followed by a publication by the National Cancer Action Team (2012) that highlighted the variation in availability of Cancer Drugs Fund drugs in different regions, and a media statement from the Department of Health (2012) confirming the variation in total spend from region to region.

At the present time there is national work through the NHS National Commissioning Board to harmonize the Cancer Drugs Fund and create a single list of available drugs that can be accessed through a single system of application. This work will eventually be led by the new Chemotherapy Clinical Reference Group which is being established as part of the reorganization of the health service.

Nationally, concern continues, however, that uptake varies considerably by hospital (Rarer Cancers Foundation, 2013a) and anecdotal reports suggest that even within hospitals, uptake varies considerably between clinicians with similar sub-specialty expertise.

The future

In January 2013 anxieties were raised in the health select committee that no firm arrangements are yet in place for the future of the Cancer Drugs Fund. This received broad coverage in the press, reinforced by cancer charity publicity (Rarer Cancers Foundation, 2013b) of a survey sponsored by Roche that suggested that over 80% of oncologists were expressing concerns about the future of the Cancer Drugs Fund.

Assuming the new value-based drug pricing scheme comes into operation in 2014, it will face the same pressures to restrict drug spending as existing systems and there is certainty that NHS funding will remain under restraint for the foreseeable future. It is hard to conceive of a system of value-based drug pricing that can encompass ever-increasing numbers of high cost drugs of the type supported by the Cancer Drugs Fund, even if they are eventually subjected to the scrutiny that is intended to be delivered by NICE. It will, however, be very difficult politically to back-track on the availability of funding for the type of newly approved drug or drugs for unreviewed indications that have been supported by the Cancer Drugs Fund.

The principles of evaluation of effectiveness by NICE have effectively been undermined or at least sidelined by the Cancer Drugs Fund and in December 2012 Professor Sir Mike Rawlings raised concern in the health select committee that its restriction to cancer drugs is unreasonable. Any new drug pricing scheme will need to address this concern.

The beginnings of systems that may address this are coming into place with the establishment of a national list of approved Cancer Drugs Fund drugs. One issue for the compilers of this list will be that some drugs currently funded through the Cancer Drugs Fund in one region may be available within commissioned services elsewhere. One effect of a national Cancer Drugs Fund may be to ensure that drugs funded nationally through the Cancer Drugs Fund can only be funded in that way at a specific point in time. This will lead to a levelling of access both within and without the Cancer Drugs Fund and possibly a move back towards a greater reliance on NICE evaluations.

The development of the Systemic Anti-Cancer Treatment database (www.ncin.org.uk/collecting_and_using_data/data_collection/chemotherapy.aspx), that requires upload of all chemotherapy data from all trusts providing treatment from April next year, will allow the identification of prescribing outliers and thus further rationalization of use of outdated or less effective therapies. Although this will be of direct benefit to patients and may allow for some savings, it may create cost pressures of its own as cheaper outdated therapies are replaced with costlier new technologies, some of which may require greater levels of support.

Conclusions

Following the publication of The Francis Report (Francis, 2013) the health service needs to ensure that whatever it is able to deliver is done within a framework of high quality and patient focus. Within such an environment, no target-related efficiency gains and/or relocation of care to the primary sector will be able to offset the unrelenting pressure to fund new health technologies.

There is, thus, an urgent need for clarity on the government's intention with respect to high cost drug funding. No doubt there is ongoing discussion with the pharmaceutical industry on how drugs can be made more affordable; however, if the planned value-based scheme can not deliver the funding of new high cost drugs in all indications then an open debate must be established on what the modern health service can afford, how much explicit rationing can be accepted, and how much society is prepared to pay for more complex health care through increased taxation. We are facing an unrelenting tsunami of new innovation. The government, the Department of Health and NHS at times seem to have their heads in the sand. This cannot serve the nation or individual patients. **BJHM**

Conflict of interest: none.

Berrino F, Verdecchia A, Lutz JM, Lombardo C, Micheli A, Capocaccia R, the EUROCARE Working Group (2009) Comparative cancer survival information in Europe. *Eur J Cancer* **45**: 901–8

Boseley S, Sparrow A (2008) Johnson lifts NHS ban on top-up treatment. *The Guardian* 4 Nov (www.guardian.co.uk/politics/2008/nov/04/nhs-health-cancer-topup-treatment accessed 28 February 2013)

Department of Health (2008) Improving access to medicines for NHS patients. www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_089952.pdf (accessed 28 February 2013)

Department of Health (2010a) Extent and Causes of International Variations in Drug usage. www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_117977.pdf (accessed 25 February 2013)

Department of Health (2010b) £50M additional funding for cancer drugs. http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_117970 (accessed 25 February 2013)

Department of Health (2011) The Cancer Drugs Fund. http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Aboutus/Features/DH_125762 (accessed 25 February 2013)

Department of Health (2012) Statement on Cancer Drugs Fund usage. http://mediacentre.dh.gov.uk/2012/08/29/cancer-drugs-fund-usage/ (accessed 25 February 2013)

Francis R (2013) *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry.* Executive Summary. The Stationery Office, London

Hope J (2012) £60m promised to cancer victims hasn't been spent: Patients 'having to jump through hoops' to get drugs they need. www.dailymail.co.uk/health/article-2133721/60m-promised-cancer-victims-spent-Patients-having-jump-hoops-drugs-need.html (accessed 25 February 2013)

National Cancer Action Team (2012) Cancer Drugs Fund Bulletin – August 2012. http://ncat.nhs.uk/news-and-events/cancer-drugs-fund-bulletin-august-2012 (accessed 25 February 2013)

National Institute for Health and Clinical Excellence, (2010) Measuring effectiveness and cost effectiveness: the QALY. www.nice.org.uk/newsroom/features/measuringeffectivenessandcosteffectivenesstheqaly.jsp (accessed 26 February 2013)

Rarer Cancers Foundation (2013a) New RCF analysis shows big variation in hospital usage of NICE-approved cancer drugs. www.rarercancers.org.uk/index.php?option=com_content&view=article&id=377:new-rcf-analysis-shows-big-variation-in-hospital-usage-of-nice-approved-cancer-drugs&catid=43:england-news&Itemid=5 (accessed 25 February 2013)

Rarer Cancers Foundation (2013b) The Rarer Cancers Foundation (RCF) has warned that access to cancer drugs could return to 'dark days' in England once the £200m-a-year Cancer Drugs Fund ends in March 2014. www.rarercancers.org.uk/index.php?option=com_content&view=article&id=374:rcf-warns-that-access-to-cancer-treatments-will-go-backwards-post-cdf-without-urgent-action&catid=11:latest-news&Itemid=5 (accessed 25 February 2013)

KEY POINTS

- The Cancer Drugs Fund is intended to address concerns regarding survival of cancer patients in the UK and access to new cancer drugs.
- The fund makes new cancer therapies available as soon as possible when high quality evidence suggests benefit, sometimes before licensing and usually before they can be assessed by the National Institute for Health and Clinical Excellence.
- The fund is limited to malignant disease although similar challenges exist in other therapeutic areas.
- The fund was intended to be a fixed-term solution to the problems of cancer patients until 2014.
- The future of the fund is currently uncertain.