Lessons learned from a national catastrophic fund: England's Cancer Drugs Fund.

An English perspective

Kalipso Chalkidou, MD, PhD
Professor of Practice, Global Health, Imperial College London
Director of Global Health Policy, Centre for Global Development

IADB, Nov 2019

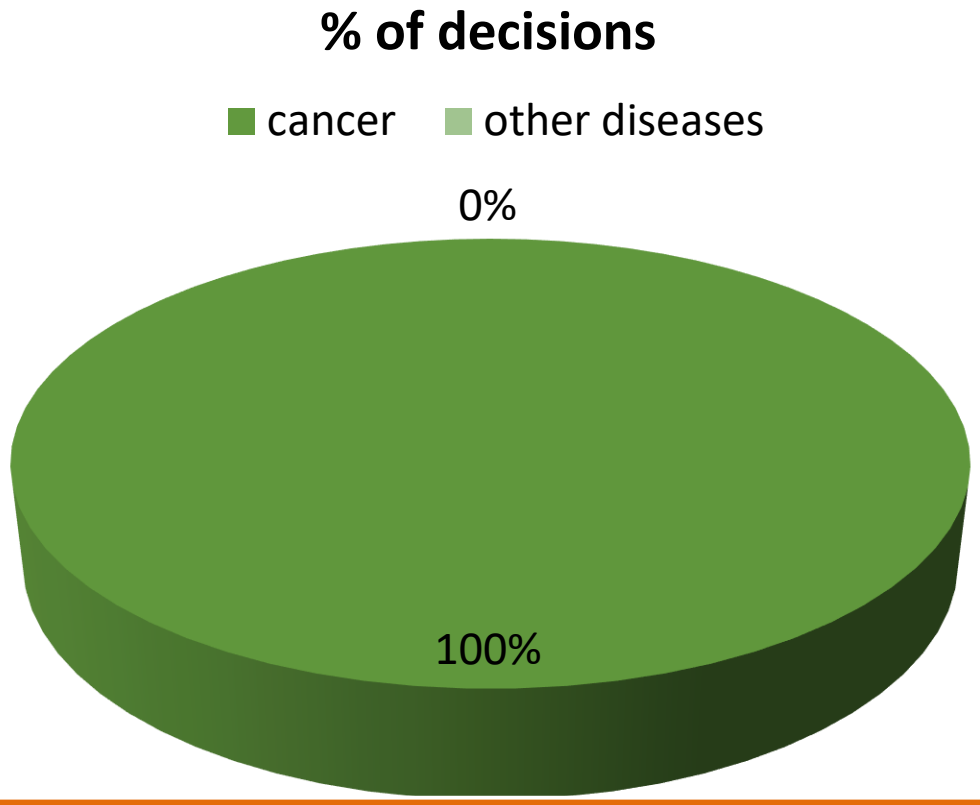
Policies for improving timely access to new cancer drugs

- Single Technology Appraisal (2005)
- NICE End-of-Life policy (2008/9)
- Cancer Drugs Fund (2010/11)
- Orphan drugs evaluation (2013/14)
- Value Based Assessment (2014/closed down)
- CDF as part of NICE (2016)

The launch of NICE's End-of-Life policy (2009)

- "A QALY is a QALY is a QALY" NICE Methods Manual 1999-2009
- NICE is asking that its advisory committees "consider recommending seemingly cost-ineffective treatments which are life-extending for patients with short life expectancy, and which are licensed for indications affecting small numbers of patients with incurable illnesses." NICE Supplementary Guidance to its Advisory Committees – January 2009

End of Life decisions as of May 2014



But NICE's committees still find some cancer drugs not to be good value for money or clinically effective

Cancer Drugs Fund in pre-election manifesto

"We will create a Cancer Drugs Fund to enable patients to access the cancer drugs their doctors think will help them…"

Freedom

Fairness

Responsibility

The Coalition:
our programme
for government

An election promise

What does the evidence say about what the people think?

Donkey and pigs from the 1954 film Animal Farm. Photograph: Halas & Batchelor

ALL DISEASES ARE EQUAL BUT CANCER IS MORE EQUAL THAN OTHERS…

The view of the UK's major cancer charity

CANCER RESEARCH UK

Let's beat cancer sooner

- "Any healthcare system has to make difficult decisions about how to allocate its finite resources. Cancer Research UK believes that, in general, NICE performs this difficult job well, and should be properly resourced to continue to do so, and to improve into the future. This is especially important in the context of the current financial pressures on the NHS…"
  - Health Select Committee, written evidence from Cancer Research UK (Oct 2012)

www.parliament.uk

DoH compulsory prelaunch policy evaluation

Title:	Impact Assessment (IA)
Impact Assessment of Proposal for a Cancer Drug Fund	**IA No:** 5012
Lead department or agency: DH	**Date:** 26/10/2010
Other departments or agencies:	**Stage:** Consultation
	Source of intervention: Domestic
	Type of measure: Other

- "While there may be support in principle for greater weighting of QALYs provided to patients with severe conditions, there is currently no robust evidence in the literature to support a particular magnitude of weighting. **It should also be noted that no evidence has been found for prioritising cancer above other severe conditions, or for prioritising drug treatments above any other interventions for cancer."**

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30 September 2012 Last updated at 08:24

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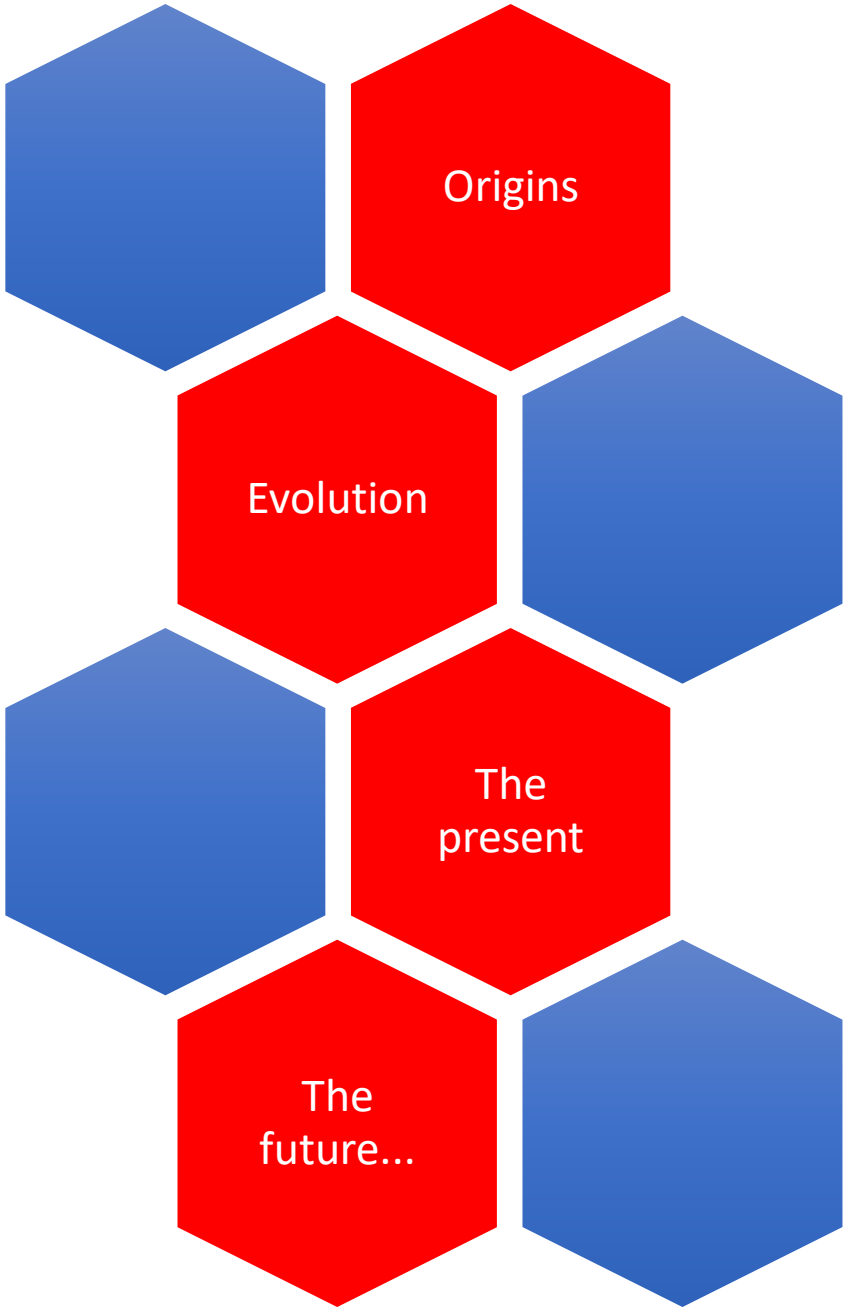
- His team surveyed more than 4,000 people across Wales, England and Scotland to find out whether they valued delivering health benefits to cancer patients more highly than to patients with other conditions.
- "The result that we found were that the majority - about 64% - were not in favour of prioritising one or the other. They wanted fair allocation, regardless of the disease, all else being equal. There was a consistent message that there wasn't general support for cancer [being a special case] versus other conditions." [Linley and Hughes, 2013, Health Econ, 22(8), 948]

evidence that it will improve quality of life or survival rates.

The English Cancer Drugs Fund



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Cancer drugs fund to be £20

The cancer drugs fund to pay for medi
will be worth £200m a year, ministers

Andrew Lansley, health secretary, has confirmed
April as planned Photo: EDDIE MULHOLLAND

By Rebecca Smith, Medical Editor
7:30AM BST 27 Oct 2010

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Feature » NICE

At last, NICE to take over the Cancer Drugs Fund

BMJ 2016 ; 352 doi: https://doi.org/10.1136/bmj.i1324 (Published 07 March 2016)
Cite this as: *BMJ* 2016;352:i1324

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Nicholas Timmins, senior fellow

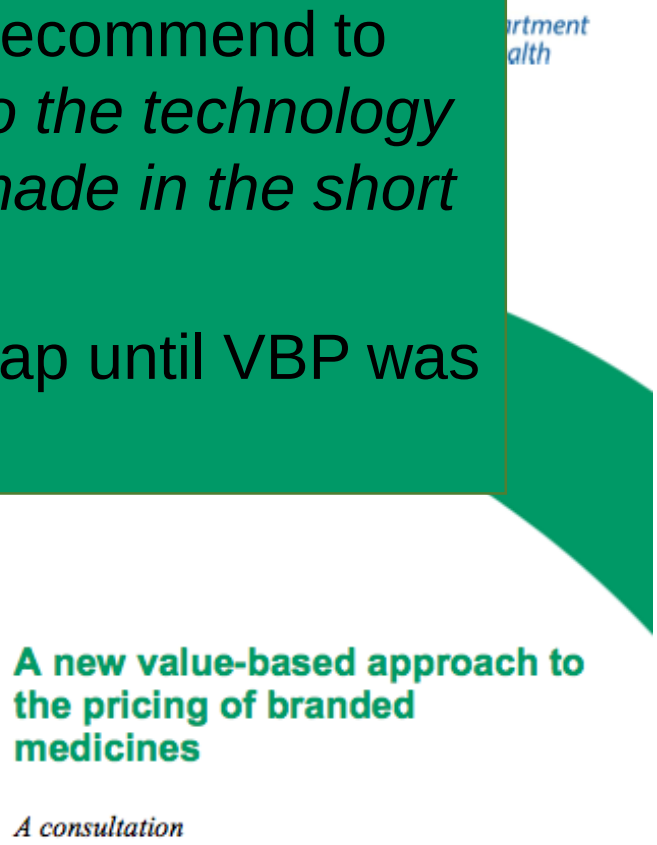
Author affiliations

n.timmins@kingsfund.org.uk

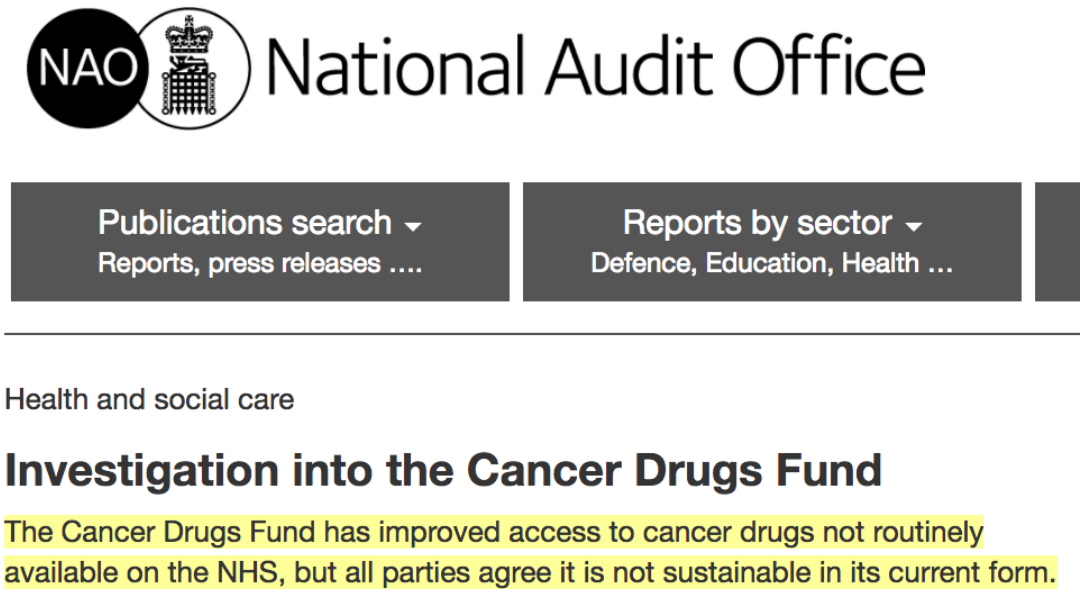
CDF: a temporary solution that became (semi) permanent…

- Following a wide and inconclusive consultation, the working group at NICE decided to recommend to the NICE Board that "*no changes to the technology appraisal methodology should be made in the short term*". The NICE Board agreed.
- But thw CDF, meant to bridge the gap until VBP was launched, survives…

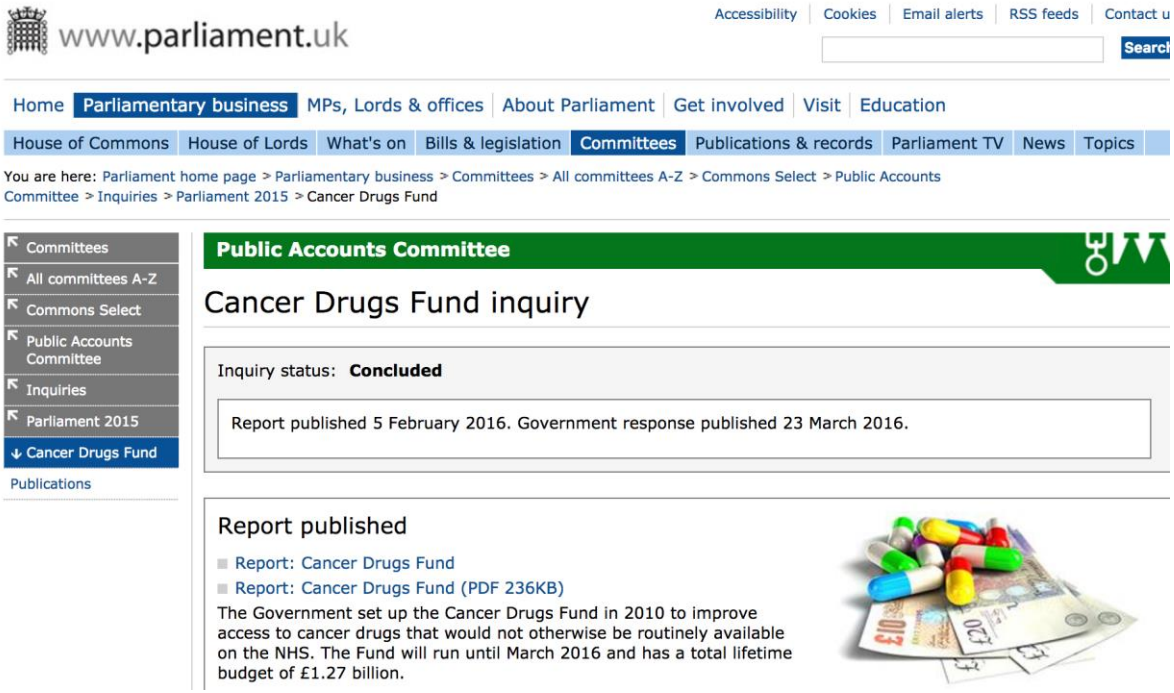
- Based on DH Terms of Reference, **NICE went to consultation** on a possible approach to what is now known as 'value based assessment'.



Sep 2015: the country's National Audit Office investigates



- **"Did it improve outcomes?** Due to a lack of data, it is not possible to evaluate the impact that the Fund has had on patient outcomes, such as survival.
- **What impact did it have on prices?** The cost of the Fund from 2010 to 2015 was £968 million, slightly above the allocated budget. In the early years [it] was underspent. However, taking 2013-14 and 2014-15 together…the cost of the Fund rose by £241 million – an increase of 138%. Over half of the rise was because of an increase in the average cost of treatment per patient…"



- "There is no assurance that the Department and NHS England are using their buying power effectively to pay **a fair price** for cancer drugs, including drugs paid for through the Fund.
- It is unacceptable that the Department and NHS England still **do not have data to evaluate the impact of the Fund on outcomes** for patients five years after the Fund was set up."

February 2016: The country's Parliament investigates

The press

"a populist gesture that gives the impression of benefiting patients, but in fact rewards poor quality drugs while benefiting a handful of pharmaceutical companies at the expense of the taxpayer and the full range of NHS patients" Dec 2014

"This mechanism for diverting taxpayers' money to enhance, to little or no purpose, the profits of Big Pharma might be more aptly named "the Drug Company Fund"" Dec 2014

Health

Cancer Drugs Fund 'huge waste of money'

By Nick Triggle
Health correspondent

28 April 2017

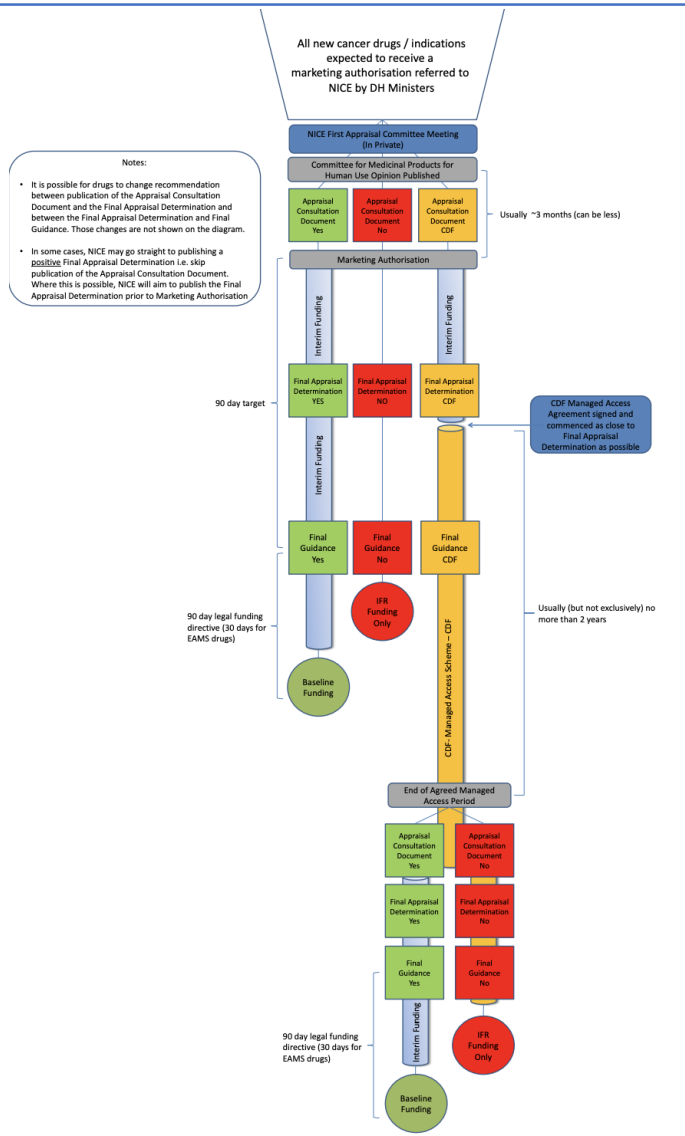
The Payer takes back control: NHS England

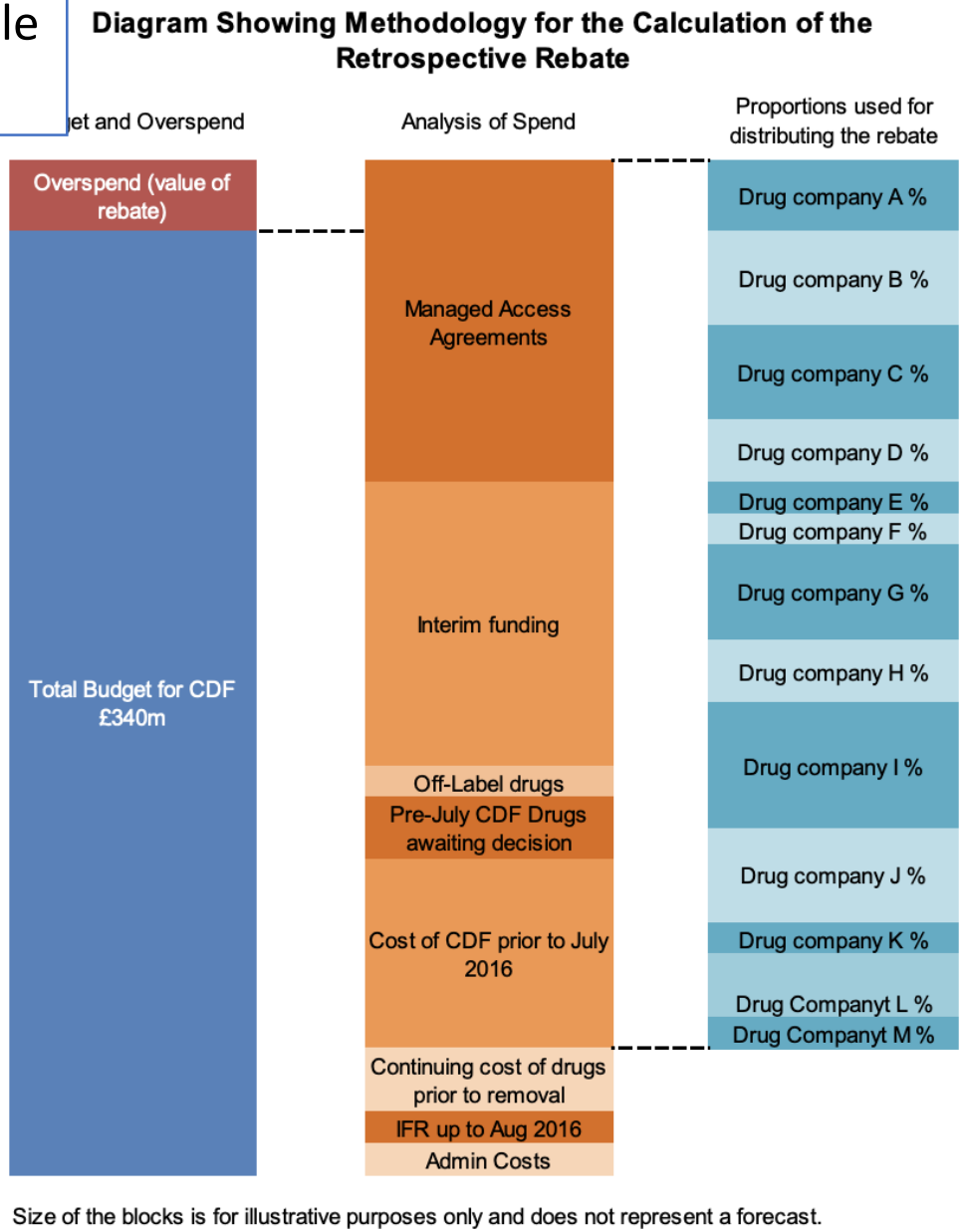
- Access to promising new treatments, via managed access arrangement, while further evidence is collected to address clinical uncertainty.
- Interim funding for all newly recommended cancer drugs, giving patients access to these treatments many months earlier than before.
- **The expenditure control mechanism ensures that the CDF will not overspend.**

Appraisal and Funding of Cancer Drugs from July 2016 (including the new Cancer Drugs Fund)

A new deal for patients, taxpayers and industry

The new arrangements cap the total, set up companies and products to compete against one another and make the whole idea of the CDF “unappealing”





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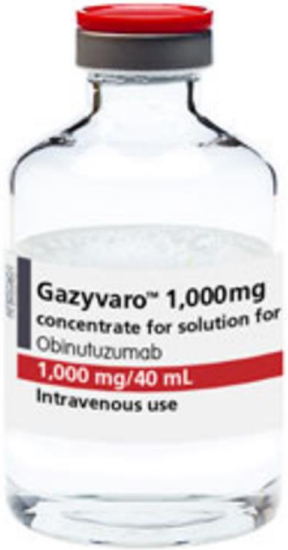
Patients getting faster access to cancer drugs as NICE approves three quarters of the Cancer Drugs Fund

Liver cancer drug, sorafenib has been approved for routine NHS use, marking three quarters of the way through the Cancer Drugs Fund (CDF) without a negative decision.



Roche hails 4 year NICE access deal for Gazyvaro

July 26, 2017

Mail Online

New hope for victims of 'Cinderella' bladder cancer that kills in months as new drug encourages immune system to destroy tumours

- Bladder cancer patients have new hope of longer life thanks to a new drug
- Atezolizumab can help those with advanced stage of the disease survive an average of almost 16 months compared with 7.9 months on chemotherapy
- It strikes around 10,000 people a year and one in ten find it has already spread when they are first diagnosed

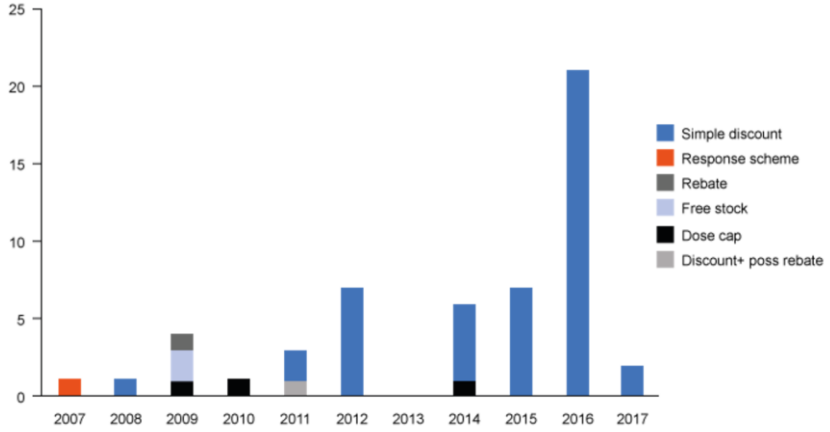
By MARTYN HALLE FOR THE MAIL ON SUNDAY
PUBLISHED: 22:01, 19 August 2017 | UPDATED: 22:01, 19 August 2017

Celgene

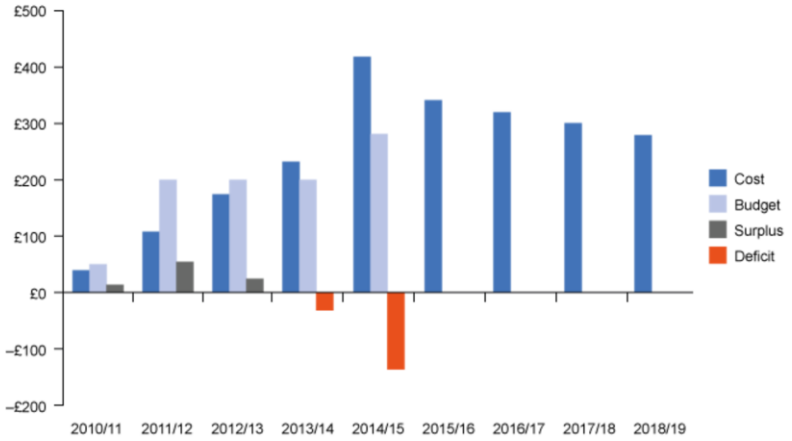
NICE recommends Celgene pancreatic cancer drug

August 4, 2017

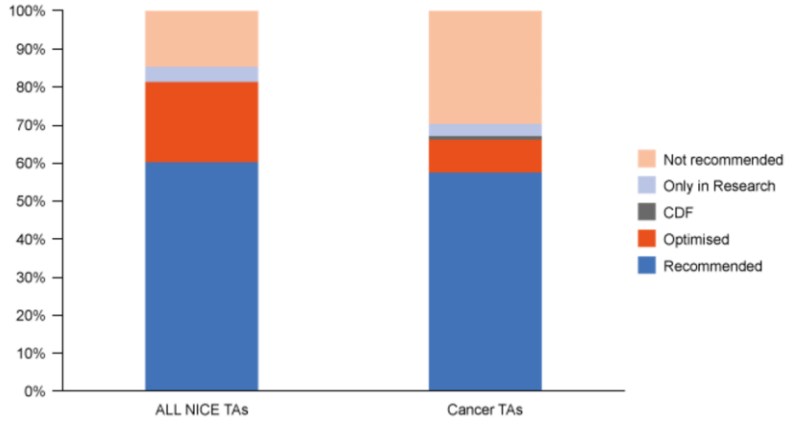
NICE risk sharing schemes



CDF budget balance



NICE cancer appraisals



PharmaForum, Leela Barham, 2017

Office of Health Economics Research

Research Paper 16/03

A Review of NICE Methods Across Health Technology Assessment Programmes: Differences, Justifications and Implications

April 2016

Emma Brockis, Grace Marsden, Amanda Cole and Nancy Devlin

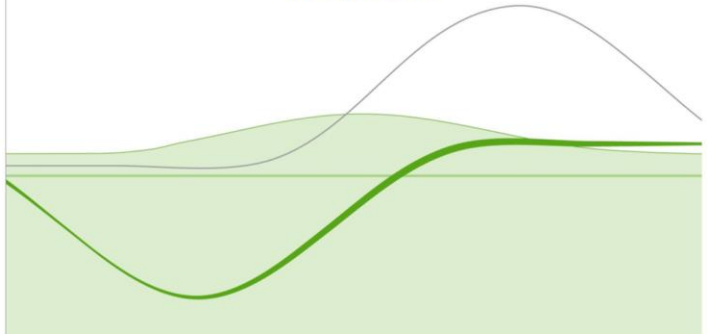


Table 1: Remit and Scope of each NICE HTA programme

	Technology Appraisal Programme	Medical Technologies Guidance	Diagnostics Assessment Programme	Highly Specialised Technology Programme	Clinical Guidelines
What is appraised?	Medicines, medical devices, diagnostics, surgical procedures, therapeutic technologies, systems of care, screening tools.	Medical devices (active, active implantable, in vitro), genetic tests.	Diagnostic technologies/ tests, genetic tests.	Drugs for very rare conditions.	Condition specific care and services.
Referral	Primarily HSRIC; Formal referral required from Secretary of State for Health.	Primarily product sponsors; Also HSRIC.	Product sponsors, national clinical directors, medical royal colleges, professional bodies, national expert bodies, or HSRIC.	Primarily HSRIC; Formal referral required from DH.	Topic oversight group.
Selection/ routing	Must have been granted, or be soon to receive, marketing authorisation; Significant benefit to patients; new formulation at lower price; appropriate evidence available.	Have CE mark (or expected within 1 year); New or innovative technology; Cost saving or cost neutral technology.	CE marking (before publication); Potential to improve health outcomes, but at an increased cost to the NHS.	Criteria same as those used by AGNSS; Process similar to TAP.	Priority topics and those where existing NICE guidance does not cover the whole topic.
Prioritisation criteria	Significant health benefit; Significant impact on NHS resources and other government policies; Inappropriate variation in the use across the country.	Provide most benefit to patients and the NHS; Scoring system.	Particular urgency to the NHS.	Not stated.	Discussion between NHS England, DH and Public Health England.

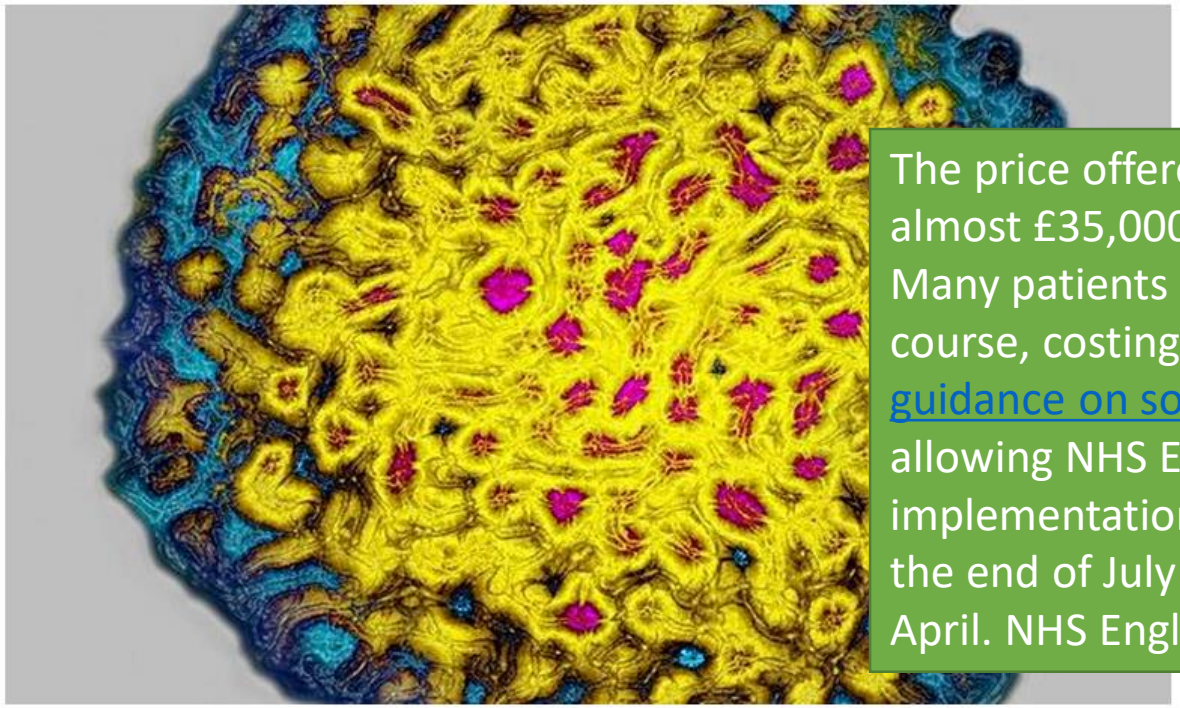
Source: NICE (2011a), NICE(2011b), NICE(2011c), NICE(2011d†), NICE(2011e†), NICE (2013a), NICE (2013b), NICE (2013c), NICE (2015a), NICE (2015b), NICE (2015c).
Abbreviations: AGNSS: Advisory Group for National Specialised Services; CE mark: European Conformity mark; DH: Department of Health; HSRIC: Horizon Scanning Research & Intelligence Centre.

Multiple methodological and process ‘fixes’ to accommodate pressures…

Cancer not the main/only problem… Sovaldi: “Cost-effective” but unaffordable?

Hepatitis C drug delayed by NHS due to high cost

NHS England balks at bill for dispensing sofosbuvir: £1bn for every 20,000 people treated



The price offered by Gilead in the UK is almost £35,000 for a 12-week course. Many patients will need a 24-week course, costing £70,000. In its final draft guidance on sofosbuvir, Nice said it was allowing NHS England to postpone implementation for four months, until the end of July instead the beginning of April. NHS England failed to comment.

When budgets don't follow recommendations

February 19, 2015 12:00 am

Expensive drugs cost lives, claims report

Andrew Ward, Pharmaceuticals Correspondent

The adoption of expensive new drugs by the NHS is doing patients more harm than good, according to a study that urges a sharp reduction in the price pharmaceuticals companies are paid for their products.

Research by the University of York found that lives were being lost and quality of life diminished because spending on overpriced drugs was diverting resources from other kinds of healthcare that would produce more benefit.

Editorial: High cost of new drugs

The new PPRS: capping growth—industry reimburses the NHS

Period	Aggregate net sales covered by the PPRS payment Column 1	Resulting aggregate PPRS payments Column 2
2013	£7,901M	N/A
2014	£8,340M	£311M
2015	£8,179M	£847M
2016	£8,062M	£628M
2017	£8,147M	£387M
2018 Q1	£2,003M	£156M
2018 Q2	£2,013M	£157M
2018 Q3	£1,968M	£153M
2018 Q4	£1,903M	£148M

Table 3: Estimated UK and England income from PPRS payments (rounded to nearest £10m).

£m	2017/18	2018/19
UK	440	470
England	350	370

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/668673/PPRS_Payment_percentage_2018.pdf
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761834/voluntary-scheme-for-branded-medicines-pricing-and-access-chapters-and-glossary.pdf

The future: Accelerated Access Review – Nov 2016

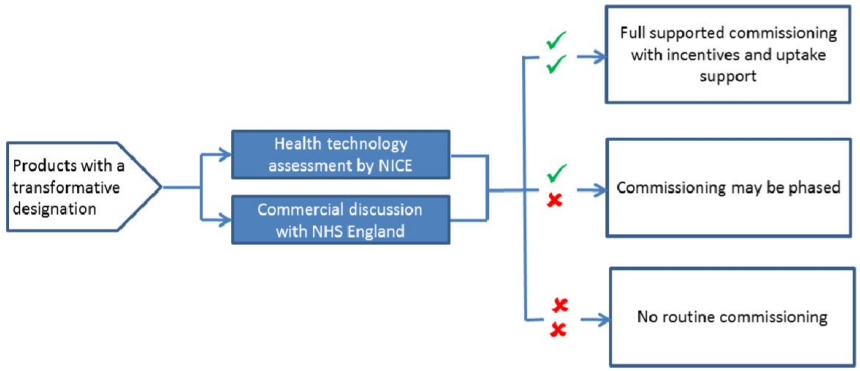


Figure 10: Products that reach a commercial deal will move swiftly to reimbursement

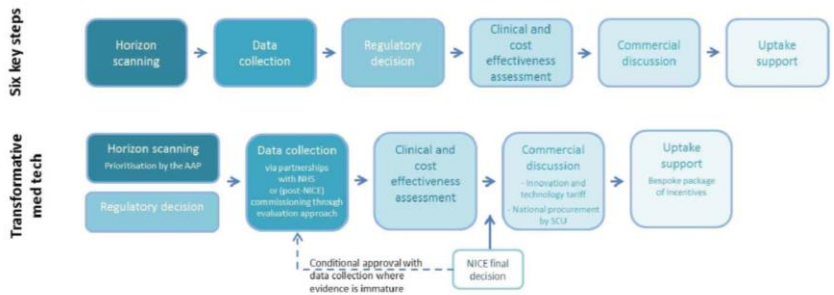


Figure 11: The sequencing of the Accelerated Access Pathway for strategically important medical technologies

Putting a break on NICE…

- Introduce a 'fast track' NICE technology appraisal process for the most promising new technologies, which fall below an incremental cost-effectiveness ratio of £10,000 per QALY (quality adjusted life year), to get these treatments to patients more quickly.
- Operate a 'budget impact threshold' of £20 million, set by NHS England, to signal the need for a dialogue with companies to agree special arrangements to better manage the introduction of new technologies recommended by NICE. This would apply to a small number of technologies that, once determined as cost effective by NICE, would have a significant impact on the NHS budget.
- Vary the timescale for the funding requirement when the budget impact threshold is reached or exceeded, and there is therefore a compelling case that the introduction of the new technology would risk disruption to the funding of other services.
- Automatically fund, from routine commissioning budgets, treatments for very rare conditions (highly specialised technologies) up to £100,000 per QALY (5 times greater than the lower end of NICE's standard threshold range), and provide the opportunity for treatments above this range to be considered through NHS England's process for prioritising other highly specialised technologies.

Further reform needed according to leading UK academics

Editorials

Cancer Drugs Fund requires further reform

BMJ 2016 ; 354 doi: https://doi.org/10.1136/bmj.i5090 (Published 27 September 2016)
Cite this as: *BMJ* 2016;354:i5090

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Richard Grieve, professor1,Keith Abrams, professor2,Karl Claxton, professor3,Ben Goldacre, senior clinical research fellow4, Nicholas James, professor5,Jon Nicholl, professor6,Mahesh Parmar, professor7,Chris Parker, consultant oncologist8, Jasjeet S Sekhon, professor9,Liam Smeeth, professor10,David Spiegelhalter, professor11,Mark Sculpher, professor3

Author affiliations

Correspondence to: R Grieve richard.grieve@lshtm.ac.uk

- Once introduced, hard to disinvest
- Real world observational data unreliable, biased and undermine RCTs
- Link to national cancer registers and Clinical Practice Datalink non-existent

http://www.bmj.com/content/354/bmj.i5090

Did the CDF deliver value for the English society?

The evidence:

- Of the 47 CDF approved indications, only 18 (38%) reported a statistically significant OS benefit, with an overall median survival of 3.1 months
- When assessed according to clinical benefit scales, only 23 (48%) and 9 (18%) of the 47 drug indications met ASCO and ESMO criteria, respectively.
- NICE had previously rejected 26 (55%) of the CDF approved indications because they did not meet cost-effectiveness thresholds.
- Four drugs—bevacizumab, cetuximab, everolimus and lapatinib—represented the bulk of CDF applications and were approved for a total of 18 separate in
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Conclusions

We conclude the CDF has not delivered meaningful value to patients or society. There is no empirical evidence to support a ‘drug only’ ring fenced cancer fund relative to concomitant investments in other cancer domains such as surgery and radiotherapy, or other noncancer medicines. Reimbursement decisions for all drugs and interventions within cancer care should be made through appropriate health

to

their

Drug name (generic)	Name of study	Primary efficacy endpoint	Randomisation	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of reported result	Overall risk of bias
Cabozantinib	XL184 -301	PFS	some concerns	high	high	low	low	high
Trametinib	MEK114267	PFS	low	some concerns	high	low	low	high
Trametinib	BRF113220	Response, PFS	low	some concerns	high	high	low	high
Trametinib	MEK115306	PFS	low	low	high	low	low	high
Obinutuzumab	BO21004/CLL11	PFS	low	some concerns	low	low	low	low
Idelalisib	GS -US -312-0116	PFS	low	low	high	low	low	high
Ibrutinib	Study 1112	PFS	low	some concerns	high	low	low	high
Nintedanib	LUME Lung 1–1199.13	PFS	low	low	high	low	low	high
Olaparib	D0810C00019	PFS	low	low	low	low	low	low
Ramucirumab	I4T-IE-JVBD (REGARD)	OS	low	low	low	low	low	low
Ramucirumab	I4T-IE-JVBE (RAINBOW)	OS	low	some concerns	low	low	low	low
Lenvatinib	E7080-G000-303 (SELECT)	PFS	low	some concerns	low	low	low	low
Nivolumab	CA209-066	OS	low	low	low	low	low	low
Nivolumab	CA209-037	Response, OS	low	some concerns	high	low	low	high
Pembrolizumab	Study P002	PFS, OS	low	some concerns	low	low	low	low
Pembrolizumab	Study P006	PFS, OS	low	some concerns	low	low	low	low
Sonidegib	CLDE225A2201 (BOLT)	Response	low	low	high	low	low	high
Panobinostat	CLBH589D2308 (Panorama I)	PFS	low	some concerns	low	low	low	low
Carfilzomib	PX-171-009 (ASPIRE Study)	PFS	low	high	low	low	low	high
Cobimetinib	GO28141 (coBRIM)	PFS	low	low	low	low	low	low
Talimogene laherparepvec	Study 005/05	Response	low	some concerns	low	some concerns	low	some concerns
Pegaspargase	CCG-1962	No efficacy	some concerns	some concerns	low	low	low	some concerns
Pegaspargase	DFCI-87-001	EFS	low	some concerns	high	high	low	high
Pegaspargase	DFCI-91-01	EFS	low	some concerns	some concerns	high	low	high
Pegaspargase	DFCI-05-001	DFS, OS, HRQoL	low	some concerns	low	high	low	high
Pegaspargase	AALL07P4	No efficacy	some concerns	some concerns	some concerns	low	low	high
Pegaspargase	ASP-304	Response	high	some concerns	low	high	low	high
Necitumumab	I4X-IE-JFCC (SQUIRE)	OS	low	some concerns	low	low	low	low
Trifluridine/tipiracil	TPU-TAS-102-301 (RECOURSE)	OS	low	some concerns	low	low	low	low
Elotuzumab	CA204-004	PFS, Response	low	some concerns	low	low	low	low
Elotuzumab	CA204-009	PFS	low	low	low	high	low	high
Daratumumab	MMY2002	Response	high	high	low	low	low	high
Lenvatinib	E7080-G000-205	PFS	low	low	low	low	low	low
Cabozantinib	XL184-308	PFS	low	low	low	low	low	low
Irinotecan hydrochloride trihydrate	NAPOLI-1	OS	low	some concerns	low	low	low	low
Olaratumab	I5B-IE-JGDG (JGDG)	PFS	low	some concerns	low	low	low	low
Palbociclib	1023 (PALOMA-3)	PFS	low	some concerns	low	high	low	high
Palbociclib	1008 (PALOMA-2)	PFS	low	high	low	low	low	high
Ixazomib	C16010	PFS	low	low	low	low	low	low

● High ● Some concerns ● Low

The CDF is gone but the problem of cancer exceptionalism when it comes to evidence, is here to stay…

Conclusions Most pivotal studies forming the basis of EMA approval of new cancer drugs between 2014 and 2016 were randomised controlled trials. However, almost half of these were judged to be at high risk of bias based on their design, conduct, or analysis, some of which might be unavoidable because of the complexity of cancer trials. Regulatory documents and the scientific literature had gaps in their reporting. Journal publications did not acknowledge the key limitations of the available evidence identified in regulatory documents.

Cancer Drugs Fund: “a difficult legacy”

“But the real change to help get these drugs into the market in the UK will not come from siloed funds, but rather from these drugs costing less in the first place.

Both the government and pharma play on the fear surrounding cancer for their own ends, but pricing a cancer drug artificially high simply because it treats a feared disease does not seem fair to the NHS or, more pertinently, to patients”

PharmaFile, Feb 2014; http://www.pharmafile.com/news/182224/cancer-drugs-fund-assessing-difficult-legacy

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IN BRIEF: Senegal to offer free breast and cervical cancer treatment

19 Sep 2019

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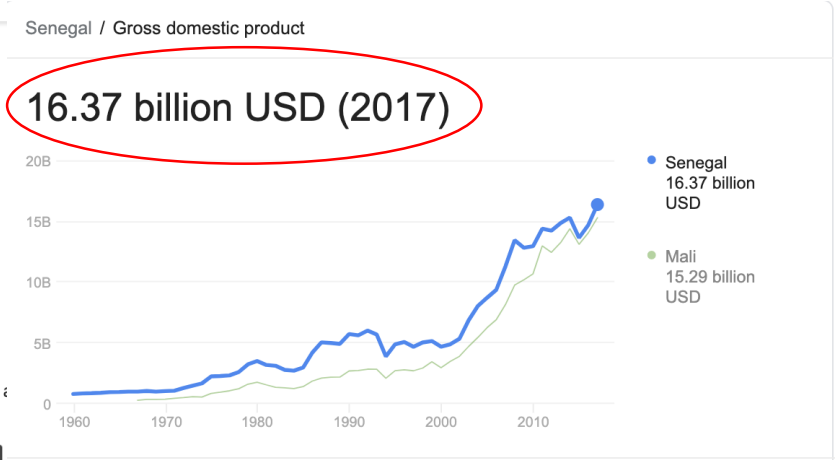

Senegal's government says that women suffering from breast or cervical cancer will be offered free chemotherapy in public hospitals from the beginning of October. For other types of cancers, 60% of the costs will be reimbursed, the government says. For other types of cancers, 60% of the costs will be reimbursed, the government says. Other countries, like Rwanda, Namibia and Seychelles, also offer free chemotherapy. An estimated **$1.6bn** has been allocated by the Senegalese government for this new measure.

kalipso.chalkidou@gmail.com

Gracias!