

**WEBINAR TRANSCRIPTION:
LESSONS LEARNED FROM A
NATIONAL CATASTROPHIC FUND:
ENGLAND'S CANCER DRUGS FUND.**

Presented by Kalipso Chalkidou. November 14th, 2019.

Social Protection and Health Division
Inter-American Development Bank
www.iadb.org/es/salud - scl-sph@iadb.org

Copyright © 2018 Inter-American Development Bank. This work is licensed under a Creative Commons IGO 3.0 Attribution-NonCommercial-NoDerivatives (CC-IGO BY-NCND 3.0 IGO) license (<http://creativecommons.org/licenses/by-nc-nd/3.0/igo/legalcode>) and may be reproduced with attribution to the IDB and for any non-commercial purpose. No derivative work is allowed. Any dispute related to the use of the works of the IDB that cannot be settled amicably shall be submitted to arbitration pursuant to the UNCITRAL rules. The use of the IDB's name for any purpose other than for attribution, and the use of IDB's logo shall be subject to a separate written license agreement between the IDB and the user and is not authorized as part of this CC-IGO license.

Any dispute related to the use of the works of the IDB that cannot be settled amicably shall be submitted to arbitration pursuant to the UNCITRAL rules. The use of the IDB's name for any purpose other than for attribution, and the use of IDB's logo shall be subject to a separate written license agreement between the IDB and the user and is not authorized as part of this CC-IGO license.

Note that link provided above includes additional terms and conditions of the license.

The opinions expressed in this publication are those of the authors and do not necessarily reflect the views of the Inter-American Development Bank, its Board of Directors, or the countries they represent.



LESSONS LEARNED FROM A NATIONAL CATASTROPHIC FUND: ENGLAND'S CANCER DRUGS FUND.

November 14th, 2019.

Presented by **Kalipso Chalkidou.**

ENCUENTRA EL WEBINAR EN REDCRITERIA.ORG

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)

Minute 00:10:00

Kalipso Chalkidou: Thank you very much. Thank you for the kind introduction and thank you for having me. It's a pleasure to be able to speak in this platform and I look forward also to the discussion that follows. So, I will talk to you about the Cancer Drugs Fund, which was setup and still exist though in a different form here in England as part of the National Health Service.

So, over the years the National Health Service through the National Institute for Health and Care Excellence, its health technology assessment agency, has introduced a series of policies to improve access to drugs, mostly in response, as of all you will appreciate, to political pressure, to media pressure, to public pressure. So, in 2005 we introduced something called the single technology appraisal looking basically at a single drug at a time, as opposed to classes of drugs, with a view to do things faster. Then in 2008 or 2009 there was something called 'the end of life policy', which still holds and effectively gives a premium, a financial premium to products that address needs towards the end of life and you see the majority of those products are cancer products.

In 2010, and you will see how this came about, the Cancer Drugs Fund was set up.

There's been different more initiatives in blue that I would not talk much about, but I will talk to you about also the Cancer Drugs Fund now in its latest incarnation as part of NICE and the impact it's having currently.

So, let me take you through a journey of the different policies in England's National Health Service to improve access to medicines.

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

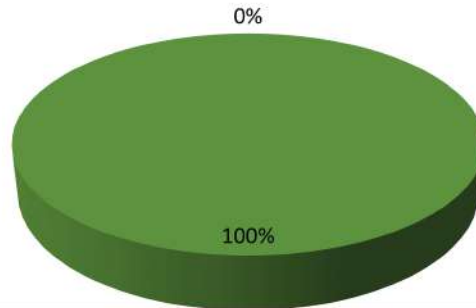
Minute 00:12:00

I mentioned the 2009 end of life policy. When NICE was setup back in 1999 its methods were underpinned by a very important principle: "a QALY is a QALY is a QALY", so, this quality adjusted life year, one year in full health, would have equal value whether you are young or old, whether you have cancer or congestive heart failure, whether you live in the north or the south, whether you are a man or a woman, the same value. However, NICE departed from this principle approximately 10 years after it was set up.

So, in 2009 NICE issued guidance to its committees to consider recommending things that seem to be not cost effective, but extended life towards the end of life to people who are terminally ill and whose life could be extended by few months, all to be given priority. And so, NICE started to issue guidance at that point to approve things at relatively high prices given the benefit, products which targets diseases, severe diseases and help people towards the end of their lives, as long as they affect small number of patients with incurable illness and you'll appreciate that a small number qualification has to do with budget impact considerations. It's a big issue and I will discuss this a bit further down.

End of Life decisions as of May 2014

% of decisions
■ cancer ■ other diseases



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

Minute 00:13:31

Now, which drugs ended up benefiting from this end of life rule? well, a 100% of cases, cancer drugs. That's an interesting revelation, if you like, because at the time the objective was not to favour cancer drugs alone, but ultimately the products that qualified were not just the majority, a 100% of them were cancer drugs.

So, already we see from an early period 2009 onwards a preference towards cancer.

Minute 00:14:06

And this continues because even though the end of life premium applied to cancer drugs and got them over the line for NICE to say yes, and the NHS to reimburse, NICE's committees would still find some cancer drugs not to be good value for money or effective, even clinically effective, and as a result, there would always be a backlash in the press.

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

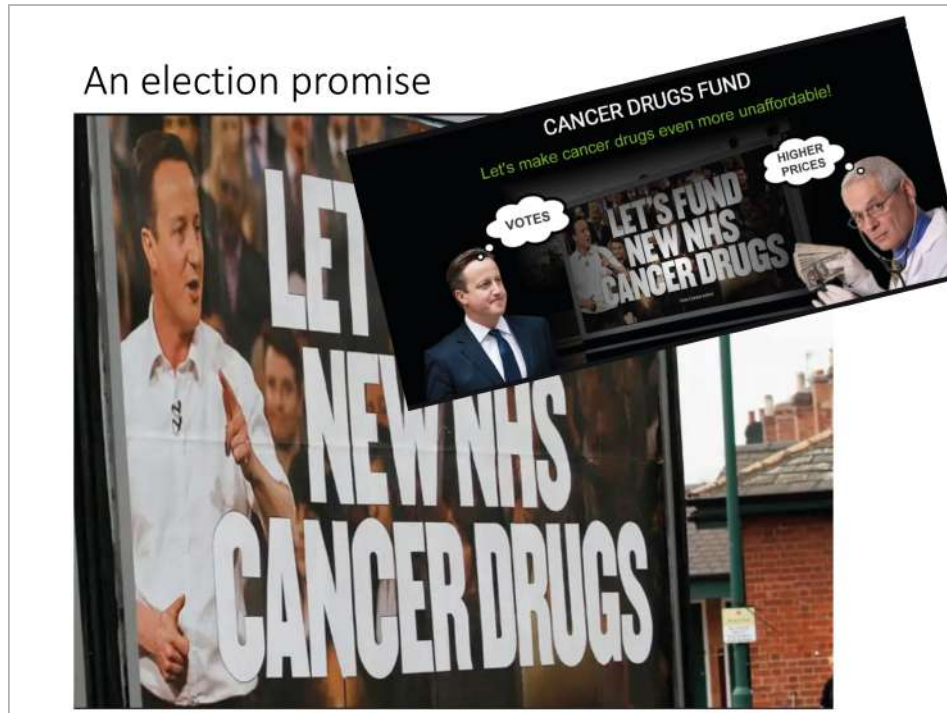
The Coalition:
our programme
for government

Minute 00:14:30

The media would say this is not acceptable: "we don't want the population not to have access to absolutely every cancer drug in particular" and that pressure led to cancer becoming a big issue, cancer drugs in particular, a big issue in the election campaign almost 10 years ago now around 2010. So, the pre-election manifesto of the Tory government, the conservative government at the time, set out this vision of a Cancer Drugs Fund: "we will create the (NE [00:15:02]) Cancer Drugs Fund to enable the patients to access the cancer drugs their doctors think will help them". And then when they became government, in coalition with the more left-wing party, they incorporated this into their plan for government.

So, this policy got them to some extent some votes I guess and then, when they were in power, they established the Cancer Drugs Fund.

An election promise



Minute 00:15:27

And here is what you would see if you were driving around the streets of Britain small towns or London, around 2009-2010, during the election campaign. The event leader of the conservatives, David Cameron, who then became the prime minister, in big billboards with big letters "let's fund new NHS cancer drugs". So, big political promise.

Some might thought that the Cancer Drugs Fund would not work, that perhaps it was about votes, perhaps it was about money. Nevertheless, at the time this was a promise and the promise became the reality when the conservatives began government.

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...

Minute 00:16:08

So, cancer had, and still does, a very special place when it comes to health policy in the UK and, in particular, cancer drugs, not the other things that had to do with improving cancer; cancer drugs in particular.

So, what is the situation about the public? What do people think?

The view of the UK's major cancer charity



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

Minute 00:16:26

Does this view resonate with [others [00:16:31]]? and here is a quote from a major, one of the largest charities and the biggest cancer charity in the UK, Cancer Research UK.

So, the Cancer Research UK submitted evidence in 2012 to parliament and acknowledge that actually we don't have that much money, resources are finite and, ultimately, it's important to make good decisions. So, at the time Cancer Research UK said: "NICE is doing a good job, we like what NICE does, we appreciate the trade-offs to be made", and this is coming from a charity that is pushing for more cancer drugs. Nevertheless, they are sympathetic to the cause of NICE and of the National Health Service.

DoH compulsory prelaunch policy evaluation

Title: Impact Assessment of Proposal for a Cancer Drug Fund	Impact Assessment (IA)
Lead department or agency: DH	IA No: 5012
Other departments or agencies:	Date: 26/10/2010
	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.**”

Minute 00:17:17

What does the public say?

Now this is from a 2010 document an impact assessment that is in the public domain, every single policy the government introduces: health, education, whatever, has to have an impact assessment. So, what would the impact be on resources? what is the rationale also, in terms of public acceptability of the policy or public pressure for the policy? So, is there a basis for introducing a Cancer Drugs Fund? and the civil servants wrote this and it was put in the public domain and they found that there was no evidence for prioritizing cancer above other severe conditions or for prioritizing drugs above any other interventions for cancer, such as surgery, for instance.

So, this is an important piece of evidence. They ran surveys, they did reviews, this was published and submitted to ministers before the Cancer Drugs Fund was actually funded and established. So, some evidence that actually the public, going beyond parliament, going beyond the press, were not that kin specifically for cancer drugs, nevertheless this became a political, hot political issue.

All diseases are equal, but cancer is more equal than others,

...or is it?



Cancer drug fund support lacking, Bangor University survey suggests

New research suggests that most people do not support paying more for cancer drugs over other medicines for equally serious conditions.

The results of the survey by Bangor University come as Welsh Conservatives call on the public to sign a petition for a cancer treatments fund for Wales.

The Welsh government has said there is no evidence that it will improve quality of life or survival rates.



In England the NHS has a cancer drugs fund worth £200m



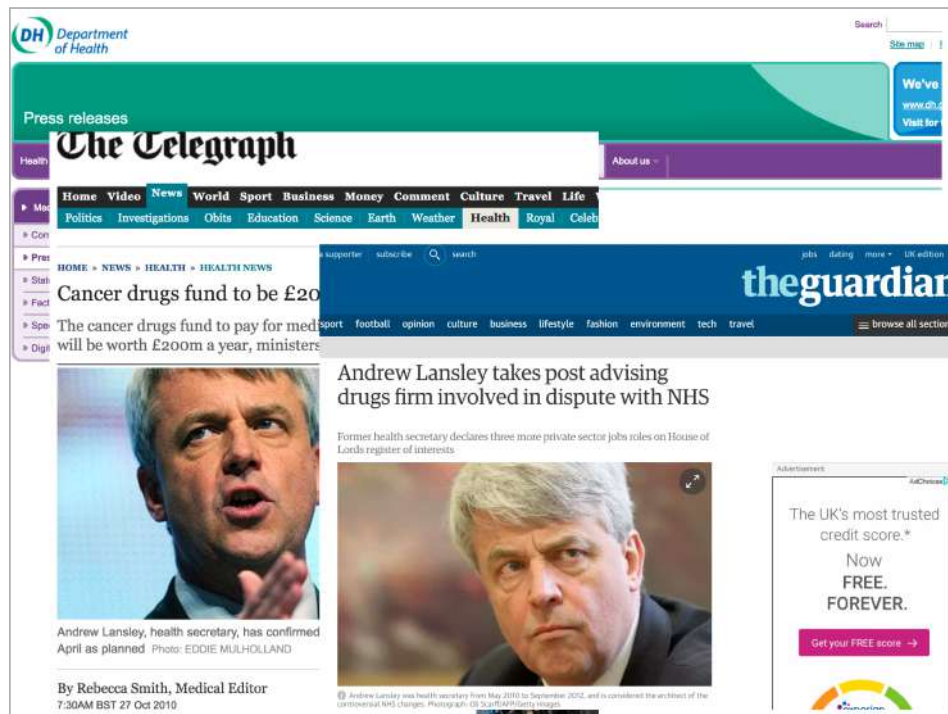
- His team surveyed more than 4,000 people across Wales, England and Scotland to find out whether they valued delivering health benefits to cancer patients more highly than to patients with other conditions.
- "The result that we found were that the majority - about 64% - were not in favour of prioritising 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.

Minute 00:18:30

So, what do the academics say about cancer? A series of studies were published around that period about the Cancer Drugs Fund and this is one published by Bangor University and what they found having surveyed 4000 people withstanding Wales, England and Scotland, asking them what do they value in terms of health benefits when it comes to cancer? And, is cancer more important than other conditions? They found that about 64% were not in favour of prioritizing one over the other, they wanted fairness, fair allocation regardless of the disease and, in general, there was no support for cancer being a special case versus other conditions.

So, an important piece of evidence that again turned the debate in the years to follow, but at the time, the Cancer Drugs Fund was still up and running.



Minute 00:19:24

So, we've talked a little bit about its origins. Let's look at the evolution of the fund.

So, the fund was announced, it was funded with about 60 million and then more and more money was put into the fund. So, 200 million a year, 600 million over 3 years, it ended up escalating to about 1.5 billion over a period of 4 years or so, and interestingly the minister who scoped the whole thing out as in opposition, as a shadow minister, Andrew Lansley, resigned soon after the drugs fund became (defund/defined? [00:20:04]) and took a job with (rushed of all [00:20:07]) companies who has a very important drugs portfolio.

So, it's an interesting story to tell, I guess, how of course you all know how political these decisions are and that was the development of at least in the way the minister moved on career wise.

The screenshot shows a news article from The Telegraph and The Guardian. The article is titled "Cancer drugs fund to be £200m a year, ministers" and "At last, NICE to take over the Cancer Drugs Fund". The article is by Rebecca Smith, Medical Editor, and is dated 7:30AM BST 27 Oct 2010. The article features a photo of Andrew Lansley, health secretary, and mentions that he has confirmed the fund will be worth £200m a year. The article also mentions that NICE will take over the fund. The article is published in BMJ 2016; 352: doi: https://doi.org/10.1136/bmj.1324 (Published 07 March 2016). The article is cited as: BMJ 2016;352:i1324. The article is available in full text at: https://doi.org/10.1136/bmj.1324. The article is also available in full text at: https://doi.org/10.1136/bmj.1324. The article is also available in full text at: https://doi.org/10.1136/bmj.1324.

Minute 00:20:26

In the meantime, the British Medical Journal in 2016 announces the fact that NICE will take over the Cancer Drugs Fund. After that point, NICE had no say, the Cancer Drugs Fund was independent and was set up to fund things effectively that NICE had said not to. So, if something the Cancer Drugs Fund will go to NICE, NICE would reject it, despite the end of life rule, the cancer fund will pick it up and fund it, and hence the inflationary characteristics of the fund.

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

March 2013:

- Government confirmed that “**NICE will be responsible** for the full value assessment of medicines under the future system.”



March-June 2014:

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



A new value-based approach to the pricing of branded medicines

A consultation

Minute 00:20:56

So, the Cancer Drugs Fund was a temporary solution. So, the vision of the government at the time was not to create a catastrophic fund and then keep it as such forever. The idea was: we will start with cancer because the public tell us that cancer matters; we've seen that this may not have been the case, nevertheless this was the idea. So, Cancer is important, we'll pick cancer as our pilot project, but ultimately what we are going to do is we are going to move NICE to more of a value assessment and looking at societal benefits, looking at productivity benefits and, effectively, ending up saying yes to all medicines. That was the ideal situation for our minister, which of course was too good to be true because whether NICE say yes to everything, there wouldn't be enough money to fund everything. So, it was not really a realistic plan for NICE to change the way to assess things in order to make them all affordable and therefore make all the pressure and the bad press disappear.

In the context of this effort and why the Cancer Drugs Fund was running in parallel with NICE, the department of health asked NICE to consult on this new value-based approach, the pricing of medicines was rather complex, we can talk about it if you wish, but ultimately the idea would be that NICE looks at the broader benefits of drugs to society. An idea that many people have brought forward, why are we only looking at efficiency? let's look at productivity, let's look at values that

people appreciate, let's look at whole, let's look at all these things that matter to people and then let's pay premiums for all of these things; but, of course, the problem was there was not enough money in the system. And not only that, after the consultation NICE ran, it seems that not even the pharmaceutical industry agreed on the methodology for appraising drugs that would go beyond health benefits and as a result NICE's board said: "no changes to the appraisal methodology in the short term".

So, the government was in a bit of a pickle, it had pushed NICE to revise its methods to be more agreeable, more positive. It was running the Cancer Drugs Fund, but the Cancer Drugs Fund was swallowing more and more money, more and more money, and in the meantime NICE process had not changed; and so, this pilot, became a permanent condition. It was just very problematic.


National Audit Office

Publications search ▾
Reports, press releases ....

Reports by sector ▾
Defence, Education, Health ...

Health and social care

Investigation into the Cancer Drugs Fund

The Cancer Drugs Fund has improved access to cancer drugs not routinely available on the NHS, but all parties agree it is not sustainable in its current form.

- **“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...”

Sep 2015: the country’s
National Audit Office
investigates

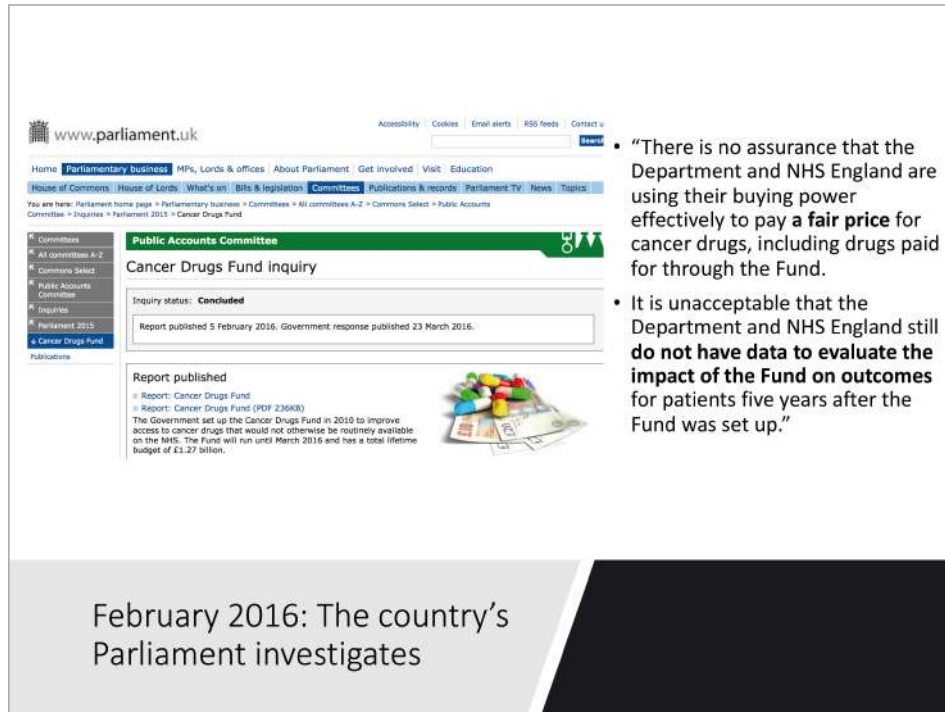
Minute 00:23:19

As all of this was happening, some independent government institutions worried about the inflationary pressures started to look into the Cancer Drugs Fund.

So, we had a body called the National Audit Office, it is independent, it is funded by government, but it picks the topics it looks at, in health, education, defence... and it issues reports about due process, about efficiency, about good public principles of spending and it decided to look into the Cancer Drugs Fund. So, it concluded that all parties agreed that it was not sustainable, though it improved access to cancer drugs that the NHS would not pay for, because NICE said not to it. Did it improved outcomes? Well, we couldn't tell, the National Audit Office found because we're not collecting the data. And the what about prices? and what about total spending? Well, the total cost of the fund in 5 years between 2010-2015 was about 1 billion pounds, about the allocated budget of 600 million for 3 years. In the early years it was under spent, but gradually was spending more and more and more, and there was an increase of 138%.

The government started to worry, you could see that initially it said it would be 50 million a year and only temporary, then it was 200 million a year, then it became 300 million a year, and they were observing an increase of about 138% year on year. An increase, not because more people were being treated, but because the companies that could see that could get access to the fund

without the NICE obstacle, if you'd like, were increasing the prices. So, more than 50% of the raised spending, was not because more people were getting access, was because the companies were charging more and more and more per pill or per injection, because they could see there was a pot of money they could access without much scrutiny.



www.parliament.uk

Home Parliamentary business MPs, Lords & offices About Parliament Get involved Visit Education

House of Commons House of Lords What's on Bills & legislation Committees Publications & records Parliament TV News Topics

You are here: Parliament home page > Parliamentary business > Committees > All committees A-Z > Commons Select > Public Accounts Committee > Inquiries > Parliament 2015 > Cancer Drugs Fund

Committees

- All committees A-Z
- Commons Select
- Public Accounts Committee
- Inquiries
- Parliament 2015
- Cancer Drugs Fund

Public Accounts Committee

Cancer Drugs Fund inquiry

Inquiry status: **Concluded**

Report published 5 February 2016. Government response published 23 March 2016.

Report published

- Report: Cancer Drugs Fund
- Report: Cancer Drugs Fund (PDF 236KB)

The Government set up the Cancer Drugs Fund in 2010 to improve access to cancer drugs that would not otherwise be routinely available on the NHS. The Fund will run until March 2016 and has a total lifetime budget of £1.27 billion.

- “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

Minute 00:25:16

The parliament also took a look at it. There's a cross party, a committee that looks at health with membership from all parties and they, in February 2016, decided to investigate the Cancer Drugs Fund. So, in their enquiry they concluded that there's no insurance from the department of health and NHS England were using their buying power to pay a good price for cancer drugs, including through the fund, and they found unacceptable that there was no data as the National Audit Office noted, just assessed impact on the fund outcome.

So, 5 years after it was set up, a billion pounds later, we still did not know whether this people that were getting the drugs that the fund paid for were actually doing better than those who did not and this was flagged as a big weakness.

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

The Telegraph



"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

Minute 00:26:07

And the press was an interesting and important partner of this. Sometimes in similar newspapers who were pushing for more access to cancer drugs, were now sceptical about the Cancer Drugs Fund.

The financial times concluding that the Cancer Drugs Fund was about a populist gesture, giving the impression that it benefits patients but really rewards poor quality drugs and benefits a small number of pharmaceutical companies at the expense of the taxpayer.

And the daily Telegraph, fairly right winged newspaper, who concludes after interviewing Jeremy Hunt at the time the health minister who replaced the gentleman who joined the pharmaceutical industry, that this mechanism for diverting taxpayer's money to enhance too little or no purpose the profits of big pharma, might be more aptly named "the drug company fund". And this is a newspaper that is generally supportive of the policies of the government. So, a significant push back, a significant pushback.

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.**

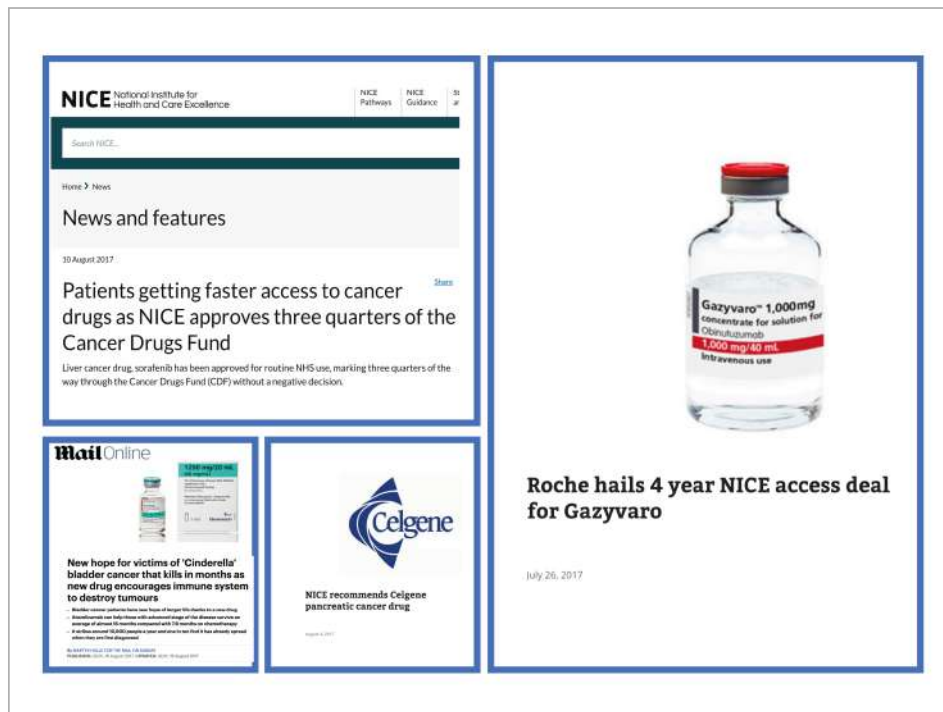
Appraisal and Funding of Cancer Drugs from July 2016 (including the new Cancer Drugs Fund)

A new deal for patients, taxpayers and industry



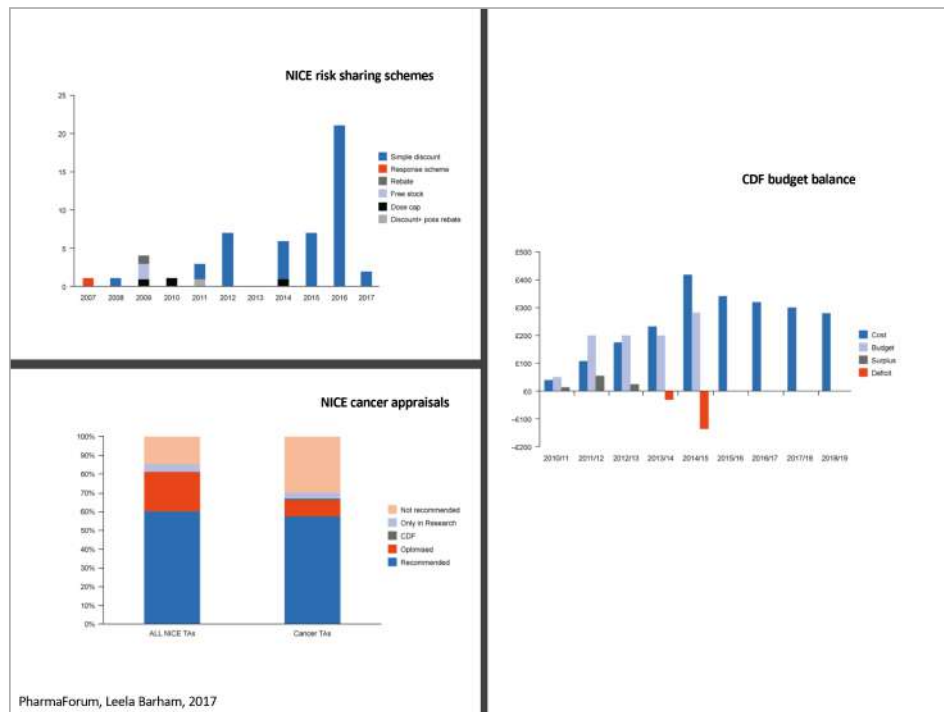
Minute 00:27:15

And then, at this point the NHS England Agency in 2017 takes control of the Cancer Drugs Fund. It issues a policy which is in the public domain and it's effectively setting an expenditure control around the fund and makes it a managed entry scheme subjected to data submission and caps the spending, so there's no inflationary pressure, there's no runaway costs.



Minute 00:28:49

So, NICE still claims true to itself that the Cancer Drugs Fund offers access to cancer drugs to patients. It seems to be opening up to more cancer drugs, you can see the press releases are basically Cancer Drugs Fund under NICE's leadership leads to some compromise and more cancer drugs coming through perhaps in a more affordable way.



Minute 00:29:17

And you can see here, in the NICE cancer appraisals at the bottom in pink the things that NICE said no to, and you see that when it comes to cancer on the right the pink is bigger, so more cancer drugs get rejected than non-cancer drugs on the left; but only now the CDF budget balance is under control, so it's not in deficit and it's a set budget, there's no more: "we'll give you a budget but you can overspend", no more red bars, because the government has capped the total amount.

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

Article

Related content

Metrics

Responses

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

Author affiliations ▼

Correspondence to: R Grieve richard.grieve@shrm.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>

Minute 00:29:52

All that said, things are still not perfect. A group of academics, and you can see their names on the left side, signed a BMJ called to reform the Cancer Drugs Fund even further, to collect real world observational data that are unbiased as oppose to prospective cohorts information which undermines randomized trials to link it to national cancer registers; and then also they're calling for more caution, because ultimately some of this products once introduced even through temporarily and capped funds, they still find their way into the market, they become entrenched and it's difficult to get rid of them even when they've shown no value.

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 indications. 13 of these

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 technology appraisal processes.

Minute 00:30:38

So, did the Cancer Drugs Fund deliver value for the English society?

This is the definitive evaluation I will say, published in April 2017 by a group of really good colleagues from King's College and elsewhere. So, they found that only 38% of drugs reported statistically, not clinically, significant overall survival benefit and we're looking at a median of 3 months, we're talking about billion times over, over the period of the fund. When assessed against the ASCO and ESMO criteria only a fraction of them met the criteria, the American more (linear [00:31:16]) framework than the European. A few drugs really represented the bulk of applications bevacizumab for various indications, cetuximab, everolimus and lapatinib. So, a lot of these ended up being delisted by NICE, when NICE takes over takes a good look into the base line and delists these drugs, not because they were not cost effective but because they were not clinically effective, so, these drugs were paid for, and they shouldn't have been, not because they were not cost effective but because there was no evidence that they were actually clinically effective. That's really important, they might have been save but they were not better than much cheaper alternatives, so we did not have evidence that they actually work. A total of fund 1.3 billion roughly spent on the fund and, of course, no usable data collected on exactly what the impact has been on patients. [00:32:15] And they concluded the Cancer Drugs Fund has not delivered meaningful value to

patients, there's no empirical evidence to support a drug only ring fenced cancer fund relatively to investment in other cancer domains as we all know: having surgery, having radio therapy, having non-cancer medicines, all improve survival including on cancer patients. And they recommended reimbursement decisions for all drugs and interventions within cancer, all to be made through appropriate health technology assessment processes. This is their recommendation.

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: Benefit and Scope of each NICE HTA programme

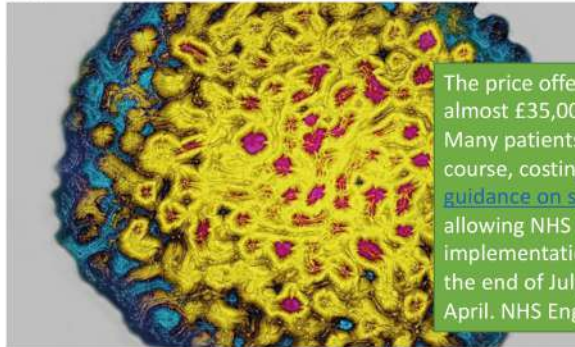
	Technology Appraisal Programme	Medical Technologies Guidance	Diagnostic Assessment Programme	Highly Specialised Technology Programme	Clinical Guidelines
What is assessed?	Medicines, medical devices, diagnostics, surgical procedures, interventional techniques, evidence of care, screening tests.	Medical devices (active, active/moderate, in vitro), genetic tests.	Diagnostic technological tests, genetic tests.	Drugs for very rare conditions.	Guidelines for care and services.
Referral	Primarily HSRIC; formal advice required from Ministers of State for Health.	Primarily product sponsors; also HSRIC.	Product sponsors, national clinical directors, medical royal colleges, professional bodies, relevant expert panels, in HSRIC.	Primarily HSRIC; national advice required from DH.	Topic oversight group.
Selection/ routing	Must have been granted, or be seen to require, marketing authorisation. Significant benefit to patients, new information at lower price, appropriate evidence available.	Have CE mark (or expected within 1 year); New or improved technology. Cost saving or cost neutral technology.	CE marking (definition of publication); Expected to improve health outcomes, but at an increased cost to the NHS.	Criteria same as those used by HSRIC. Process similar to that.	Priority topics and those where existing NICE guidance does not cover the whole field.
Priority review criteria	Significant health benefit; Significant impact on NHS resources and cost; government policies; disproportionate impact in the use across the country.	Provides most benefit to patients and the NHS; saving system.	Particular urgency to the NHS.	Not stated.	Discusses between NHS England, DH and NHS Health England.

Source: NICE (2016a), NICE(2016b), NICE(2016c), NICE(2016d), NICE(2016e), NICE(2016f), NICE(2016g), NICE(2016h), NICE(2016i), NICE(2016j), NICE(2016k), NICE(2016l), NICE(2016m), NICE(2016n), NICE(2016o), NICE(2016p), NICE(2016q), NICE(2016r), NICE(2016s), NICE(2016t), NICE(2016u), NICE(2016v), NICE(2016w), NICE(2016x), NICE(2016y), NICE(2016z), NICE(2017a), NICE(2017b), NICE(2017c), NICE(2017d), NICE(2017e), NICE(2017f), NICE(2017g), NICE(2017h), NICE(2017i), NICE(2017j), NICE(2017k), NICE(2017l), NICE(2017m), NICE(2017n), NICE(2017o), NICE(2017p), NICE(2017q), NICE(2017r), NICE(2017s), NICE(2017t), NICE(2017u), NICE(2017v), NICE(2017w), NICE(2017x), NICE(2017y), NICE(2017z), NICE(2018a), NICE(2018b), NICE(2018c), NICE(2018d), NICE(2018e), NICE(2018f), NICE(2018g), NICE(2018h), NICE(2018i), NICE(2018j), NICE(2018k), NICE(2018l), NICE(2018m), NICE(2018n), NICE(2018o), NICE(2018p), NICE(2018q), NICE(2018r), NICE(2018s), NICE(2018t), NICE(2018u), NICE(2018v), NICE(2018w), NICE(2018x), NICE(2018y), NICE(2018z), NICE(2019a), NICE(2019b), NICE(2019c), NICE(2019d), NICE(2019e), NICE(2019f), NICE(2019g), NICE(2019h), NICE(2019i), NICE(2019j), NICE(2019k), NICE(2019l), NICE(2019m), NICE(2019n), NICE(2019o), NICE(2019p), NICE(2019q), NICE(2019r), NICE(2019s), NICE(2019t), NICE(2019u), NICE(2019v), NICE(2019w), NICE(2019x), NICE(2019y), NICE(2019z), NICE(2020a), NICE(2020b), NICE(2020c), NICE(2020d), NICE(2020e), NICE(2020f), NICE(2020g), NICE(2020h), NICE(2020i), NICE(2020j), NICE(2020k), NICE(2020l), NICE(2020m), NICE(2020n), NICE(2020o), NICE(2020p), NICE(2020q), NICE(2020r), NICE(2020s), NICE(2020t), NICE(2020u), NICE(2020v), NICE(2020w), NICE(2020x), NICE(2020y), NICE(2020z), NICE(2021a), NICE(2021b), NICE(2021c), NICE(2021d), NICE(2021e), NICE(2021f), NICE(2021g), NICE(2021h), NICE(2021i), NICE(2021j), NICE(2021k), NICE(2021l), NICE(2021m), NICE(2021n), NICE(2021o), NICE(2021p), NICE(2021q), NICE(2021r), NICE(2021s), NICE(2021t), NICE(2021u), NICE(2021v), NICE(2021w), NICE(2021x), NICE(2021y), NICE(2021z), NICE(2022a), NICE(2022b), NICE(2022c), NICE(2022d), NICE(2022e), NICE(2022f), NICE(2022g), NICE(2022h), NICE(2022i), NICE(2022j), NICE(2022k), NICE(2022l), NICE(2022m), NICE(2022n), NICE(2022o), NICE(2022p), NICE(2022q), NICE(2022r), NICE(2022s), NICE(2022t), NICE(2022u), NICE(2022v), NICE(2022w), NICE(2022x), NICE(2022y), NICE(2022z), NICE(2023a), NICE(2023b), NICE(2023c), NICE(2023d), NICE(2023e), NICE(2023f), NICE(2023g), NICE(2023h), NICE(2023i), NICE(2023j), NICE(2023k), NICE(2023l), NICE(2023m), NICE(2023n), NICE(2023o), NICE(2023p), NICE(2023q), NICE(2023r), NICE(2023s), NICE(2023t), NICE(2023u), NICE(2023v), NICE(2023w), NICE(2023x), NICE(2023y), NICE(2023z), NICE(2024a), NICE(2024b), NICE(2024c), NICE(2024d), NICE(2024e), NICE(2024f), NICE(2024g), NICE(2024h), NICE(2024i), NICE(2024j), NICE(2024k), NICE(2024l), NICE(2024m), NICE(2024n), NICE(2024o), NICE(2024p), NICE(2024q), NICE(2024r), NICE(2024s), NICE(2024t), NICE(2024u), NICE(2024v), NICE(2024w), NICE(2024x), NICE(2024y), NICE(2024z), NICE(2025a), NICE(2025b), NICE(2025c), NICE(2025d), NICE(2025e), NICE(2025f), NICE(2025g), NICE(2025h), NICE(2025i), NICE(2025j), NICE(2025k), NICE(2025l), NICE(2025m), NICE(2025n), NICE(2025o), NICE(2025p), NICE(2025q), NICE(2025r), NICE(2025s), NICE(2025t), NICE(2025u), NICE(2025v), NICE(2025w), NICE(2025x), NICE(2025y), NICE(2025z), NICE(2026a), NICE(2026b), NICE(2026c), NICE(2026d), NICE(2026e), NICE(2026f), NICE(2026g), NICE(2026h), NICE(2026i), NICE(2026j), NICE(2026k), NICE(2026l), NICE(2026m), NICE(2026n), NICE(2026o), NICE(2026p), NICE(2026q), NICE(2026r), NICE(2026s), NICE(2026t), NICE(2026u), NICE(2026v), NICE(2026w), NICE(2026x), NICE(2026y), NICE(2026z), NICE(2027a), NICE(2027b), NICE(2027c), NICE(2027d), NICE(2027e), NICE(2027f), NICE(2027g), NICE(2027h), NICE(2027i), NICE(2027j), NICE(2027k), NICE(2027l), NICE(2027m), NICE(2027n), NICE(2027o), NICE(2027p), NICE(2027q), NICE(2027r), NICE(2027s), NICE(2027t), NICE(2027u), NICE(2027v), NICE(2027w), NICE(2027x), NICE(2027y), NICE(2027z), NICE(2028a), NICE(2028b), NICE(2028c), NICE(2028d), NICE(2028e), NICE(2028f), NICE(2028g), NICE(2028h), NICE(2028i), NICE(2028j), NICE(2028k), NICE(2028l), NICE(2028m), NICE(2028n), NICE(2028o), NICE(2028p), NICE(2028q), NICE(2028r), NICE(2028s), NICE(2028t), NICE(2028u), NICE(2028v), NICE(2028w), NICE(2028x), NICE(2028y), NICE(2028z), NICE(2029a), NICE(2029b), NICE(2029c), NICE(2029d), NICE(2029e), NICE(2029f), NICE(2029g), NICE(2029h), NICE(2029i), NICE(2029j), NICE(2029k), NICE(2029l), NICE(2029m), NICE(2029n), NICE(2029o), NICE(2029p), NICE(2029q), NICE(2029r), NICE(2029s), NICE(2029t), NICE(2029u), NICE(2029v), NICE(2029w), NICE(2029x), NICE(2029y), NICE(2029z), NICE(2030a), NICE(2030b), NICE(2030c), NICE(2030d), NICE(2030e), NICE(2030f), NICE(2030g), NICE(2030h), NICE(2030i), NICE(2030j), NICE(2030k), NICE(2030l), NICE(2030m), NICE(2030n), NICE(2030o), NICE(2030p), NICE(2030q), NICE(2030r), NICE(2030s), NICE(2030t), NICE(2030u), NICE(2030v), NICE(2030w), NICE(2030x), NICE(2030y), NICE(2030z), NICE(2031a), NICE(2031b), NICE(2031c), NICE(2031d), NICE(2031e), NICE(2031f), NICE(2031g), NICE(2031h), NICE(2031i), NICE(2031j), NICE(2031k), NICE(2031l), NICE(2031m), NICE(2031n), NICE(2031o), NICE(2031p), NICE(2031q), NICE(2031r), NICE(2031s), NICE(2031t), NICE(2031u), NICE(2031v), NICE(2031w), NICE(2031x), NICE(2031y), NICE(2031z), NICE(2032a), NICE(2032b), NICE(2032c), NICE(2032d), NICE(2032e), NICE(2032f), NICE(2032g), NICE(2032h), NICE(2032i), NICE(2032j), NICE(2032k), NICE(2032l), NICE(2032m), NICE(2032n), NICE(2032o), NICE(2032p), NICE(2032q), NICE(2032r), NICE(2032s), NICE(2032t), NICE(2032u), NICE(2032v), NICE(2032w), NICE(2032x), NICE(2032y), NICE(2032z), NICE(2033a), NICE(2033b), NICE(2033c), NICE(2033d), NICE(2033e), NICE(2033f), NICE(2033g), NICE(2033h), NICE(2033i), NICE(2033j), NICE(2033k), NICE(2033l), NICE(2033m), NICE(2033n), NICE(2033o), NICE(2033p), NICE(2033q), NICE(2033r), NICE(2033s), NICE(2033t), NICE(2033u), NICE(2033v), NICE(2033w), NICE(2033x), NICE(2033y), NICE(2033z), NICE(2034a), NICE(2034b), NICE(2034c), NICE(2034d), NICE(2034e), NICE(2034f), NICE(2034g), NICE(2034h), NICE(2034i), NICE(2034j), NICE(2034k), NICE(2034l), NICE(2034m), NICE(2034n), NICE(2034o), NICE(2034p), NICE(2034q), NICE(2034r), NICE(2034s), NICE(2034t), NICE(2034u), NICE(2034v), NICE(2034w), NICE(2034x), NICE(2034y), NICE(2034z), NICE(2035a), NICE(2035b), NICE(2035c), NICE(2035d), NICE(2035e), NICE(2035f), NICE(2035g), NICE(2035h), NICE(2035i), NICE(2035j), NICE(2035k), NICE(2035l), NICE(2035m), NICE(2035n), NICE(2035o), NICE(2035p), NICE(2035q), NICE(2035r), NICE(2035s), NICE(2035t), NICE(2035u), NICE(2035v), NICE(2035w), NICE(2035x), NICE(2035y), NICE(2035z), NICE(2036a), NICE(2036b), NICE(2036c), NICE(2036d), NICE(2036e), NICE(2036f), NICE(2036g), NICE(2036h), NICE(2036i), NICE(2036j), NICE(2036k), NICE(2036l), NICE(2036m), NICE(2036n), NICE(2036o), NICE(2036p), NICE(2036q), NICE(2036r), NICE(2036s), NICE(2036t), NICE(2036u), NICE(2036v), NICE(2036w), NICE(2036x), NICE(2036y), NICE(2036z), NICE(2037a), NICE(2037b), NICE(2037c), NICE(2037d), NICE(2037e), NICE(2037f), NICE(2037g), NICE(2037h), NICE(2037i), NICE(2037j), NICE(2037k), NICE(2037l), NICE(2037m), NICE(2037n), NICE(2037o), NICE(2037p), NICE(2037q), NICE(2037r), NICE(2037s), NICE(2037t), NICE(2037u), NICE(2037v), NICE(2037w), NICE(2037x), NICE(2037y), NICE(2037z), NICE(2038a), NICE(2038b), NICE(2038c), NICE(2038d), NICE(2038e), NICE(2038f), NICE(2038g), NICE(2038h), NICE(2038i), NICE(2038j), NICE(2038k), NICE(2038l), NICE(2038m), NICE(2038n), NICE(2038o), NICE(2038p), NICE(2038q), NICE(2038r), NICE(2038s), NICE(2038t), NICE(2038u), NICE(2038v), NICE(2038w), NICE(2038x), NICE(2038y), NICE(2038z), NICE(2039a), NICE(2039b), NICE(2039c), NICE(2039d), NICE(2039e), NICE(2039f), NICE(2039g), NICE(2039h), NICE(2039i), NICE(2039j), NICE(2039k), NICE(2039l), NICE(2039m), NICE(2039n), NICE(2039o), NICE(2039p), NICE(2039q), NICE(2039r), NICE(2039s), NICE(2039t), NICE(2039u), NICE(2039v), NICE(2039w), NICE(2039x), NICE(2039y), NICE(2039z), NICE(2040a), NICE(2040b), NICE(2040c), NICE(2040d), NICE(2040e), NICE(2040f), NICE(2040g), NICE(2040h), NICE(2040i), NICE(2040j), NICE(2040k), NICE(2040l), NICE(2040m), NICE(2040n), NICE(2040o), NICE(2040p), NICE(2040q), NICE(2040r), NICE(2040s), NICE(2040t), NICE(2040u), NICE(2040v), NICE(2040w), NICE(2040x), NICE(2040y), NICE(2040z), NICE(2041a), NICE(2041b), NICE(2041c), NICE(2041d), NICE(2041e), NICE(2041f), NICE(2041g), NICE(2041h), NICE(2041i), NICE(2041j), NICE(2041k), NICE(2041l), NICE(2041m), NICE(2041n), NICE(2041o), NICE(2041p), NICE(2041q), NICE(2041r), NICE(2041s), NICE(2041t), NICE(2041u), NICE(2041v), NICE(2041w), NICE(2041x), NICE(2041y), NICE(2041z), NICE(2042a), NICE(2042b), NICE(2042c), NICE(2042d), NICE(2042e), NICE(2042f), NICE(2042g), NICE(2042h), NICE(2042i), NICE(2042j), NICE(2042k), NICE(2042l), NICE(2042m), NICE(2042n), NICE(2042o), NICE(2042p), NICE(2042q), NICE(2042r), NICE(2042s), NICE(2042t), NICE(2042u), NICE(2042v), NICE(2042w), NICE(2042x), NICE(2042y), NICE(2042z), NICE(2043a), NICE(2043b), NICE(2043c), NICE(2043d), NICE(2043e), NICE(2043f), NICE(2043g), NICE(2043h), NICE(2043i), NICE(2043j), NICE(2043k), NICE(2043l), NICE(2043m), NICE(2043n), NICE(2043o), NICE(2043p), NICE(2043q), NICE(2043r), NICE(2043s), NICE(2043t), NICE(2043u), NICE(2043v), NICE(2043w), NICE(2043x), NICE(2043y), NICE(2043z), NICE(2044a), NICE(2044b), NICE(2044c), NICE(2044d), NICE(2044e), NICE(2044f), NICE(2044g), NICE(2044h), NICE(2044i), NICE(2044j), NICE(2044k), NICE(2044l), NICE(2044m), NICE(2044n), NICE(2044o), NICE(2044p), NICE(2044q), NICE(2044r), NICE(2044s), NICE(2044t), NICE(2044u), NICE(2044v), NICE(2044w), NICE(2044x), NICE(2044y), NICE(2044z), NICE(2045a), NICE(2045b), NICE(2045c), NICE(2045d), NICE(2045e), NICE(2045f), NICE(2045g), NICE(2045h), NICE(2045i), NICE(2045j), NICE(2045k), NICE(2045l), NICE(2045m), NICE(2045n), NICE(2045o), NICE(2045p), NICE(2045q), NICE(2045r), NICE(2045s), NICE(2045t), NICE(2045u), NICE(2045v), NICE(2045w), NICE(2045x), NICE(2045y), NICE(2045z), NICE(2046a), NICE(2046b), NICE(2046c), NICE(2046d), NICE(2046e), NICE(2046f), NICE(2046g), NICE(2046h), NICE(2046i), NICE(2046j), NICE(2046k), NICE(2046l), NICE(2046m), NICE(2046n), NICE(2046o), NICE(2046p), NICE(2046q), NICE(2046r), NICE(2046s), NICE(2046t), NICE(2046u), NICE(2046v), NICE(2046w), NICE(2046x), NICE(2046y), NICE(2046z), NICE(2047a), NICE(2047b), NICE(2047c), NICE(2047d), NICE(2047e), NICE(2047f), NICE(2047g), NICE(2047h), NICE(2047i), NICE(2047j), NICE(2047k), NICE(2047l), NICE(2047m), NICE(2047n), NICE(2047o), NICE(2047p), NICE(2047q), NICE(2047r), NICE(2047s), NICE(2047t), NICE(2047u), NICE(2047v), NICE(2047w), NICE(2047x), NICE(2047y), NICE(2047z), NICE(2048a), NICE(2048b), NICE(2048c), NICE(2048d), NICE(2048e), NICE(2048f), NICE(2048g), NICE(2048h), NICE(2048i), NICE(2048j), NICE(2048k), NICE(2048l), NICE(2048m), NICE(2048n), NICE(2048o), NICE(2048p), NICE(2048q), NICE(2048r), NICE(2048s), NICE(2048t), NICE(2048u), NICE(2048v), NICE(2048w), NICE(2048x), NICE(2048y), NICE(2048z), NICE(2049a), NICE(2049b), NICE(2049c), NICE(2049d), NICE(2049e), NICE(2049f), NICE(2049g), NICE(2049h), NICE(2049i), NICE(2049j), NICE(2049k), NICE(2049l), NICE(2049m), NICE(2049n), NICE(2049o), NICE(2049p), NICE(2049q), NICE(2049r), NICE(2049s), NICE(2049t), NICE(2049u), NICE(2049v), NICE(2049w), NICE(2049x), NICE(2049y), NICE(2049z), NICE(2050a), NICE(2050b), NICE(2050c), NICE(2050d), NICE(2050e), NICE(2050f), NICE(2050g), NICE(2050h), NICE(2050i), NICE(2050j), NICE(2050k), NICE(2050l), NICE(2050m), NICE(2050n), NICE(2050o), NICE(2050p), NICE(2050q), NICE(2050r), NICE(2050s), NICE(2050t), NICE(2050u), NICE(2050v), NICE(2050w), NICE(2050x), NICE(2050y), NICE(2050z), NICE(2051a), NICE(2051b), NICE(2051c), NICE(2051d), NICE(2051e), NICE(2051f), NICE(2051g), NICE(2051h), NICE(2051i), NICE(2051j), NICE(2051k), NICE(2051l), NICE(2051m), NICE(2051n), NICE(2051o), NICE(2051p), NICE(2051q), NICE(2051r), NICE(2051s), NICE(2051t), NICE(2051u), NICE(2051v), NICE(2051w), NICE(2051x), NICE(2051y), NICE(2051z), NICE(2052a), NICE(2052b), NICE(2052c), NICE(2052d), NICE(2052e), NICE(2052f), NICE(2052g), NICE(2052h), NICE(2052i), NICE(2052j), NICE(2052k), NICE(2052l), NICE(2052m), NICE(2052n), NICE(2052o), NICE(2052p), NICE(2052q), NICE(2052r), NICE(2052s), NICE(2052t), NICE(2052u), NICE(2052v), NICE(2052w), NICE(2052x), NICE(2052y), NICE(2052z), NICE(2053a), NICE(2053b), NICE(2053c), NICE(2053d), NICE(2053e), NICE(2053f), NICE(2053g), NICE(2053h), NICE(2053i), NICE(2053j), NICE(2053k), NICE(2053l), NICE(2053m), NICE(2053n), NICE(2053o), NICE(2053p), NICE(2053q), NICE(2053r), NICE(2053s), NICE(2053t), NICE(2053u), NICE(2053v), NICE(2053w), NICE(2053x), NICE(2053y), NICE(2053z), NICE(2054a), NICE(2054b), NICE(2054c), NICE(2054d), NICE(2054e), NICE(2054f), NICE(2054g), NICE(2054h), NICE(2054i), NICE(2054j), NICE(2054k), NICE(2054l), NICE(2054m), NICE(2054n), NICE(2054o), NICE(2054p), NICE(2054q), NICE(2054r), NICE(2054s), NICE(2054t), NICE(2054u), NICE(2054v), NICE(2054w), NICE(2054x), NICE(2054y), NICE(2054z), NICE(2055a), NICE(2055b), NICE(2055c), NICE(2055d), NICE(2055e), NICE(2055f), NICE(2055g), NICE(2055h), NICE(2055i), NICE(2055j), NICE(2055k), NICE(2055l), NICE(2055m), NICE(2055n), NICE(2055o), NICE(2055p), NICE(2055q), NICE(2055r), NICE(2055s), NICE(2055t), NICE(2055u), NICE(2055v), NICE(2055w), NICE(2055x), NICE(2055y), NICE(2055z), NICE(2056a), NICE(2056b), NICE(2056c), NICE(2056d), NICE(2056e), NICE(2056f), NICE(2056g), NICE(2056h), NICE(2056i), NICE(2056j), NICE(2056k), NICE(2056l), NICE(2056m), NICE(2056n), NICE(2056o), NICE(2056p), NICE(2056q), NICE(2056r), NICE(2056s), NICE(2056t), NICE(2056u), NICE(2056v), NICE(2056w), NICE(2056x), NICE(2056y), NICE(2056z), NICE(2057a), NICE(2057b), NICE(2057c), NICE(2057d), NICE(2057e), NICE(2057f), NICE(2057g), NICE(2057h), NICE(2057i), NICE(2057j), NICE(2057k), NICE(2057l), NICE(2057m), NICE(2057n), NICE(2057o), NICE(2057p), NICE(2057q), NICE(2057r), NICE(2057s), NICE(2057t), NICE(2057u), NICE(2057v), NICE(2057w), NICE(2057x), NICE(2057y), NICE(2057z), NICE(2058a), NICE(2058b), NICE(2058c), NICE(2058d), NICE(2058e), NICE(2058f), NICE(2058g), NICE(2058h), NICE(2058i), NICE(2058j), NICE(2058k), NICE(2058l), NICE(2058m), NICE(2058n), NICE(2058o), NICE(2058p), NICE(2058q), NICE(2058r), NICE(2058s), NICE(2058t), NICE(2058u), NICE(2058v), NICE(2058w), NICE(2058x), NICE(2058y), NICE(2058z), NICE(2059a), NICE(2059b), NICE(2059c), NICE(2059d), NICE(2059e), NICE(2059f), NICE(2059g), NICE(2059h), NICE(2059i), NICE(2059j), NICE(2059k), NICE(2059l), NICE(2059m), NICE(2059n), NICE(2059o), NICE(2059p), NICE(2059q), NICE(2059r), NICE(2059s), NICE(2059t), NICE(2059u), NICE(2059v), NICE(2059w), NICE(2059x), NICE(2059y), NICE(2059z), NICE(2060a), NICE(2060b), NICE(2060c), NICE(2060d), NICE(2060e), NICE(2060f), NICE(2060g), NICE(2060h), NICE(2060i), NICE(2060j), NICE(2060k), NICE(2060l), NICE(2060m), NICE(2060n), NICE(2060o), NICE(2060p), NICE(2060q), NICE(2060r), NICE(2060s), NICE(2060t), NICE(2060u), NICE(2060v), NICE(2060w), NICE(2060x), NICE(2060y), NICE(2060z), NICE(2061a), NICE(2061b), NICE(2061c), NICE(2061d), NICE(2061e), NICE(2061f), NICE(2061g), NICE(2061h), NICE(2061i), NICE(2061j), NICE(2061k), NICE(2061l), NICE(2061m), NICE(2061n), NICE(2061o), NICE(2061p), NICE(2061q), NICE(2061r), NICE(2061s), NICE(2061t), NICE(2061u), NICE(2061v), NICE(2061w), NICE(2061x), NICE(2061y), NICE(2061z), NICE(2062a), NICE(2062b), NICE(2062c), NICE(2062d), NICE(2062e), NICE(2062f), NICE(2062g), NICE(2062h), NICE(2062i), NICE(2062j), NICE(2062k), NICE(2062l), NICE(2062m), NICE(2062n), NICE(2062o), NICE(2062p), NICE(2062q), NICE(2062r), NICE(2062s), NICE(2062t), NICE(2062u), NICE(2062v), NICE(2062w), NICE(2062x), NICE(2062y), NICE(2062z), NICE(2063a), NICE(2063b), NICE(2063c), NICE(2063d), NICE(2063e), NICE(2063f), NICE(2063g), NICE(2063h), NICE(2063i), NICE(2063j), NICE(2063k), NICE(2063l), NICE(2063m), NICE(2063n), NICE(2063o), NICE(2063p), NICE(2063q), NICE(2063r), NICE(2063s), NICE(2063t), NICE(2063u), NICE(2063v), NICE(2063w), NICE(2063x), NICE(2063y), NICE(2063z), NICE(2064a), NICE(2064b), NICE(2064c), NICE(2064d), NICE(2064e), NICE(2064f), NICE(2064g), NICE(2064h), NICE(2064i), NICE(2064j), NICE(2064k), NICE(2064l), NICE(2064m), NICE(2064n), NICE(2064o), NICE(2064p), NICE(2064q), NICE(2064r), NICE(2064s), NICE(2064t), NICE(2064u), NICE(2064v), NICE(2064w), NICE(2064x), NICE(2064y), NICE(2064z), NICE(2065a), NICE(2065b), NICE(2065c), NICE(2065d), NICE(2065e), NICE(2065f), NICE(2065g), NICE(2065h), NICE(2065i), NICE(2065j), NICE(2065k), NICE(2065l), NICE(2065m), NICE(2065n), NICE(2065o), NICE(2065

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.

Minute 00:33:45

And hepatitis C is one such example. NICE was up for the price, including a preferential discount, but ultimately, even though NICE said yes to the product, NHS England came forward and said "we cannot afford that, we do not have enough money to pay such a big amount up front, so we'll have to delay".

When budgets don't follow recommendations

thebmj Research ▾ Education ▾ News & Views ▾ Campa



Feature

A pill too hard to swallow: how the NHS is limiting access to high priced drugs

A joint investigation by *The BMJ* and Cambridge and Bath universities uncovers how NHS England tried to limit access to expensive new drugs for hepatitis C. Jonathan Gornall, Amanda Hoey, and Piotr Ozieranski report

1 response

Analysis: Betting on hepatitis C: how financial speculation in drug development influences access to medicines

Editorial: High cost of new drugs

Minute 00:34:06

And so, that's what the feature in the BMJ referred to "a pill too hard to swallow", basically the NHS has to limit access to high priced drugs, even if they're seemingly cost-effective simply because there's not enough money.

ft.com > uk >

Politics & Policy

Home UK World Companies Markets Global Economy Lex Commen

Africa Americas Asia-Pacific Europe Middle East & North Africa UK US Science &

Click here to try our new website — you can co

February 19, 2015 12:00 am

Expensive drugs cost lives, claims report

Andrew Ward, Pharmaceuticals Correspondent

Share Author alerts Print Clip Gift Article Comments

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

When budgets don't follow recommendations

Minute 00:34:23

At the same time, there's pressure from the other side for instance the University of York has done some works to show that actually NICE's overly generous, says yes too often and that's spending on overpriced drugs, not just through the fund which was initially outside of NICE but in general, through a fairly generous NICE, with a fairly high threshold, was diverting the resources away from other kinds of health care.

So, a complex environment, for which the cancer drug is only an element and now is under NICE, but NICE is under pressure to say yes more often and it's finding its way through this current environment.

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.



27

Minute 00:35:01

And what I find really interesting is that, though NICE was set up to be independent of the NHS of the budget holder, not to hold the budget itself, but rather to make recommendations of the services held to respond to NHS England now at the time of almost recession in the economy, many more stronger pressures on budgets and now things have changed and it's a single stake in control of the final decision has set something it calls a budget impact threshold of 20 million.

So, any product that NICE says yes to, but whose budget is greater than 20 million a year, could be faced, in other words, it's updated could be delayed. So, NHS England is legitimately saying to NICE "well you tell us that this thing is cost-effective, but, you know, we can't really afford it, so we're going to have to delay implementations".

So, this is a really difficult situation for a country or a system which always has prided itself for using estimates of value to inform purchasing decisions and, to some extent, this is because the value as assessed by NICE was actually perhaps too great for the return.

The new PPRS: capping growth—industry reimburses the NHS

Table 1: forecasts and profile of annual payment percentages

	2014	2015	2016	2017	2018

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

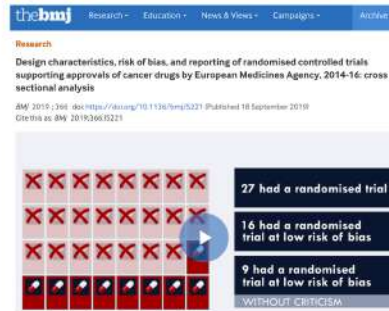
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/68673/PPRS_Payment_percentage_2018.pdf
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761834/voluntary-scheme-for-branded-medicines-pricing-and-access-chapters-and-glossary.pdf

Minute 00:36:12

In addition to the budget impact ceiling that the government has introduced, the department of health this time, was a new pricing or reimbursement scheme, pharmaceutical pricing/reimbursement scheme which now caps the growth of the budget for drugs. So let's set NICE aside, set the NHS budget impact threshold of 20 million aside, there is a rule now that companies who sell to the NHS, (as follow through [00:36:44]) but most of them have agreed to it, will have to reimburse the NHS if they end up selling more drugs and making more money effectively than what they'd agreed to do with the government.

So, for 2018 for instance, if they go above a certain growth rate and you can see here what the allowed growth rate is, and the expend then they could be asked to pay up to 7.8% of their proceeds back to the NHS. And the money the NHS gets back is not insignificant if you see 2018 Q1, Q2, Q3, Q4 you'll see how much money the NHS spent on drugs through the PPRS, this is mostly drugs for hospitals and on patented drugs, and you see on the right hand side, the payments, the rebates basically that the companies are paying back and there's a formula that looks at the share of each product in terms of the total budget and then this helps calculate the rebate by the industry.

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.

Minute 00:37:50

So, I think it is really important to acknowledge that despite NICE's adventure with the Cancer Drugs Fund or the NHS adventure with the Cancer Drugs Fund, ultimately this exceptionalism when it comes to cancer is probably here to stay. So, this is from a review of the EMA between 2014 and 2016, and you can see that most of the studies that form the basis for EMA approval over this three years, this is our European FDA, more than half of this had carried bias. So, there was a risk of bias based in the design, their analysis, their conduct and yet the regulators approved the products and then payers, most of the time, ended up having to pay for them. So, an exceptionalism when it comes to cancer's running all the way through from regulation to reimbursement.

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>

Minute 00:38:55

So, I'm about to close. This is what I think is a really interesting conclusion on the Cancer Drugs Fund in particular, it's interesting because it comes from a pharmaceutical industry publication, this is not academia, this is not the journalists, this is not civil servants or parliament, this is pharma file. It concludes that the real change to help get this drugs in the market in the UK will not come from solo funds but from this 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 is not fair to the NHS or more pertinently to patients". So, this is a call by pharma effectively people to their colleagues not to become too arrogant in producing, manufacturing, pushing, promoting and overpricing cancer drugs.

What should Latin American countries do (and NOT do) about catastrophic funds?

DO

- Signal the government cares about disease priorities through evidence informed and cost effective National Cancer (or CVD etc) Plans
  - Cost out and budget for them; monitor implementation and impact on outcomes/mortality
  - Ensure wholistic take—ie health taxes, prevention, screening, early detection, radiotherapy, surgery, palliative care
- Use evidence of what the new drugs/techs add in terms of health compared to existing alternatives when making a decision
- Set up consultative deliberative processes including industry, patients, tax payers, judiciary, media...
- Explain trade offs: paying for X is the equivalent of Y hip operations or vaccinating Z number of children

DO NOT DO

- DON'T set up vertical funds:
  - sends the wrong signal to industry and advocates and results in more and more expensive of whatever is singled out, neglecting other needs
  - Has overall inflationary impact on the budget with, usually, worse health outcomes and accentuates inequalities
- DON'T earmark funds for specific technologies or diseases:
  - goes against principle of pooling and undermines government's ability to negotiate better deals;
  - generates inefficiencies across the healthcare portfolio.

Minute 00:39:54

Now, I wanted to, if I may, make some suggestions based on our experience as to catastrophic funds which may be specific to cancer or indeed other diseases, rare diseases or however one might decide those...

I will say that's important that the government signals that it cares about disease priorities, is not necessary to say "every disease is the same, everybody is the same", that's not necessarily politically practicable or indeed fair, but, ultimately, if we want to say we care about cancer more, we need to think about national plans, a national cancer plan which the UK at least has and can finance better, and take a holistic perspective looking at things like health packages, for instance, prevention, screening, early detection, which makes most of the difference; but also radio therapy, surgery, palliative care which are also very important at least without surgery or radio therapy cancer drugs alone will not deliver outcomes.

Second point, use the evidence of what these new drugs add, what is the evidence about what they add, you'll see that at the regulatory stage more than half of the drugs, cancer drugs approved for cancer indications between 2014 and 2016, have very weak evidence of clinical benefits. So, forget about the economics even, but let's look at the clinical evidence.

Set up consultative processes include industry, include patients but also tax payers and other stake-

holders and explain the trade-offs. So, if we pay for this product this what we're going to be forgoing, we can't pay for x, y, z.

I'm not a fan of the vertical funds I think it sends the wrong signal to the industry and we've seen this with the cancer drugs fund; things become more and more expensive because people know there's a bucket of money that will probably go and they can go through instead of the normal process, and this has an inflation pressure. And by ill marketed funds you're undermining your own governments, your own payers, purchasing power, negotiating power, undermines the principal pulling and the ability of government to negotiate better prices and, ultimately, this creates inefficiencies across the health care portfolio because inevitably, there would be other things that would be much better value than paying for the latest cancer drugs.

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

IN BRIEF: Senegal to offer free breast and cervical cancer treatment 19 Sep 2019

Admin · 2 days ago · 1,861 · Less than 1

Share

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. 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!

Year	Senegal GDP (billion USD)	World Average GDP (billion USD)
1960	~10	~5
1970	~20	~10
1980	~30	~15
1990	~40	~20
2000	~60	~30
2010	~100	~50
2017	16.37	~10

Minute 00:42:10

So I'll finish by just putting here a quote from a newspaper in Senegal: "all countries that talk about these issues in our countries are relatively wealthier, but very poor countries also suffer from very singular problems". This is Senegal, a fairly poor country which recently announced that it will spend or allocate by around 6 billion dollars, government money specifically for chemotherapy and starting with breast and survival cancers, and not early, not screening, not prevention, not holistic management but the drugs alone. And this matters because Senegal's Gross Domestic Product (GDP), I mean obviously this will be spread over a longer period, they have 1.6 billion, but look at that this is about 10% of its GDP, assigned to chemotherapy alone for two types of cancer over a period of years. So poor countries make big decisions with significant opportunity cost, significant trade-offs.

Thank you very much for listening and I look forward to the discussion.

QUESTIONS & ANSWERS

Minute 00:44:15

Question:

¿Can you explain how the NHS arrive at the budget capped and the max growth rate for drug sales? *From Catalina Gutierrez.

Kalipso Chalkidou:

So, this was a negotiation basically so they looked at historical data, they looked at how the growth rate was going up and at some point, I think around 2013 or 2014, an agreement was reached that companies will just not grow at their sales on aggregate for a period of two or three years. So, there was a freeze and this was a negotiated solution because the NHS had much less growth money than it had before, in 2002 and 2009, 2010, we had a year on year significantly increasing spending, over that period over about 50% real terms increase, with a significant injection of cash, afterwards 2009-2010 this started levelling off at some point it had negative growth, now the growth is marginal. And so, during that period, the government sat down with the pharmaceutical industry and said: "ok, we can't afford to pay you anymore, here's the size of the pie, let's agree together that we will freeze growth for the next couple of years and beyond that we'll help manage growth".

So this was [force trading [00:45:45]], people sat down and agreed on rates, and I think The Association of the British Pharmaceutical Industry were quite happy ultimately with the deal that came out, at least there's public saying they were. And part of that pressure budgets was what justified also the re-bumping, the changes in the Cancer Drugs Fund because some companies could see that the size of the pie was set and one or two companies were taking a large piece of that pie through the Cancer Drugs Fund so they brought that back, saying "well, you know we're happy for you government to dismantle effectively the Cancer Drugs Fund but on the other hand, you know, let's negotiate about the total size of the pie and how can we share it between us more equitably". So that was more or less the basis, there's not scientific, you know, there's no formula to explain why that particular percentage's going and it's still subject to negotiations part of the PPRS.

Question:

¿Do you believe that an antitrust policy on the managing of the cancer drugs fund is necessary or could be helpful to prevent a perhaps unethical behaviour of companies who manufacture new cancer drugs pricing? *Student from Colombia.

Kalipso Chalkidou:

So, policies against monopolies... Well, listen I think one could wish for a situation where you have companies basically pricing reasonably, but it's very hard to do in the current situation because companies have patents rights and the rational for that is they raised private capital or they acquired other companies but there's still money involved and they want to recuperate that investment made and make lots of more money on top of that, and they are (in the health [00:47:53]) industry. So, what I think is really important is that governments can manage that relationship and can exert their purchasing power. So, first of all, governments need to be payers, need to be in a position to say: "well your drug doesn't work", you know, if more of half the cancer indications that get through the EMA, the European Medicines Agency, have actually no clinical benefits data, I would argue that in the first instance government should be brave enough to discuss this with the public and say: "well, these drugs don't seem to be working, at least not better than the stuff we had", so, you could give them drugs for free but they won't want that to happen, that's not something you want to have, because even at zero cost this drugs are really toxic and even if the price is zero, that's still a non-eligible cost.

The next step will be to say: "ok, now for the things that we think do work let's negotiate, so if we can guarantee you some volumes you need to drop your prices to x, y, z". Then these issues of patterns protection and it's the pattern regime fair? is it too long, too deep, too wide? and I think is the thing with the patents and needs reforming and that's also an important step. But, what I don't think is that these drugs are wonderful, everybody should have them for free because this way, I think, we fall into the trap of the PR machine of big pharma that says: "we produce these things that are great and everybody should have them". Ultimately, I think evidence matters and governments need to be able to work with academics, work with the universities to show what the impacts of these products are, some are very good some are not, those are good deserved premium but need to be reasonable and affordable, and be different if the country is poor, if it can't pay what they're asked to pay as much as richer countries are paying. So, that's my perspective, I believe, before we get to the stage where everything is free for everybody and monopolies are all lifted.

Question:

***¿In your opinion, what's going to happen in the future with the Cancer Drugs Fund?
¿Do you think it will eventually disappear? *Pamela.***

Kalipso Chalkidou:

I do, yes. I think ultimately it will disappear. I think government has now complete control over the total size of the pie so it can slowly shrink that pie. I think it has conversations with the industry as a whole and is becoming a paradigm of the pharmaceutical industry, you know, there is not shared some companies interest in cancer, obviously some companies have more predominant cancer portfolio but industry as a whole doesn't so, this idea that only cancer benefits from a ring fenced budget does not appeal the industry as a whole either. And I think also in terms of general public there's now a lot more information in the public domain, the media, more (switch on [00:51:03]), so I don't think it will survive, I think it will shrink and then gradually it will disappear and the money will be pulled again alongside the other drugs, patented drugs.

Question:

¿As I understood it, this fund was only for purposes of drugs, do you know of any initiatives or funds for the research and development of new drugs?

Kalipso Chalkidou:

Funds for research and development? So, well, there's certainly government year marked funds to do that indeed, if that's the question. I'm not aware of government year marked funds to do specifically in cancer, though obviously big charities like Cancer Research UK invest a lot of money in cancer research but from public money, there're certainly year marks for health-related R&D and this is going up, so, I'm not aware of the fund guide arrangement.

Question:

I'm from Argentina and in here we have a highly segmented and fragmented health system with very different financing capacities, even within the same subsector, and many times here, the possibility of funding a high cost fund or a catastrophic disease fund was discussed. One of the things or the problems we discussed here was that here was the availability of finances to decrease the demands for these technologies and also increase the inflation or the prices of these technologies generating an exponential growth of the funds needs and the expenditure; but on the other side here it says that as we have these differences in the financing capacities of public spending or the financers, could benefit with these kind of funds, but we've never found the way or the institutional form to go in this direction. From your experience, do you believe that this is a good idea in the country like Argentina with these characteristics in the health system? or the interventions or the institutional form that we need to meet to avoid the problems that you mentioned in your presentation, are very difficult to achieve [NE [00:54:06]] with a fund like this?

Kalipso Chalkidou:

You know, I'm completely against these funds, I don't think they help with efficiency, I don't think they help with health outcomes and access ultimately of the whole, I don't think they help dynamically with the type of signal that you send to industry because they will for sure redirect their efforts in terms of R&D or launches to products that you seem to be favouring, so, other patients will miss out, the system will become more inefficient, more inequitable... And ultimately, I think even politically, once the budget is grown too much perhaps, and you can't control it, it becomes politically unviable as well. So we've seen in the UK for instance now no party will come out and say in this current election: "we will set up a fund", they are saying "we are going to fund the NHS, we are going to put more money into the NHS", all of them are, but nobody is, you know, picking up cancer because it has been a very bad experience with the way this fund operated. So, I can't think of a situation where a country that's poorer or with a weaker system were this type of vertical fund could work, If anything we see is that even in very poor countries, where the (NE [00:55:30]) the global fund for instance, comes in and fund TB, malaria, HIV but even there there're huge distortions in the way that this systems operate, precisely because you have a pot of money you have to spend in TB where even if there aren't many TB drugs to spend it on, you will spend it on that and then others go without and, ultimately, you create these distortions. And that's very difficult to undo, once you've done them, it's hard to undo them and you can't really

envision a UHC agenda with lots of vertical funds, that's not the way to do it. So, it's a difficult path to take and it gets narrower, narrower, narrower and then ultimately you crash, I don't see how they will be beneficial to anybody, at least that's what the experience from here in the UK suggests and I haven't seen any others experiences that suggest that actually they're a good idea. But, obviously it depends, it could be in a certain setting.

Question:

Do you think that funds that cover multiple very costly diseases make any sense in the end? Can you share with us good experiences from other countries in funding these diseases?

Kalipso Chalkidou:

I think that's a difficult one, and I mean, the Cancer Drugs Fund was expensive because ultimately it end up affecting very many people and the unit prices went up in parallel, one can envision a situation with very expensive drug or very acute people and governments usually give in and provided that, and this is a strong argument there if you have a truly often disease, you know, how can you not cover that? on the ground that of course this things are very rarely going to be cost effective, so what do you do in those cases?

In the National Health Service because sometimes these conditions also appear in clusters because they're genetically driven and it's not fair on regional budget holders to have to pay for these (on their own [00:57:37]) budgets, so what happens is the National Health Service, has some [NE [00:57:41]] scheme so money's taken out from every region and there's a pot of money that funds these type of products, and this part sits through the NHS England and NICE does evaluate these products and the highly specialized technology, using a much higher thresholds than normal but there's still some pressure on the evidence.

So, what I would advise is that you can't say outright no to these products, but be careful about the indication and indication [NE [00:58:12]] and we've seen this in the NHS where companies will launch on one indication and then will expand. So, there isn't a way to take away their often characterisation wants to expand to enough indications to cover more of the population.

And secondly, do build a process of reevaluating the evidence around those products because most of the time, what we use to see at NICE at least, is that those products fail not because they were cost ineffective, most of the times they would be, but because the clinical effects were not proven. So, this is a product that will come in the market with a very small number of patients

obviously, very difficult to do the trial, etcetera, and ask a very significant price with no particular settings in terms of results. So, these products could be covered in the conductor research at first, but the price needs to be subject to some evidence that they work and once companies start generating this evidence, then fine, but, once they'd start expanding the indications, then they could be losing their orphan designation and otherwise you'll see this type of escalation. So, it has to be a nuanced approach but to look at the clinical evidence, because a lot of the time that's not there.

Question:

What is your opinion on public drug distribution companies that focus mainly on the distribution of biosimilars like Mexico's recent proposal? Are they more cost effective than purchasing patented drugs from pharmaceutical companies? Does it reduce the room for price manipulation and corruption? Do you believe it's feasible for most Latin American countries to produce these drugs in such a large scale and meet the populations needs? *Rodrigo Bogalar.

Kalipso Chalkidou:

Well, I think is a doubtful. I mean I know that the government of China is putting a lot of money, is not a cheap endeavour, I think governments can do it, but, then you need to be serious about it. The manufacturing costs are also significant, so, you have the R&D cost and the you have the manufacturing costs themselves, and they're not insignificant, like in most sort of simple molecules, and this manufacturing cost will also drive prices up but probably and hopefully not to the levels of that of patented drugs do.

I think that could be a solution if the significant investment continues investing to build a knowhow, to build a cohort of scientists, to build the infrastructure and continue to invest in it. But ultimately, I think it's also a trade-off, I mean if you can import these things more cheaply say from India or from somewhere else and negotiate low enough prices, then that's fine.

So, if you can get competition to work as it does for simple molecules and generics market in some cases then that might be a better bet than building up your own... and, of course not every country can do that. China can do it, Mexico can do it but some smaller countries will not be able to do this themselves, so domestic production is not a solution for everybody.

For those who can do and can invest in it, and, aspire to exporting as well, because that's what China wants to do, then I think it's something that could be considered, but it's a big... it needs a

serious investment. For those that don't, I think encouraging biosimilar completion, changing the legislation around regulations to encourage biosimilars to come in the country to launch and looking at the quality elements of course. but encouraging them to come in. The EMA has done this in Europe, the FDA has been much more reluctant so see many more biosimilars in Europe even though we might not be producing them ourselves, driving prices down, whereas in the US they don't see that yet. So, these regulatory obstacles, these commercial obstacles, these issues around competition, and ultimately the domestic manufacturing is a possibility including exporting to make it worldwide, then I think that is something worth to look at.

