

# Investigation reveals how the NHS is impeding access to high-priced drugs

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An investigation published by *The BMJ* today reveals how the NHS is impeding access to high priced drugs for hepatitis C.

Researchers from the University of Cambridge and the University of Bath, and *The BMJ*, show how NHS England, unable to budget for broad access to these drugs, tried to alter the outcome of the NICE process, and when it failed, defied NICE's authority by rationing access to them.

The investigation also exposes key weaknesses in our current system of assessing the value of new therapies and delivering them to patients - and asks, is company pricing to blame?

Hepatitis C is a virus that can infect the liver. There are an estimated 214,000 individuals chronically infected in the UK which, if left untreated, can cause life-threatening liver damage.

In 2014, two [new drugs](#) for hepatitis C infection were launched (Sovaldi and Harvoni, manufactured by Gilead Sciences) - offering cure rates of over 90%. But with prices ranging from around \$90,000 per patient in the US to almost £35,000 in England and 41,000 euro in France, they have sparked a global debate about access to high priced medicines for governments with limited resources.

During the course of this investigation, it has emerged how apparent panic over high prices and affordability led NHS England to deploy many delaying tactics, which succeeded in hampering timely access to

these drugs.

For Sovaldi, NHS England spuriously asked for six months to implement guidance (the mandatory 90 days and an additional three months), saying it needed time to set up a proper database to audit patients and usage of the new drugs.

NHS England also tried to completely block Harvoni and two other competitor drugs undergoing appraisals at NICE, and questioned the level of clinical evidence.

Andrew Ustianowski, a consultant in infectious diseases at Pennine Acute Hospitals NHS Trust, says: "I think some people in NHS England would love to clip NICE's wings and turn it into a kind of recommendatory rather than mandatory body. And if you are going to choose a fight then choosing this battlefield is quite a sensible thing to do - a marginalised population, very high-cost drugs."

Dr Ustianowski resigned from NHS England's clinical advisory group, in protest at deliberate attempts to delay access to treatment. "I didn't want to be associated with what was happening," he told The BMJ.

NICE did eventually succeed in publishing guidance recommending these drugs for the majority of hepatitis C patients. But NHS England is not fully following NICE's mandate, which requires that approved drugs are made available within the NHS.

Instead it has restricted use of the new drugs by forcing quotas on clinical teams around the country.

This rationing has left many clinicians facing hard decisions and difficult conversations with patients who have already seen their treatments delayed several times. And there is now growing evidence that some

frustrated patients are turning to overseas "buyers' clubs" to source the drugs at their own expense.

NHS England says its delivery of drugs is entirely within the parameters of the NICE guidance - and highlighted Gilead's pricing as the key reason why treatment was being delayed.

This echoes major criticisms of Gilead's pricing strategy in the US, where legislators said the company had adopted a strategy "designed to maximise revenue with little concern for access or affordability."

So why didn't NHS England strike a better pricing deal with Gilead? Under current rules, NHS England is unable to negotiate specific deals with individual drug companies.

A spokesperson for NHS England said it was "exploring the potential for a longer term strategic procurement for a supply agreement with the industry to improve the affordability of and access to treatment further."

Whatever the reason for the failure to achieve broad access to the new hepatitis drugs in England, the Hepatitis C Trust, a patient advocacy organisation, believes the NHS is risking legal action over its decision to ration them. Chief Executive, Charles Gore, said the Trust has "already spoken to solicitors to take on any cases that come up, because we are not going to have NHS England pick on a disenfranchised group."

In a linked analysis, researchers argue that the acquisition strategies of drug companies magnify development costs and leave the public paying twice - for research and high priced medicines.

Solutions, they say, include giving health systems increased power to negotiate pricing and payment models, limiting share buybacks, and

testing other ways to encourage and reward drug development.

In a linked editorial, Professor Mariana Mazzucato at the University of Sussex discusses why government must negotiate a better deal for publicly funded research.

She believes that an effective pricing system "should ensure accessibility but also reflect the public contribution so taxpayers don't pay twice, through publicly subsidised research and high priced medicines." Importantly, she adds, "[drug](#) pricing must be completely transparent, so that governments can negotiate for better value on behalf of their populations."

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

[www.bmj.com/content/354/bmj.i4117](http://www.bmj.com/content/354/bmj.i4117)

Betting on hepatitis C: how financial speculation in drug development influences access to medicines [www.bmj.com/content/354/bmj.i3718](http://www.bmj.com/content/354/bmj.i3718)

Editorial: High cost of new drugs [www.bmj.com/content/354/bmj.i4136](http://www.bmj.com/content/354/bmj.i4136)

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