

IS GENERAL PRACTICE IN TROUBLE?

John Appleby unpicks the data on funding of primary care and asks, is it in crisis?

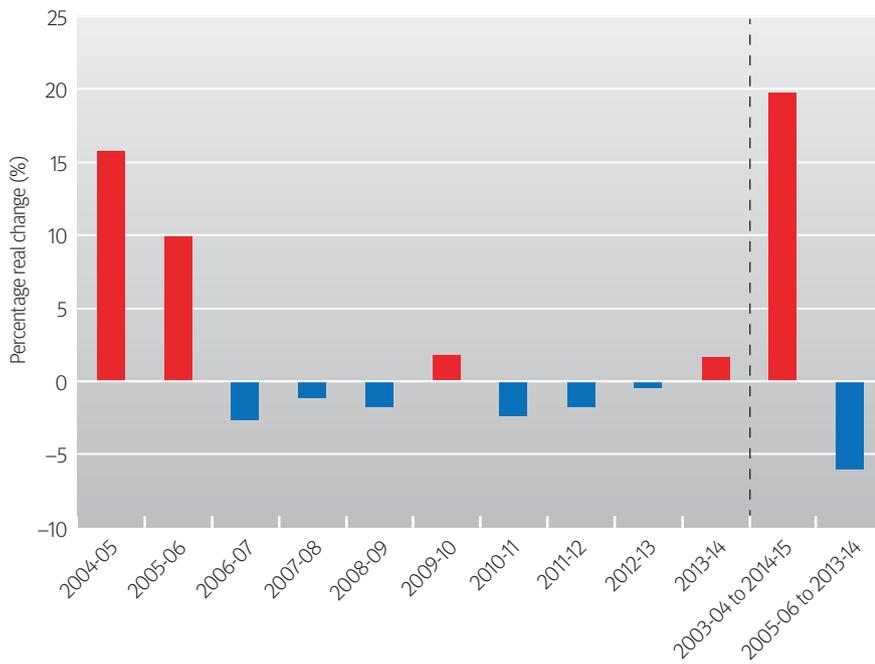


Fig 1 | Year on year change in total investment in general practice (2013-14 prices), England 2004-05 to 2013-14⁴⁻⁶

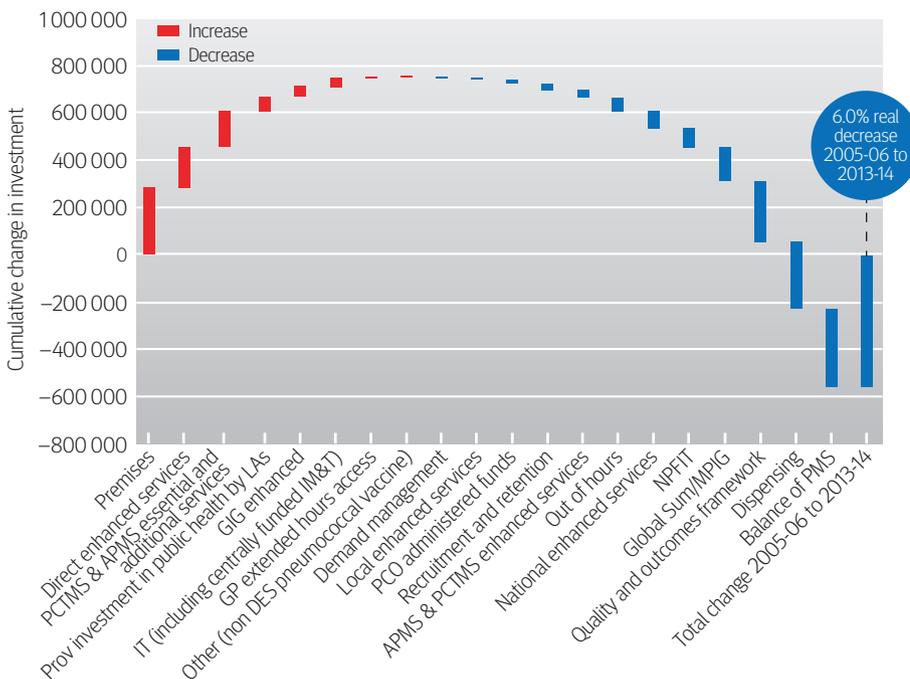


Fig 2 | Breakdown of change in total investment in general practice (2013-14 prices) in England, 2005-06 to 2013-14⁴⁻⁶ (APMS= alternative provider medical services, DES=directly enhanced service, GIG=gross investment guarantee, IM&T=information management technology, IT=information technology, LA=local authority, MPIG=minimum practice income guarantee, NPFIT=National Programme for IT, PCO=primary care organisation, PCTMS=primary care trust medical services, PMS=personal medical services)

Like other parts of the healthcare system over the past four years, general practice has been under pressure financially. But is it, as the Royal College of General Practitioners' current campaign suggests, in need of saving¹ or, as a recent Nuffield Trust review reports, "in crisis"?² And, if general practice is in trouble, why do three quarters of the public remain satisfied with it?³

In terms of funding, general practice accounted for around £8.8bn (8%) of total NHS spending in 2013-14. This share has reduced by about 0.7% since 2008-09. It has also reduced in real terms. Between 2005-06 and 2013-14 total investment in general practice fell by 6% in real terms—equivalent to nearly £560m (€710m; \$880m, fig 1). Over the period of the current parliament (since 2010-11), it fell by 2.5%. This is in contrast to a real rise in total NHS spending of 4.4% since 2010-11.⁴⁻⁶

A slightly longer view provides a somewhat different perspective, however. As figure 1 also shows, in the two years following the introduction of a new contract for GPs (2004-05 and 2005-06) there was a substantial real increase in total investment of over 27%. And over the whole decade from 2003, this meant that there was a real increase of nearly 20%.

Figure 2 gives another view of spending on general practice, with the change in spending from 2005-06 to 2013-14 broken down by the many different elements of general practice funding—from payments for practice premises to the performance related funding element of the Quality and Outcomes Framework. GP-NHS contractual arrangements are anything but straightforward, and there is no room here to explain all the details. However, it is worth noting that one item that accounts for just over half the 6% total real reduction—"dispensing"—does not affect patient care itself but rather the income some GPs make in their role as dispensing practices. The fall in this payment item is largely due to reductions in the discount paid by the Department of Health to offset part of the cost of drugs that dispensing practices purchase. Similarly, reductions in some other items do not necessarily adversely affect patients if there are compensating service provisions elsewhere in the NHS (such as payment for out of hours services organised by clinical commissioning groups rather than GPs).

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Around a third of all spending on general practice ends up as personal income for GPs—after the expenses of running a practice are deducted from gross earnings. Following a 42% real rise over the three years to 2005-06 (from around £95 000 to over £134 000), GPs' mean real income before tax has reduced each year to 2012-13 and now stands at just over £105 000—a combination of a small real cut in gross income and rising real expenses (fig 3).⁷

While changes in income have a direct effect on GPs, the knock-on effect for patients and their care is more complicated and will in part depend on how GPs react and the effect real pay cuts have on, for example, GP numbers. Data on the number of full time equivalent GPs (fig 4) show an increase from around 30 000 in 2003 to 36 300 in 2013—equivalent to a rise per 100 000 population of nearly 12% (but with a much smaller rise over the second half of this decade).⁸

If general practice is in trouble, why do three quarters of the public remain satisfied with it?

Given all this, is general practice in trouble? It's hard to say. Although the data on inputs—spending and staffing—provide part of the picture about the state of general practice, it remains partial (and not easy to interpret). Crucially, there remains a dearth of information about outputs—activity and outcomes—in general practice. This is exemplified by the fact that the most up to date data on the number of consultations in general practice is from a sample of around 500 practices in 2008.⁹

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Fig 3 | Mean earnings, practice expenses, and income before tax for general practitioners (2012-13 prices), England 2002-03 to 2012-13⁷



Fig 4 | Full time equivalent general practitioners per 100 000 population, England, 2003-13⁸

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Will WHO Tamiflu recommendations change this winter?

Andrew Jack reports on renewed pressure to remove the antiviral drug oseltamivir from the World Health Organization's powerful list of essential medicines

The World Health Organization is at the centre of a fresh debate on whether it should remove an antiviral drug from its influential list of recommended medicines, following a growing number of studies scrutinising the medicine's value in treating influenza.

Members of the Cochrane collaboration have called for oseltamivir (Tamiflu) to be taken off WHO's essential medicines list, a document of more than 300 drugs considered necessary to meet basic healthcare standards. It was first added in 2009, the year the H1N1 pandemic flu strain was identified.¹

Chris Del Mar, professor of public health at Bond University in Australia and one of the Cochrane authors, said: "Oseltamivir was included at a time when it looked as though it

was effective and it seemed prudent to planners to stockpile."

His comments come after the publication of an update to the Cochrane review of clinical trials of oseltamivir and another neuraminidase inhibitor, zanamivir.² Their work followed more than four years of efforts by the researchers and *The BMJ* to obtain raw trial data from drug companies and to track down submissions to regulators made around the world (www.bmj.com/tamiflu). The Cochrane authors concluded, on the basis of a meta-analysis of 46 trials covering 24 000 patients, including data not previously made public, that the drugs shortened symptoms in seasonal influenza cases by less than a day and did not reduce the number of hospital admissions.

However, the PRIDE Consortium, led by Stella Muthuri from the University of

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Nottingham, reviewed observational data from 29 000 patients admitted to hospital with the H1N1 pandemic influenza strain during 2009-10 and concluded that use of the drug reduced mortality by 19% in this population (odds ratio 0.81, 95% confidence interval 0.70 to 0.93; $P=0.0024$).³ The study was funded by Roche, which manufactures oseltamivir.

Jonathan Nyugen-Van-Tam, a coauthor of the paper, said: "I remain convinced that neuraminidase inhibitors are a very useful part of our armamentarium against influenza, especially with regard to early treatment in high risk patients and those (irrespective of underlying risk conditions) who clinically appear to be at risk of complications or a serious outcome."

OPPORTUNITY COSTS

One former senior WHO employee, who did not want to be named, questioned the decision to originally include oseltamivir for stockpiles on the grounds of either cost or effectiveness. "If the same resources were spent on increasing the immunisation rates and vaccine production capabilities we would be much better off," he said.

Del Mar, professor of public health out of Bond University, Australia, and Cochrane author, also had concerns about

maintaining oseltamivir on the essential medicines list: "My worry is that if there is a serious doubt about efficacy, there is an opportunity cost. What does work against flu is quarantine and barrier methods. Perhaps we should be stockpiling facemasks for flu."

Another former senior WHO official, who also did not want to be named, argued that it was unusual for the essential medicines list to include drugs indicated for use only in extreme situations such as a



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pandemic. But he said that the inclusion of oseltamivir in the essential medicines list meant that stockpiling of oseltamivir in low and

middle income countries had taken place primarily as a result of donations from the pharmaceutical industry rather than through large purchases.



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Continued arguments

The Cochrane team has criticised the PRIDE study, but the Cochrane review, which concentrates on oseltamivir's use for treating seasonal influenza, has also been questioned by the manufacturer. Roche has submitted a 69 page rebuttal criticising its methods. The company's report will be published shortly and a reply from the Cochrane team in due course.

Separately, the Multiparty Group for Advice on Science (Mugas), a network chaired by Stuart Pocock, professor of medical statistics at the London School of Hygiene and Tropical Medicine, has submitted for peer reviewed publication a rival analysis of oseltamivir that includes a review of individual patient data. The group had travel and accommodation costs paid by Roche for a meeting under the auspices of the European Scientific Working Group on Influenza but says the company has not paid fees or honorariums to any of its members.⁴

The European Scientific Working Group on Influenza has in turn received funding from Roche and other drug companies.⁵ An investigation by *The BMJ* suggested that the organisation also influenced decisions to stockpile antiviral drugs.⁶ The controversy has triggered several technical discussions, including by the European Centres for Disease Control, which concluded this summer that although the studies published this year—the PRIDE study and updated Cochrane reviews—“provide limited new evidence on effectiveness of antivirals against severe disease... they do not give reasons for changing the current approach to public health use of antivirals, including prophylaxis, pandemic preparedness, stockpiling or use in outbreaks.”⁷

Essential medicine?

That leaves open the question of the role of WHO's essential medicines list, first approved nearly four decades ago at the World Health Assembly and updated regularly since it was first published in 1977. The list is designed to highlight drugs that are judged safe, effective, and cost effective as a tool for policy makers and prescribers around the globe, partly in an effort to ensure that they are available and affordable.⁸

The fresh debate on oseltamivir comes as consultations close shortly on which drugs should be included in the next edition, due out in 2015.

The current edition, updated in October last year, includes oseltamivir, which it describes as being for “potentially severe or complicated illness due to confirmed or suspected influenza virus infection in accordance with WHO treatment guidelines.”⁹

Current WHO guidelines recommend use of oseltamivir for treatment of influenza strain H1N1 when patients have complications or are in high risk groups¹⁰ and for suspected or confirmed cases of the more dangerous H5N1 and H7N9 strains.^{11 12} The guidelines stress that the advice is a “strong recommendation, based on low quality evidence.”¹⁰

Peter Doshi, assistant professor of pharmaceutical health services research at the University of Maryland, an author of the Cochrane review, and an associate editor of *The BMJ*, argues that the decision to include the drug in the 2009 list was entirely based on studies of its use in seasonal influenza rather than on the subsequent observational data analysing its

effectiveness in pandemic strains. He said the seasonal flu studies were mostly funded by the manufacturer, and on fuller evaluation were not as convincing as was previously thought. There are no randomised trials of oseltamivir in pandemic flu. He said: “All planning was built on assumptions from oseltamivir's performance with seasonal influenza.”

Nahoko Shindo, who leads the influenza and respiratory disease team at WHO, said: “Our main concern is severe influenza from non-seasonal influenza viruses. Our fundamental recommendation for seasonal influenza is the use of seasonal vaccines. The Cochrane review does not have a major impact on our position.”

She said the organisation did not currently recommend pandemic stockpiling of oseltamivir and had no guidelines for seasonal influenza. It is set to consider revised guidance for all types of influenza in an expert review that is now likely to take place early next year; the review has been delayed by the current focus on Ebola.

The information emerging over the next few weeks will contribute to a more comprehensive review of the evidence. Then the debate will turn again to how these varying views should be reconciled, and what advice should be given to doctors, health systems, and international agencies in broader flu treatment guidelines and the revised essential medicines list

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Wearable home baby monitors: real peace of mind?

The peace of mind on which their marketing depends may be illusory, **David King** writes

Wearable devices for infants are a growing industry. In April 2014, the US company Owlet announced that it had raised \$1.85m (£1.2m; €1.5m) to develop and launch a “smart sock” to monitor a newborn baby’s vital signs.¹ Parents can use a smartphone to check heart rate, oxygen concentrations, and skin temperature and to receive alerts if the child rolls over.

Owlet’s chief executive, Kurt Workman, is ambitious. “We see the wearable future will include every single baby coming home from the hospital with a wearable monitor,” he told the *Telegraph*.¹ The company states that these devices will give parents “peace of mind and maybe even a full night’s sleep.”² The product will cost \$250.

Another company, Rest Devices, has developed Mimo, available for \$199.99. This baby grow has inbuilt sensors that monitor respiratory rate and temperature.³ Sproutling is another start-up aiming to capitalise on this market. It has released details of a similar device to sell at \$299.⁴

In the 1980s and 1990s a plethora of similar products was sold with the intention of reducing sudden infant death syndrome (SIDS). Unfortunately epidemiological studies showed that such devices had no effect on the incidence of SIDS in healthy infants.⁵⁻⁷ The American Academy of Pediatrics states that home cardiorespiratory monitors should not be used as a strategy to reduce the risk of SIDS.⁸

Owlet, Rest Devices, and Sproutling do not claim that their devices reduce the risk of SIDS. However, parental fears have driven the development of their products—and the themes in their marketing. Workman, in a press release for the Owlet monitor, said that part of the inspiration for the product was that he “had a cousin pass away from [SIDS].”¹⁰ The chief executive of Sproutling, Chris Bruce, was quoted in *Time* magazine as saying that the idea arose because he was incessantly checking the baby monitor after the birth of his first child.¹¹

In its promotional video, Owlet shows a mother saying that she is “one of the mums who puts my fingers in front of [my baby’s] nose to make sure she is breathing and my hand on her chest to make sure it is going up and down.”¹² Rest Devices does not mention SIDS in its marketing but states that use of its device gives “relief from that heavy anxious feeling” and “keeps babies safe.”³

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Owlet markets its “smart sock” as giving parents “peace of mind and maybe even a full night’s sleep”

Both Sproutling and Rest Devices include a disclaimer on their websites to say that there is no evidence that their devices can reduce the risk of SIDS.³⁻⁴ However, in the case of Rest Devices this disclaimer is in small print under its terms of service.

Regulatory approval not needed

None of these products requires approval from the US Food and Drug Administration. They are not yet available in Europe, and it is unclear whether regulatory approval will be needed here. Owlet and Rest Devices originally wanted their products to be sold as medical devices and were planning to gain FDA approval before launch. However, representatives from both companies have said that the time and expense that this process would have required made it unfeasible.¹³⁻¹⁴

They both acknowledged that they modified their products so that they could sell them direct to consumers without any need to apply to the FDA. Owlet’s cofounder Jacob Colvin explained that the

alarm was removed so that it could be sold as an unregulated monitoring device.¹²

Similarly, Dulcie Madden, head of Rest Devices, said that by removing any

alarms and making the Mimo a product for consumers, rather than a medical device, the company could circumvent the need to apply to the FDA for regulatory approval.¹³

Owlet states on its website that the device “alerts you if something appears wrong with your baby’s heart rate or the amount of oxygen in his/her body.”¹¹ Rest Devices claims that its product allows parents to see their “baby’s breathing patterns, in real-time.”³ Sproutling says that it will let you know “if your baby is sleeping soundly or if something is wrong.”⁴ No published data support any of these claims, and because the devices are being sold as consumer rather than

medical devices such data are not required. Ideally, manufacturers would be required to undertake observational studies or randomised trials to support any claims they make concerning the efficacy of wearable devices in infants—even if they are categorised as consumer devices.

But until that time medical professionals and consumers need to be aware that such devices have no proved use in safeguarding infants or detecting health problems, and they certainly have no role in preventing SIDS. Healthcare professionals should not recommend these products but should instead focus on interventions that have been proved to work, such as encouraging parents to put infants on their back to sleep.⁸

Despite disclaimers in small print on the companies’ websites saying that the products are not medical devices, parents may not be fully aware of the implications of this when spending several hundred dollars on these products. Manufacturers should place prominent disclaimers at the point of sale to emphasise that they are not medical devices and that no evidence shows that they reduce the risk of SIDS or have any other health benefits.

Workman told me that Owlet was planning to place a disclaimer on its website saying that the device did not reduce the risk of SIDS. He was keen to emphasise that its main function was to offer parents “reassurance.” In addition, he wished to highlight that some small trials were ongoing and that the company eventually planned to apply for FDA approval. Rest Devices and Sproutling did not reply to my attempts to contact them.

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