Single jab “33% effective against B.1.617.2”

The government has been urged to speed up giving two doses of the covid vaccine after data showed a single dose was only 33% effective against the B.1.617.2 variant first detected in India, which continues to see a rapid growth in cases in the UK.

A preprint paper released by Public Health England showed that between 5 April and 16 May the Pfizer vaccine was 88% effective, two weeks after the second dose, against the B.1.617.2 variant and 93% against B.1.1.7, known as the UK or Kent variant. The AstraZeneca was 60% effective against B.1.617.2 two weeks after the second dose and 66% against the Kent variant. But both vaccines were only 33% effective against symptomatic disease from B.1.617.2 three weeks after the first dose but were 50% effective against B.1.1.7.

Christina Pagel, of University College London and a member of the Independent Scientific Advisory Group for Emergencies, said ministers should not proceed to the next stage of the roadmap to end lockdown before more people were fully vaccinated, given that cases of B.1.617.2 rose sharply in the week to 19 May.

Paul Hunter, professor of medicine at the University of East Anglia, said, “What is clear from this research is that the main thing we can do to reduce the spread of this variant is to ensure we get our second dose of vaccine, whatever vaccine we had for our first injection.”

Pagel said full vaccination should be augmented with support for isolation, local contact tracing, targeted testing, and safer indoor spaces. She said this particularly applied to schools and called on PHE to release data on the spread of B.1.617.2 in schools, amid accusations that the government had suppressed these data.

In its latest risk assessment PHE said, “It is likely that B.1.617.2 is more transmissible than B.1.1.7. The magnitude of the change in transmissibility remains uncertain.”

Pagel said, “The data do not support moving to step 4 of the roadmap unless the risk assessment of B.1.617.2 reduces significantly. Waiting too long [to act] as we did in March, September, and December means that restrictions if they do come will be longer and harsher. We don’t want to do that again.”

Matt Hancock, England’s health secretary, has said the government would announce on 14 June whether to end restrictions on 21 June.

Gareth Iacobucci, The BMJ
Cite this as: BMJ 2021;373:n1346
Practices in poor areas should get extra “levelling-up” funding, says charity

The government must inject more funding into general practice in deprived areas as part of its national “levelling-up” agenda, the Health Foundation has argued. It said general practices in areas of high deprivation, with the greatest health needs, lacked funding and doctors.

“The persistence of the inverse care law in general practice is a consequence of policies failing to allocate resource according to need,” said Rebecca Fisher, senior policy fellow at the foundation and author of a briefing paper on general practice funding. “Government has an opportunity within the levelling-up agenda to tackle this.”

The paper calls for the current Carr-Hill funding formula for general practice to be revised. “General practice everywhere is stretched—not just in areas of high deprivation—and it is understandable that GPs whose practices stand to lose out might oppose such a move,” it said. “But political will—in the form of additional funding—could offer a way around this. GP funding could be adjusted using a ‘distance from target’ approach. Using this method, a new, more equitable funding formula could be applied, but with adjustments made gradually and with an overall increase in funding. The income of all practices would increase, but the income of some practices would increase more, and faster.”

Gareth Iacobucci, The BMJ

Covid-19

PM announces plan for “global pandemic radar”

Boris Johnson launched plans for a “global pandemic radar” to identify emerging covid-19 variants and track new diseases around the world. The network of surveillance hubs is expected to be up and running by the end of the year. The government has been working with the Wellcome Trust, the World Health Organization, and other governments’ centres of disease control, and research groups, to improve global health security as part of its G7 presidency.

Extremely vulnerable people continued shielding

Half of the 3.7 million people in England identified as clinically extremely vulnerable, including those undergoing treatment for cancer (below), reported continuing to shield despite mostly being aware that national advice to shield was paused from 1 April, found a study by the Department for Health and Social Care, NHS Digital, and the Office for National Statistics. The ONS’s Tim Gibbs said it was crucial to monitor the impact of lockdown changes on clinically extremely vulnerable people.

Pilot sites will help people to self-isolate

Nine areas in England with high rates of covid-19 were named as pilot sites for a £12m programme to get more people who are at risk of catching and transmitting SARS-CoV-2 to come forward for testing and to self-isolate successfully if they test positive. The initiatives include providing alternative accommodation for people in overcrowded households, increasing existing social care support for vulnerable adults, providing “buddying” services for people whose mental health has been affected by lockdown and the variant outbreaks, and language communications support for people whose first language is not English.

Workforce

“Offer staff military-style mental health support”

When designing services for NHS staff who have worked during the pandemic the government should take inspiration from mental health services offered to armed forces veterans, said 13 organisations, including the BMA and several royal colleges, in a letter to England’s health secretary, Matt Hancock. They wrote, “Despite the difference in context between the military on deployment and healthcare staff working during the pandemic, there are key similarities in terms of the exposure to trauma and risk to psychological and physical health, and we have much to learn from the veterans’ mental health services.”

Healthworker infections highest in dentistry staff

A study of 2063 healthcare staff working in various roles in the east of Scotland found that 300 (14.5%) had been infected with SARS-CoV-2 between May and September 2020, three times higher than in the local population. Around a fifth were asymptomatic. Infections were highest among dentistry workers (26%), healthcare assistants (23%), and hospital porters (22%) and were lower among admin staff and doctors (21%). Having a positive antibody test was linked to 85% protection against a future infection, found the study in ERJ Open Research.

Vaccines

Study in 16 sites tests efficacy of booster vaccine

The government launched the £19.3m Cov-Boost study to test the immune responses elicited by seven covid-19 vaccines given as a booster or third dose in nearly 3000 volunteers at 16 sites in England. The initial findings are expected in September and will help inform decisions by the Joint Committee on Vaccination and Immunisation on plans for a booster programme from the autumn. Vaccines being trialled include Oxford-AstraZeneca, Pfizer-BioNTech, Moderna, Novavax, Valneva, Janssen, and CureVac.

Most UK adults had antibodies after one dose

In a study of 8517 adults in England and Wales by University College London’s Virus Watch project, 96.42% of people who had had one dose of the Oxford-AstraZeneca or Pfizer-BioNTech vaccine were found to have developed antibodies 34 days later, rising to 99.08% after 14 days of the second dose. The results, published as a preprint, lend support to the UK’s policy to prioritise first doses.
**Homeopathy**

Charity is told to take down misleading articles

The Advertising Standards Authority told Homeopathy UK to remove from its website articles stating that homeopathy can help such conditions as depression, diabetes, infertility, psoriasis, and asthma. The authority ruled the articles breached a provision in the advertising code banning marketing that would discourage essential treatment for conditions that require medical supervision.

**Regulation**

Pfizer-BioNTech shelf life is extended to 31 days

Thawed vials of the Pfizer-BioNTech vaccine can be stored at normal fridge temperatures for up to 31 days, the UK’s Medicines and Healthcare Products Regulatory Agency said after a review of stability data from the manufacturer. June Raine, MHRA chief executive, said, “Now that the jab can be stored at normal fridge temperatures for up to 31 days, it can be used in a wider range of healthcare settings, giving patients greater access to the Pfizer vaccine.”

India is urged to boost vaccine production

A group of 567 public health practitioners, doctors, economists, unions, human rights groups, and civil society organisations in India called on the prime minister, Narendra Modi, to speed up vaccine rollout and ensure free access. At the current pace, India’s vaccination drive will take 2.4 years to complete, they said, during which time the virus may mutate. The group suggested that India could achieve universal coverage if it temporarily relaxed intellectual property rights, patents, and other provisions.

**Consultants**

Senior hospital doctors have “moral injury”

The pandemic has left some hospital consultants with moral injuries after working long hours, sometimes without adequate personal protective equipment, while seeing patients and colleagues die in unprecedented numbers, said Rob Harwood, chair of the BMA’s Consultants Committee, on 19 May. He renewed calls for a pay uplift for consultants of at least 5% as part of the BMA’s Fairness for the Frontline campaign. He said, “The government’s proposal of a 1% pay rise was disappointing, mean spirited, and insulting—although not surprising.”

**Transparency**

Less than half of vaccine trials are published

Results from less than half (45%) of 86 clinical trials registered for the top 20 vaccines had been announced up to March, an analysis by Transparency International and Toronto University has found. Of those announced, 41% provided only top-level results in a press release or press conference, with the full data not made available. Clinical trial protocols had been published for just 12% of trials.

Cite this as: BMJ 2021;373:n1319

**Air quality**

Lockdowns around the world may have prevented at least 32000 deaths because of reduced NO2 emissions from vehicles and power plants. China avoided the most deaths—21000—while Europe had an estimated 6600 fewer deaths

[Science Advances]

Cite this as: BMJ 2021;373:n1318

**Communication breakdown?**

You could say that. Not for the first time during the pandemic, the UK government has been less than crystal clear in its messaging around the coronavirus.

**Managing the message?**

Not managing would be more appropriate. This week, ministers were falling over themselves to contradict each other when discussing England’s new traffic light system for international travel, as they tried to explain whether people should or shouldn’t be taking holidays abroad this year.

**Why the confusion?**

While the guidance itself is quite clear that people shouldn’t travel to either “amber” or “red” countries for leisure purposes, ministers have been behaving more like inexperienced learners than seasoned road veterans when steering this new system.

**So, can we go on amber or not?**

On 18 May the environment secretary, George Eustice, said, “We don’t want to stop travel altogether, and the reason we have the amber list is there will be reasons people feel they need to travel, either to visit family or indeed to visit friends.” But within hours the PM, Boris Johnson, waded in, saying, “It’s important for people to grasp what an amber list country is: it is not somewhere you should be going on holiday.”

**Would “stop” or “go” be better?**

That might solve a few problems. But after mixed messages such as “Work from home,” “Don’t work from home,” and “Eat out,” “Don’t eat out,” perhaps we shouldn’t underestimate how confusing two diametrically opposed things can be to ministers.

**Thank goodness the NHS knows how to communicate.**

Hold on there. The BMA described a letter from NHS England telling GPs to offer face-to-face appointments as “tone deaf,” while the head of Manchester’s devolved health system told HSJ that NHS England’s centralised control of communications throughout the pandemic had made it a “nightmare” for local hospitals to get messages to the public. All in all, it’s not been a great week for comms.

Gareth Iacobucci, The BMJ

Cite this as: BMJ 2021;373:n1318
GPs pass vote of no confidence in NHS England

The BMA’s General Practitioners Committee has passed a motion of no confidence in NHS England in response to a “tone deaf” letter sent last week instructing GPs to return to offering face-to-face appointments without prior triage.

The motion, passed at the GPC’s online meeting on 20 May, said the committee was “outraged by NHS England and NHS Improvement’s lack of understanding of the pressures facing general practice” and urged the GPC executive to “immediately cease” all formal meetings with NHS England until the issue had been resolved.

Earlier this week the GPC chair, Richard Vautrey, called for an urgent meeting with the health secretary, Matt Hancock, to discuss the “widespread anger, frustration, and disappointment” at the letter, sent by NHS England’s medical director for primary care, Nikki Kanani (above), and director of primary care, Ed Waller.

Before issuing the letter the NHS had been advising practices to use the “total triage” model to cut the risk of Covid infection spreading. But the updated guidance, published in full on 20 May, said “all GP practices must ensure they are offering a blended approach of both face to face and remote appointments.”

Vautrey said the “woefully badly judged” letter was the “final straw for many hardworking GPs who have gone above and beyond over the last year.”

He added, “Instead of issuing tone deaf letters… NHS England and the government must face the reality of years of failing to value, support, and invest in general practice.”

A Department of Health and Social Care spokesperson said, “GPs and their teams have played an enormous role throughout this pandemic and we are incredibly grateful for their tireless efforts.”

Gareth Iacobucci, The BMJ

Cite this as: BMJ 2021;373:n1311

Legal bid launched to stop US takeover of GP services

 Patients and doctors are backing a legal challenge to a takeover of NHS general practice services by a private US health company. They want a judicial review of a decision by North Central London Clinical Commissioning Group to allow eight general practices to be taken over by health insurance giant Centene to expand the firm’s UK portfolio.

Campaigners, including the group Keep Our NHS Public, argue that the decision to allow change of control lacked transparency and should be declared unlawful. They said it posed risks to patients’ care and could lead to unprofitable services being closed down and personal data leaving the UK.

A Crowdjustice fundraising appeal was launched on 20 May in support of the judicial review bid being brought by Anjna Khurana, a patient and Tollington ward councillor for the London Borough of Islington. She said that 375 000 NHS patients were not told about the takeover.

“I am so afraid that our NHS is being dismantled bit by bit, with the private sector playing a bigger and bigger part,” she said.

The concerns centre on Operose Health, a wholly owned subsidiary of the Centene corporation. Operose Health recently acquired AT Medics, which runs 37 general practices in London, mostly under alternative provider medical services (APMS) contracts. AT Medics directors had to ask the NHS to permit the transfer in control to Operose Health, which will now run more than 50 general practices in total in England.

Rich nations putting “relationships with big pharma ahead of ending pandemic”

Some rich countries are continuing to put their relationships with big pharma ahead of ending this pandemic,” said Oxfam’s health policy adviser in response to commitments made by G20 leaders at the Global Health Summit.

Anna Marriott described the action agreed by world leaders at the summit (below), co-hosted by the European Commission and Italy on 21 May, as like throwing a bucket of water on a forest fire.

The summit reaffirmed support for the Access to Covid-19 Tools Accelerator (ACT), launched by WHO just over a year ago to hasten the development of tests, treatments, and vaccines and to ensure equitable distribution. However, as the global death toll surpasses three million, there is still a funding gap of $18.5bn (£13.1bn) for ACT. Covax, which distributes vaccines to low income countries, also has low stocks.

The world leaders made vaccine pledges, including the delivery of 1.3 billion doses to lower income states by the end of the year, but few other changes—despite WHO’s estimate that ending the pandemic through ACT-Accelerator would cost less than 1% of what governments are spending on the consequences of the pandemic.

Marriott said that while leaders spoke eloquently about the “gross inequalities of global vaccinations,” their solutions were still the “same tired ones that have failed billions of people.”

She added that they had “once again ceded control of this pandemic to a handful of pharmaceutical corporations” that had “put profits before people at every turn.”

Elisabeth Mahase, The BMJ

Cite this as: BMJ 2021;373:n1342

29 May 2021 | the bmj

298
North Central London Clinical Commissioning Group is one of 13 CCGs in London that authorised the transfer of their AT Medics practices to Operose Health. The group said in March 2021 that it approved the transfer “as there was no legal or contractual basis” to reject it and it would not alter the service provided under the contract. It said “no concerns” were raised during a due diligence process that was undertaken “independently by a solicitor” and collectively on behalf of the 13 London clinical commissioning groups affected.

But critics say that the CCG had not been open with patients and had not considered the possible effects of the decision or the track record and debt load of the US firm, which they believe could destabilise services.

### Strategy of divestment

Louise Irvine, a London GP and member of Keep Our NHS Public, said the UK parent company of Operose, MH Holdings International (UK), had a stated strategy of divesting itself of businesses or contracts that did not reach its profitability targets.

Irvine told *The BMJ*, “There’s concern that, if the main motive is profitability, efforts will be made to drive up profits in the practices to get the maximum out of them. That could mean cutting back on skill mix and numbers of GPs and getting less skilled staff who are cheaper. People are really worried about that.”

Irvine added that patients had had no say and were worried about what would happen to personal data.

### If the main motive is profitability, efforts will be made to drive up profit

Louise Irvine

---

**FACT CHECK Are B.1.617.2 rates linked to vaccine hesitancy?**

England’s health secretary, Matt Hancock, has linked high rates of infection and hospital admissions of people with the B.1.617.2 variant of covid first identified in India to vaccine hesitancy.

In an update to MPs on 17 May, Hancock said most of the 19 people admitted to hospital with the variant in the hotspot area of Bolton were eligible for a covid-19 vaccine but had not had it.

He added, “That shows the new variant is not tending to penetrate into older vaccinated groups and underlines again the importance of getting the jab—especially, but not only, among the vulnerable age groups.”

**Was Hancock right to frame the situation in this way?**

Bolton NHS Foundation Trust said it could not issue information about individual patients and could only refer *The BMJ* to national data on vaccination uptake. These data show that, while Bolton has the highest covid case rate in England (424 cases per 100 000 people as of 18 May), its vaccine uptake, with 67.6% of adults having received a first dose by 24 May, is broadly similar to the England average.

Similarly, in Blackburn with Darwen, the area of England with the second highest prevalence of B.1.617.2 (215.1 cases per 100 000 people on 18 May), 63.4% of first vaccine doses have been administered.

By comparison, Tower Hamlets in east London, which has the lowest percentage of first doses administered (36.6%), has just 10.8 cases of the variant per 100 000 people. Hackney and the City of London combined, the next lowest borough area, with 39.1% of first doses given, has 10.7 cases per 100 000.

The Isle of Wight has the highest percentage of first doses administered in England (78.3%) and has 4.2 cases per 100 000.

Gabriel Scally, visiting professor of public health at Bristol University and a member of the Independent Scientific Advisory Group for Emergencies, believes it was wrong for Hancock to link Bolton’s vaccine uptake with hospital admissions.

Writing in the *Guardian* Scally wrote, “How did the health secretary know such detailed clinical information about these individuals? How accurate were these numbers? And was it appropriate to suggest that a small number of people currently battling a deadly infectious disease in hospital had brought this illness upon themselves?”

Helen Lowey, Bolton’s director of public health, said, “There is no evidence these variants cause more severe illness; there is some evidence the Indian variant spreads more easily than others so it is the one we want to stop and contain.”

Helen Wall, senior responsible officer of the vaccination programme in Bolton, said, “We have a good track record of vaccination and a high level of confidence in the programme already in Bolton, and we aim to build on that with some targeted vaccination work to try to nip this in the bud to protect everyone in Bolton.”

Gareth Iacobucci, *The BMJ*

---

Bolton has England’s highest covid case rate (424 cases per 100 000 people as of 18 May), but its vaccine uptake, with 67.6% of adults having received a first dose by 24 May, is broadly similar to the national average.
GMC calls for doctors’ duty to declare interests to be enforced

The current system of voluntary registers is “chaotic, burdensome, and difficult to navigate” and does not work for doctors or the public, reports Rebecca Coombes

The GMC has backed a call to enforce doctors’ duty to declare their interests and in a form that is easily accessed by patients. But questions remain over whether these interests should be linked to the GMC register, a move the council doesn’t favour. The government is also believed to want a scheme managed locally by employers, as well as one that includes all healthcare staff.

The GMC’s support for a mandatory register came in a meeting last week hosted by the All Party Parliamentary Group First Do No Harm and The BMJ. Colin Melville, the GMC’s director of education and standards, said the registering of interests should be enforceable “so the public can trust it is credible. It can’t be right patients are not made aware of any real or potential conflicts of interests.”

The GMC already requires doctors to declare conflicts of interest to patients and employers, although Melville acknowledged it was a grey area, adding that some doctors didn’t declare because the system was “not always obvious” and that “probably only small numbers” were avoiding transparency.

Transparency campaigners have said that a register held by the GMC was the only effective way to stop harm to patients caused by competing interests. The change could be legislated for under an amendment to the Health and Social Care Bill set out in this month’s Queen’s speech.

Julia Cumberlege, who chaired the recent safety review into vaginal mesh, sodium valproate, and Primodos, said, “The case is clear. The review found that transparency of payments to physicians needs to improve and the register should expand to include a list of financial and non-pecuniary interests for all doctors.”

Fiona Godlee, BMJ editor in chief, said the voluntary declaration system for UK doctors was “chaotic, burdensome, and difficult to navigate.” NHS employers require staff to declare conflicts of interest, which are then recorded in a local register, but studies have shown that adherence is poor.

Big problems

Margaret McCartney, a GP in Glasgow, spoke of her current research into the accessibility of local registers to the public: “We have found big problems. A third of registers are older than two years, and only 12% of registers were asking for the value of what was being declared. In some hospitals over a third of consultants and pharmacists were not making declarations of interest at all.” She said the system represented a “bureaucratic load” for doctors filling in forms but also for hospital staff who are having to manage huge registers that are often “repetitive, tedious, and unintelligible.”

McCartney added, “These systems are too poorly designed to be useful. We see some professionals worrying about declaring a box of chocolates, while other trusts are publishing registers with redaction of names receiving thousands of pounds from industry. It’s a small number of professionals who have a disproportionate effect on healthcare.”

Academic doctor and broadcaster Chris van Tulleken said it was important to focus on doctors because they had “the greatest power to influence individual patient decisions, and also clinical guidelines.”

“As a broadcaster I notice my colleagues who have enormous power but deep and undeclared interests. Patients listen to us more than many other healthcare professionals,” he said. Even if he wanted to, the system didn’t make it possible to make a full declaration of interests. “The GMC should make it possible for doctors like me, who don’t have just one employer, to make a central declaration. There is mounting evidence that patients are harmed by competing interests, and the GMC

A THIRD of registers are older than two years, and only 12% of registers were asking for the value of what was being declared

Kath Sansom, founder of Sling the Mesh, a campaign group with 9000 members set up to raise awareness of the risks associated with vaginal and rectal mesh, said it was “vastly unacceptable to expect patients to go trawling around NHS trusts to look for conflicts of interest—we may not even know where a surgeon works, or they may work at multiple outlets.” She added, “We have got to tackle conflicts of interest or we will see another mesh or breast implant scandal.”

“...could those with a conflict of interests, please leave the room

Margaret McCartney, a GP in Glasgow, spoke of her current research into the accessibility of local registers to the public: “We have found big problems. A third of registers are older than two years, and only 12% of registers were asking for the value of what was being declared. In some hospitals over a third of consultants and pharmacists were not making declarations of interest at all.” She said the system represented a “bureaucratic load” for doctors filling in forms but also for hospital staff who are having to manage huge registers that are often “repetitive, tedious, and unintelligible.”

McCartney added, “These systems are too poorly designed to be useful. We see some professionals worrying about declaring a box of chocolates, while other trusts are publishing registers with redaction of names receiving thousands of pounds from industry. It’s a small number of professionals who have a disproportionate effect on healthcare.”

Academic doctor and broadcaster Chris van Tulleken said it was important to focus on doctors because they had “the greatest power to influence individual patient decisions, and also clinical guidelines.”

“As a broadcaster I notice my colleagues who have enormous power but deep and undeclared interests. Patients listen to us more than many other healthcare professionals,” he said. Even if he wanted to, the system didn’t make it possible to make a full declaration of interests. “The GMC should make it possible for doctors like me, who don’t have just one employer, to make a central declaration. There is mounting evidence that patients are harmed by competing interests, and the GMC
may end up facing a legal test case where patients take them to court as responsible for harm.”

The campaign to set up a centrally held register, accessible to patients, has gathered pace in recent months after backing from medical professional bodies. A survey by The BMJ found that nine out of 10 bodies supported the move, including the Royal College of Physicians and the Royal College of Surgeons of England.

“Simple, single annual disclosure”

Speaking at the event, Royal College of Surgeons president Neil Mortensen said the college favoured a “simple, single, annual disclosure.” “Medics should be able easily to upload a declaration of interest at minimal expense and there should be sanctions for failure to submit. As far as surgeons are concerned, the majority make for dull reading as they have fewer temptations than physician colleagues working with big pharma,” he said.

Cyril Chantler, vice chair of the Cumberlege review and a former member of the GMC, said the council was the obvious organisation to take responsibility. “The public need one place to go to obtain information. Each doctor would need to complete or update one form, and only one form, each year. Such forms already exist and are mandated by some hospitals. The form would be checked and validated by the appraisal process and then lodged with the employer. It would also be accessible to the public on their websites with a link to the GMC register from which it could be accessed.”

But Melville questioned whether a central register was the solution. “We think patients are more likely to look at local healthcare providers for information, but if we were required to provide a central register, of course we would publicise it,” he said.

Rebecca Coombes, The BMJ
Cite this as: BMJ 2021;373:n1329

We have got to tackle conflicts of interest or we will see another mesh or breast implant scandal

Kath Sansom

Women harmed by faulty breast implants should be compensated, court rules

A Paris appeal court has ruled that around 2700 women, including 540 from the UK, are entitled to compensation from the German company that certified as safe faulty breast implants made by a French manufacturer.

The court ruled that TUV Rhineland was negligent when it certified the safety of implants made by Poly Implant Prothèse (PIP).

The implants, which were marketed for 10 years, were made with cheap industrial grade silicone used in mattresses and not cleared for human use. The European safety certificates given by TUV allowed PIP to market the product around the world.

They are thought to have been given to up to 400 000 women in 65 countries, including around 47 000 in the UK. The scandal emerged in 2010 when doctors noticed the implants had a high rate of rupture. Even without rupture, the silicone can spread through the body, leading to inflammation.

Decision on damages

The court is expected to decide in September on the damages for a first group of patients. The women’s lawyer, Olivier Aumaître, is asking for sums ranging from €20 000 to €70 000 (£17 200 to £60 350) per patient, depending on the severity of the injury.

Aumaître said, “After 10 years of waiting and fierce combat, the German certifier will have to compensate the victims fully.”

PIP went into liquidation in 2010, and its founder, Jean-Claude Mas, was later given a four year jail sentence for fraud. He told the police investigation that his employees used to remove evidence of the industrial silicone gel before TUV made its annual inspections. He died in 2019.

Parm Sahota, a solicitor at the law firm Slater and Gordon who represents hundreds of British women suing over PIP implants in France, said, “The decision is a positive step for our clients whose case is currently being heard in the court of Nanterre in France. While we’re pleased with this recent ruling, it remains to be seen if TUV will appeal the decision and how it will affect our case.

“TUV have long maintained a denial of liability in all of the class actions that have been brought against them by hundreds of women, and have refused mediation, and we anticipate they will continue to look to exhaust all avenues open to them within the French court process.”

TUV response

TUV told news outlets it would study a translated judgment before commenting. In the past the company has said that it had acted diligently, in compliance with applicable regulations, and had never been aware that the PIP implants were not compliant.

Mary O’Brien, president of the British Association of Aesthetic and Plastic Surgeons (BAAPS), said, “The human cost to many women and their families following surgery involving PIP implants is sobering.

It is for this reason that BAAPS supports the breast implant registry, and research and collaboration with other professional associations, and acknowledges the important role of the Medicines and Healthcare Products Regulatory Agency in ensuring this situation is never repeated.”

Clare Dyer, The BMJ
Cite this as: BMJ 2021;373:n1307
The Royal College of Physicians has moved into its new northern home, RCP at The Spine in Liverpool.

Built over five years in partnership with the city council, the building will be opened in stages: the assessment floor is already being used for exams, and the new education spaces will open in July, with other floors opening in the autumn.

The Spine, says the RCP, which will maintain its London HQ, has been built to the highest environmental standards and will be a “groundbreaking, world leading example of biophilic architecture, supporting mental and physical wellbeing for staff and visitors.”

Alison Shepherd, The BMJ

Cite this as: BMJ 2021;373:n1330

THE BIG PICTURE

Royal college opens its second home

1. The main entrance and foyer of the RCP’s new home in the north
2. The Axis restaurant will have panoramic views when it opens in September
3. The building will be in a medical and scientific precinct, with close neighbours including the new Royal Liverpool Hospital
Mental health support during and after covid-19
Primary care needs urgent investment in services

Covid-19 has raised the prevalence of anxiety, depression, post-traumatic stress disorder, and psychological and mental distress among the general population. Rates of suicidal thoughts increased in people aged 18-29 during the pandemic, highlighting the particular toll of covid-19 on young people.

Repeated episodes of lockdown, periods of self-isolation after contact with infected people, social distancing, and the fear of contracting covid-19 when outside the home can lead to heightened fear and anxiety in people of all ages. Self-isolation is associated with symptoms of post-traumatic stress, anxiety, adjustment disorder, confusion, and anger.

The implications of covid-19 for people with pre-existing mental illness are of particular concern, along with the likelihood that covid-19 will further widen mental health inequalities for ethnic minority groups.

Against this backdrop, mental health support through primary care is a priority for patients, the public, commissioners, researchers, and policy makers.

Around 90% of mental health problems are managed entirely in primary care, and general practitioners report that mental health constitutes around 40% of their workload. The World Health Organization suggests that good primary care management of people with mental health problems reduces stigma and improves access to treatment. Early intervention in primary care has been shown to reduce subsequent mental health problems and be cost effective.

Primary care is now at the forefront of the predicted increase in mental health presentations: covid-19 is thought to have affected or be likely to affect the mental health of around 10 million people.

Patients with long covid describe the fear, uncertainty, and despair caused by persistent symptoms and emphasise mental health support as a key part of recovery. People with active covid-19 are worried about their prognosis, while those admitted to intensive care—and their families and carers—experience substantial mental health distress. These are all risk factors for subsequent mental illness.

Rates of self-harm and common mental health problems are higher among those admitted to intensive care—and their families and carers—experience substantial mental health distress. These are all risk factors for subsequent mental illness.

Future priorities
Primary care needs urgent and sustained mental health investment to provide early identification of mental health conditions, timely intervention and treatment, prevention, ongoing support, and access to specialist mental healthcare services. This should be a priority for the integrated care systems at the heart of NHS restructuring proposals.

Increased capacity and enhanced access to psychological therapies in primary care is essential for all age groups along with increased support for grassroots community initiatives.

Remote primary care consultations for mental health have not been evaluated in the UK, and the loss of in-person interaction between clinician and patient may undermine the rapport essential for effective mental healthcare. Remote consultation may also reduce a clinician’s ability to identify important cues, including the possibility of substance misuse, domestic violence, self-harm, grief, low mood, signs of psychosis, or anxiety, particularly in young people, parents, and carers. Primary care professionals must have the time and resources required to support patients to self-care, in line with recent guidance by the Royal College of General Practitioners.

Research to identify best practice for remote mental health consultations in primary care is urgently required, including studies exploring both enablers and barriers to accessing remote mental health support. Changes to services must not be allowed to widen health inequalities further, through digital exclusion, for example. How to provide safe and effective care for people without stable access to digital devices should be a research priority.

We must refocus, rebuild, and revitalise mental health support through primary care to aid the recovery from covid-19.

Cite this as: BMJ 2021;373:n1064
Find the full version with references at http://dx.doi.org/10.1136/bmj.n1064

Editorial Board: NIHR doctoral fellow, School of Medicine, Keele University, UK
Muhammad Z Hossain, postdoctoral research associate, University of Liverpool
Angela Brady, deputy chief medical officer, NHS Birmingham and Solihull Clinical Commissioning Group
Judy Samuel, lay member of board representative, Royal College of General Practitioners Midland Faculty, Birmingham
Carolyn A Chew-Graham, professor of general practice research, School of Medicine, Keele University

The implications of covid-19 for people with pre-existing mental illness are of particular concern

Faraz Mughal, NIHR doctoral fellow, School of Medicine, Keele University, UK f.mughal@keele.ac.uk
Muhammad Z Hossain, postdoctoral research associate, University of Liverpool
Angela Brady, deputy chief medical officer, NHS Birmingham and Solihull Clinical Commissioning Group
Judy Samuel, lay member of board representative, Royal College of General Practitioners Midland Faculty, Birmingham
Carolyn A Chew-Graham, professor of general practice research, School of Medicine, Keele University

See supplementary files for references.
Democratising healthcare decision making

Post-pandemic reforms should prioritise wide public and patient consultation and collaboration

The devastating health, social, and economic effects of the pandemic, in rich and poor countries alike, has precipitated radical changes in healthcare practices and highlighted outdated ways of working that are not fit for purpose in the digital age. It also stalled progress on shared decision making and patient and public involvement in healthcare. Early in the pandemic, well-embedded structures for involvement were suddenly disrupted at a time when the concerns of patients and the public could scarcely have been greater.

In response, patient advocates, organisations, and civil society groups in many countries have worked in overdrive, supporting their communities, collating information about the nature and impact of the pandemic, and urging policy makers to heed the findings and work collaboratively with them to develop new inclusive and equitable policies.

The devastating health, social, and economic effects of the pandemic, in rich and poor countries alike, strengthens the call for wider patient and public participation in policy making and research. This call is being endorsed by the World Health Organization and facilitated by increasing participation in virtual meetings. Responding to the huge challenges countries currently face requires sharing expertise, experiential knowledge, and new approaches to involving patients and the public in research.

The BMJ has advocated for partnership with patients and the public for decades, and seven years ago we launched a formal strategy (https://www.bmj.com/campaign/patient-partnership). This has fundamentally changed how we work—and think. Patient involvement has become the norm, as has inviting patients and carers to co-write and comment on articles. Our feedback suggests that encouraging authors to involve patients and patient advocates in the development of their articles has influenced professional mindsets and broadened the relevance and reach of our content.

We owe much to the support and agenda setting role of our international patient and public advisory panel. Its input regularly informs editorial commissioning decisions and longer term strategy.

Next steps

The BMJ continues to chart and comment on the effects of the pandemic, publish new research findings, extend professional and public debate on key concerns, and advocate for equitable access to healthcare and more collaborative working. We recently worked with WHO on a collection of articles focusing on the need for knowledge to be co-produced and increased our interaction with national, European, and international policy making bodies and patient organisations.

In response to input from our patient and public advisory panel, we have decided to focus on two areas over the coming year. Firstly, as systems look to adapt and rebuild, we seek to identify, discuss, and disseminate initiatives that involve patients and the public in service reconfiguration and healthcare innovation. There is an opportunity, as well as an ethical imperative, to adopt creative approaches to co-design and the evaluation of new models of care. There is no universal solution, and we seek to spread learning from effective initiatives in different countries and settings and welcome suggestions for contributions to the Partnership in Practice series.

Second, recognising the digital and data driven world we live in, we will advocate more strongly in support of a key principle: that healthcare systems should provide patients with real time online access to all their health information and data. In the US a new law has just mandated this, and evidence of the benefit it brings to both patients and health systems is growing. Access to personal health records, and their use to promote self-management and improved communication with health professionals, will entail clearing substantial cultural and educational hurdles as well as technological ones. To chart international developments on patients’ access to records, we are publishing a collection of articles and working with an international interdisciplinary group to set up a series of webinars to debate key questions around health records, including access, understanding, sharing, control, and use.

The pandemic has shown that we live in an interdependent world but also how easily patient and public voices and preferences can be lost. Personal health, public health, and environmental sustainability depend on ensuring policy makers acknowledge that all voices count and are listened to.

Cite this as: BMJ 2021;373:n1225

Find the full version with references at http://dx.doi.org/10.1136/bmj.n1225
How independent were the US and British covid-19 vaccine advisory committees?

Advisers on both panels are asked to disclose any industry ties and other conflicts of interest. But Paul D Thacker finds that disclosure standards differ widely, often leaving the public in the dark.

In the wake of lightning fast authorisations of covid-19 vaccines in the UK and the US, public health officials have worked hard to maintain confidence in these new products. British and American officials have emphasised the independence of the experts who authorise vaccines and those who issue advice on them. But an investigation by The BMJ has found that some of these experts have significant industry ties that government agencies do not always disclose.

We looked at experts sitting on the covid-19 authorisation committees at the US Food and Drug Administration (FDA), as well as those on the UK’s Joint Committee on Vaccination and Immunisation (JCVI). It was not possible to repeat the exercise with the UK’s Medicines and Healthcare Products Regulatory Agency (MHRA), which licenses medicines and gave temporary authorisation for covid-19 vaccines, because the MHRA and its adviser, the Commission on Human Medicines, make almost none of their meetings or documents public.

Both the FDA and the UK government require panellists to disclose conflicts only from the previous 12 months, which can miss significant financial payments that occurred in recent years. We also found examples where panellists disclosed to committees their grants, patents, and other industry relationships in their publications, but it seems that the committees did not find these matters worth making public, and they remained undisclosed until now.

No conflicts registered

Most experts on the FDA and JCVI committees registered no conflicts of interest. From the JCVI’s meeting on 22 December 2020, the minutes report that 18 of 19 members had “no registered conflicts of interest,” a pattern repeated in its eight other minuted meetings. Among FDA experts who were not industry or consumer representatives, the agency reported that 20 of 21 voting members had no conflicts at the 10 December advisory committee, as well

There needs to be standardisation of what should be disclosed

Adriane Fugh-Berman

as the same or a similar proportion at other covid vaccine meetings.

Adriane Fugh-Berman, professor of pharmacology and physiology at Georgetown University in Washington, DC, is not surprised at this low level of declarations. “Twelve months is too short. It’s not going to give you a complete picture,” she says. She adds that it’s preferable for government bodies to rely on experts who have had no financial ties for several years previously. The International Committee of Medical Journal Editors, for example, calls for disclosure of relationships going back 36 months.

In some cases, an expert has made a disclosure but the committee has not deemed it a conflict. For example, in the case of the JCVI, the chair of the covid-19 meeting is Wei Shen Lim, a professor at the Nottingham Biomedical Research Centre, who JCVI says has “no registered conflicts of interest.” The same document, however, further states that Lim’s “institution has received unrestricted investigator-initiated research funding from Pfizer for a study in pneumonia in which Professor Lim is the chief investigator (non-vaccine related).” And in a preprint published only months before the JCVI’s December meeting, Lim reported this Pfizer grant.

Similar matters exist with Adam Finn, professor at Bristol University, UK, as the JCVI reports him as having “no personal payments from manufacturers of vaccines” but adds that he is a local principal investigator for the Oxford-AstraZeneca covid vaccine. In disclosures for the New England Journal of Medicine in 2020 and in a disclosure the same year to The BMJ, Finn reported a study grant from GlaxoSmithKline (GSK). And in 2019 he published a study disclosing that his institution received funding from various drug companies and that he was president of a medical society whose annual meeting received sponsorship from vaccine manufacturers.

For Maarten Postma of the University of Groningen in the Netherlands, the matter is rather complex. The JCVI reports no conflicts for his work on the covid-19 guidance, while he discloses board membership for two scientific consultancies on his website. And in a 2018 paper published in JAMA Oncology Postma disclosed grants and honorariums from more than a dozen drug companies, including AstraZeneca, Pfizer, and GSK. He also disclosed grants and personal fees from various pharmaceutical industries and financial support from the flu vaccine company Seqirus in studies he had published in recent months.

“I declare my conflicts of interest to JCVI in the field of vaccines,” wrote Postma in an email to The BMJ. “They are indeed aware of those in the field of vaccines. Outside vaccines, I am happy to declare, but I think we decided we felt these are not relevant.” He also emailed The BMJ a list of his conflicts that JCVI reported for the main JCVI meeting, which was more expansive than what it reported for Postma for the covid meeting.

A Public Health England spokesperson told The BMJ that for a single issue meeting of the JCVI such as for covid-19, conflicts of interest must be reported “only if they relate directly to that matter, rather than more widely.”

Transparency problems increase with the UK’s MHRA, which authorises vaccines after
seeking advice from the Commission on Human Medicines, an independent expert scientific advisory body to government ministers. The commission does not make its advice public, publishes a scant record of meeting minutes, and has not disclosed its members’ declarations of financial interest since 2018.

**Seeking the full picture**

In the US, outside experts advise the FDA on whether to approve or authorise products. Only two members were reported to have conflicts of interest among several covid authorisation panels that met in late 2020. But The BMJ found panelists who had significant financial matters by looking at the Open Payments disclosure website and examining panelists’ published papers.

For example, Open Payments reported that Arnold Monto, professor at the University of Michigan School of Public Health and acting chair for the FDA’s covid vaccine authorisation meetings, had received over $24,000 (£16 970) in payments from drug companies in 2019. That same year, Open Payments reports that Myron Levine, a panelist from the University of Maryland School of Medicine, received about $30,000, mostly in consulting fees.

In 2019, Open Payments reports, Robert Schooley of the University of California at San Diego received over $25,000 in payments. It also reports that Ofer Levy at Boston Children’s Hospital received $5,500 in mostly travel expenses from GSK. And in a 2020 publication Levy disclosed that he was a named inventor on several patent applications related to vaccine adjuvants.

Ofer explained in an email that GSK was not a sponsor for either of the covid vaccine panels. He added that the pending adjuvant patents

### The JCVI’s and FDA’s disclosure policies require advisory members to disclose matters going back only 12 months

“were revealed to FDA in my disclosures and these were appropriately deemed by FDA as irrelevant to the subject matter being considered.”

In another email an FDA spokesperson explained that all potential candidates were required to report detailed financial matters to evaluate possible conflicts of interest. The email advised, “To protect the credibility and integrity of advisory committee advice, the FDA routinely screens members of all advisory committees carefully for potentially disqualifying interests or relationships and makes changes to committee meeting rosters as needed.”

However, a recent analysis by the Pink Sheet, an industry newsletter, found that the FDA had issued six conflict of interest waivers for experts who advised the agency on whether three oncology drugs should be withdrawn after failed clinical outcome studies. And a 2006 study published in JAMA found that conflict of interest disclosures were common at FDA advisory meetings but that they seldom resulted in recusals.

The BMJ reviewed a blank copy of the FDA's disclosure form and found that, as in the case of the JCVI’s disclosure policy, the FDA requires advisory members to disclose matters going back only 12 months.

Fugh-Berman says that these results reveal how confusing disclosure is and that common rules are needed. Few people realise that there’s no common standard for what must be disclosed and how far back, she explains, nor that disclosure is a two step process. Experts disclose interests to an entity—such as a journal, university, or government agency—which then decides what to disclose to the public.

Fugh-Berman adds that she’s sometimes disclosed her own conflicts to editors when writing op-eds for newspapers, for example, and the outlets didn’t make them public. She says, “There needs to be standardisation of what should be disclosed and how it should be disclosed.”

Joel Lexchin of York University in Toronto, who publishes research on conflicts of interest, says, “Twelve months is really quite short. I think that’s not acceptable.” He also suggests that government agencies should publish everything that experts disclose to them, instead of picking and choosing what to make public. “The best policy is disclose everything,” he says. “Second best, pretty far down, is to have clear rules about why certain things don’t need to be disclosed.”

Schooley explains that the various time windows required by different disclosure policies can make it appear that an academic has reported financial interests in one case but not in another. More consistent disclosure policies are needed, he says—and universities, agencies, and journals should come together to normalise standards.

“If all of this were harmonised, it would improve transparency and reduce the time required for all involved,” he wrote to The BMJ. “In the meantime, we can try to answer each request as best we can based on how we interpret each query.”

Lexchin agrees that a standardised, universal disclosure form would make compliance easier for people and help avoid confusion about which financial matters should be disclosed and what the institutions should make public. As he explains, “People can legitimately follow whatever rules they encounter, but important things may get still get left out.”

Open Payments reported that Ofer Levy received $5,500 from GSK in 2019

Paul D. Thacker, investigative journalist, Madrid
thackerpd@gmail.com

Cite this as: BMJ 2021;373:n1283
A new dawn for transparency of doctors’ interests

Nine out of 10 medical professional bodies think patients have a right to know if their doctor has financial or other links with pharmaceutical or medical device companies. Abi Rimmer considers the next steps towards the UK introducing a compulsory, national disclosure regime.

What is a register of doctors’ interests?

NHS England defines a conflict of interest as “a set of circumstances by which a reasonable person would consider that an individual’s ability to apply judgement or act, in the context of delivering, commissioning, or assuring taxpayer funded health and care services is, or could be, impaired or influenced by another interest they hold.” These include financial, non-financial, and indirect interests.

Lobby group Sunshine UK explains that these interests arise when doctors receive money or benefits in addition to their NHS salary. For example, doctors might be paid by a pharmaceutical company to give lectures, conduct research, or travel to attend conferences. According to NHS England guidance, staff should be supported to understand that “having interests is not in itself negative, but not declaring and managing them is.”

Why is it of interest now?

The matter was brought back to light by Julia Cumberlege in her Independent Medicines and Medical Devices Safety Review report, published last year. The independent review investigated the harmful side effects of three medical interventions—hormone pregnancy test Primodos, anti-epileptic drug sodium valproate, and pelvic mesh—across the NHS.

A key recommendation of the report was that patients should have the right to know if their doctor has links with pharmaceutical or medical device companies. “The register of the GMC should be expanded to include a list of financial and non-pecuniary interests for all doctors, as well as doctors’ particular clinical interests and their recognised and accredited specialisms,” the report recommended.

“In addition, there should be mandatory reporting for pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions, and individual clinicians.”

Currently, there is no central register of clinicians’ financial and non-financial interests in the UK. Doctors’ interests are, however, often collected by their employer at a local level. Sunshine UK hosts a voluntary register and the Association of the British Pharmaceutical Industry (ABPI) hosts another, called Disclosure UK, for doctors receiving payments from its members. The Cumberlege report suggested expanding Disclosure UK and making it mandatory.

There is increasing support from the medical community for a central register. A survey by The BMJ found nearly 90% of medical professional bodies agree the UK should have a mandatory and public register of doctors’ interests. Those organisations with no official position include the Royal College of Pathologists, Royal College of Psychiatrists, and Royal College of Ophthalmologists.

“Sunshine” legislation is needed. There has been too much autonomy without sufficient monitoring

Michelle Moffatt
Why does it matter?
In her report, Cumberlege said that “the healthcare system is reliant on people motivated by the best outcomes for their patients.” During the review, she heard from patients concerned that clinicians had been paid or otherwise incentivised by manufacturers in a way that might influence their practice.

Michelle Moffatt, from the patients’ campaigning group Sling the Mesh, called for US-style “sunshine” legislation. “Greater controls are needed to mitigate conflicts of interest between device manufacturers and clinicians; there has been too much autonomy without sufficient monitoring,” she told the review.

Carl Heneghan, director of the Centre for Evidence Based Medicine at the University of Oxford, told the review that surgeons were paid “and flown around the world to become world experts in the latest mesh device.” He said, “The whole system is commercially conflicted. It’s important that if I’m treating you, you should know who’s paying me.”

In terms of surgical procedures, Neil Mortensen, president of the Royal College of Surgeons of England, says, “If I was going to see somebody and they said, ‘You should have implant X or Y,’ it would be absolutely right that I knew whether they had a particular interest in that device or implant.” Conversely, Mortensen adds, patients might not see a surgeon’s interest or expertise in a particular area as a bad thing.

For Susan Bewley, chair of Healthwatch UK and a co-founder of Sunshine UK, a register of interests is about creating trust in the medical profession. “Nobody gives presents to doctors for no reason. The evidence is that even small gifts change behaviour. Why wouldn’t your regulator be interested in something that has influenced your behaviour?”

She says that while some doctors might view gifts or payments as a perk of an otherwise difficult job, “if we have a problem with our working conditions, we need to tackle that.” She adds, “These little perks don’t look small when the outside world sees the total amounts that are being spent on influencing doctors.”

What registries currently exist?
Several voluntary initiatives exist, but requirements vary and all are currently voluntary.

Whopayythisdoctor.org, Sunshine UK’s website, allows doctors to submit amounts within financial brackets, such as £2000-£5000 rather than forcing doctors to disclose exact amounts.

Bewley says the idea was to pilot a form “to see if it is manageable.”

“It was done on a voluntary basis because the GMC declined the suggestion that it was their responsibility,” she says, adding, “It is obvious that the only place you can hold this information centrally and make it matter—because it does matter—is through the GMC register. It doesn’t have to be on the register, but it must be connected to it. It’s also obvious now that it can be connected through annual appraisal.”

Separately, the ABPI’s Disclosure UK records payments and benefits in kind made by pharma to doctors, nurses, and other health professionals and organisations. All ABPI members, and other companies who have signed up, disclose certain payments and other benefits in kind made to healthcare professionals. There is no minimum amount required for disclosure.

Under data protection laws, however, healthcare professionals can refuse to have their name published. So, while the amount awarded to a healthcare professional would be submitted to Disclosure UK by a pharmaceutical company, the recipient can opt to remain anonymous.

In 2017, the Academy of Medical Royal Colleges recommended that all doctors should voluntarily comply with Disclosure UK. But, two years later, just 55.9% of healthcare professionals (including doctors, nurses, and others) who had received non-research and development funding had agreed to be named on Disclosure UK, according to the ABPI.

That same year, pharmaceutical companies spent £160.9m on non-research and development collaborations with healthcare organisations and healthcare professionals. Of this, £3.6m was spent on registration fees, £34.1m on sponsorship agreements with organisations or third parties, £10.4m on travel and accommodation, £4.2m in donations and grants to organisations, £56.6m on fees, £7.5m on expenses agreed for services or consultancy contracts, and £4.6m on “joint working.”

But is the ABPI the best place to hold such information? Bewley describes this as being “like putting the fox in charge of the chicken coop.”

“It’s a marvellous initiative but they are not a safe holder of the data,” she says, “They should hand all of the information over to the GMC, then the task would be less onerous for doctors. We can’t have the ABPI responsible for holding the trust of the medical profession.”

Richard Torbett, chief executive of the ABPI, said the organisation was proud of Disclosure UK. “We continue to work with medical communities to encourage as many healthcare professionals as possible to agree to be included by name on Disclosure UK and support the ambition of the Cumberlege review to improve individual disclosure.”

In addition, many doctors and medical academics will be used to declaring their interests to their employer, conferences, and journals. Different organisations require different levels of disclosure, which can be confusing and time consuming for those declaring. For example, doctors and experts sitting on the Joint Committee on Vaccination and Immunisation are required to declare competing interests going back only 12 months. By contrast, The BMJ asks authors to declare interests in the 36 months before the declaration and those known to be occurring during the next 12 months.

Bewley explains, “Academics are used to it. We’re just fed up with filling out a form every time, which is sometimes incredibly complicated. A lot of people who declare their interests regularly would welcome a simpler way of doing it.”

Margaret McCartney, a GP and health journalist, agrees with the Cumberlege review that the GMC is the only organisation suitable to hold a register of doctors’ interests as it is the only organisation that holds a list of all registered doctors in the UK.
The GMC did not comment on whether it would be willing to hold a register of doctors’ interests.

What would a central register of interests look like?
Mortensen says, from his own perspective, a central register should include any kind of financial interest a doctor may have in a device or medicine. “We want patients to know they are getting unbiased advice around what they should have done and what they should have implanted in them.

“Obviously if a company is giving any kind of financial support for travel or for educational activities that should be declared,” he says, “Around the edge of direct surgical care there would also be the question of whether you have any shares in companies which would give rise to a conflict of interest.”

The register, Mortensen says, would need to be easy to use and not cost doctors a lot of money. “We’d need to be convinced that it was light touch, effective, and that it was going to make a difference.”

For McCartney, the aim of any central register should be to decrease bureaucracy for healthcare professionals and increase transparency for patients. “Any register that we use has to be done on the understanding that that is the central register that anyone who asks for your conflicts should be using, for example NHS trusts, academic institutions, journals, conferences,” she says.

“These third parties could collect the data from the central register and then doctors could be asked to confirm that it’s correct.”

McCartney and a team of researchers have been assessing the current practice of declarations of interest in the NHS. “We’ve found that some places are doing very well with template driven declarations of interest, in other places the information that’s collected and published seems to be random. A central register would be a better way.”

Finding out whether someone doesn’t have a declaration of interest can be remarkably difficult, McCartney says, because it’s trying to prove a negative. “Unless you have a positive declaration that someone has no declaration to make you can end up chasing your tail.

“The advantage of having a central register means that if someone has a declared competing interest you know it must be there.”

What about other health professionals?
In response to the Cumberlege report, the government said any publication of declarations of interest should cover all clinical decision making staff, not just doctors.

Cumberlege told The BMJ that the situation for each profession should lie with their specific regulator. “But doctors are the principal decision makers in patient care, they determine the treatment, they perform surgery,” she says. “It is with doctors that we must start.”

Bewley agrees, “While we know that there is a lot more money being used to influence people making decisions outside of the medical profession it is ridiculous to say that a register for doctors has to wait for everyone else.” She adds, “This is where doctors and the GMC should be showing leadership. It’s clear that the most expensive, most frequent, and most harmful decisions are made by doctors.”

Colin Melville, medical director and GMC’s director of education and standards, says the regulator had taken note of the findings of Cumberlege’s review. “Our guidance states that doctors must be open about conflicts of interest, including when it is uncertain whether or not a conflict exists.

“It is clear that changes are needed to make sure patients have access to this information to support them in making decisions about their care. It is vital that we create a culture of greater transparency and honesty.”

How does it work elsewhere?
In the US, the Physician Payments Sunshine Act 2010 places a statutory responsibility on medical product manufacturers to declare any payments or other transfers of value (including expenses) valued at over $10 made to physicians or teaching hospitals. Anyone can search the Open Payments database for their doctor or healthcare organisation and see if they have received payments, including for research, meals, travel, gifts, or speaking fees.

Among countries in the Organisation for Economic Co-operation and Development, six others have adopted statutory “sunshine” regulations: Denmark, France, Greece, Latvia, Portugal, and Romania.

In France, the Bertrand Law requires that payments to health professionals and health entities are accessible on a government website. Under the provisions, any direct or indirect transfers of value over €1 to health professionals, including doctors, must be reported. France has also prohibited transfers of value over €1 to health professionals, including doctors, who are employed by healthcare providers or are in a position to influence their purchasing decisions. The provisions also apply to transfers of value to health entities, such as medical equipment or pharmaceuticals.

In Romania, the law requires that all payments to health professionals be reported on a government website. The provisions also apply to transfers of value to health entities, such as medical equipment or pharmaceuticals.

In Greece, the law requires that all payments to health professionals be reported on a government website. The provisions also apply to transfers of value to health entities, such as medical equipment or pharmaceuticals.

In Latvia, the law requires that all payments to health professionals be reported on a government website. The provisions also apply to transfers of value to health entities, such as medical equipment or pharmaceuticals.

In Portugal, the law requires that all payments to health professionals be reported on a government website. The provisions also apply to transfers of value to health entities, such as medical equipment or pharmaceuticals.

In Denmark, the law requires that all payments to health professionals be reported on a government website. The provisions also apply to transfers of value to health entities, such as medical equipment or pharmaceuticals.