The sexual abuse of children in healthcare settings has typically been carried out under the guise of medical procedures, the independent inquiry into child sexual abuse in England and Wales has concluded.

Perpetrators were commonly male practitioners in positions of trust, whose actions were not questioned by parents, children, or other staff, a research report for the inquiry found. The inquiry’s fifth report is based on victims’ experiences from the 1960s to the early 2000s as told to the Truth Project. Set up in 2015 to look at failures to protect children from abuse and exploitation, it has reported on religious and custodial institutions, residential care, and sports.

Cloaking abuse under the guise of clinical care made it difficult for the children to identify it as abuse, the report found, and only a quarter reported the incidents. One victim said, “Under the guise of performing a medical test, called a high vaginal swab, he used that as an opportunity to rape me. I thought I was dying, but I also thought I had to be very quiet, because it was the right thing to do.”

Apart from the victims’ lack of medical knowledge, the position of trust held by healthcare professionals and physical isolation in private consultation rooms were factors facilitating the abuse identified by the report. Some victims explained that the GP was trusted by their family, who had a long relationship with him. One said that, when the GP was being investigated, her parents wrote a letter in his support, highlighting the level of trust they had in him.

Only 3% of victims (109) who talked to the Trust Project had been abused in a health setting. Of these, 83 had been abused by a healthcare professional (59 by doctors). Accounts describe abuse in hospitals, psychiatric institutions, and GP surgeries. Some doctors who used examinations as a cover for abuse have since been convicted and are serving long jail sentences. Manish Shah, a GP who mainly assaulted women but whose victims included a 15 year old girl, was handed three life sentences last February. Myles Bradbury, a consultant paediatric haematologist at Addenbrooke’s Hospital in Cambridge, is serving 16 years for the sexual abuse of 18 boys aged 10 to 15. Alan Tutin, a GP who sexually molested women and girls, was jailed for 10 and a half years in 2019.

From left: doctors Alan Tutin, Manish Shah, and Myles Bradbury have all been convicted for the sexual abuse of children.
amatexdropdown

**SEVEN DAYS IN**

**GPs call for hospitals to be fined for inappropriate workload transfer**

Hospitals should be fined if they do not act to reduce the amount of work being transferred from secondary to primary care, GPs have said, after noting a rise in hospital doctors “dumping” inappropriate work on them during the pandemic.

A motion passed at the annual conference of England’s local medical committees on 27 November called on the BMA’s General Practitioners Committee to ensure that GPs were not held responsible if patients deteriorated while on a waiting list for hospital care. It called on the GPC to agree financial sanctions against providers that did not reduce the transfer of work, with resulting funds payable directly to the practices affected.

The motion also said the GPC should urgently negotiate to make it mandatory “that all investigations initiated in secondary care are followed up in secondary care.”

Proposing the motion, Mitch Garsin of Hillingdon LMC warned that general practice was in danger of collapse because of work backlogs, staff vacancies, and the mass covid-19 vaccination programme. He said, “We’ve had to also manage a tsunami of work that’s been dumped on us by a secondary care system following the age old maxim of, ‘If we’re too busy to do it or don’t know what to do with it, send it to the GP, they can sort it out.’”

Abi Rimmer, The BMJ  
Cite this as: BMJ 2020;371:m4724

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**Covid-19**

**Further demand for immediate public inquiry**

Members of the Covid-19 Bereaved Families for Justice group joined trade unions and campaigning organisations to demand an immediate statutory public inquiry into the government’s handling of the pandemic, to minimise further loss of life. In a letter to the prime minister they argued that a pandemic inquiry must begin with a “rapid review phase” like that at the beginning of the Taylor inquiry after the Hillsborough disaster, so that initial findings can be reported quickly.

**Empower local councils to enforce measures, say MPs**

The All-Party Parliamentary Group on Coronavirus said that the UK could “reduce the scars of covid-19” by recognising the unequal impact of the virus on communities. Among the recommendations in an interim report the group said that local authorities should be allowed to enforce forms of non-pharmaceutical interventions at a local level, such as lockdowns and school closures. They should also be empowered to deliver a find, test, trace, isolate, and support system, backed by proper financial support and assistance for people isolating, the report said.

**Social media platforms delete misinformation**

Facebook and its subsidiary Instagram said they would delete misinformation about covid-19 vaccines that has been debunked by public health experts. Claims that the vaccine contains a microchip or anything not in its listed ingredients are examples of falsehoods that will be removed, the company said, as are claims that vaccines are being tested on groups without their knowledge. Facebook’s previous policy only “downranked” false claims about covid vaccines, pushing them down the list of search results.

**Puberty blockers**

**Children under 16 should not be referred**

NHS England ordered a pause on referrals of children under 16 for puberty blockers, after the High Court ruled that under 16s were unlikely to fully understand the long term effects of the treatment and give informed consent. Implementation of the High Court ruling has been stayed until 22 December or until the determination of any appeal by the Tavistock and Portman NHS Foundation Trust, which runs the UK’s only gender identity development service.

**NHS and social care staff in Scotland get bonus**

A £500 bonus will be paid to all full time NHS staff and social care workers in Scotland in recognition of their “extraordinary service” during the pandemic. The payment was announced by Scotland’s first minister, Nicola Sturgeon (right), who said it was a “demonstration of what we collectively owe you, and a heartfelt ‘thank you’ for the sacrifices you have made.” More than 300 000 staff will benefit.

**International news**

**Iranian researcher’s execution is on hold**

Iran has put on hold the execution of a medical researcher who was sentenced to death three years ago on a charge of spying that he denies, although his fate is still uncertain, said Amnesty International.

Ahmadreza Djalali, a scholar in disaster medicine who has dual Iranian and Swedish nationality, was arrested in 2016 on a research trip to Iran. Djalali, who worked for the Karolinska Institute in Stockholm, has been held since 2016. He is supported by 153 Nobel laureates, who recently wrote to the Iranian supreme leader, Ali Khamenei, calling for his release.

**Primary care**

**Vertical integration saved some general practices**

The process of hospital trusts running primary care services has saved some GP surgeries from closure but should not be imposed, an evaluation concluded. A University of Birmingham and RAND Europe study examined the rationale for and the early impact of vertical integration at two sites in England and one in Wales. It said, “Vertical integration is a valuable option to consider when GP practices look likely to fail. But it is not an option that should be imposed from the top down.”
Public health
Coke “funded conferences to shift obesity blame”
The Coca-Cola Company worked with its sponsored researchers on topics to present at major international public health conferences in a bid to shift blame for rising obesity and diet related diseases away from its products and onto people’s physical activity and individual choice, a report claimed. Academics in Australia and the US worked with US Right to Know, which lobbies for transparency in the food industry, to obtain and analyse emails between Coke and public health figures about events run by the International Society for Physical Activity and Health.

Malaria
WHO: Africa’s malaria deaths may dwarf covid-19
Excess malaria deaths caused by prevention and treatment shortfalls during the pandemic will probably dwarf numbers of direct deaths from covid-19 in sub-Saharan Africa, the World Health Organization warned. The progress made against malaria in the first decade of this century has stalled since 2016 as donors drifted away. But 2020 is likely to be the first year in decades to see a rise in deaths, WHO warned in its 2020 World Malaria Report. Annual case numbers in sub-Saharan Africa have not changed since 2016 at about 230 million.

Radiotherapy
Cancer charity raises alarm at drop in activity
MacMillan Cancer Support expressed concern about data from Public Health England showing that 14% fewer people with cancer had radiotherapy in England from April to July 2020 than in the same period in 2019. Sara Bainbridge, head of policy and influence at Macmillan, said, “This data supports what we have been sounding the alarm about for months: covid-19 has caused significant disruption to cancer diagnoses and treatment. It is critical that cancer does not become the ‘forgotten C’ in this pandemic.”

Workforce
European doctors continue to join GMC register
The proportion of doctors joining the General Medical Council register in the year to 30 June who qualified in the European Economic Area increased by 7.5% from the previous year. In 2020, 2268 EEA doctors joined the register, up from 2108 in 2019. Despite this increase the number of EEA doctors joining the register has also changed in recent years, with greater numbers moving from central and eastern Europe and Baltic countries, GMC data showed.

RESEARCH
Since March 637379 people from across the UK have taken part in 73 public health research studies into the effects of, and treatment for, covid-19 [DHSC]

Analysis of emails showed Coca-Cola worked with public health figures to shift blame for obesity

SIXTY SECONDS ON . . . JVT

DON’T YOU MEAN DVT?
No, this has nothing to do with blood clots—though it has certainly sent some people’s blood pressure soaring. We’re talking about Jonathan Van-Tam, England’s deputy chief medical officer, who is a new entry in Grazia’s Chart of Lust, five places above Hollywood heart-throb Matthew McConaughey.

HE’S A FAST MOVER
You’re right, and JVT loves nothing more than a transport metaphor to explain the complexities of the pandemic. Referring to the imminence of a vaccine, he said, “Do I believe we are now on the glide path to landing this plane? Yes, I believe I do. Over.” And welcoming the approval of the Pfizer BioNTech vaccine he said, “The train has now slowed down safely. It has now stopped in the station. And the doors have opened—that was the authorisation by the Medicines and Healthcare Products Regulatory Agency. What we need now is for people to get on that train and travel safely to their destinations.”

DO HIS METAPHOR SKILLS END THERE?
Absolutely not. The Boston United fan also loves a football analogy. In November he compared the positive results from the Pfizer and Moderna trials to a penalty shootout. “This is like getting to the end of the play-off final, it’s gone to penalties, the first player goes up and scores a goal,” he told a No 10 press conference. “You haven’t won the cup yet, but what it does is it tells you that the goalkeeper can be beaten.”

ANY OTHER INTERESTING TRAITS?
Yes, JVT also saved Christmas. Asked at a briefing whether Santa would be at the front of the vaccine queue, he replied, “Absolutely, the Joint Committee on Vaccination and Immunisation made a special case for Father Christmas. He is going to be top of our list.”

NO ONE IS THAT SAINTLY, SURELY?
When JVT was appointed in 2017, Tom Jefferson from the Cochrane Collaboration raised questions about his conflicts of interests as a former employee of Roche, Aventis Pasteur MSD, and GSK. Jefferson also pointed out that as head of the Pandemic Influenza Office from 2004 to 2007 JVT bore responsibility for the UK’s stockpiling of Tamiflu, which was criticised by the Public Accounts Committee in 2013. JVT’s office pointed to his online profile.

Zosia Kmietowicz, The BMJ
Cite this as: BMJ 2020;371:m4757
Mass testing in Slovakia may have cut infections

Covid infections fell in Slovakia after rapid population-wide testing, but experts are not sure how much of the drop was a result of testing, as other restrictions were introduced simultaneously.

A preliminary analysis of three rapid antigen testing rounds reported that prevalence of detected covid infections decreased by 58% (95% confidence interval 57% to 58%) within a week in Slovakia’s 45 counties that were subject to two rounds of mass testing.

The authors, from the London School of Hygiene and Tropical Medicine, said this decrease could not be explained solely by the other restrictions and that it highlighted the effect of isolating people who tested positive and quarantining the members of their households.

However, while experts said the paper showed that mass testing “can contribute to a reduction in cases,” they said it was difficult to separate the effect of other restrictions, such as school closures and closing hospitality venues. They added that PCR testing was not used to confirm results, meaning the accuracy of the testing was not clear.

More than five million tests were completed in the programme, which started with a pilot from 23 to 25 October and was followed by a round of national testing on 31 October and 1 November. High prevalence counties were then targeted with a subsequent round a week later. The scheme involved swabbing by trained medical staff using the SD Biosensor Standard Q antigen test approved by WHO.

Elisabeth Mahase, The BMJ
Cite this as: BMJ 2020;371:m4761

Fears for safety as lateral flow tests miss half of cases

The lateral flow devices used in the community testing pilot in Liverpool picked up only half the covid-19 cases detected by PCR tests and missed three in 10 cases with higher viral loads, the government’s own policy paper said.

Given the low sensitivity of the Innova lateral flow devices when used in the field, experts are asking how they can be used to allow care home residents to have contact with relatives over Christmas safety or for students to know for certain that they are not infected before returning home.

The information can be found only by looking in annex B of Community Testing: A Guide for Local Delivery, published on 30 November. This is the first publicly available information about the field evaluation of the Innova tests in Liverpool, which has been criticised for its lack of transparency, accuracy of the tests used, and costs and potential harms.

“The results are hidden”

Jon Deeks, professor of biostatistics at the University of Birmingham and leader of Cochrane’s covid-19 test evaluation activities, told The BMJ, “The results are hidden as a single sentence in the annex of a document.

“This is not the way important scientific findings should be made public, particularly when the test is going to be introduced simultaneously.

Blanket DNR orders “led to potentially avoidable deaths” in care homes

Some care home residents were wrongly subjected to decisions ruling out attempts at cardiopulmonary resuscitation in the early stages of the pandemic, leading to potentially avoidable deaths, the Care Quality Commission has concluded.

Inappropriate or unlawful

Advance instructions not to attempt CPR should a patient’s heart or breathing stop should be discussed with patients, if they have the capacity to consent, or with their family, and made on an individual basis. But amid fears that hospitals would be overwhelmed with covid-19 patients, some care homes were given blanket DNACPR (“do not attempt cardiopulmonary resuscitation”) notices. An Amnesty International report in October, which called for a public inquiry, found inappropriate or unlawful use of DNACPRs by hospitals, care homes, and GPs.

In an interim report the CQC found that “providers sometimes conflated decisions about DNACPR with decisions about whether to admit people to hospital or provide covid-19 treatment.” There were examples where ambulances were not called straight away or there was a delay in calling doctors.

The Department for Health and Social Care for England commissioned the CQC to carry out the review.

“It is unacceptable for clinical decisions—which could dictate whether someone gets the right care when they need it most—to be applied in a blanket approach to any group of people,” said Rosie Benneyworth, chief inspector of primary medical services and integrated care at the CQC. “There is very real concern that decisions were made which not only overlooked the wishes of the people they affected but may have been made without their knowledge or consent.” Some people reported that they were unaware that a relative had a DNACPR decision until the relative was quite unwell.

The CQC will carry out a full review into the use of DNACPRs as part of advance care planning during the pandemic, reporting in February, to “inform national learning and improvement, and support good practice development.”

Clare Dyer, The BMJ
Cite this as: BMJ 2020;371:m4733
used off label with hundreds of thousands of people.”

The Department of Health and Social Care said that more than a million lateral flow tests had already been sent to 385 care homes and more would be sent over December to enable visiting by Christmas.

Susan Hopkins, senior medical adviser to Public Health England and NHS Test and Trace, told The BMJ, “No test will detect every single case, but these tests are proving to be accurate and reliable. In care homes they can help make planned visits safer by identifying visitors who are unknowingly carrying high levels of virus.”

However, public health and social care directors in some areas, including Greater Manchester and Sheffield, have written to care homes warning them not to use the rapid tests until there is more information from the government on the tests’ accuracy and training in how to use them.

**All tier 3 areas**

The government has invited all tier 3 areas to offer community testing of asymptomatic people after what it described as the “positive impact” of the Liverpool pilot scheme. The guidance says the Innova lateral flow tests offer 99.6% specificity and the “measured test sensitivity, in ideal hands” is 76.8% but was “likely to be lower under operational conditions.”

The document then adds, “In the field evaluation in Liverpool, compared with PCR tests, these tests picked up five out of 10 of the cases PCR detected and more than seven out of 10 cases with higher viral loads, who are likely to be the most infectious.”

Deeks said, “These results are devastating. They are missing a third of those with high viral loads. They are not fit for purpose.”

The Scottish National Party MP Neale Hanvey has submitted two written parliamentary questions calling for publication of the full data about the community testing pilot in Liverpool.

He told The BMJ, “My main concern is false reassurance. There is a clear risk that those with a false negative result will feel overly confident about mixing with vulnerable people over Christmas.”

Jacqui Wise, London

Cite this as: BMJ 2020;371:m4744

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**Abolishing CCGs must not dilute GPs’ influence, say leaders**

NHS England has proposed abolishing clinical commissioning groups by April 2022 and moving their functions to statutory integrated care systems.

A document outlining NHS England’s legislative recommendations proposes that integrated care systems become “a statutory corporate NHS body . . . that additionally brings CCG statutory functions into the ICS.”

Until now, NHS England has avoided recommending wholesale reorganisation to achieve its vision for integration. But it said the pandemic had “increased the appetite for statutory clarity for [integrated care systems] and the organisations within them.”

Abolishing CCGs is one of two options proposed.

The other is a less radical move to create a “statutory committee model . . . that binds together current statutory organisations.” But NHS England indicated that its preference was to make integrated care systems full statutory bodies, to provide “greater long term clarity in terms of system leadership and accountability” and “a clearer statutory vehicle for deepening integration across health and local government over time.”

Lou Patten, chief executive of NHS Clinical Commissioners, which represents CCGs, said, “While recognising that the majority of commissioning functions will continue at integrated care system level . . . the great work at neighbourhood and place, enhanced by the focus on the pandemic, must continue. We cannot throw the baby out with the bathwater.”

**Protect jobs**

England now has around 130 CCGs (originally 211 in April 2013) and 42 integrated care systems or sustainability and transformation partnerships

All trusts will be expected to group together with other local organisations and act in the interests of the population, to manage waiting lists and share staff, for example. Clinical networks will be expected to work across systems to try to reduce unwarranted variation, and, at a neighbourhood level, there will be a “leading role for clinical primary care leaders through primary care networks,” the document adds.

Richard Vautrey, chair of the BMA’s GP Committee, said the changes offered a chance to “undo some of the damage” caused by the 2012 NHS reorganisation but warned, “This must not be counterproductive, and we have serious concerns about the risk of vertical integration, which would lead to an end to the independent contractor model for general practice.”

Gareth Iacobucci, The BMJ

Cite this as: BMJ 2020;371:m4730

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ENGLAND now has around 130 CCGs (originally 211 in April 2013) and 42 integrated care systems or sustainability and transformation partnerships

**The great work at neighbourhood and place must continue**

Lou Patten
How was the first covid vaccine approved? How will it be rolled out, and who will get it?

As UK hospitals take possession of the Pfizer and BioNTech vaccine and begin a complex nationwide vaccination programme, The BMJ asked experts to answer some of the many questions raised.

**How was the MHRA able to approve the vaccine so quickly?**
The Medicines and Healthcare Products Regulatory Agency gave temporary authorisation to the supply of specific batches of Pfizer and BioNTech’s vaccine on 2 December, on the basis of efficacy data submitted between 1 October and 2 December. The regulator credits the rapid turnaround to its “rolling review” process, which allowed it to analyse the data as they were submitted. The MHRA has not published specific details about the approval process, but a spokesperson told The BMJ that scientists and clinicians had “carefully and scientifically reviewed the safety, quality, and effectiveness data—how [the vaccine] protects people from covid-19 and the level of protection it provides.”

The agency added, “The data included results from the lab and clinical trials in humans, manufacturing and quality controls, product sampling, and testing of the final product. This process is designed to make sure that any vaccine approved meets the expected high standards of safety, quality, and effectiveness.”

Phase III data from the Pfizer and BioNTech vaccine trial have not yet been published.

**Why was the vaccine given temporary authorisation?**
Usually, the UK would wait for the European Medicines Agency to approve a vaccine before looking to distribute and administer it, but in an emergency EU countries are allowed to use their own regulator to issue temporary authorisation.

In October the government made changes to the Human Medicines Regulations 2012 to allow the MHRA to grant temporary authorisation of a covid-19 vaccine without needing to wait for the EMA to approve it.

A temporary use authorisation is valid for one year only and requires the pharmaceutical companies to complete specific obligations, such as ongoing or new studies, says the law firm Brodies. Once comprehensive data on the product have been obtained, standard marketing authorisation can be granted. This initially lasts five years but can be renewed and is not subject to specific obligations.

**Have only certain batches of the vaccine been approved?**
Yes, but this is the standard procedure for all new vaccines, says David Salisbury, former director of immunisation at the Department of Health for England until the end of 2013 and now an associate fellow for the global health programme at the think tank Chatham House.

He explained, “Each batch of vaccine that gets released for use will have gone through both the manufacturer’s own testing and independent external testing from an agency such as the NIBSC [National Institute for Biological Standards and Control].

“And until NIBSC is satisfied, and the manufacturer is able to provide the evidence and the regulator is satisfied, all batches get tested.”

**What about other European countries?**
Most European Union countries are waiting for the EMA to grant approval. The EMA has said it will decide by 29 December whether to provisionally authorise the Pfizer and BioNTech vaccine. Unlike the UK’s temporary authorisation, the EMA is hoping to grant the vaccine “conditional marketing authorisation” for its use in any EU country.

The Swiss medical regulator Swissmedic has said it did not have all the data it needed to approve the vaccines, especially when it came to use in people with pre-existing illnesses. “We lack data on the effectiveness of the clinical trials and on the important subgroups that participated in these large studies,” said Claus Bolte, head of Swissmedic’s authorisation division, at a press briefing on 1 December.

**Does approval have anything to do with Brexit?**
Though some MPs have suggested that this approval process has been made possible only because the UK is leaving the European Union, Salisbury said that is not true. The MHRA acted in line with EU regulations, and any other EU country could have done the same, he said.

Stephen Evans, professor of pharmacoepidemiology at the London School of Hygiene and Tropical Medicine, has said that still being in the transition period may have helped speed up the approval because UK staff have not had to assess new vaccines or drugs intended for the whole EU for the past 18 months, allowing them to focus on the UK authorisation.

However, this will change from 1 January when the MHRA will become responsible for handling all applications for new drugs and vaccines to be authorised in the UK.
And the US?
Leaders in the US seemed to have criticised the UK’s process, with Food and Drug Administration commissioner Stephen Hahn and National Institute of Allergy and Infectious Diseases director Anthony Fauci suggesting that the US’s approval system was better.

Hahn, who was called to the White House to explain why the US would not be the first country to distribute a vaccine, said in a recent interview, “We’re not going to take a summary from a company and take their conclusions and base our decision on that... We’re going to crunch the numbers ourselves.”

Fauci said that the US had the “gold standard of a regulatory approach” and that “the UK did not do it as carefully” but later apologised, saying, “Our process is one that takes more time than it takes in the UK. I did not mean to imply any sloppiness even though it came out that way.”

Salisbury said he trusted the MHRA’s scrutiny. “I have full confidence that they will have undertaken due diligence. They will have scrutinised all of the information as thoroughly as was appropriate. And to my knowledge, neither Tony Fauci, for whom I have great respect and know, nor the FDA commissioner were members of the MHRA.”

The MHRA defended its processes. A spokesperson told The BMJ, “Covid-19 vaccines, including this one, are being developed in a coordinated way that allows some stages of this process to happen in parallel to condense the time needed, but it does not mean steps and the expected standards of safety, quality, and effectiveness have been bypassed.”

Who will get the vaccine first?
Although care home residents were initially deemed the highest priority for vaccination, the challenge of delivering the vaccine at −70°C and the fact it comes in batches of 975 doses have meant a change to plans. From 8 December care home staff and people aged over 80 will be called in to 50 “hospital hubs” around England for their first vaccination and recalled three weeks later for their second shot. Any appointments not used will go to healthcare staff at higher risk of serious illness from covid-19. Once more vaccine becomes available, more than 1000 local vaccination centres, operated by groups of GPs, will be set up across the country, and pharmacies will also be able to deliver shots after vaccine units can be split. The health services in Wales, Scotland, and Northern Ireland will run their own vaccination programmes.

Do people who have had covid-19, including those with long covid, need to be vaccinated?
Yes, says Salisbury. “We do not know the length of immunity of the natural infection and therefore having a vaccine will not do them harm and has the probability of doing benefit... I can’t think of reasons why you should not be vaccinated,” he said.

“We do know that people who’ve had covid can be reinfected. My judgment would be, if you’re offered the vaccine, to have it. But there are many questions to which as yet we don’t have evidence based answers.”

If I’m vaccinated do I still need to self-isolate?
Government sources told the Telegraph that “people who get vaccinated will have to stick to the same rules as everyone else because we don’t know if it stops people being carriers and passing the virus on to others.”

Who shouldn’t be vaccinated?
The vaccine has not been approved for use in pregnant women, and women of childbearing age should be advised to avoid pregnancy for at least two months after their second dose. The vaccine should also not be used during breastfeeding. People receiving “anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration,” the MHRA has said. The Joint Committee on Vaccination and Immunisation has also specified that only children (under 16) at “very high risk of exposure and serious outcomes, such as older children with severe neuro-disabilities that require residential care, should be offered vaccination.”

Do we know anything about interactions with other drugs?
No. In guidance to healthcare professionals the MHRA said that “no interaction studies have been performed.”

Cite this as: BMJ 2020;371:m4759

THE CHALLENGE

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This year The BMJ’s appeal is supporting the Independent Food Aid Network, a charity that helps independent food banks and other community meal providers. The covid pandemic has led to a sharp rise in demand for the services provided by independent food banks such as North Paddington Foodbank in London, pictured here.

To donate and help stop families going hungry this winter please see the coupon (left).

Tom Moberly, The BMJ

Cite this as: BMJ 2020;371:m8272
Vaccinating the UK against covid-19
Primary care can do it but needs extra support to do it fast, safely, and effectively

The global covid-19 pandemic has led to more than 50,000 deaths in the UK, disrupted health services, and led to massive increases in unemployment and government debt. Following the government’s failure to implement an effective test, trace, and isolate programme—so successfully deployed by countries such as South Korea and New Zealand—mass vaccination against covid-19 offers us the best way to finally bring the pandemic under control. It is essential that the covid-19 vaccination programme is implemented well and avoids the many mistakes made during other components of the government’s response to covid-19.

Primary care should be at the heart of the UK’s covid-19 vaccination strategy. General practices are embedded in communities, easy to access, and enjoy public trust. A decade of underinvestment, however, has led to serious shortages of primary care doctors, overstretched primary care teams, and a reduced ability to respond to new challenges.

The government should take immediate steps to reduce pressures on primary care by, for example, suspending appraisals, revalidation, and CQC inspections to relieve the administrative burden on practices and enable them to step up to this critical task.

Extra funding is required to pay for new vaccination centres, provide existing clinics with facilities such as equipment for transporting and storing vaccines, and to meet the costs of administering a complex vaccination regime to people living in care homes, or being cared for in their own homes.

Funding will also be needed for additional trained staff to administer vaccines and provide administrative support. Primary care services for the management of acute and long term problems, and preventive programmes such as children’s immunisations, must continue to operate normally. Additional capacity should be created to ensure the vaccination programme does not displace or delay other essential clinical work.

Logistics
Adenoviral vector vaccines such as the Oxford vaccine (ChAdOx1 nCoV-19) are logistically easier to use as they can be stored long term in standard vaccine fridges and administered by primary care teams working in their usual premises. By contrast, the mRNA vaccine developed by Pfizer-BioNTech must be stored at very low temperatures and used soon after defrosting. This vaccine will require large vaccination centres that can handle a higher throughput of patients.

As more data on safety and efficacy become available, the government should focus its attention on a small selection of vaccines, rather than the current scattergun approach to vaccine procurement. This would simplify the overall programme, cut costs, and help ensure that patients receive two doses of the same vaccine, both at the right time.

We do not yet know how long vaccine induced protection will last. Booster doses of vaccine may be required at regular intervals, and the NHS should plan accordingly. Good recall systems will be essential, preferably provided by general practices, which keep computerised medical records and have extensive experience in delivering large vaccination programmes safely.

Large, carefully designed postmarketing studies will be essential to track vaccine failures (infections following vaccination) and adverse events. The UK’s computerised primary medical care record systems and comprehensive national health coverage makes the UK well placed to generate these and other important data, particularly if linked to other routine datasets such as Hospital Episode Statistics and mortality records. Early problems afflicting the test, trace, and isolate programme, such as failure to notify infected patients’ general practitioners, can be avoided by recording covid-19 vaccinations in each patient’s primary care record rather than a centralised and disconnected IT infrastructure.

Care should be taken not to create unrealistic expectations of timescale while the NHS, and in particular primary care, prepares to administer the millions of vaccinations so critical to the health, wellbeing, and economic security of the UK. Errors and delays would be inexcusable when the stakes are this high.

The full cost of delivering a rapid, comprehensive, and successful vaccination programme should be provided promptly so lifesaving vaccinations can begin at scale, proceed rapidly through all at-risk populations in the UK and finally allow something resembling normal life to return.

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Alcohol and brain health

Harm prevention policies must take a lifecourse perspective

The maintenance of brain health is central to health and wellbeing across the lifespan. Evidence suggests three periods of dynamic brain changes that may be particularly sensitive to the neurotoxic effects of alcohol: gestation, later adolescence (15-19 years), and older adulthood (over 65 years). Highly prevalent patterns of alcohol use may cause harm during these sensitive periods, including low level prenatal alcohol exposure, adolescent binge drinking, and low- to moderate alcohol use in older adulthood. Although these patterns of alcohol exposure may be associated with less harm to individuals than sustained heavy drinking, the overall burden of harm in populations is likely to be large.

From cradle to grave

From fetal development to later life, the human brain goes through several periods of dynamic change. The prenatal period is characterised by extensive production, migration, and differentiation of neurons, accompanied by substantial apoptosis. Adolescence is characterised by synaptic pruning and increased axonal myelination. Older adulthood is associated with brain atrophy, which accelerates after the age of 65 years, largely driven by decreases in neuron size and reductions in the number of dendritic spines and synapses. Each of these changes in neurocircuitry could increase sensitivity to the effects of environmental exposures such as alcohol.

Globally, around 10% of pregnant women consume alcohol. Heavy alcohol use during pregnancy can cause fetal alcohol spectrum disorder, associated with widespread reductions in brain volume and cognitive impairment. But recent evidence indicates that even low or moderate alcohol consumption during pregnancy is significantly associated with poorer psychological and behavioural outcomes in offspring.

More than 20% of 15-19 year olds in European and other high income countries report at least occasional binge drinking (defined as 60 g of ethanol in a single drinking occasion). Longitudinal studies indicate that the transition to binge drinking in adolescence is associated with reduced neocortical volume and functional connectivity, attenuated white matter development, and small to moderate deficits in a wide range of cognitive functions. In older people, alcohol use disorders were recently shown to be one of the strongest modifiable risk factors for all types of dementia (particularly early onset) compared with other established risk factors such as hypertension and smoking.

Although alcohol use disorders are relatively rare in older adults, many older people frequently consume low to moderate amounts of alcohol. Recently, even moderate drinking was shown to be associated with small but significant loss of brain volume in midlife. It is currently unclear whether these structural changes translate into functional cognitive impairment.

The evidence for the adverse effects of alcohol on brain health is compelling, but it is limited by the observational nature of the analyses. These findings require further replication, with a focus on more rigorous causal modelling.

Demographic trends

Demographic trends may compound the effect of alcohol use on brain health. Women are now just as likely as men to drink alcohol and experience alcohol related harms. In higher income countries, consumption has increased among older people while in low and middle income countries, consumption and related harms have increased across the population.

Global consumption is forecast to rise further in the next decade. The effects of the covid-19 pandemic on alcohol use and related harms are unclear, but alcohol use increased in the long term after other major public health crises.

A lifecourse perspective on brain health supports the formulation of policy and public health interventions to reduce alcohol use and misuse at all ages. An integrated approach to harm reduction across the lifespan is required in public health, mental health, primary care, social care, and voluntary sectors.

Population based interventions such as guidelines on low risk drinking, alcohol pricing policies, and lower drink driving limits need to be accompanied by the development of training and care pathways that consider the human brain at risk throughout life. The effect of harm reduction strategies on maintaining brain health in both individuals and populations can then be more fully evaluated.

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В полной мере нейтральная защитная маска — решение, которое может быть недоступно для многих.

Сегодня группа докторов, инженеров, а также специалистов по медицинской технической подготовке показала, что подход, основанный на стандартизации, не обеспечивает должной защиты для врачей, у которых есть разные размеры головы, лица и тела — особенно женщин и представителей различных этнических групп. Кроме того, группа работает над решением этой проблемы, разработав индивидуальные рецептуры для медицинского оборудования.

Недавние исследования показывают, что один из четырех врачей считает, что их персонально-защитное оборудование является опасным. Эти выводы, которые были получены в результате исследования, проведенного в Кембриджском университете и Кембриджском университете больничных учреждений (CUH), и проведенных под руководством Центра инженерии по улучшению здравоохранения в Кембридже (Cambridge based Centre for Engineering Better Care), приводят к системе безопасного защитного оборудования, которая планируется запустить к началу 2021 года.

Архивы социальных сетей и другие чаты були наполнены предложениями по разработке аналогичных решений — учитывая, что в начале пандемии докторам приходилось использовать защитные маски, которые не были подходящими для их конкретных тел. 

В рамках этой работы, доктор Ambika Chadha, специалист по максиллофациальной хирургии, получила первое рукоятворное определение ограничений защитных масок в качестве старшего врача в Addenbrooke’s Hospital в начале пандемии. “Я столкнулась с проблемой, когда попыталась использовать маски, которые предназначены для использования в промышленных условиях. Они не подходили нормально и менял голоса. Я не могла одновременно носить маску и визор, так что хирургия стала значительно более утомительной, — сказала она.

Через некоторое время стало ясно, что доктор Chadha не была единственной, и что метод тестирования на соответствие для FFP3 респираторов, внедренный на всех сотрудников медицинского персонала в мае, не был эффективным. “Несмотря на то, что метод тестирования на соответствие для FFP3 респираторов был вводимым, это не означало, что нужно искать иные способы обеспечения безопасности для врачей, работающих в высоконагруженных клинических условиях,” — сказал Kanwalraj Moar, ведущий специалист по хирургии женщин и детей в Addenbrooke’s Hospital.

Предупреждения со стороны BMA о недостаточной эффективности масок, предлагаемых на ассортименте, также были распространены в последних сообщениях. “Медицинское оборудование является опасным для женщин, — говорит Helen Fidler, заместитель председателя Комитета по вопросам врачей Великобритании, — и по мнению таких докторов, около 40% из них не прошли тест на соответствие для защитных масок. В одном из этих случаев женщина даже попросила прощения за свою маленькую и непривлекательную внешность,” — сказала она.

Несмотря на то, что специалисты по хирургии, в том числе женщины и представители различных этнических групп, испытывают трудности с носимыми медицинскими масками, был проведен ряд исследований, показывающих, что у многих врачей есть проблемы с носимыми масками, включая звуковые помехи и ухудшение обзора. Эти исследования также показали, что у некоторых врачей есть проблемы с дыханием в масках, что может приводить к усталости и ухудшению качества работы.

Возможность носить защитную маску в течение всего дня является важным фактором, который влияет на эффективность работы врача. Кроме того, неправильная установка маски может привести к возникновению проблем со здоровьем, включая проблемы с артериальным давлением и инсулином.

Таким образом, эта работа показывает, что введение индивидуальных рецептур для медицинского оборудования может быть важным шагом в улучшении условий работы врачей и улучшении результатов лечения пациентов.
The proposed solution is to hand responsibility for fitting masks to occupational health departments.

At the same time, the work with CUH staff will identify the need for bespoke masks for particular people and particular activities, alongside a programme of work that will map the process of individualised mask delivery.

**Sustainable equipment**

Sustainability is another key aspect of the project. The team is in negotiations with Invisi Smart Technologies, a British biotechnology company that has developed a light activated virucidal coating with proved activity against covid-19. “It means the mask, and PPE generally, can be decontaminated by placing them in a light box for a period of time, eventually perhaps ending the need for disposable PPE,” says Clarkson.

The collaboration is currently in talks to access external funding for the research study while the funding for product and process development is likely to be taken on by the biotechnology partner—with the aim of delivering safer mask design and production as speedily as possible.

The problem is that with hospitals under renewed pressure from covid-19 admissions, the bespoke mask design process is likely to take up to two years to reach a global market, says Clarkson. “Of course, we want to get this system up and running as soon as possible. But it’s got to work for everyone and is too important for shortcuts,” says Chadha.

For those with low risk jobs or a conventional facial shape, PPE can be off the shelf. Others will require customised masks, identified for a single person’s use.

From early 2021, the team will “explore the process of matching people to existing masks with CUH staff,” explains Clarkson. “The insights gained will inform current mask manufacturers of the range of sizes that could better fit the user population, leading to rapid improvements in the range of off the shelf masks,” he says.
Little is known about the interests of the doctors, scientists, and academics on whom ministers have relied during the pandemic. Attempts to discover more are frequently thwarted, finds Paul D Thacker.

As the number of UK deaths caused by covid-19 reached 50 000 in early November, England went into a second national lockdown to control the epidemic. Boris Johnson’s government resorted to these measures after months of controversial and sometimes confusing policies, including the “rule of six,” regional tiered controls, and directions to “stay alert.” At the same time, the government has faced mounting questions about procurement decisions, from personal protective equipment to testing kits, from vaccine deals to the services of logistics companies.

Calls for greater transparency around such decisions have included those bodies focused on science and health, such as the Scientific Advisory Group for Emergencies (SAGE), as well as the vaccine and testing taskforces. Although No 10 has become more transparent in those bodies focused on science and health, such as the Scientific Advisory Group for Emergencies (SAGE), as well as the vaccine and testing taskforces. Although No 10 has become more transparent in disclosing advice it has received from SAGE it has, however, kept members’ financial conflicts of interest unpublished and shows little concern that advisers to the coronavirus Vaccine Taskforce have financial interests in pharmaceutical companies receiving government contracts. When The BMJ sought further information on these bodies, such as lists of members’ interests, the information was denied or requests were unanswered.

Information withheld

After months of criticism about SAGE secrecy, the government reversed course this summer and began releasing the names of SAGE members, minutes of meetings, and some of its policy papers. Still, the government has refused to release to The BMJ the financial interest forms signed by SAGE members, leaving the public in the dark.

Criticism over SAGE’s secrecy first appeared in a Nature editorial in March. In April, the government’s chief scientific adviser Patrick Vallance sent a letter to parliament stating that SAGE’s membership, recommendations, supporting documents, and meeting minutes would be published, but only after the group ceased meeting about covid-19. Vallance argued that secrecy protected SAGE members and shielded them “from lobbying and other forms of unwanted influence which may hinder their ability to give impartial advice.”

Rob Weissman, president of Public Citizen, an American non-profit organisation focusing on government transparency, was troubled by this statement because, he says, corporate interests are always granted access to government decision makers: “It’s never a secret from the companies. The secrecy is selective. Secrecy becomes the way to selectively make information available to the powerful, and connected corporations, while the public is kept in the dark.”

Within days of Vallance’s statement, the Guardian published the names of SAGE members, which included two political advisers to Downing Street, one of whom was the prime minister’s now former chief political adviser, Dominic Cummings.

As pressure increased for greater openness, the government finally relented in late May with a pledge for SAGE transparency, publishing dozens of documents, including minutes from the group’s first meeting on covid-19 in late January. Reversing his previous statement to parliament, Vallance said, “Openness and transparency around this disease is a social imperative, which is why it’s important we don’t wait to publish minutes and evidence.”

Vallance’s decision puts SAGE more in line with recommendations made by the Commons Science and Technology Select Committee in 2011 that SAGE membership should not be kept secret. He has, however, ignored the same committee’s call to publish SAGE members’ declarations of financial interest.
Independence and balance questioned

Meanwhile, the matter of SAGE’s independence persists. “It’s not independent,” says Martin McKee, professor of European public health at the London School of Hygiene and Tropical Medicine. “It cannot set its own agenda. They can only answer questions the government sends them. They should have more freedom to reshape the questions.” The term “independent” does not appear anywhere in the 64 pages of current guidance that governs SAGE.

Many experts contacted by The BMJ also argued that SAGE appears unbalanced, favouring certain types of scientific proficiency over others. Some claim that SAGE has relied too much on disease modellers who have been given priority over behavioural researchers. Others point out that public health experts, who best understand how to control communicable diseases, should have been given more seats at the table. Meanwhile, it remains difficult to confirm if the government is following SAGE’s advice.

“They’re not ignoring SAGE,” says Linda Bauld, professor of public health at the University of Edinburgh, who is not a member of the committee, “They’re selectively taking their advice.” Bauld says that after the government sends questions to SAGE and gets the group’s feedback, the government then works in other considerations, such as economics, public opinion, and politics. Unlike the advice from SAGE, these other inputs that inform policy are never made public, making it impossible to know if the government has ignored scientific expertise. She adds that SAGE is now more transparent than the Scottish government advisory group, which publishes minutes of their meetings, but which she says contain little information and are not useful.

Like other specialists, The BMJ contacted, Bauld also wondered if SAGE requires members to report their financial conflicts of interest. “I’ve not seen that information published anywhere,” she says. The BMJ then contacted the Government Office for Science (GOS) to ask whether SAGE members were required to fill out financial disclosure forms. We also requested copies of any such forms for current members. A spokesperson for GOS confirmed that SAGE members must declare their financial conflicts of interest and provided us with an empty template copy of the SAGE disclosure form.

The BMJ is making this form available to the public (see bmj.com). GOS declined to provide SAGE members’ signed disclosures, adding that they are looking at options to make these declarations public while complying with relevant data protection legislation. The BMJ is now seeking the financial disclosure forms of SAGE and Vaccine Taskforce members through freedom of information requests.

“Citizens need to be able to trust the advice of professional scientific advisers. We need transparency,” says Margaret McCartney, a Scottish general practitioner and former BMJ columnist who has campaigned for financial transparency. “Public trust is paramount and I know there are a huge number of scientists and doctors working extremely hard just now. I don’t want those efforts wasted because there hasn’t been enough openness.”

Interests exposed

In many cases, the government’s lack of financial transparency in combating covid-19 has resulted in negative headlines. In April, the government announced that it was placing Vallance in charge of a new Vaccine Taskforce to expedite research to produce a coronavirus vaccine. Among the named members were AstraZeneca, the Wellcome Trust, and John Bell of Oxford University. The following month, Kate Bingham was named as chair of the taskforce, while taking temporary leave from her post of managing partner at SV Health Investors, a life sciences venture capital firm. Bingham is married to the Conservative minister Jesse Norman.

SAGE is not independent. It should have more freedom

Martin McKee

Ministers are selectively taking SAGE’s advice

Linda Bauld
Covid cronyism: transparency is “even more important” in a crisis

In these exceptional times when, for example, contracts are being awarded outside usual procurement rules, it is essential that government decisions are properly documented and made transparent to maintain public trust. So said the National Audit Office (NAO) earlier this month in its report into government procurement during the covid-19 crisis.

It highlighted “a lack of transparency and adequate documentation” on some key decisions, including how the government identified and managed conflicts of interest. The report said it was “even more important to have a clear approach to managing conflicts of interest when contracts are awarded directly to suppliers without any competition.”

Because so many covid-19 contracts have been awarded to companies with ties to the Conservative party, the government has faced charges of cronyism.

“You want these things to work,” says Peter Geoghegan, a journalist who has been covering the UK’s failed covid-19 contracts for openDemocracy, where he is investigations editor, “it’s taken a long time for the penny to drop about how this isn’t working.”

Digging up untendered covid-19 contracts involved diligent spade work. Contracts can be published on different websites, which are not easily searchable. Furthermore, the government has been ignoring requirements to publish contracts within 30 days, meaning that it took many months after the pandemic started before the untendered contracts became public.

In awarding contracts, a cross government process called the “high priority lane” assessed commercial leads brought in by officials, ministers, MPs, and lords through a special mailbox and were treated as more credible than leads going in by officials, ministers, MPs, and lords through a special mailbox and were treated as more credible than leads going through ordinary channels, the NAO reported.

Critics of UK contracting tell The BMJ it is impossible to trace the influence of lobbyists in the decisions to award contracts because little lobbying information is published or even collected in the first place. “Considering the gravity of decisions under ministers’ consideration, there should be much greater transparency over who’s trying to influence them, how, and over what decisions, than is currently the case,” says Alex Runswick, senior advocacy manager at Transparency. “We know more about lobbying activity in rural Ireland than we do in Whitehall.”

Passed in 2014, Britain’s lobbying law requires only rudimentary information to be reported, most importantly, the name of the lobbyist, their company and address, and the names of clients. In the US, lobbyists must disclose much more information and forms are disclosed quarterly. For each client, lobby companies must disclose the names of their lobbyists; list the matters or specific bills that were lobbied on; who was lobbied, such as specific congressional committees, government agencies, or White House offices; and how much was spent lobbying, meaning lobbyist salaries and expenses.

“It tells you more than nothing, but not much more,” says Rob Weissman, president of Public Citizen, an American non-profit focusing on government transparency, of the UK lobby disclosure forms. He says that the US system requires such extensive information because any one company has broad interests before the government. Pharma companies are considered the most powerful lobby in Washington and they lobby on everything from drug safety to labour laws to healthcare policy, tax matters, contracting law, defence spending, and government subsidies. In contrast, in the UK, “you’ve got no way to assess what they’re actually up to,” Weissman says.

By July the government had signed a coronavirus vaccine deal for an undisclosed sum with GlaxoSmithKline, securing 60 million doses of an untested treatment that was still being developed. In September, media outlets reported that Vallance had £600 000 worth of shares in the company. The government responded to say that, while he heads the government’s Vaccine Taskforce, Vallance “has no input into contractual and commercial decisions on vaccine procurement, which are taken by ministers following a robust cross government approvals regime.”

Days later, the Daily Mail broke another story, this time focusing on Bell. On top of his role with the Vaccine Taskforce, Bell also headed the National Covid Testing Scientific Advisory Panel and chaired the government’s new test approvals group. But the Mail discovered something The BMJ first reported back in 2012—that Bell had substantial financial interests, now amounting to £773 000 worth of shares in pharma company Roche, which had sold the government £13.5m of antibody tests in May.

Following the deal, Bell appeared on Channel 4 News and Radio 4’s Today, calling the tests a major step forward. Yet Public Health England found the tests unreliable.

Bell told the Mail that he had no role in the deal and that he had disclosed to the government “a long list of my interests.”

The BMJ asked the Department for Business, Energy, and Industrial Strategy (BEIS), which announced the Vaccine Taskforce, to confirm that Bell had reported his “long list” of financial interests. We also asked to see any forms Bell had filled out as evidence. Contradicting their own press release which listed Bell as a taskforce member, a BEIS spokesperson told The BMJ, “Sir John Bell is a member of the expert advisory group to the Vaccine Taskforce, rather than a member of the taskforce itself.”

The spokesperson added that the expert advisory group is not involved in commercial decision making, and that those involved must declare their conflicts of interest. The spokesperson did not respond to The BMJ’s request for copies of Bell’s declarations.

The BMJ also approached Oxford University, Bell’s employer, to ask for documents that confirm he had disclosed his “long list” of financial interests. Stephen Rouse, Oxford University’s head of communications, responded, “Professor Sir John Bell has always declared his financial interests and board membership at Roche, in accordance with the university’s conflict of interest policy for all staff.”

Oxford did not respond to The BMJ’s repeated request to see evidence of this disclosure.

The BMJ is now seeking the financial disclosure form of John Bell through a freedom of information request to Oxford.

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