this week

DRUGGLES page 297 • **CONTACT TRACING APP** page 298 • **BLOOD CLOTS** page 300

Severe covid patients to get remdesivir

Selected NHS patients in hospital with covid-19 will be given the antiviral drug remdesivir after early trial data showed that it shortened the time to recovery by about four days, the UK government has said.

Remdesivir, which is manufactured by Gilead and given intravenously, has previously been tested against Ebola virus and two coronaviruses: Middle East respiratory syndrome and severe acute respiratory syndrome. It is not licensed or approved anywhere in the world.

Last month the US National Institutes of Health (NIH) reported interim findings from a randomised controlled trial that began in February involving 1063 patients from several countries, including the US, the UK, and Singapore. Although no findings have yet been published, the NIH said that remdesivir reduced the median time to recovery from 15 to 11 days when compared with placebo, and it cut mortality to 8% among patients taking remdesivir, versus 11.6% in the placebo group.

Remdesivir has been made available in the UK through the Early Access to Medicines Scheme (EAMS) after a positive scientific opinion from the Medicines and Healthcare Products Regulatory Agency. Similar arrangements have already been made in other countries, including an emergency authorisation from the US Food and Drug Administration and by regulatory authorities in Japan.

Because of limited supplies any treatment in the UK will be prioritised for patients who have the greatest likelihood of deriving the most benefit, and allocation will be guided by expert advice, said the government.

Stephen Griffin, associate professor at Leeds School of Medicine, said that remdesivir was the most promising antiviral in current trials among covid-19 patients.

"Rolling out remdesivir via the EAMS will likely mean that the most severe covid-19 patients will receive it first," he said. "While this is clearly the most ethically sound approach, it also means we ought not to expect the drug to immediately act as a magic bullet. We can instead hope for improved recovery rates and a reduction in patient mortality."

Treating less severely affected patients with remdesivir would become possible only with the publication of trials, said Griffin, although the drug would not be useful for preventing symptoms because of its intravenous route of administration.

Zosia Kmietowicz, *The BMJ*

Cite this as: *BMJ* 2020;369:m2097

International trials found the unlicensed drug reduced recovery time and cut mortality rates

LATEST ONLINE

- UK government's defence of senior aide has damaged public and NHS confidence
- Covid-19: Japan ends state of emergency but warns of a "new normal"
- Roll out of 10 million antibody tests to begin next week, government announces

SEVEN DAYS IN

Intensive care consultant has suspension cut short to help fight pandemic

A consultant in intensive care medicine and anaesthesia has had his 12 month suspension from the medical register cut to eight months after his NHS trust wrote to the GMC without his knowledge, saying he was needed to work during the pandemic.

In March the GMC issued guidance for medical practitioners' tribunals on requests to relax or revoke sanctions in response to covid-19. The guidance advises that the risk of harm to the public should be weighed against the risk of harm presented by the virus and the doctor's ability to alleviate it. It was to this principle that John Bleasdale (left), a consultant at Sandwell and West Birmingham Hospitals NHS Trust, appealed.

Bleasdale was suspended last September for misconduct after being on call for NHS and private hospitals concurrently on 33 occasions, but there had been no complaint about his clinical work or competence. In March the trust's clinical lead for critical care wrote to the GMC, arguing that "I need every consultant I can get, let alone clinically excellent colleagues like John Bleasdale." At a tribunal hearing to consider revoking the sanction, the GMC counsel said the regulator was "neutral" but invited the tribunal to consider whether public interest might now be better served by Bleasdale's return.

Clare Dyer, *The BMJ* Cite this as: *BMJ* 2020;369:m2040

Covid-19

Anaesthetists lack faith in return of regular services

More than a third (34%) of anaesthetists had low confidence in their hospitals' preparedness for restoring non-covid NHS services, showed a poll by the Royal College of Anaesthetists. The survey also highlighted ongoing concern over sustainable access to personal protective equipment, anaesthetic drugs, and testing. The college surveyed its members over a 24 hour period on 13-14 May. It received around 1500 responses, which it said highlighted the need for a "measured approach" to restoring non-covid NHS services in a safe and sustainable way.

Doctors take Hancock to court over PPE

Two NHS doctors will go ahead with a High Court legal challenge against Matt Hancock, health and social care secretary for England, over inadequate supplies of PPE to frontline staff during the covid-19 pandemic. Meenal Viz and Nishant Joshi are seeking a judicial review over government guidance reducing the requirement to wear PPE and allowing for its reuse in some cases. The pair argue that this goes against guidance from the World Health Organization and breaches the human rights of health and social care workers, many of whom have died in the pandemic.

Data privacy

Labour calls for probe of "alarming" breach

The Labour Party demanded an investigation, after a mistake by the outsourcing company Serco led to the email addresses of almost 300 contract tracers being shared. Serco is training staff to trace cases of covid-19 on behalf of the government. Rachel Reeves (below), Labour's shadow chancellor of the Duchy of Lancaster, sent a letter to her opposite number, Michael Gove, urging the government to publish details of the contracts handed to Serco, the basis for the company being chosen to run vital elements of the government's covid-19 response, and the effects of the data breach.

Pandemic response

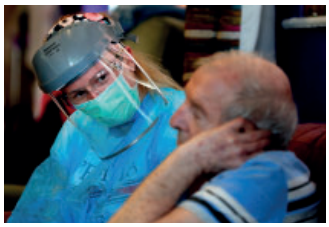
Cycle of lockdown and relaxation may be effective

An alternating cycle of 50 days of lockdown followed by 30 days of easing could be effective in reducing deaths and intensive care admissions from covid-19, an international modelling study showed. But this would need to be accompanied by efficient testing, case isolation, contact tracing, and shielding of vulnerable people, said researchers from the Global Dynamic Interventions Strategies for Covid-19 Collaborative Group. The study, published in the *European Journal of Epidemiology*, assessed the likely impact of alternating between stricter measures, such as lockdown, and intervals of more relaxed social distancing.

Care homes

Over a third in England have had covid outbreak

More than a third (36%) of England's care homes have now had cases of covid-19, the Care Quality Commission reported. A report from the regulator said that the regions worst affected were the north east, where 47% of all care homes had had an outbreak, followed by London (42%) and the north west (41%). The report came as the UK government continued to face criticism over its handling of the



outbreak in care homes, where almost 12 000 people had died from the virus since the pandemic began (as of 19 May, Office for National Statistics data show).

Welsh government may be investigated over rights

The older people's commissioner for Wales, Heléna Herklots, reported the Welsh government to the Equality and Human Rights Commission over fears that older people's rights may have been breached by delays to testing in care homes. Reacting to the news, Plaid Cymru's shadow local government minister, Delyth Jewell, said that lives could have been saved if a universal testing policy had been in place in care homes "from the start," and she called on the Welsh government to apologise to the families of people who had suffered.

MEDICINE

Smoking

"Overdue" ban of menthol cigarettes is welcomed

The charity Action on Smoking and Health (ASH) welcomed the "long overdue" ban on "child friendly" menthol cigarettes in England, which came into force on 20 May. All other characterising flavours in cigarettes were banned in May 2017, but the date for banning menthol was delayed by three years after lobbying from the tobacco industry. Despite a long term decline in smoking among children in England, ASH noted that an estimated 280 children aged under 16 started smoking each day, highlighting why the menthol ban was needed.

Menthol cigarettes are now banned, three years after other flavours

Immigration

NHS fee is scrapped for overseas health workers

Doctors welcomed the decision to scrap the immigration health surcharge for healthcare workers. The charge requires people from outside the EU to pay £400 per person each year to use the NHS. After pressure from medical groups and the Labour Party the government said on 21 May it would remove the charge for NHS and social care workers "as soon as possible." Chaand Nagpaul, BMA council chair, described the move as a moral victory that would bring relief to people facing bills of thousands of pounds.

Vaginal mesh

Scotland sets aside £1m for harmed women

Women in Scotland whose health has suffered as a result of transvaginal mesh implants are eligible to receive payments of £1000. The Scottish government set up a £1m fund to help women with costs associated with emotional or practical support arising from complications of mesh surgery. The payments are not seen as compensation "for any perceived wrongdoing by the NHS." Mesh surgery was suspended in Scotland in 2014 and halted completely in 2018.

Clinical research

Patient recruitment centres are launched

Five new regional patient recruitment centres were launched in England, aiming to provide easier access to clinical research opportunities for NHS patients and increase the number of studies in England. The centres, funded by £7m of government investment, will be managed by the National Institute for Health Research and run by five NHS trusts in Blackpool, Bradford, Exeter, Newcastle upon Tyne, and Leicester.

Talc

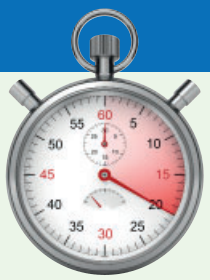
Baby Powder is withdrawn in North America

Johnson & Johnson will stop selling its talcum based Baby Powder in Canada and the US and instead offer a corn starch alternative. The original product will still be sold elsewhere. J&J said the decision was prompted by shifts in demand brought on by the pandemic, which had led it to discontinue more than 100 products. The company has been sued by more than 16 000 North American plaintiffs over mesothelioma or ovarian cancer allegedly caused by Baby Powder, which critics say contains asbestos. The company continues to argue that the product is safe.

Cite this as: *BMJ* 2020;369:m2074

THIRD SECTOR

The government awarded more than £22m in cash grants to health charities to help them continue regular activities while meeting increased demand from covid-19. Major beneficiaries include St John Ambulance (£6.8m), Air Ambulances UK (£6m), and mental health charities (£4.2m)



SIXTY SECONDS ON . . .
THE DRUGGLE

THAT'S A FUNNY WORD!

That's the point. Druggle is the name of Watford General Hospital's prescribing or drugs huddle. Started by Ashley Reece, a consultant paediatrician and director of medical education, the druggle is where everyone comes together to discuss common prescribing errors and what to look out for, and to celebrate difficult tasks done well.

HUDDLE UP

Reece, who is also the officer for assessment at the Royal College of Paediatrics and Child Health, said the idea came from a patient safety initiative piloted by the college. He said, "The huddle is a well described short intervention. I had a lightbulb moment when I thought if we're talking about safety meetings why don't we think about a medicines safety meeting, a medication safety huddle, a drugs huddle, and that's where this slightly silly name came from."

WAS DRUGGLE A STRUGGLE TO EMBED?

While the concept of a meeting to discuss these matters isn't new, Reece said they can be difficult to embed, and that's where the name became important. "Embedding something that people take on and actually works is tricky. But the catchy name seems to have resonated. Within a few months, people started saying, 'Okay, now it's time for the druggle,' and it didn't have to be led by me. The local spread has been good, and we've been able to keep it up," he said.

HOW DOES IT WORK?

In Watford, pharmacists lead the druggle. Each week they create a list of prescribing learning points from the paediatric ward and present it at the end of rounds. There are three or four main points and added "gems" (things that were done well) and "pearls" (things that really need to be remembered), such as Care Quality Commission issues. The points are then emailed, to be inserted into e-portfolios as evidence of learning.

HAS IT UNCOVERED ANY DIAMONDS?

"The pharmacists report that prescribing on the whole is better: they see far less inaccurate prescriptions for tricky drug regimes," Reece said. The initiative is now in use in other hospitals and countries.

Elisabeth Mahase, *The BMJ*

Cite this as: *BMJ* 2020;369:m2075

Tracing app deadline to be missed across UK

Matt Hancock pledged the app would be widely available by mid-May but now says it won't be ready by 1 June

The future of the UK's much vaunted covid-19 contact tracing app seems uncertain after James Brokenshire, the security minister, said on 21 May that he was "unable to give [a] definitive timeline" on when the app might launch.

England's health and social care secretary, Matt Hancock, had previously said that the app, which started trials on the Isle of Wight in early May, would be widely available by mid-May, but the launch has been repeatedly pushed back. At the daily Downing Street briefing on 21 May Hancock acknowledged that a tracing app would not be ready by 1 June, when England is due to enter the next phase of lockdown easing.

John Newton, Public Health England's director of health improvement, told the briefing, "The test and trace programme has more than one component . . . which are completely independent of the proximity app. They are distinct but complementary. And it's perfectly okay, in fact possibly advantageous, to introduce the one before the other."

Contact tracing has been used for decades to control the spread of infectious diseases, but the UK government abandoned it for covid-19 on 12 March when testing capacity was refocused from the community to hospitals.

In mid-April, however, a team from Oxford University showed that a single day's delay in contact tracing could mean the difference between getting the virus under control and a resurgence and suggested that a mobile phone contact tracing app could speed up contact tracing and ease the lockdown.

Pilot faltering

But doubts about the UK's app have grown as it seems to have faltered during testing on the Isle of Wight. In April the University of Oxford's Big Data Institute predicted that 80% of current smartphone users would need to use an app to have an effect on the pandemic. By early May, however, Matthew Gould, chief executive of NHSX, the unit charged with the digital transformation of care, said that 60% of the population needed to adopt the app to "substantially reduce" the virus spreading, adding that just 20% uptake would still give "important insights into how the virus is spreading."

So far, the NHSX app has been downloaded around 60 000 times, government figures show, although the app can be downloaded outside the test zone, so the true number of people using it on the Isle of Wight, whose total population is around 140 000, is uncertain.

The app's safety and efficiency have been called into question after experts found that personal and health information could be available to cyber-criminals.

There are also doubts over the usefulness of any app. Iceland's Rakning C-19 app has been downloaded by 38% of Iceland's population of 364 000, but Gestur Pálmason, a detective inspector with the Icelandic Police Service who is overseeing contact tracing efforts, described the technology as "more or

ICELAND'S Rakning C-19 app, which has been downloaded by 38% of the 364 000 population, has been described by an official as "not a game changer"

"Risk to children would halve" if schools reopen 14 days later than plan

It is not safe to open schools on 1 June, an independent committee of experts has warned, saying that before this happens local authorities must have evidence of low infection rates in the community and be able to track and trace new cases of covid-19.

The draft consultation report of the Independent Scientific Advisory Group for Emergencies (iSAGE)—set up because of perceived need for transparency in the scientific advice offered to government—said a delay of two weeks would halve the risk to children, while waiting until September was less risky still.

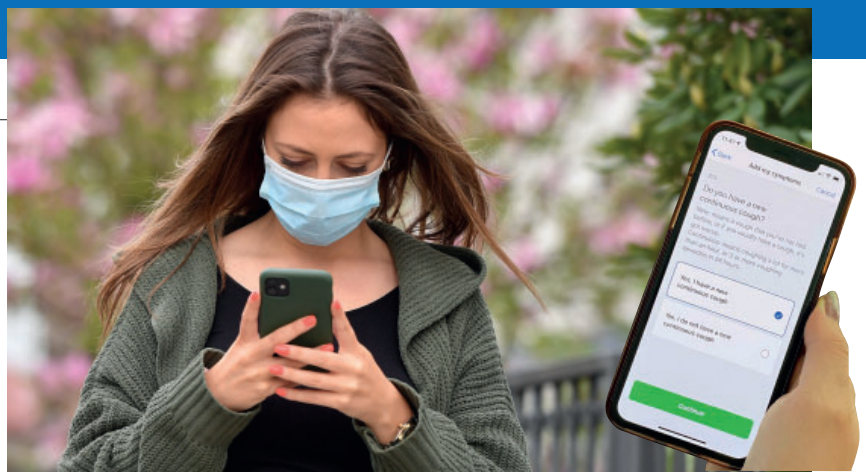
The government's announcement on 10 May that reception and years 1 and 6 classes in England would resume on 1 June was met with opposition from teachers' unions and others, including the BMA.

Teaching unions fear a return to school after half term will put their members and children at risk

The draft report was discussed at a public session on 22 May supported by *The BMJ* and the online forum Mumsnet, with teachers and parents contributing to the discussion. A final report will be sent to the government next week.

David King, the committee's chair, told the meeting that decisions to open schools should be "made at a local level, involving all local stakeholders, and be based on evidence of low local covid-19 infection rates."

Teachers' unions were not reassured that the published documents presented to SAGE, the official group advising the government, showed it was safe for schools to reopen on 1 June. They said the government needed to show it had met its five tests for relaxing social distancing, such as having testing and tracing capacity in place.



less . . . I wouldn't say useless, but it's the integration of the two [tracing and testing] that gives you results. I would say it has proved useful in a few cases, but it wasn't a game changer."

Eva Blum-Dumontet, senior researcher in charge of healthcare issues at the charity Privacy International, told *The BMJ* that the very idea of the app was tackling the problem "the wrong way around."

"If we had a system where any person who may be at risk could have access to a test easily, then we can have a conversation about the relevance of an app," she argued. "Instead we have a complex problem. We have the highest death rate in the world, the government doesn't know how to get out of this situation, so they've created an app. This is part of a wider problem that predates covid-19: Matt Hancock relying on technology firms to solve complex issues."

Stephen Armstrong, London

Cite this as: *BMJ* 2020;369:m2085

THE TECHNOLOGY BEHIND TRACING APPS

Contact tracing apps use wireless technology such as Bluetooth to exchange a "digital handshake" with another user when they come within a set distance of each other for a particular length of time, two metres and 15 minutes in the case of the UK app. This handshake can run in two ways: Apple and Google's "exposure notification API," which was released this week, allows phones to inform each other anonymously if their owners have been in contact and one develops covid-19, or the NHSX method, which uses existing software to inform the NHS and other smartphone users. NHSX is already working on a second app, with sources telling *The BMJ* that this alternative, being made "in parallel," according to NHSX's Matthew Gould, is less reliant on a central database, though it is unclear whether it involves the Apple and Google API.

iSage emphasised the very low risk of a child dying from the infection: 0.23 per million if back in school on 1 June and 0.02 per million three months later. However, it said that although it was difficult to assess the true risk of infected children transmitting the virus, delaying school reopening by a couple of weeks could allow time to find solutions to local challenges and set up local testing procedures.

Allyson Pollock, co-director of the Newcastle University Centre for Excellence in Regulatory Science and a committee member, said, "The lack of good local real time data is a huge issue. We are not capturing data on suspected cases and cases in the community."

The draft report said that robust testing and tracing procedures, along with support for families to isolate, would reduce the chances of infectious staff, parents, or children attending school.

It said that, before being allowed to open, schools should carry out a risk assessment, including the ability to enable social distancing and for staff and children to be outside or in very well ventilated buildings.

Jacqui Wise, London

Cite this as: *BMJ* 2020;369:m2079

Mathematical modelling by iSAGE estimates that the chances of a child being infected with the virus at school would be 1.46% on 1 June but 0.72% on 15 June and 0.15% on 1 September

FIVE MINUTES WITH . . .

Claire Hopkins

The ear, nose, and throat surgeon who sought to have anosmia recognised as a symptom of covid-19

"Postviral smell loss is relatively common, though in a typical month I would usually see only one or perhaps two patients with the condition.

"People with covid-19 can lose their sense of smell because the virus injures the nerve endings in the olfactory epithelium and damages the olfactory bulb. The British Rhinological Society and ENT UK published guidelines on treating patients with anosmia to coincide with the announcement that it is a recognised symptom of covid-19.

"The advice for GPs is essentially that if the patient has been shown to have covid-19 then they do not need further investigation. What we're seeing is that around 90% of patients improve spontaneously in two to three weeks. For those with ongoing symptoms we have made recommendations for treatment options.

I CALCULATE AROUND 100 000 PATIENTS WILL HAVE LONG LASTING LOSS OF SENSE OF SMELL

"The evidence for any treatment for postviral smell loss is very poor, but there is something called smell training that is repeated stimulation of the olfactory nerves to try to get them working. There are a small number of other treatments, but largely it's supportive measures.

"For the group still without a sense of smell at around two months there is a reasonable chance they will recover spontaneously—around a third within six months, and two thirds at 18 months. But some people will never get their sense of smell and taste back. My back of the envelope calculation is that there will be around 100 000 patients in the UK who will have long lasting loss of sense of smell from covid-19.

"In terms of support, there are two very good charities: Fifth Sense (fifthsense.org.uk) and Abscent (abscent.org). They can advise patients on how to do smell training and give them access to support groups. Losing your sense of smell has a high risk of associated depression. These patients need support, and GPs don't have the resources to do that, but these charities do."

Claire Hopkins is president of the British Rhinological Society

Abi Rimmer, *The BMJ*

Cite this as: *BMJ* 2020;369:m2095

NEWS ANALYSIS

Covid-19 and thrombosis: what do we know about the risks and treatment?

High blood clot rates are being seen in ICU coronavirus patients, but best practice is vague, reports **Jacqui Wise**

How common is thrombosis in critically ill covid-19 patients?

A recent Dutch study of 184 patients with covid-19 pneumonia admitted to an intensive care unit found a 49% cumulative incidence of thrombotic complications—mainly changes seen on computed tomography (CT) pulmonary angiograms.

The authors said that this level was "remarkably high," given that all patients received at least standard doses of thromboprophylaxis. Other studies from France and the Netherlands have also indicated that thrombosis occurs in 20-30% of critically ill covid-19 patients, even with prophylaxis.

"The extent of thrombosis we are seeing with covid is extraordinary," Roopen Arya, clinical director for haematology at King's College Hospital, told *The BMJ*. "I would say that one third of those severely affected with covid in critical care is a conservative estimate."

Why are covid-19 patients at particular risk of thrombosis?

Covid-19 causes massive inflammation boosting cytokines, which increase the liver's production of clotting factors, says Beverley Hunt, medical director of Thrombosis UK and a practising clinician. For example, fibrinogen levels in a severely ill covid-19 patient are 10-14 g/L, compared with 2-4 g/L normally and 5-6 g/L in a pregnant woman. "A covid patient's blood is enormously sticky," she said.

Is the thrombosis rate higher among covid-19 patients?

"All patients in critical care are at increased risk from clots because they are immobile, and when you are sick you have sticky blood," says Hunt. Studies of venous thromboembolism rates among non-covid patients in critical care show that rates of thrombosis can be as high as 28% if patients are not given any prophylaxis. Prophylaxis halves that rate. So, we seem to be seeing significantly higher rates of thrombosis in covid patients.

Is thrombosis contributing to the covid-19 death rate?

"Thrombosis is definitely contributing to the high mortality," says Hunt. "Not only can it lead to a pulmonary embolism, which can be fatal, but there are also higher rates of strokes and heart attacks."

Do covid-19 patients' clots differ from those in other patients?

Postmortem studies are finding clots in the capillaries of the lungs in covid-19 patients, restricting the oxygenated blood from moving through the lungs. Hunt says, "We are not only seeing high rates of deep vein thrombosis and pulmonary embolisms in covid patients, we are also seeing immunothrombosis with lung destruction because of inflammation."

How should covid-19 patients be treated to prevent thrombosis?

In the NHS, anyone coming into hospital is routinely assessed for risk of hospital associated venous thromboembolism and given appropriate prophylaxis with blood thinners. "However, we are still seeing these high rates of deep vein thrombosis, pulmonary embolism, and immunothrombosis in covid patients. Some people are arguing we should be giving bigger doses," says Hunt. Without randomised controlled trials, however, it is not clear what the correct dose should be.

A RECENT Dutch study of 184 patients with covid-19 pneumonia. . .found a 49% cumulative incidence of thrombotic complications

Some UK hospitals are going ahead and using a higher treatment dose of heparin, rather than a prophylactic dose, for seriously ill patients with covid. "It's like the Wild West out there, with lots of different protocols," says Arya. "But giving a higher dose could increase the risk of bleeding. Our hospital is taking a pragmatic approach. Instead of giving the standard prophylactic dose of heparin we are giving half the treatment dose."

Doctors should definitely use a treatment dose in patients who have had a pulmonary embolism, Hunt advises. But she also favours intermediate doses for other patients because of the as yet unknown risk of bleeding with higher doses. However, she says that clotting is right down the chain of events with covid. "If you have less viral load, you would have less inflammation, less sticky blood, and less VTE [venous thromboembolism] and immunothrombosis," she says.

ALAMY

The pandemic is putting far, far more people at risk, and clinicians need specialist guidance as soon as possible
Lyn Brown, MP

What has happened to the NHS England guidance?

NHS England commissioned a group of experts to write clinical guidance on thrombosis and critical care for patients with covid, which was submitted for dissemination on 28 April. Hunt, who was one of the experts consulted, says that she feels frustrated that this guidance is not yet out there to help clinicians.

Lyn Brown, the Labour chair of the all party parliamentary thrombosis group, has submitted a written

BURGER / PHANIE / SPL

Postmortem studies are finding clots in the pulmonary capillaries, restricting the oxygenated blood from moving through the lungs

question to the health secretary, Matt Hancock, asking when the guidance will be published. "We've known for many years that preventable thrombosis kills large numbers every year in the UK. The pandemic is putting far, far more people at risk, and clinicians need specialist guidance as soon as possible," she says.

"Despite this, the guidance that NHS England has commissioned, and which was delivered more than two weeks ago, still hasn't been published. We need to move much more quickly to save lives."

What research is needed?

Even when the guidance comes out it will be limited, as there is so little research. A randomised controlled trial is needed to compare the standard prophylactic dose of heparin with a standard treatment dose in severely ill patients with covid-19.

Hunt says she and others are "hugely frustrated" that a submitted research proposal was turned down by Public Health England as a "low priority." After pressure from researchers the question is eventually going to be included as part of the RMAP-CAP platform trial. However, Hunt believes researchers have "missed the boat somewhat" and should have been gathering data during the peak of infections.

Another question that urgently needs answering, says Hunt, is whether blood thinners should be given to covid-19 patients when they leave hospital. She says, "Covid patients are still going to have sticky blood when they go home, and we know that 60% of patients will have clots in the 90 days after discharge."

Jacqui Wise, London

Cite this as: *BMJ* 2020;369:m2058

Pandemic response has so far cost the UK an "unprecedented" £124.3bn

The government's response to the pandemic has so far cost more than £124.3bn, according to the National Audit Office.

The money comprises spending on the main actions taken in England, funding to devolved administrations to 4 May, and subsequent large commitments, said an NAO report.

The entire budget for the Department of Health and Social Care in England for 2019-20 was £140.4bn.

Loan, benefits, support

Some £82.2bn was for schemes for businesses—such as job retention and loans—and £19.5bn went towards benefits, sick pay, and support for vulnerable people.

Spending on health and social care measures for equipment, testing services, and vaccine development, among other things, amounted to £6.6bn, although this figure does not include £13.4bn of NHS debt written off from 1 April.

The commitment for public services and the wider emergency response—including funding for local government, education, and children's services—totalled £15.8bn. And the commitment for other support, such as public information campaigns, was £2m.

Of the £6.6bn of commitments for health and social care, £4bn has been allocated for the supply of personal protective equipment up to the end of July 2020, £1.3bn has been committed to support discharge from the NHS and up to £454m to support the design and manufacture of ventilators. Allocations of £25m were made for rapid research responses—including vaccine development, drug repurposing, and diagnosis—and £6m for the contact tracing app. Some £5m was committed to mental health funding. Specific cost estimates were not yet available for testing, treatment costs, and staffing levels (including the seven Nightingale hospitals), or for procurement of medical equipment.

Local authorities

The NAO noted the significant role of local authorities across all response areas. Of the £15.8bn support for public services and the emergency response to covid-19, £3.2bn has been allocated to support pressures across local services, including the adult social care workforce and public health services. An additional £713m has been committed to tackle the spread of covid-19 in care homes.

"The scale and nature of the pandemic and the government's response are unprecedented in recent history," said Gareth Davies, head of the NAO.

He said the report would form the basis of a substantial programme of independent reports from his office on how the money has been spent and the lessons learnt.

The NAO noted that many costs are not yet final and that limitations include overlap between covid-19 additional funding and costs that are "business as usual." It also said that the figures may not represent how much additional funding to departments and devolved administrations will eventually be needed, as some measures will be deliverable by reprioritising existing resources.

Shaun Griffin, London

Cite this as: *BMJ* 2020;369:m2057

Of the £6.6bn in commitments for health and social care, £4bn has been allocated for the supply of PPE up to the end of July 2020, and £1.3bn to support discharge from the NHS

Of the £15.8bn from central government for local authorities, £3.2bn has been allocated to support the adult social care workforce and public health services

The scale and nature of the pandemic and the government's response are unprecedented in recent history
Gareth Davies, National Audit Office

THE BIG PICTURE

Brazil mass buries its covid-19 victims

Relatives mourn during a mass burial at a cemetery in the city of Manaus, as Brazil's number of confirmed covid-19 cases became the third highest in the world, behind only the US and Russia.

Data from the Johns Hopkins University Coronavirus Research Center show that as at 20 May Brazil's total number of cases reached at least 291 579. It also recorded more than 1000 daily deaths for the first time, with 1179 on 19 May—18 859 in total.

The country has its third health minister since the outbreak of the pandemic. Luiz Henrique Mandetta was fired, and Nelson Teich resigned after clashes with President Jair Bolsonaro, who has repeatedly undermined social distancing and lockdown measures while pushing state governors to reopen the economy.

Brazilian military cabinet members are pushing Bolsonaro to keep the interim health minister, the active army general Eduardo Pazuello, in charge until the end of the pandemic, on the basis that Pazuello will follow Bolsonaro's orders without question, unlike his predecessors, who are doctors.

As covid-19 spreads through the country, demand for beds in intensive care units is set to exceed hospitals' capacity. There are also fears that prisons have become a potential time bomb, with more than 800 cases and 30 deaths, in a jail population of 748 000—the third largest in the world.

Rodrigo de Oliveira Andrade, São Paulo

Cite this as: *BMJ* 2020;369:m2059

ANDRE COELHO/GETTY IMAGES

EDITORIAL

Covid-19 and alcohol—a dangerous cocktail

Tackling alcohol harms must be an integral part of the nation's recovery

As the UK and most other countries went into lockdown, the need to save lives from covid-19 rightly took priority over longer term health concerns. Many people reacted to the closure of pubs and restaurants by stocking up to drink at home in isolation, and alcohol, along with household items and storecupboard food, disappeared from supermarket shelves. In the week to 21 March, alcohol sales were up 67%. In comparison, overall supermarket sales increased by only 43%.[1]

Now, as signs emerge of control over new cases of covid-19, it is becoming clear that if we don't prepare for emerging from the pandemic, we will see the toll of increased alcohol harm for a generation.

By chance, and just before the pandemic hit the UK, Alcohol Health Alliance started a commission on alcohol harm, aimed at highlighting the damage to individuals, families, and communities (and we are commissioners). The response was remarkable, with more than 140 organisations and individuals providing evidence, writing about their experiences, and describing changes in the system that might have avoided their downward spiral. As we took oral evidence (latterly by video link as the virus tightened its grip), it became clear to commissioners that covid-19 has the potential to be an exemplar of our ambivalent relationship with alcohol and its consequences.

Two groups in particular need our attention. The first is those already struggling with alcohol dependence. Many support organisations moved services online with impressive speed. This has proved more appealing to some, but the new format leaves others, often without the technology or the privacy to use it, falling through the gap. The second group is those on the brink of dependence during lockdown and beyond. For them, dependence will be triggered by bereavement, job insecurity, or troubled relationships.

Dependence will be triggered by bereavement, job insecurity, or troubled relationships

Before covid-19, only one in five harmful and dependent drinkers got the help they need; the proportion will be even lower now. We cannot claim to be a nation recovering from covid-19 if we do not adequately support the most vulnerable among us.

Domestic violence

Alcohol is strongly associated with domestic violence, and an early feature in lockdown was a rise in calls to domestic violence charities. It is difficult to gather causal data on alcohol and domestic abuse, and the relationship between alcohol and domestic violence is complex. However, research finds that 25-50% of perpetrators of domestic abuse have been drinking at the time of the assault, and in some studies this is as high as 73%.[2] Strathclyde Police data from 2004-12 found that the accused party was under the influence of alcohol in about 60% of police callouts for domestic incidents.[3] The Home Office review in 2016 showed that alcohol was involved in almost half of domestic homicides.[4]

Supermarket shelves were stripped of alcohol ahead of lockdown

As in so many aspects of the coronavirus epidemic, it will be only in hindsight that we can measure the effect of social isolation, job losses, and financial meltdown on the alcohol balance sheet. Even at the best of times, alcohol costs the NHS in excess of £3.5bn and the wider economy at least £21bn each year.[5]

Our commission report will come out later in the year, documenting some of the personal tragedies of those directly affected by alcohol harm, the children and partners around them, and the effect on communities. We will be calling for evidence based, population level action on key drivers of harm, such as price, availability, and marketing, and for the implementation of innovative and cost effective sobriety schemes to reduce alcohol fuelled crime. But we fear that these calls will struggle to be heard amid the avalanche of issues to be tackled once the pandemic wanes.

The health and economic harms from alcohol have previously mirrored changes in society, and in bad times they get worse. A healthy population drives a healthy economy, and so recovery must focus both on the economy and on the public's health. Presentations of alcoholic liver disease, already increasing before the covid-19 crisis,[6] will rise further. A similar surge will occur in the need for alcohol treatment services, which are traditionally an easy target for cuts when finances are tight.

We know that investing £1 in alcohol treatment services will save £3, as well as directly helping affected individuals, often the most vulnerable in society.[7] This time, let's be ready. Tackling alcohol harms is an integral part of the nation's recovery.

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EDITORIAL

Public inquiry into UK's response to covid-19

A rapid, transparent review is needed before a second wave

A public inquiry into the UK's response to covid-19 now seems inevitable, with political and public demands for one that can command widespread support.[1] While a comprehensive inquiry at some point will be essential, the traditional model takes years. The UK needs answers within months, before a second wave develops. At least five main areas require scrutiny.

The first is governance. When the prime minister addressed the nation, he failed to point out that his messages applied only to England.[7] Local government leaders, including the large metropolitan authorities, have been excluded from discussions.[8]

Further, it is not clear that parliament has been able to scrutinise the actions of ministers. A rapid inquiry cannot risk getting bogged down in the detailed scientific advice, but it will be crucial to examine how it was used, especially when there was uncertainty, as well as issues around transparency and independence.

Outsourced

The second is procurement of goods and services. A hollowed out civil service has long turned to outsourcing companies, despite their repeated failures.[10] Companies with little relevant experience have struggled to organise viral testing[11] or contact tracing.[12] The task of coordinating activities with existing organisations, such as NHS laboratories or local public health departments, is too complex for their business model. The procurement of products, such as ventilators and protective equipment, has been beset by problems, echoing longstanding problems in the NHS.

Procurement of products such as ventilators and protective equipment has been beset by problems

The third is coordination of existing structures. The fragmentation created by the 2012 Health and Social Care Act in England has created major barriers to coordination and leadership across the Department of Health and Social Care, the NHS, Public Health England, and local public health departments.[4] Similarly, the structural disconnect between the NHS and social care in England has contributed substantially to the pandemic's spread. The limited powers of local government, coupled with the absence of regional structures, also pose a problem. It is inexplicable that mayors of metropolitan authorities have been ignored by ministers.[8]

The fourth is the disproportionate burden on ethnic minority populations. Responses must draw on expertise in basic, clinical, and social sciences, with strong representation from the communities affected.

Finally, international collaboration is essential.[13] The UK's engagement with its European neighbours was chaotic. The looming crisis of a no deal Brexit,[14] with shortages of food and medicines that could coincide with a second wave, is clearly a huge concern but is beyond the scope of a covid-19 inquiry. Nevertheless, we need be to seek practical ways to overcome the obstacles that the government seems determined to create concerning the UK's future relationship with the EU.

This inquiry must be quick, broad, ambitious, able to command widespread public and stakeholder support, and focus on the most important weaknesses to date. Given the complexity of the issues involved, the need for specialist expertise, and for speed, we recommend a series of panels with membership capable of tackling these issues. Each panel would be asked to find workable solutions that do not require primary legislation or major organisational change, both of which can come later. Nor should panels seek to allocate blame.

Each panel should include a range of disciplines and experience, including those on the front line. Achieving public trust will be difficult but essential, given the secrecy around the official Scientific Advisory Group for Emergencies (SAGE).

Effective model

One possible model might be the Parliamentary Commission on Banking Standards, which was set up in the wake of the Libor (London inter-bank lending rate) scandal.[15] This was a joint committee of both Houses of Parliament, including several specialist panels with external experts, which was able to rapidly review the causes and make recommendations. Many were subsequently accepted and taken forward.

This is an ambitious agenda, and it is naive to think that these challenges could be dealt with comprehensively before the second wave of covid-19. Rather, what we need is measures to be put in place to mitigate the worst aspects of what has proved to be a deeply dysfunctional system of governance and administration. It will be unforgiveable if we fail to prepare for a second wave.

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COVID-19

What we are learning from the armed forces in the fight against a viral enemy

Military planning has been invaluable in efforts to tackle the pandemic. But how does it differ from civilian NHS planning? **Geoff Watts** and **Emma Wilkinson** report

Governments around the world have been seeking the help of the military in tackling the spread of covid-19. Some of these interventions have been substantial: as early as the beginning of March, the Chinese state news agency Xinhua was reporting that 10 000 military medics were already "working at the front line" and that 3000 beds had been set up by 63 military hospitals for treating infected patients.

The UK Ministry of Defence is no exception to this involvement in what are normally civilian affairs. From building new hospitals to delivering bulk oxygen supplies and taking the strain off employees at hard pressed NHS supply depots, soldiers have been in evidence.

A large, disciplined, and flexible workforce able to step in and provide some muscle at short notice is clearly valuable. Less immediately obvious is the benefit of another element of the ministry's assistance: the deployment of military planners, not least in the transformation of large enclosed spaces—conference centres such as London's Excel Centre—into temporary hospitals. The NHS has planners of its own, so what are the distinguishing features of the military approach?

Soldiers have been much in evidence at the emergency Nightingale hospitals

PETER BYRNE/PA

Planning not plans

Richard Jones is a consultant cardiologist at Queen Alexandra Hospital in Portsmouth, host to the country's largest Ministry of Defence hospital unit. He's not a military personnel member but works closely with them. "What the military do so well is planning for huge surges, because that's in the nature of their challenges," he says.

"In the health service we tend to plan new services or service changes over months or years; engagement with patients and other service users takes time." Because the changes in demand are mostly gradual—population ageing, for example—this time can be available.

What the military do so well is planning for huge surges
Richard Jones, Queen Alexander, Portsmouth

Military input enabled the conversion of large buildings into hospitals in just a few weeks

ANDREW PARSONS/10 DOWNING STREET HANDOUT

By contrast, planning for sudden, fast moving events like epidemics is, as Jones puts it, the military's stock in trade. "They spend their lives working through unexpected scenarios . . . The NHS does have major incident plans, and every so often they're rehearsed. But this [the pandemic] is on a rather different scale."

Mark Norton, a former lieutenant colonel in the British army, talks of a distinctive "philosophy of planning" that puts an emphasis on process. "The process of planning is what's important rather than the actual plan as an output," he says. This perhaps counterintuitive conclusion is a consequence of what Norton refers to as the great truism of military planning: "that no plan survives contact with the enemy."

Military planning thus emphasises the continual gathering of intelligence that might prompt changes to a plan. Norton comments, "It's a different philosophy to the one I've encountered in business, where a plan is usually made at the beginning of the year, and then you just work it through."

Scale and speed

Tim Whittlestone, chief medical officer of the 300 bed Bristol Nightingale Hospital—which was opened up to NHS staff for clinical training after just two weeks—has experienced this flexibility first hand. At first he envisaged soldiers coming in with hammers to put everything together, he admits. In reality, the "building" was all done by private contractors; the military input was something else entirely.

"I say, for each patient I will need a 15 square metre cubicle with a ventilator and oxygen and this equipment in a trolley—and their expertise is scaling that up to 300, 500, whatever patients," Whittlestone says. "They are bringing the logistical support for that to happen at incredible speed. I'm used to working in the NHS where to build a hospital is 15 years of planning. This has been done in 15 days."

He likens the military support to a professional service. "They will take your wish list and provide you with a solution. What I have found fascinating is that I think of the army as people on the battlefield, but in order to provide that frontline service there is a whole organisation of materials, logistics, and programme management—and that's the bit we're tapping into."

Military planning emphasises the continual gathering of intelligence that might prompt changes to a plan

And if you have forgotten something or made an error, they are not fazed at all: the attitude is one of problem solving not blame. "They are very good at just making it happen; they don't go away and debate it and have committee meetings," says Whittlestone. "They take the instruction and operationalise that for you at great speed."

Chain of command

This is down to one of the most well known features of military organisations: their hierarchy, with defined chains of command that people respond to quickly, possibly without questioning.

Managing a health service has never much resembled managing an army, and Jones sees the gap as having widened over the years. "The mood in the NHS has been away from command and control, which used to be the culture," he says. "It's been followed by a more distributed leadership style, encouraging local systems to take the lead on sorting out problems."

This is only one of many cultural differences between military and civilian organisations, so how will mixed teams of planners have coped with working together?

The military are very good at just making it happen
Tim Whittlestone, Bristol Nightingale

On this point Norton and Jones are in agreement. The current crisis is pressing, and the goals—particularly the creation of new hospitals—are clear cut. As Norton puts it, "So long as there is a galvanising force, cross agency collaboration can work well." He quotes examples of successful military-civil collaboration such as in the event of terrorist bombing campaigns in London and outbreaks of foot and mouth disease. Other past joint planning ventures include hurricane Irma in 2017, which saw UK forces taking part in the organisation of disaster relief to Caribbean islands.

Whittlestone says that he watched the building of the first Nightingale Hospital in the Excel Centre in London and was impressed by the efficiency with which teams—NHS, military, and private contractors—worked together. A week later the regional rollout began. "The NHS response has been phenomenal, and it shows it can be adaptable. But as clinicians we focus on the patient and the disease in front of us. We reach out to the trolley and take the syringe out of the top drawer, hardly ever considering how it got there, let alone how a hospital was designed and built," he says.

"Working with the military to build a field hospital at pace demonstrates how they are uniquely placed to take the concept of a clinical unit and scale it, perfectly replicated for 300 patients."

The Bristol Nightingale has yet to be used to treat patients, but it is thanks to the input of the British army that it is ready to do so. Whittlestone says, "I have every confidence that when doctors and nurses start to receive patients at Bristol Nightingale Hospital, they will reach out and find a trolley—and the syringe will be in the top drawer."

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PUBLIC HEALTH

Unexpected benefits of the world's response to the pandemic

As the coronavirus continues its deadly path, dramatic changes in how people live are reducing instances of other common medical problems. **Bryn Nelson** reports that the irony may hold valuable lessons for governments

Virtually car-free streets in cities, including New York (above) and Los Angeles (below), have meant lower air pollution levels and fewer road accidents around the world

Doctors and researchers are noticing some curious and unexpectedly positive side effects of the abrupt shifts in human behaviour in response to the covid-19 pandemic. Skies are bluer, fewer cars are crashing, crime is falling, and some other infectious diseases are fading from hospital emergency departments.

Other changes are unquestionably troubling. American doctors have expressed alarm over a nosedive in patients presenting to emergency departments with heart attacks, strokes, and other conditions, leading to fears that patients are too afraid of contracting covid-19 to seek necessary medical care. Calls to poison control centres are up by around 20%, attributed to a rise in accidents with cleaners and disinfectants even before President Donald Trump questioned whether injected disinfectants might stop the virus. Calls to suicide prevention lines are soaring, while health experts are fretting about signs of rising alcohol and drug use, poorer diets, and a lack of exercise among those cooped-up at home. Millions of people are hungry and unemployed.

But doctors, researchers, and public health officials say the pandemic is also providing a unique window through which to view some positive health effects from major changes in human behaviour. And the virus may lead to a public more willing to accept and act on public health messages.

Alice Pong, a paediatric infectious disease physician and the medical director for infection control at Rady Children's Hospital in San Diego, California, said the hospital has seen a sharp decline in paediatric admissions for respiratory illnesses. These include diseases such as influenza, parainfluenza, respiratory syncytial virus, and human metapneumovirus.

Satellites have documented significant reductions in air pollution in major cities

"We track positive viral tests through our hospital lab and those numbers have gone down dramatically since everybody went into quarantine," Pong told *The BMJ*. "We do think that's a reflection of kids not being in day care or school." The hospital is testing fewer patients, she said, which could be because more children might be staying home with respiratory symptoms. But more serious cases and intensive care unit admissions are down as well, suggesting a true decline in life threatening illnesses.

Social distancing is not only reducing the occurence of disease. Pong said she believes children and families are taking advice on hand washing, personal hygiene, and other prevention measures seriously. "I think this is going to be a good lesson for everybody," she said. "The public is seeing why public health officials have advised them stay home when they feel sick, for example, and why they've emphasised hand washing and covering a cough or sneeze. Kids growing up now will know this is how germs are spread." That message could spread to their families and broaden awareness.

Fewer cars, blue skies

With covid-19 shutting down economic activity in most parts of the world and people staying closer to home, street crimes like assault and robbery are down significantly, though domestic violence has increased. Traffic has plummeted as well. As a result, NASA satellites have documented significant reductions in air pollution—20-30% in many

cases—in major cities around the world. Based on those declines, Marshall Burke, an environmental economist at Stanford University, predicted in a blog post that two months' worth of improved air quality in China alone might save the lives of 4000 children under the age of 5 and 73 000 adults over the age of 70 (a more conservative calculation estimated about 50 000 saved lives).

Although baseline pollution levels in the US are lower, Burke said a similar 20-30% reduction in pollution would still likely yield significant health benefits. "A pandemic is a terrible way to improve environmental health," he emphasised. It may, however, provide an unexpected vantage to help understand how environmental health can be altered.

"It may help bring into focus the effect of business as usual on health outcomes that we care about," he says. "In some sense, it helps us imagine the future." Getting there, Burke says, could instead come through better regulation and technology.

A separate report coauthored by Fraser Shilling, director of the Road Ecology Center at the University of California at Davis, found that highway accidents—including those involving an injury or fatality—fell by half after the state's stay at home order on 19 March. "The reduction in traffic accidents is unparalleled," and yielded an estimated $40m ((£32m; €36m) in public savings every day, according to the report.

Whereas average traffic speeds increased by only a few miles per hour, traffic volume fell by 55%. Hospitals in the Sacramento region reported fewer trauma related admissions while other reports indicated fewer car collisions with pedestrians and cyclists.

In Washington, collisions on state highways fell even further—by 62%—in the month after the state's stay at home order went into effect on 23 March, compared with the previous year, according to the Washington State Patrol. The question, Shilling said, is whether researchers can learn from the information to design safer transportation patterns. "We're not going to be guessing anymore about what happens when you take half the cars away," he said.

Emptier highways, though, may be triggering reckless driving that could undo the mortality reductions. Washington State Patrol spokesperson Darren Wright said that troopers are seeing a "scary trend" of more drivers travelling at extreme speeds—a phenomenon also observed in Missouri. "We're seeing speeds in the 120 and 130 miles per hour range," Wright said. One motorcyclist was clocked at more than 150 miles per hour.

Researchers in Portugal and the UK say they are beginning to see shifts in the incidence of sexually transmitted infections

Reassessing priorities

If the pandemic has prompted risky behaviour for some, it has encouraged others to embrace preventive measures. Randy Mayer, chief of the Bureau of HIV, STD, and Hepatitis at the Iowa Department of Public Health, said the public has become more responsive to calls from the department's partner services, which perform contact tracing for people who test positive for HIV, gonorrhoea, and syphilis. "People are really interested in calling us back and finding out what information we have for them," he said. That increased cooperation, Mayer said, may be a benefit of people associating public health departments with trying to keep them safe from covid-19.

Even so, he worries that a noticeable reduction in the number of new HIV diagnoses may partially reflect a reduction in available testing with many clinics open for limited hours, if not completely closed. But growing evidence suggests that more people are also heeding recent pleas by public health officials and even dating apps to reduce the risk of covid-19 infection by avoiding sex with new partners. Researchers in Portugal and the UK told *The BMJ* that they are beginning to see shifts in the incidence of sexually transmitted infections but were still collecting data to support their observations.

Miguel Duarte Botas Alpalhão, a dermatovenereologist and invited lecturer in the Faculty of Medicine at the University of Lisbon, said that he expects to see a lower rate of sexually transmitted infections during the lockdown. The crisis has caused people to question their priorities "and how much they are willing to give up to protect their lives and those of their loved ones," he said.

"People are now more aware that nothing really matters when health is lacking, and this raised awareness may be the driving force towards healthier habits. We will have to wait and see."

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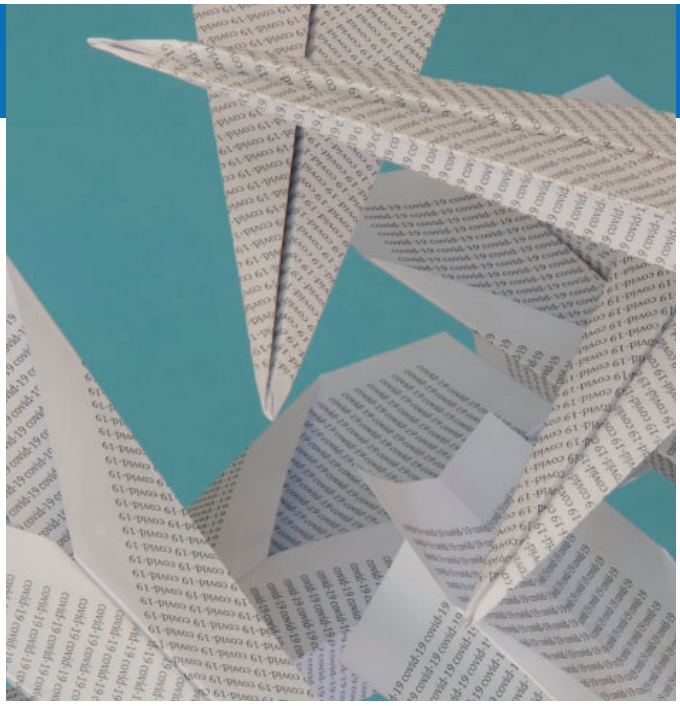
MEDICAL RESEARCH

How a scramble for covid-19 evidence is leaving clinicians and the public wanting

The rush to publish and report during the pandemic is compromising research quality, worried experts tell **Stephen Armstrong**



On 11 April Neel Shah, assistant professor of obstetrics, gynaecology, and reproductive biology at Harvard Medical School, published a grim assessment of the scientific research into covid-19 and its effects on pregnancy.

"I've never felt as dependent as I am today on shaky data to make what could be life or death decisions," he wrote. "In a normal month I . . . quickly cast aside studies that include just a handful of patients or provide no formal way of accounting for context. Yet today these kinds of studies are all I have to go on."

Shah explains his concerns to *The BMJ*: "I understand the challenge of providing evidence based research [on the pandemic]. But people like me on the front line have to make life or death decisions based on the information that we have. We have to be willing to update what we believe more rapidly—and yet there's so much information that is hard to trust it makes our jobs very difficult."

The pandemic has created an urgent need for scientific evidence to help politicians, doctors, researchers, and the general public understand this evolving situation. The problem is that good science, which requires scrutiny and replication, simply cannot move at the speed of the rolling news cycle.

Over the past 20 years responses to the misreporting of medical theories has resulted in a series of checks and balances to protect all concerned from hasty or even bad science. The professionals at the helm of those controls say they are worried: quality seems to be slipping, and there are question marks over research findings and problems with publishing and reporting of studies.

System breakdown

Fiona Fox is chief executive at the UK's Science Media Centre, established in the wake of the measles, mumps, and rubella vaccine controversy to ensure that the media covered scientific issues with the best evidence and expertise. "What we are seeing is worrying signs of a compromise in quality," she says.

Many of the science stories covered in the news media come from press releases issued by around 10-15 of the world's top journals, including *The BMJ*, the *Lancet*, and *JAMA*. The Science Media Centre gets sight of these before the embargos lift, allowing Fox's team to recruit experts who can contextualise and explain the significance of the study to journalists. "When the deluge of new [covid] findings came out this embargo system broke down," Fox explains. "Journals are now often releasing papers for immediate release, making it harder for us to get third party comments to the journalists in time.

"Suddenly all our tried and tested ways of helping journalists to report findings more responsibly have been removed. It's making it hard for us to do our job, but it feels more important than ever. We don't need to slow the wheels of science when people are dying, but neither do we need bad science that falls below acceptable standards and makes things worse."

We don't need to slow the wheels of science when people are dying, but neither do we need bad science that falls below acceptable standards and makes things worse
Fiona Fox, Science Media Centre

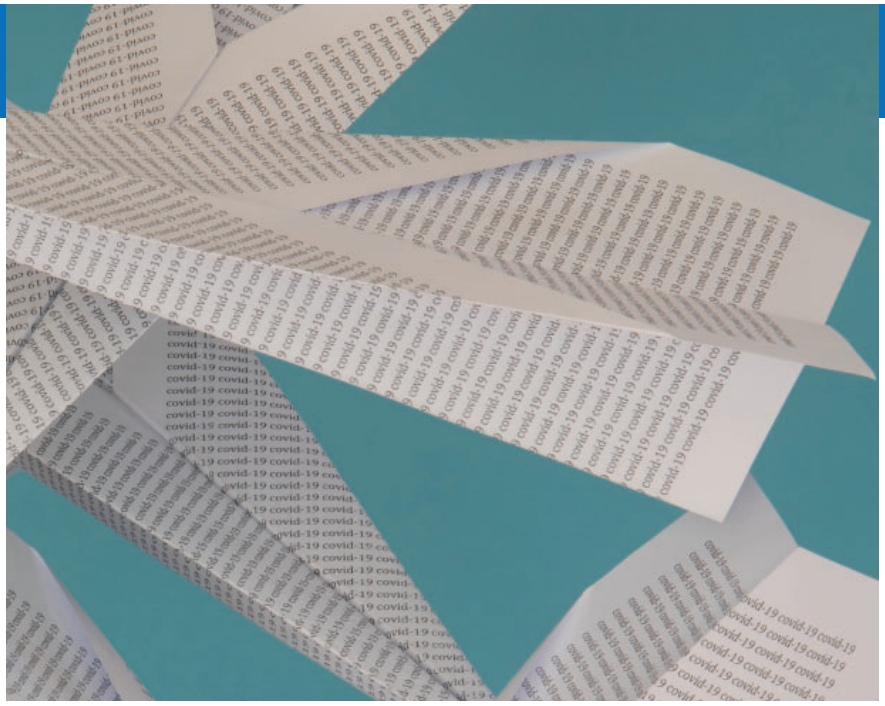
Moreover, Fox says, with the thirst for information on covid-19 far outstripping the usual demand for medical science coverage, journalists are reporting on more preprint studies that have not been peer reviewed and vary in quality.

The centre has recently issued retroactive contextualising—and in some cases critical—comments on several preprints, including one by a professor of microengineering that compared deaths from covid-19 and social distancing measures in nine countries, an observational study of covid-19, high blood pressure, and blood pressure lowering drugs, and a study that compared the risk of infection in different blood groups.

Cite-bait and hype

Why, amid a global pandemic, should the quality of medical research and its reporting seem to drop? "Because there are imperfect incentives at every stage in the process," says Marcus Munafò, professor of biological psychology at Bristol University's MRC Integrative Epidemiology Unit, who leads the UK Reproducibility Network (UKRN), set up last year to improve research quality.

"Part of what may be drawing researchers to this is seeing the amount of covid-19 work in respectable journals and thinking they can get published in those journals too.



"There is a similar risk for journals. Their incentive is to put something out there that's 'cite-bait': journals survive by publishing stuff that people read and cite so that more people read the journal. Do journals like *The BMJ* have an expedited review process, and what checks and balances are in place?"

Munafò also points out, "Much of the hype in medical reporting can come from the press release—written by the university's PR department but approved by the study authors. Then it reaches journalists who have a need for clicks or sales. All of those things have always happened, but they seem to be happening to a greater degree in the current climate."

He believes most research is well intentioned but points to the UKRN philosophy: "Fast, cheap, good . . . you can only have two." He adds, "There is an urgent need for data and knowledge, but false information is worse than no information."

Speed versus quality

The issue was recently illustrated by one 22 April study in *JAMA*, which reported 88% mortality among patients ventilated for covid-19. Crucially, however, that figure did not include the relatively large number of patients still alive and ventilated at the time of reporting, but the paper was nevertheless covered in the media under headlines such as "New study shows nearly 9 in 10 covid-19 patients on ventilators don't make it."

The authors have since issued a correction. This said that 38 ventilated patients were discharged alive, 282 died, and 831 remained in hospital, giving a ventilator mortality of 24.5% rather than close to 90%.

Karina Davidson, senior vice president of research for Northwell Health, the US chain of non-profit hospitals where the research was conducted, explained, "What we thought was important, given that we had so many patients who were presenting for hospitalisation over four days, was to get out their presenting symptoms, triage lab values, and initial course, so that we could have some descriptive data for others from our country.

"We usually report when total outcome denominators are known. In our article we reported only on the subset for which outcomes were known in those few days. Everyone is struggling with the correct balance between judicious careful processing and the great thirst for information on this brand new disease."

Primary research and peer review

Malcolm Macleod, professor of neurology and translational neuroscience at the University of Edinburgh and its academic lead for research integrity and improvement, has no interest in identifying individual papers for criticism.

"The improvements we need would be better served if every manuscript could be just a little bit better," he says.

Macleod is part of a team that has been working to categorise more than 12 000 unique studies gathered internationally since the start of the outbreak. They have so far categorised 2181 publications, including 304 primary research papers, so roughly 14% of publications include primary research. The proportion of primary research papers that have been peer reviewed is 27%.

"Seventy two per cent of the primary research studies have been observational stuff: 'This is what it looks like in five patients of mine,'" Macleod explains. "Hardly any of those are peer reviewed or preregistered, so there is no protection against bias.

"A lot of journals don't even say if the work has been peer reviewed, so they are presumably arrogant enough to believe we assume their papers have been peer reviewed, and yet there are some that have been accepted and published on the same day. That's an issue for the journals going forward—they need to be more transparent."

He accepts that science and medicine should, in the middle of a pandemic, hold research on covid-19 to a slightly different standard from other research—accepting a lower standard of evidence to take a drug through to clinical trial, for instance—but researchers need to go through the process of due diligence to be sure of the level of this standard.

"What improves quality is transparency at every step: sharing methodology, data, materials, code . . . everything," says Munafò. "The Imperial group's original paper on lockdown went up as a preprint, but they weren't able to share the computer code used to make their calculations at the same time because it was old code and hadn't been prepared for sharing. This meant researchers couldn't check their code.

"Lockdown is causing harm. Currently the view is that the benefits outweigh the costs. We need decisions to be informed by high quality evidence, even if it is imperfect or incomplete. Transparency will help ensure the process is seen as trustworthy."

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There is an urgent need for data but false information is worse than no information
Marcus Munafò, Univeristy of Bristol

It's a struggle between judicious processing and a great thirst for information
Karina Davidson, Northwell Health

That's an issue for the journals going forward—they need to be more transparent
Malcolm Macleod, University of Edinburgh

EDITORIAL

Waste and harm in covid-19 research

A deluge of poor quality studies is sabotaging an effective evidence based response

The medical research world is responding to the covid-19 pandemic at breathtaking speed. There has been a maelstrom of global research, with mixed consequences. Positives include the greater provision of open access to covid-19 studies, some increased collaboration, expedited governance and ethics approvals of new clinical studies, and wider use of preprints. But many problems have become evident.

Before the pandemic, it was estimated that up to 85% of research was wasted because of poor questions, poor study design, inefficiency of regulation and conduct, and non or poor reporting of results. Many of these problems are amplified in covid-19 research, with time pressures and inadequate research infrastructure contributing.

Trials

An extraordinary number of covid-19 trials have been registered since the pandemic started. The National Library of Medicine registry ClinicalTrials.gov lists 1087 studies, and though some will provide useful information, many are too small and poorly designed to be helpful. Of the 145 registered trials of hydroxychloroquine, for example, 32 have a planned sample size of ≤100, 10 have no control group, and 12 are comparative but non-randomised. Outcome measures vary widely, and only 50 seem to be multicentre. Strikingly, only one provides a protocol, and even limited registry details reveal unjustified outcome switching.

The imbalance in trial topics is worrying, in particular the paucity of trials on non-drug interventions. Despite these being the mainstay of current mitigation,[3] we found just two trials of masks on ClinicalTrials.gov and none examining social distancing, quarantine effect or adherence, hand hygiene, or other non-drug interventions. Covid-19 research funding mirrors this woeful imbalance. A search of Covid-19 Research Project Tracker, a live database of funded projects, found almost no primary research of the effects of non-drug interventions on transmissibility, compared with hundreds of drug intervention projects worth at least $74m (£60m; €67m).[4]

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Preprints

Preprints have provided valuable early access to results. Postings in MedRxiv have increased over 400% (from 586 for the last 15 weeks of 2019 to 2572 for the first 15 weeks of 2020), while views and downloads have increased 100-fold.[5] Many preprints are poorly reported, however. In systematically reviewing the proportion of asymptomatic covid-19 cases, we found the sample frame of most studies was unclear, missing cases were undocumented, and "asymptomatic" was undefined. Many such problems could be corrected before full publication (which doesn't always follow), but poor reporting is complicating the research appraisal and synthesis already occurring.

Access to preprints has also led to irresponsible dissemination as flawed studies are picked up by the media. The preprint of the first reported study of hydroxychloroquine on 20 March—a non-randomised study of 46 patients with inappropriate analyses[6]—has been cited 520 times, while a larger, randomised trial posted on MedRxiv on 14 April showing no benefits[7] has received less attention. This inbalance has triggered a wave of what is likely to be largely unnecessary or misdirected research: 135 hydroxychloroquine studies have been registered on ClinicalTrials.gov since 20 March.

Waste and duplication

Some replication of studies is important, but unnecessary duplication is wasteful. The large number of registered trials evaluating hydroxychloroquine is one illustration, but waste is also occurring elsewhere. At least five systematic reviews of face masks for people in the community have occurred in parallel.[8-12]

The paucity of non-drug intervention trails, despite being the mainstay of current mitigation, is worrying

Existing research infrastructure to enable collaboration and communication is very limited, with system cracks made more apparent by the pace and volume of covid-19 research. Registries do not exist for most study types. When there is a global rush to research a disease, a centralised, accessible portal (hosted by WHO for example) of all ongoing research and synthesis would be invaluable.

Several important collaborations are engaged with covid-19 research. Perhaps most notably, the Coalition for Epidemic Preparedness Innovations (CEPI), which already had funding and coordinating mechanisms for vaccines, is developing and testing eight candidate vaccines in parallel. Similarly, the UK's multicentre trials infrastructure has enabled the RECOVERY trial of four treatments; it has recruited more than 9000 patients from 173 centres in less than two months.[13] But there are few such examples, and coordination of many important areas of pandemic research has been lacking. Given the risk that a vaccine may be ineffective, partially effective, or delayed, there is an urgent need for a body similar to CEPI that could coordinate and support neglected research into non-drug interventions such as distancing, hand hygiene, masks, tracing, and environmental modifications, which have so far been the only effective means of control.

The massive waste in research is not new but has been exacerbated by the pandemic inspired rush to research. While the poor quality of covid-19 research needs attention immediately, other problems must be addressed long term, and certainly before the next pandemic.

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