this week

PRIVATE CARE page 380 • **GP CONTRACT** page 382 • **GENDER SERVICES** page 384

EVGENIY MALOLETKA/AP/SHUTTERSTOCK

A couple carry their injured 18 month old son into a hospital in Mariupol, Ukraine, which has been under Russian siege for two weeks

Russia hits 16 Ukrainian health facilities

The World Health Organization has verified 16 Russian attacks on health facilities in Ukraine up to 8 March, with many more still to be verified, as it reiterated its plea for humanitarian safe corridors in the country.

Speaking at a media briefing, 13 days into the invasion, WHO's regional director, Hans Kluge, strongly condemned the attacks. "It should not need saying that health workers, hospitals, and other medical facilities must never be a target at any time," he said.

Catherine Smallwood, senior emergency officer at WHO's Europe office, told the briefing the verified attacks had led to nine deaths and 16 injuries. News reports state that hospitals in cities such as Zhytomyr, in the north, Vuhledar, near Mariupol in the south west, and Kharkiv, in the north east, have all been damaged by Russian weapons.

Kluge outlined WHO's three priorities, the first being to get health supplies into Ukraine. "Lifesaving essential medicines, such as oxygen and insulin, personal protective equipment, surgical supplies, anaesthetics, and safe blood products are in short supply," he warned.

"So far, two shipments totalling 76 tonnes of trauma and emergency supplies, as well as freezers, refrigerators, ice packs, and cool boxes, are in transit. We have further shipments of 500 oxygen concentrators, and more supplies are on their way."

Beyond Ukraine, Kluge warned that the "fastest growing refugee crisis in Europe for more than 75 years" was developing and said WHO's second priority was to help equip neighbouring countries with the infrastructure and expertise to meet the urgent health needs of refugees. Teams have been sent to Hungary, Poland, Moldova, and Romania to coordinate closely with governments and partners to assess their and refugees' needs.

The third priority is Ukraine's "urgent need for trauma and injury support," for which WHO is supplying rapid refresher training, supplies, and staffing.

Re-establishing and maintaining vaccination programmes, tuberculosis and HIV treatment, and mental health services were all priorities, Kluge said. "We are working to support these essential medical needs through fixed facilities and field hospitals or mobile health services."

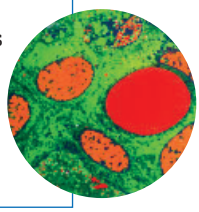
He added that Ukraine reported 731 covid deaths last week. "Sadly, this number will increase as oxygen shortages continue," he said.

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2022;376:o610

LATEST ONLINE

- *Lancet* will not retract discredited paper on tissue engineered trachea transplants
- Sajid Javid sets out reform agenda for English health service
- Breast cancer is overdiagnosed in one in six or seven cases, finds large US study



SEVEN DAYS IN

Pandemic has accelerated demand for private healthcare, report finds

More UK adults are seeking private healthcare, as poor access to care exacerbated by the pandemic threatens to create a two tier system, a report has warned.

Research by the Institute for Public Policy Research think tank found that the long term decline in NHS access and quality had been rapidly accelerated by covid-19, prompting more people to purchase private health insurance or pay for treatment. Polling by IPPR and YouGov found that almost a third (31%) of 3466 UK adults surveyed struggled to get the care they needed during the pandemic. Of these, almost one in eight (12%) used some form of paid alternative, and one in five considered doing so, with this proportion rising among wealthier people.

But support for the NHS's core principles was high, with 88% of polled people across all political viewpoints expressing support for care being free at the point of delivery.

Chris Thomas, IPPR principal research fellow, said, "People aren't opting out of the NHS because they've stopped believing in it as the best and fairest model of healthcare. Rather, those who can afford it are being forced to go private by the consequences of austerity and the pandemic—and those without the funds are left to 'put up or shut up.'"

Gareth Iacobucci, *The BMJ* Cite this as: *BMJ* 2022;376:o566

Covid-19

Baricitinib reduces deaths among hospital patients

The anti-inflammatory treatment baricitinib, which is normally used to treat rheumatoid arthritis, reduces the risk of death in patients admitted to hospital with severe covid-19 by around a fifth, the Recovery trial reported. The benefit of baricitinib was on top of those seen with dexamethasone and tocilizumab, the two other anti-inflammatory treatments previously found to reduce the risk of death in such patients. The trial's joint chief investigator, Martin Landray, said, "This opens up the possibility of using combinations of anti-inflammatory drugs to further drive down the risk of death for some of the sickest patients."

Vaccine contracts "need access provisions"

Public funding given to companies for future vaccine development should have global access requirements built into agreements to avoid the inequity seen during the covid-19 pandemic, campaigners said. Speaking on 21 February, Tahir Amin, cofounder and co-executive director of I-MAK, a US based group that campaigns for increased access to affordable drugs, said that drug companies had been given billions of dollars in public funds for vaccine development in recent years with "no strings attached." He said, "Government contracts need to have better terms and provisions that allow for greater access."

General practice

England loses 91 full time GPs in a month

England lost the equivalent of 279 fully qualified full time GPs from the workforce in the past year and 91 in the final month alone, official data showed. The BMA said that the loss of 91 doctors from December to January equated to more than 200 000 patients losing their GP in just one month. Over the same period, data from NHS Digital showed that the number of patients registered at general practices increased by 130 598.

Flu vaccination

Free vaccines will end for ages 50-64

The NHS's annual flu vaccination programme will revert to its usual eligibility criteria in the financial year 2022-23, after two years of offering vaccines to an expanded group of people during the covid-19 pandemic. The shift means that people aged 50-64 and secondary schoolchildren in years 7-11 will no longer be eligible for routine flu vaccination unless they are in a clinical risk group. In updated guidance issued on 2 March NHS England said that the vaccination programme would be offered to groups of patients who were eligible "in line with pre-pandemic recommendations."

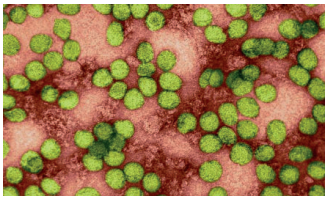
Workforce

Plan for extra obstetricians leaves "startling gap"

Health minister Maria Caulfield (below) was asked to explain a "startling gap" between the number of obstetricians and midwives that the NHS intends to recruit and estimates of the number needed. The government has said that it will hire 100 more obstetricians and 1200 midwives in a £95m recruitment drive. But Jeremy Hunt, chair of the Health and Social Care Committee, asked Caulfield to explain the figures, saying that five times as many consultants and 700 more midwives were actually needed.

Hepatitis C

Chronic cases fall sharply in England



The estimated prevalence of chronic hepatitis C (above) in England fell by 37% to around 81 000 in 2020 from 129 000 in 2015, showed UK Health Security Agency figures. Provisional data also suggested a 40% drop in people who inject drugs. Deaths from advanced liver disease relating to hepatitis C also fell, from 482 in 2015 to 314 in 2020.

Antipsychotics

Prescriptions for personality disorder rise

Antipsychotics have been increasingly prescribed to people with personality disorder but no history of severe mental illness, found a study on 46 210 people from UK general practice. The University College London study, published in *BMJ Open*, also found that 36 875 people with a record of personality disorder had no record of severe mental illness. Despite this, 25% had antipsychotics prescribed.

MEDICINE

A campaign aims to be clear about NHS advice not to feed solid food to babies younger than 6 months

Weaning

Campaign aims to tackle confusion over solid food

England's Office for Health Improvement and Disparities is promoting NHS advice on weaning in a campaign aimed at tackling confusion over when to introduce solid foods, after research found that 40% of first time mothers introduced solid food by the time their baby was 5 months old and that almost two thirds (64%) said that they received conflicting advice on what age to start weaning. NHS guidance recommends introducing solid foods gradually, from around age 6 months, alongside breast milk or infant formula.

GMC regulation

New data outline deaths during investigations

Five doctors took their own lives while being monitored or investigated by the General Medical Council from 1 January 2018 to 31 December 2020, showed a report by the regulator. The data, which will now be published annually, have been introduced as part of a new process for obtaining and recording the cause of death

of doctors who die while going through the GMC's fitness to practise procedures. Altogether, 29 doctors died in the three year review period, but the other deaths were from natural or unspecified causes.

Abortion

All women need access to safe services—WHO

The World Health Organization published new guidelines on abortion care, aimed at tackling unsafe care that has led to around 39 000 maternal deaths a year. Interventions recommended at a primary care level include task sharing by a wider range of health workers, ensuring access to medical abortion pills, and making sure that accurate information on care is available to everyone. The guidelines call for the removal of medically unnecessary barriers to safe abortion such as criminalisation, mandatory waiting times, and limits on when an abortion can take place during pregnancy.

Public health

Improve care for vulnerable immigrants, says charity

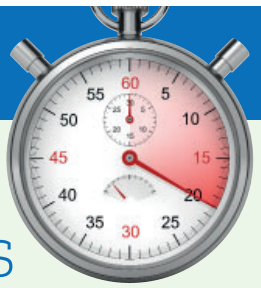
Vulnerable people released from immigration detention in the UK are too often left without crucial continuity of care, leading to quickly deteriorating health, said a report from Medical Justice, a charity that sends clinicians into immigration removal centres. The charity called on the Home Office to improve continuity of care for all people when released from their detention, including helping them to register with a general practice, informing the practice if the person is at risk, ensuring transfer of any secondary healthcare appointments, and ensuring that they have sufficient medication and their medical records.

Cite this as: *BMJ* 2022;376:o599

COVID DEATHS

Wales had Great Britain's highest rate of avoidable deaths from covid in 2020, with **36.1** deaths in every 100 000 people, compared with **28.5** in Scotland and **34.9** in England

[Office for National Statistics]



SIXTY SECONDS ON . . . RSV

IS THIS ABOUT A SURGE IN INFECTIONS?

No, rates of respiratory syncytial virus (RSV) in the UK are low, and the feared winter surge did not materialise. RSV activity usually peaks in winter, but 2021 saw an unusual rise in summer infections. This is thought to be an indirect consequence of the pandemic, with lockdowns and hygiene measures suppressing the spread of all viruses.

WHY IS RSV IN THE NEWS NOW?

Research in the *New England Journal of Medicine* showed that one injection of the monoclonal antibody nirsevimab administered to babies before the RSV season was 74.5% effective at preventing medically attended lower respiratory tract infection related to RSV and cut hospital admissions by two thirds.The study, funded by AstraZeneca and Sanofi, included 1490 healthy late preterm and term infants. The protection lasted for five months, an RSV season.

ONE JAB WOULD BE A HUGE ADVANCE

Yes, in the UK another monoclonal antibody, palivizumab, is licensed. But it needs to be injected once a month and is approved only for use in high risk infants. Other research, also published in *NEJM*, showed nirsevimab had a similar safety profile to palivizumab.

SO, ARE THESE VACCINES?

No, monoclonal antibodies are a type of passive immunisation rather than active immunisation, as they do not stimulate the body's own immune response.

ARE THERE VACCINES IN THE PIPELINE?

No, despite decades of research. Trials evaluating a potential vaccine for use in pregnant women were recently stopped by GlaxoSmithKline because of unspecified adverse events. But it is continuing a phase 3 trial of a vaccine in adults aged 60 and above. Several other companies are working on vaccines for pregnant women or older adults.

HOW SERIOUS IS RSV?

It's a common virus, and almost all children become infected with it by the age of 2 years. Most infections cause mild illness, but infants under 6 months may develop bronchiolitis and pneumonia. Children born prematurely or with underlying chronic lung disease, and elderly people with chronic disease, are also at increased risk of developing severe disease.

Jacqui Wise, Kent

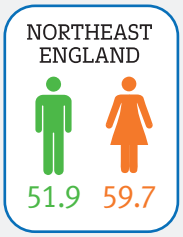
Cite this as: *BMJ* 2022;376:o590

Gains in healthy life expectancy in UK are stalling, data show

No improvement has been made since 2016-17 in reducing the number of years people in the UK live in poor health, and the situation is getting worse in some areas, official data show.

The latest data from the Office for National Statistics have led to immediate calls for a fundamental change in approach by the UK government to make improving health an explicit objective of every major policy decision.

The figures show there was no significant change in healthy life expectancy in 2018-2020, when compared with 2015-2017. But this masked big differences across the UK. Scotland registered the largest fall of more than a year among men and 11 months among women. The East Midlands was the worst affected area of England, with expectancy falling by 9.6 months for men. For England as a whole there was a slight reduction of 2.4 months for men, while it was static for women. There was no significant change in Wales and Northern Ireland.



Overall, northeast England has the lowest healthy life expectancy in the UK, at 59.1 years for men and 59.7 for women. Southeast England has the highest, at 65.5 years for men and 65.9 for women. David Finch, assistant director of healthy lives at the Health Foundation, said the differences meant a girl born today in North Ayrshire or Blackpool could expect to live 23 fewer years in good health than one born in the Orkney Islands.

The government has pledged to increase healthy life expectancy by five years and to shrink the gap between parts of the country, but a Health Foundation analysis found that, at current progress rates, this would take more than a century to achieve.

"There needs to be a fundamental shift in the approach, from a focus on people's individual responsibility and choices towards actively creating the social and economic conditions that enable them to live healthier lives," Finch said. "This means providing secure jobs, adequate incomes, decent housing, and high quality education."

Bryan Christie, Edinburgh

Cite this as: *BMJ* 2022;376:o592

OVERALL, the north east of England has the lowest healthy life expectancy in the UK at 59.1 years for men and 59.7 for women

Imposed contract forces general practices to open 9 to 5 on Saturdays

The BMA has said it is "bitterly disappointed" with NHS England's decision to impose changes to the GP contract without the union's agreement. The changes include a requirement for GPs in primary care networks to open from 9 am to 5 pm on Saturdays and 6.30 pm to 8 pm weekday evenings from October under new local arrangements.

The plans, outlined in a letter dated 1 March, specify changes to the Network Contract Directed Enhanced Service that aim to "remove variability across the country and improve patient understanding of the service."

The letter said, "The new offer is based on PCNs providing bookable appointments outside core hours within the enhanced access period of 6.30 pm to 8 pm weekday evenings and 9 am to 5 pm on Saturdays, utilising the full multidisciplinary team and offering a range of general practice services including 'routine' services such as screening, vaccinations, and health checks, in line with patient preference and need.

"PCNs will be able to provide a proportion of enhanced access outside of these hours, for example early mornings or on a Sunday, where this is in line with patient need locally and it is agreed with the commissioner."

Stalemate

GPs' current five year contract was negotiated between the BMA and NHS England in 2019-20, with provision for negotiated changes to the deal every year. But this year's negotiations reached a stalemate in February when the BMA said it had become clear NHS England would not be offering sufficient measures to ease pressure on practices.

Report: "England's GPs should become predominantly salaried"

General practice in England faces a wave of radical reform if the government adopts a Tory think tank's recommendations.

The report by Policy Exchange, offering solutions to rising demand and inadequate staffing levels, proposes phasing out the General Medical Services contract by the end of the decade and incentivising GP partners to become salaried and work at greater scale.

It envisages a £6bn "rescue package" to be gradually used to "buy out the GP owned estate." Some large "high performing" partnerships will remain, but GPs will eventually become "predominantly salaried and contracted by scaled providers," including "trusts, provider collaboratives, or large scale primary care operators," it proposes.

Significantly, the report is endorsed in a foreword by England's health secretary, Sajid Javid, who said, "The status quo is unacceptable."

But doctors' leaders said it failed to tackle what Martin Marshall, chair of the Royal College of General Practitioners, called "the elephant in the room: staffing." Neither does it directly acknowledge the failure of successive governments to meet repeated pledges to increase the size of the GP workforce.

Farah Jameel, chair of the BMA's England

A radical approach is necessary, but that does not mean taking a sledgehammer to the partnership model
Farah Jameel

HUGH HASTINGS/GETTY IMAGES

The BMA has not agreed or endorsed the changes, which it said failed to heed its call for extra funding to cover increased employers' national insurance contributions or to produce a funded pandemic recovery plan for general practice akin to the elective recovery plan in secondary care.

Farah Jameel, chair of the BMA England General Practitioners Committee, said, "We are bitterly disappointed that NHS England has chosen to ignore the appeals from the profession and the needs of patients.

"Despite our best efforts to outline a number of positive and constructive solutions, NHS England has instead decided to follow a path laid out three years ago, long before the arrival of covid-19, and roll over a contract that fails to tackle the current pressures faced by general practice.

"Failing to offer practices something as simple as reimbursement to cover additional costs for national insurance contributions means they are losing funding that should be going towards looking after patients. Therefore, a tax aimed at funding the NHS has become a tax on the NHS itself. The result will be fewer members of staff to care for the growing needs of patients."

Nikki Kanani, NHS medical director for primary care and a coauthor of the letter, said, "Our general practice teams have been working flat out throughout the pandemic to care for patients, and it is their huge efforts that have meant the NHS could protect millions of people at speed through the covid-19 vaccination programme.

"The NHS is focused on recovering services and tackling the backlogs that have inevitably built up, and so as part of the contract for general practice in 2022-23 extra funding will be given to primary care teams to increase checks for cancer and heart conditions for our patients."

Kanani added that the contract will see an increase in staff, including more mental health practitioners, and the option to book some appointments, such as for cervical screening, online for the first time.

HELEN SALISBURY, p 402

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2022;376:o560

OTHER CHANGES TO GP CONTRACT ANNOUNCED BY NHS ENGLAND

- Replacing the contractual requirement that at least 25% of practice appointments be available for online booking with a "more targeted requirement that all appointments which do not require triage are able to be booked online, as well as in person or by telephone"
- Requiring practices to respond to Access to Health Records Act requests for deceased patients, but removing the requirement for practices always to print and send copies of the electronic record of deceased patients to Primary Care Support England
- Extending the provision of £20m funding in the global sum for one additional year to reflect workload from subject access requests
- An additional £280m for PCNs to recruit staff, and
- A doubling of mental health practitioner roles to support people with complex mental health needs.

The NHS is focused on recovering services and tackling the backlogs
Nikki Kanani

GP Committee, agreed that a "radical approach is necessary to tackle staff shortages, unbalanced investment, and misaligned incentives," but added, "That does not mean taking a sledgehammer to the partnership model."

The main problem, Jameel added, was that "there are not enough GPs, and those that remain are being stretched thinner by the day. Every month, more and more GPs leave the service and the public are understandably horrified when they lose their local practice."

The report says the shift towards working at scale would be a continuation of the amalgamation process started under the primary care networks scheme, which most practices signed up to. PCNs should be retained, "but with an acknowledgement that groups of PCNs should be formally required to collaborate at both 'place' and 'system' level to achieve wider benefits of scale, with a possible shift to more formal ties," it says.

The report acknowledges that, while "interpersonal continuity—the trusted relationship between doctor and patient—carries significant benefits for certain patients," maintaining this "could be a challenge in the move to general practice at scale."

The report calls for a wider use of technological solutions and urges NHS England to enhance the NHS App "to provide a broader and more coherent range of first contact services." It also calls for "a 'smart' first contact primary care navigation programme called 'NHS Gateway'" to deliver a "more coherent, convenient, and personalised 'front door' to the NHS, while enhancing patient navigation and triage."

Redistribution

In essence, this would mean a "redistribution of current GP case volume towards other primary care professionals," it says.

The NHS should also make better use of technology to tackle shortages of GPs in deprived areas, it adds.

Marshall said that more funding, better technology, and improved premises would work only with enough GPs and other staff. He said, "The government needs to take radical action to expand the workforce and to deliver its 2019 manifesto pledge of an additional 6000 GPs and 26 000 additional practice staff by 2024—and this needs to include plans to keep existing, experienced GPs in the profession longer."

The paper also urges the government to "examine opportunities to enable NHS trained GPs to deliver remote sessions from overseas." It says there are almost 1000 GPs who have emigrated and who could be recruited.

However, this would require GMC rule changes, and the paper offers no thoughts on time zone differences.

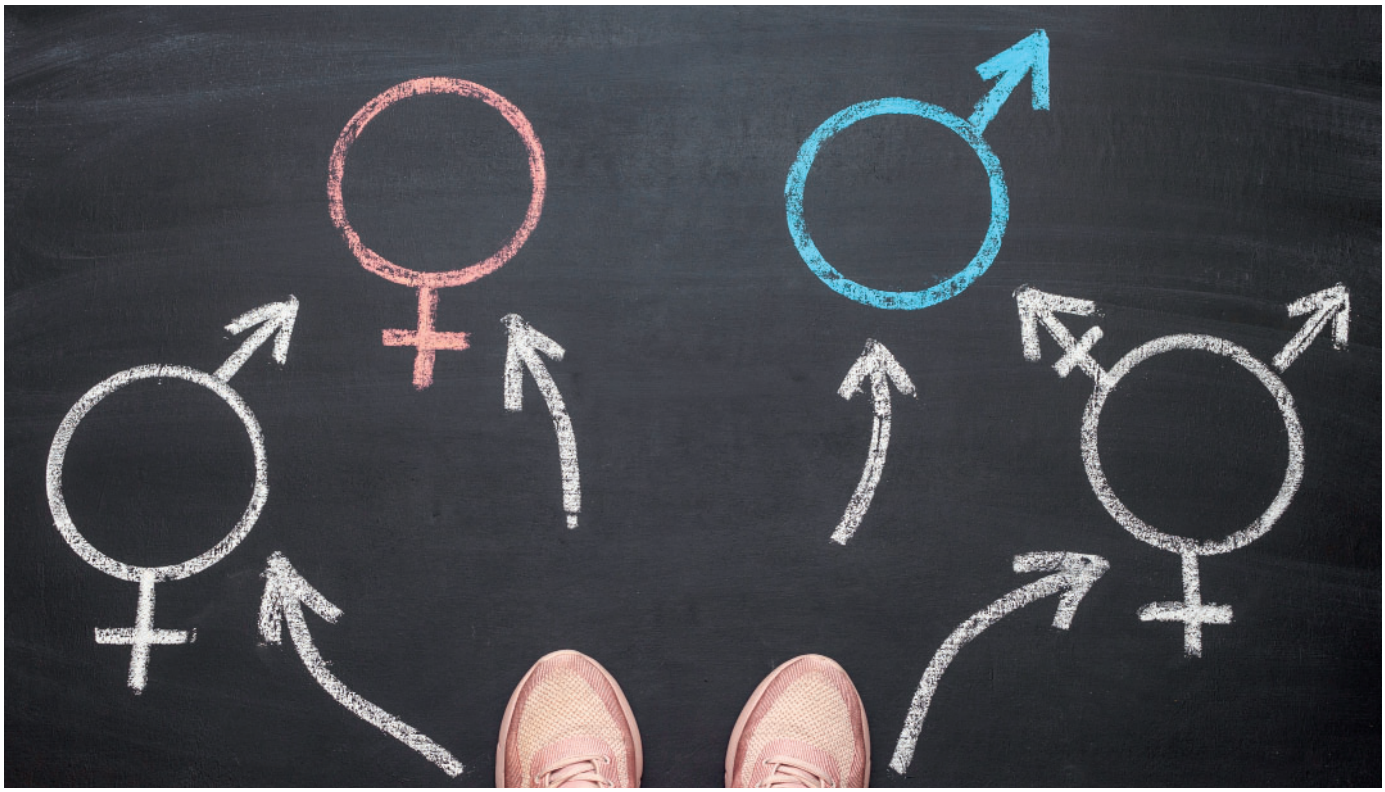
The report fails to tackle the elephant in the room: staffing
Martin Marshall

Jonathan Gornall, Suffolk

Cite this as: *BMJ* 2022;376:o594

Services for children with gender dysphoria need radical reform, says interim review

For the past 16 months the eminent paediatrician Hilary Cass has been investigating the care needs of children and teenagers who question their gender identity. **Clare Dyer** reports on her initial findings



SERGEY HRAMOV/SHUTTERSTOCK

A "fundamentally different" service model should replace the current system for assessing, caring for, and treating children and teenagers with gender identity problems, a review set up by NHS England has concluded.

Its interim report recommends that regional hubs should replace England's current sole service provider, the gender identity development service (GIDS) at the Tavistock and Portman NHS Trust in London, which has a waiting list of more than two years.

The review, chaired by Hilary Cass, a former president of the Royal College of Paediatrics and Child Health, calls for children and adolescents with gender incongruence or dysphoria to receive the "same standards of clinical care, assessment, and treatment as every other child or young person accessing health services."

It highlights major gaps in research on outcomes of treatment for gender dysphoria and a lack of routine and consistent data collection, making it difficult to design an evidence based assessment and treatment model. The small studies that have been done were mainly on birth registered boys showing gender incongruence from an early age, formerly the main cohort seeking treatment.

But from about 2015 there has been a steep rise in the number of birth registered girls coming forward in their early teens, who now form the main cohort. Many of the young people referred to GIDS have other mental health conditions, a third have autism or other types of neurodiversity, and looked-after children are over-represented.

Puberty blockers

The GIDS model requires it to decide whether young people with gender dysphoria should receive puberty blockers and, later, cross sex hormones and, if so, to refer them to paediatric endocrinologists to deliver the treatment. Some staff who have left GIDS accused it of being too ready to prescribe life changing physical treatments while leaving other aspects of the young people's distress unexplored.

After concerns about informed consent, a multiprofessional review group set up by NHS England now reviews cases being referred by GIDS to endocrinologists to ensure that procedures are being properly followed. The Cass review recommends that this should continue in the immediate term.

The review has been hearing from people with experience, professionals, and advocacy groups. It says that "its outcomes are not being developed in isolation or by committee but rather through an ongoing dialogue aimed at building a shared understanding of the current situation and how it can and should be improved."

In the longer term, it calls on service users, support groups, and professionals to collaborate with the review to reach an agreed way forward. To ensure that the new model is based on evidence, the review team has commissioned a literature review and a programme of qualitative and quantitative

research and has called for standardised data collection on cases.

The review advises that the regional centres be developed as soon as feasibly possible to assess and treat young people who might need specialist care as part of a wider pathway. Each would work with a range of local services to "ensure that appropriate clinical, psychological and social support is made available to children and young people who are in early stages of experiencing gender distress." Regional training programmes should be run for clinical practitioners at all levels, it says.

The aim is to develop a formalised assessment process, including differential diagnosis. "The assessment should be able to accurately identify those children or young people for whom physical intervention is going to be the best course of action, but it is equally important that it identifies those who need an alternative pathway or treatment," says the interim report. Paediatric endocrinologists would participate in the multidisciplinary team meeting that discusses the young people being considered for treatment.

Autism model

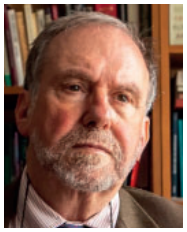
The review cites the example of autism as a condition for which standardisation of the process over time, together with an improved evidence base, made diagnosis more reliable and consistent.

GIDS came under the spotlight in 2019 when Keira Bell, who regretted taking puberty blockers and male hormones as a teenager and detransitioned back to her original female gender, took a case to the High Court, along with the mother of a 15 year old girl with autism who was on the waiting list. The court ruled that it was "very doubtful" that children under 16 would be able to understand the immediate and long term consequences of the treatment and to give informed consent, and it said doctors might want to consider court authorisation before giving over 16s the "experimental" treatment.

That decision was later overturned by the Court of Appeal, which held that it was for doctors, not judges, to take such decisions. David Bell, an adult psychiatrist who worked at the Tavistock for 24 years, applied to intervene in the appeal court case and told the court he had investigated the concerns of 10 clinicians who had worked or were working in GIDS. His report found "very serious ethical concerns as regards the modes of practice and the inadequacy of consent."

Clare Dyer, *The BMJ*

Cite this as: *BMJ* 2022;376:o589



There are very serious ethical concerns about GIDS' modes of practice
David Bell

The aim of the review is to develop a formalised assessment process, including differential diagnosis

TIMELINE OF EVENTS

2011

As part of a study, GIDS offers puberty blockers, previously available from age 16, to a group of children aged 12-15. From 2014 this became routine clinical practice

2020

JANUARY—Policy working group is established by NHS England, chaired by Hilary Cass (left), to review the published evidence on use of puberty blockers and cross sex hormones, but available evidence is not strong enough to form the basis of a policy position

AUTUMN—Cass review is set up by NHS England and NHS Improvement to make recommendations about services for children and teenagers who question their gender identity

NOVEMBER—Care Quality Commission takes enforcement action after an inspection rates GIDS overall as "inadequate," highlighting overwhelming caseloads, deficient record keeping, and poor leadership

DECEMBER—High Court ruling in case of Keira Bell (below) questions under 16s' ability to give informed consent to use of puberty blockers and suggests court approval may need to be sought

2021

MARCH—High Court decides in a separate case that parents can consent on behalf of under 16s

MARCH—NICE reviews use of puberty blockers to treat children and adolescents struggling with their gender identity and concludes that the evidence for their use is "very low"

SEPTEMBER—Court of Appeal overturns the Keira Bell judgment and rules that doctors, not judges, can decide whether a child under 16 can give informed consent to the use of puberty blockers

2022

MARCH—Cass review publishes interim report

THE BIG PICTURE

Brothers' visible scars of poverty

Afghani brothers reveal their scars after selling their kidneys on the black market to feed their families. The men live in Sayshanba Bazaar, on the outskirts of the city Herat, a settlement that is known as "one kidney village."

"We are still in debt and as poor as we were before," one of the brothers, Ghulam Nebi, told AFP news agency.

Illegal organ trading already existed in Afghanistan before the Taliban's takeover last year, but a combination of economic sanctions, severe drought, and covid have led to cases soaring. The western city of Herat, close to the border with Iran, is at the centre of the trade.

"I had to do it for the sake of my children," 32 year old Nooruddin told AFP from Herat. "I didn't have any other option. I regret it. I can no longer work. I'm in pain, and I cannot lift anything heavy," he told the agency.

Peter Kessler, a UN Refugee Agency spokesman based in Kabul, told *The BMJ* that 24 million people in the country, more than half of the population, are in need of lifesaving humanitarian aid. "Negative coping mechanisms, like selling kidneys, or even children, are a tragic symptom of Afghanistan's economic crisis," he said.

He added that 22 million people had been prioritised for assistance with a $4.4 bn (£3bn) aid appeal this year, the largest ever for a single country.

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2022;376:o587

WAKIL KOHSAR/AFP /GETTY IMAGES)

EDITORIAL

New EU trial reporting regulations

Trial reporting is now the law, but change will come only if it's enforced

In the mid-1980s, Australian epidemiologist Robert Simes called for an international system of prospective clinical trial registration to tackle prevalent non-publication of results.[1] Trial registries have since become a key regulatory tool. But trial results are still commonly withheld or incompletely reported.[2 3]

Europe's latest transparency effort is Clinical Trials Regulation 356/2014, which covers "clinical trials of interventional medicinal products" and legally requires technical and lay summaries of results to be reported within a year of trial completion. The regulation came into effect with the launch of the Clinical Trials Information System (CTIS) in January 2022, eight years after it was first approved. The CTIS will act as a regulatory portal, trial registry, and results repository. This should help improve transparency as well as reducing administrative burden for sponsors.[4]

Past EU efforts to improve clinical trials transparency have been ambitious in principle but underwhelming in practice. A previous directive created the EU Clinical Trials Registry (EUCTR), which launched in 2011. A year later, a guideline from the Commission required sponsors to post all trial results directly into the registry to ensure public dissemination independent of journal publication.[5] Compliance, however, has been poor. The European Medicines Agency has not even flagged unreported trials on the registry, despite a commitment in the guideline to do so.

In 2018, our EU TrialsTracker (eu.trialstracker.net) showed that only half of all expected trial results had been posted, mostly by industry.[5] Today, the tracker shows that nearly 80% of eligible results have been posted in the EU trial registry, a substantial increase in just three years, but this headline figure disguises deeper shortcomings. Poor data quality has been a persistent problem. In addition, any progress among academic institutions is largely driven by just a few high performing countries, such as the UK, Germany, and Belgium.[8]

JIM WEST/SPL

Some major academic institutions running trials in the EU have openly rejected calls to improve compliance

The UK in particular has taken a lead on trials transparency. Over recent years, the House of Commons Science and Technology Committee has energetically reminded research institutions of their obligations to report trial results, and hundreds of additional results have been added to the EU registry in response, helping to build public trust in research.[9] Sadly, no other European country has followed suit, and some major academic institutions running trials in the EU have openly rejected calls to improve compliance.[10]

Accountability

To ensure accountability, regulators should publicly track compliance with reporting obligations to the EU registry, as they should have been doing since 2012. Public identification of failures to report can motivate sponsors to improve behaviour.[11]

Enforcement is also key. The US Food and Drug Administration recently warned three sponsors of potential fines for non-reporting under US law, resulting in rapid compliance.[12] The new EU regulation empowers member states to create and enforce sanctions and penalties for non-compliance, and this work should begin immediately. Belgium is leading the way, becoming the first EU country to announce explicit penalties.[13]

Ethics committees and funders should also consider their responsibilities. A history of failure to report trial results should, for example, raise legitimate concerns about whether individuals or organisations should be trusted with access to patients and resources for research in the future.

Academic institutions should educate researchers about their statutory responsibilities. Actively managing research portfolios to ensure robust record keeping and oversight can help, and globally there is a growing profession of specialised staff charged with improving compliance. Any institution choosing to sponsor a trial should engage with this basic housekeeping now to avoid problems in the future.

Progress has been too slow for too long. Clinicians, patients, and the public cannot make informed choices about treatments when the results of clinical trials are routinely withheld or incompletely reported. The covid-19 pandemic has made clear the importance of building and maintaining trust in medicine and biomedical research. The ongoing failure to fully, accurately, and rapidly report trial results does needless harm to the credibility of medicine, industry, and academia. The EMA, other regulators, commercial sponsors, and universities should view this new EU regulation as a fresh opportunity to build a united front for transparency, and act.

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EDITORIAL

Ukraine: how can health professionals respond?

Join others in calling for an immediate end to the fighting

On 24 February, Russian forces invaded Ukraine. As politicians across the world continue to debate political, economic, and potentially military responses, the health consequences to consider are numerous and severe.

Most evident are the casualties from the conflict. Already substantial, these will grow as fighting continues. In the face of ongoing armed resistance from Ukrainians and fuel, weapon, and logistics shortages, fears are growing that President Putin could reduce Ukrainian cities to rubble. Those who view this as inconceivable should remember the devastation and bloodshed brought by Putin's forces in 2000 in Grozny, the capital of Chechnya.[2]

As in all conflicts, there are also major threats to public health. Beyond worsening shortages of water, food, and medicines caused by Russian attacks on vital infrastructure—these events are unfolding while Ukraine is still in the middle of the covid pandemic, with almost 25 000 new cases each day[3] at the time of writing and less than 40% of the population vaccinated. Ukraine has also had to deal with a polio outbreak that started in October 2021, in a population with very low immunisation rates. A catch-up immunisation campaign had started on 1 February but will be derailed by the fighting.

This invasion is only the latest exacerbation of tensions that date back to 2014, with Russia's annexation of Crimea. Conflict between Ukrainians and Russian backed separatists in the eastern region of Donbas had already resulted in over 1.5 million internally displaced people and a high burden of untreated post-traumatic stress disorder, depression, and anxiety.[4]

The current crisis could displace a further seven million Ukrainians,[5] many with injuries, or conditions requiring continuing medication. All need shelter and security.

ZUMA PRESS/ALAMY

The invasion of Ukraine is a public health catastrophe

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Wider international ramifications include Ukraine's importance to global food supplies. Ukraine is the world's second biggest exporter of grain. It provides much of the grain used in countries that are themselves in the middle of crises.[6] Lebanon, where storage capacity has yet to recover from a major explosion in Beirut port, receives 80% of its grain from Ukraine. Yemen, where bread prices have risen sharply in the past year, is also highly dependent on Ukrainian grain. The events in Ukraine can only exacerbate the suffering in these countries.

What we can do

So what can we, as health professionals, do, beyond contributing to humanitarian organisations working in Ukraine and neighbouring countries?

Firstly, we must join others, including fellow Russian scientists and health professionals,[7 8] to call for an immediate end to the fighting. This must go beyond exhortations that everyone should lay down their arms. We must distinguish right from wrong. There is no justification for Russia's actions, and Ukraine is entitled under article 51 of the United Nations Charter to defend itself. Russian forces must stop all hostilities and withdraw before causing further death and injury.

Secondly, European countries recovering from the pandemic face additional calls on the public purse. The end of the cold war brought a financial dividend as defence budgets were cut. However, it is now clear that in many cases this went too far, and, as in Germany, spending is likely to rise substantially.[9] We cannot call for more money to prevent threats from microorganisms but criticise spending to protect against actions by hostile states.

Thirdly, we need to add our voices to calls for stronger global governance. Although the Russian invasion is a clear breach of international law, the reality is that there is no way to hold the Russian government, as a permanent member of the UN Security Council, to account.[10] Russia has not agreed to the jurisdiction of the International Criminal Court. But neither has the United States. The world must make clear that adherence to international law is not optional.

Finally, and closer to home, the British government has never published the unredacted parliamentary report on Russian interference in British politics.[11] It is implausible that this is entirely unrelated to London's status as a global centre for money laundering. The corruption that often generates these funds deprives many health systems of money they need, causing untold death, disease, and misery.[12] We must demand that the UK cleans up this stain on its national reputation.

The invasion of Ukraine is a public health catastrophe, not just for those caught up in the fighting, but for countless others far beyond Ukraine's borders. Taken with the lessons of the covid-19 pandemic,[13] it should drive us to demand a safer and healthier world.

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FEATURE

"We've got to solve the retention side of things"—supporting workforce recovery after covid

The pandemic has stretched healthcare staff like never before. As part of the 2022 Nuffield Trust summit, *The BMJ* hosted a roundtable discussion looking at why workers leave the NHS and how staff wellbeing and retention can be improved. **Tom Moberly** reports

Why do staff leave the NHS?

Lucina Rolewicz, researcher, Nuffield Trust

"Around one in nine hospital staff—equivalent to 140 000 people—left active service in the year to September 2020. The latest annual levels of staff leaving the NHS are generally around pre-pandemic levels, having dipped during the pandemic.

"While current leave rates are fairly typical relative to previous years, there are certainly some reasons for great concern. First, we know that there is residual exhaustion and stress from the pandemic. Second, leaver rates have been suppressed because more staff who are at pensionable age were not retiring during the pandemic. And, third, we know that more staff than usual have taken the hard steps to leave. This includes, for example, a near doubling in the proportion of doctors contacting a recruiter or applying for training roles outside of medicine.

"The administrative data on reasons for leaving is fairly limited. However, data on those leaving NHS hospital and community roles—including those migrating to different jobs within the NHS—show stark increases in people citing work-life balance and their own health as reasons."

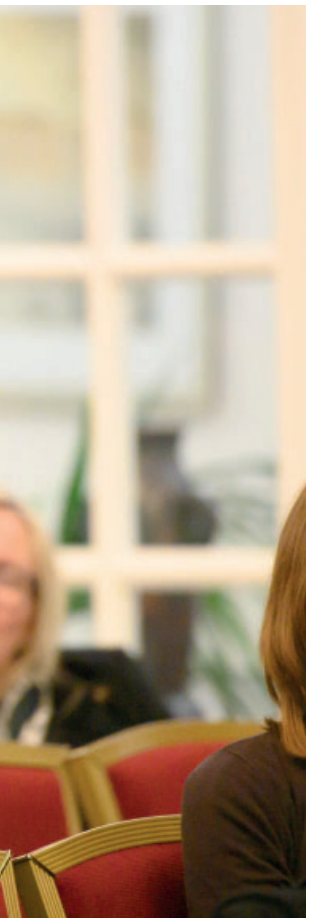
There's been a near doubling in the proportion of doctors contacting a recruiter

Rammya Mathew, GP and quality improvement lead for Islington GP Federation

"Since I started as a GP—and probably over the past 10 to 15 years or so—workload has increased exponentially within primary care. And this is in terms of both the number of patient contacts and the complexity of the work. People are asking, 'How am I going to sustain this for 10, 15, 20 years?' Looking at a long career in general practice is difficult at the moment.

"There are some promising things taking place. There's the GP retainer scheme. It allows people to choose either defined hours or a defined work schedule. It's allowing us to retain people who would otherwise leave. And we have made progress in terms of recruitment. Over the past four years, we've had successive years of increases in the number of GP trainees that we've recruited. That holds some promise for the future. But we've got to solve the retention side of things as well, because it's all well and good bringing new GPs in, but if we're not keeping them, it's not making things any better.

"The sad reality is that most of us sit in our consulting rooms and have little interaction with our colleagues. To restore that sense of wellbeing, we've got to have that time and space to meet together and to share what's going on in our lives. And also to talk about patients—it's good for them and it's good for us."



An area that deserves a bit more air time is workplace culture and inequalities

Danny Mortimer, chief executive of NHS Employers

"Supply is an important factor in retention. It gets harder to sustain doing extra hours and working extra shifts if you aren't given some sense by the government—and this is a government matter, a Treasury matter—of what the plan is for the future.

"We've got to make a massive cultural change in terms of attitudes to flexibility. This isn't just about flexibility for young people. It isn't just about flexibility for people who've got childcare responsibilities. It's about all of us wanting a very different relationship with how we plan our work.

"Organisations that can find more innovative and flexible ways of managing retirement can retain colleagues. That can be about offering part time working. It can be about educating people about what it is they can and can't do in terms of accessing their pension and then working."

We've got to make a massive cultural change in terms of attitudes to flexibility

Billy Palmer, senior fellow, Nuffield Trust

"A key reason for leaving is about opportunities and progression. We need to think about the extent to which we are offering the opportunity to increase your salary through progression. In terms of a policy lever, the current way in which we have pay review bodies is quite passive. They receive evidence from different bodies, but they don't do much in the way of commissioning research to actually answer the questions that matter. How do you prioritise the different motivations for getting people to join and stay in the NHS? That should be improved, given the importance of this matter.

"An area that deserves a bit more air time is workplace culture and inequalities. We know workplace culture is a key reason people leave. We know that one in eight NHS staff faced discrimination in the past year. We know that Bangladeshi candidates who are shortlisted are half as likely as white British people to be appointed from that shortlist. There are all sorts of matters that might be stopping people progressing and therefore they might be considering leaving. It's complex, but there are practical things that you can do to help identify the problem to then work out evidence based solutions."

Rose Penfold, National Institute for Clinical Research academic clinical fellow in geriatrics

"I asked a lot of my colleagues about the problems they face and the reasons they've thought about leaving, or have left, the NHS as trainee doctors. One key theme is a lack of flexibility—both geographical and around rotas and rostering, and the hours that trainees are required to work.

"One of the problems is about movement of national training numbers between regions. Historically that has been difficult to do. Not only do you have to have a statutory reason for doing it, but you also have to show detailed evidence of that. Removal of some of these barriers could enable people to move between regions and stay within the workforce when otherwise they may leave.

"E-rostering and e-rotas open up opportunities for more flexible working. A lot of my peers who are registrars in London want to work less than full time or to change their hours. Facilitating that would allow people to stay in the workforce more easily. It's been piloted and shown to be successful, and should be rolled out more widely."

Partha Kar, diabetes consultant and NHS England national adviser for diabetes

"We talk a lot about what the system should do differently. I don't think we look enough at what we can do. We, as consultants within secondary care, can probably do more with trainees. That pastoral role has been lost. I don't think it takes that long to make your trainees a cup of tea or coffee, or sit down or walk with them and say well done. I don't think we do enough of that.

"Mentorship has become a tick box exercise. But a lot of our mentorship was also about 'How are you doing? What's going on? What's happening in your life?' That time seems to have gone. Consultants are just struck by the busyness of the system. I don't know if any consultants wouldn't want to help.

"On the retention side, there is massive inequality—sexism, racism—and this is not an insignificant thing. Those are the things we need to do much better. The system needs to be much more robust."

Mark Britnell, vice chairman of KPMG UK

"There's a clear difference between those countries that are thinking hard about their staffing levels and those that are still on the starting blocks. Over the past two or three years in the UK there have been at least one, if not two, false dawns in terms of a new workforce strategy. We need to do more and we need this workforce plan sooner rather than later.

"When you look at the supply side in terms of clinicians, you have to think about recruitment and retention. The best workforce strategies I've seen around the world give hope in the short term and more hope in the longer term. You need to have a plan. Where you've got the NHS, which is a near monopoly employer of doctors and nurses in this country, it's important to have a signpost over the next five and 10 years for exactly how many more colleagues will be joining their ranks. And, sadly, we have failed to do that."

The best strategies give hope in the short term and more hope in the longer term

Neil Greenberg, professor of defence mental health, King's College London

"There is good evidence that making sure that teams work well to support each other makes a big difference. Making sure that all who are in a supervisory position can speak about mental health with their staff is absolutely critical.

"If you have a supervisor who feels capable of speaking about mental wellbeing with their staff, that makes a substantial difference to staff mental health and to people's ability to perform and to stay in their role.

"The mental health of healthcare workers has been problematic for a long time, and I hope that the catalyst that covid has created does place mental health support at work front and centre because it's good for staff. It's also good for the output of the healthcare systems that we are hoping to have."

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DATA BRIEFING

The public finance cost of covid-19

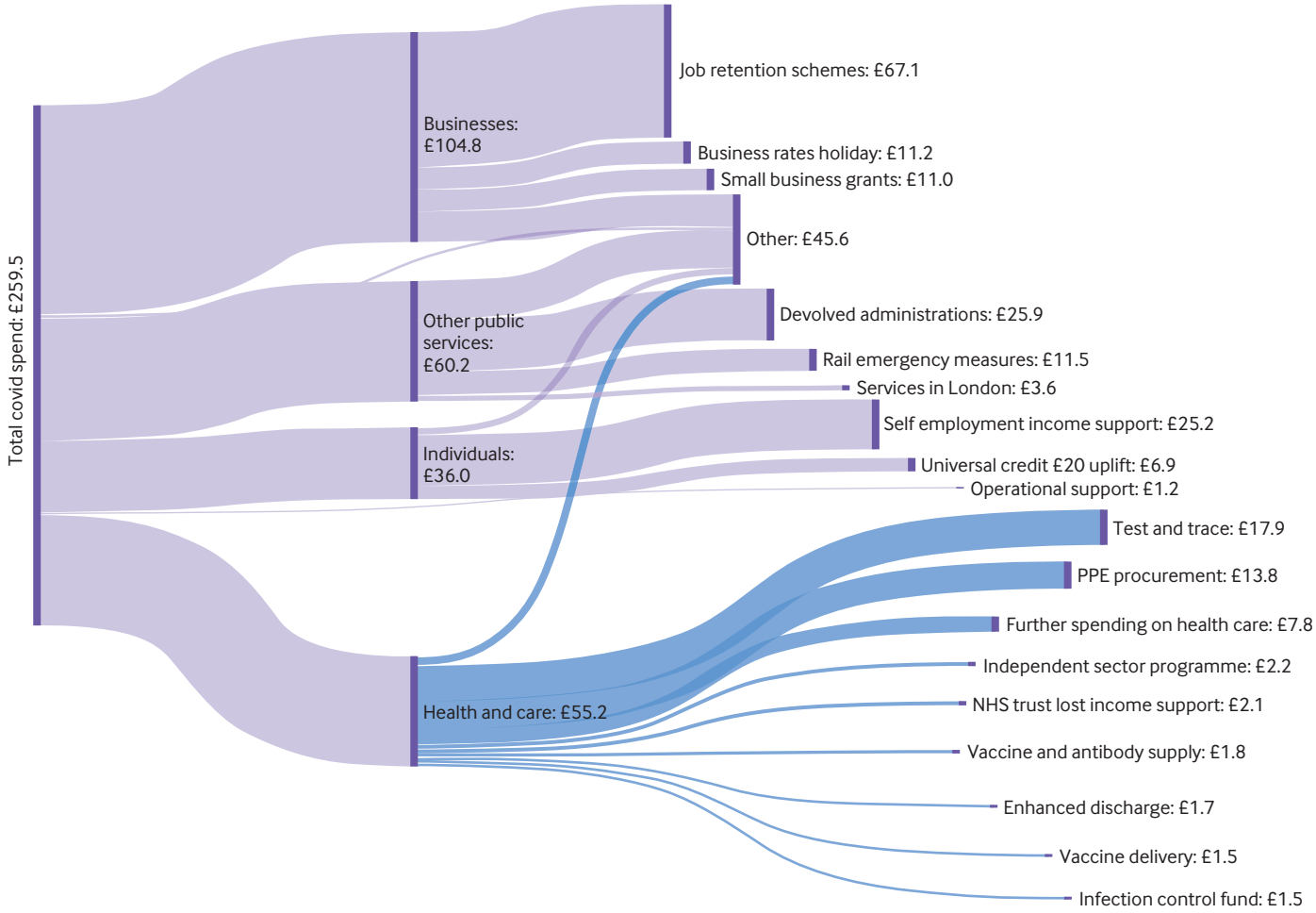
On top of the human cost, the financial impact of the pandemic has been huge. **John Appleby** looks at how much the response has cost, and what the money has been spent on

Official figures show that, globally, the covid-19 pandemic has so far claimed 5.8 million lives. But this is highly likely to be an underestimate, and some models indicate that the true excess death toll could be between 12 and 22 million. In the UK, 159 295 people have died so far, equivalent to the entire population of York.

Other costs of covid-19 include disruption to millions of children's education, lost earnings, unemployment, and lost economic output. The public finance cost of covid-19 has also been enormous. But how much is it? And what has it been spent on?

The National Audit Office has been tracking public spending on covid related measures and, as at its last update in September last

Actual UK public spending on covid-19 measures as at September 2021 (billions).[3]



year, estimates that the expected lifetime public finance costs stand at £368bn. This is equivalent to around £5500 per person in the UK and over double the annual spend on the NHS.

Some of this budgeted spend includes loans—mainly to support businesses. The expected volume of total loans amounts to £134bn. Support for businesses is expected to consume around 42% of the lifetime costs of all support, but support for health and care—budgeted at £84.3bn (23% of the total)—is the next largest area of spending.

All these figures represent a best estimate of what might be spent over the lifetime of the support. What has actually been spent in total on covid related measures as of September last year is estimated to amount to £260bn (figure). For health and care, the National Audit Office estimates that around £55.2bn of the £84.3bn budgeted for health and care support has been spent. Around 75% of this spending is accounted for by the test and trace programme (£17.9bn), procurement of personal protective equipment (£13.8bn), additional spending on the NHS (£7.8bn), and vaccine and antibody supply (£1.8bn).

What has actually been spent in total on covid related measures as of September last year is estimated to amount to £260bn

The sums involved in supporting health services, individuals, and the wider economy have been huge, and whether every last pound has been spent to best effect is debatable. But we must bear in mind the cost of not spending this money—the impact on people's lives and the economy of financial inaction would have been much more costly. An indication of these costs comes from early modelling in 2020, which estimated that, without any mitigation, global covid-19 deaths could have amounted to around 40 million.[4] More recent estimates indicate that this was an overestimation, but still predict around twice the number of deaths than have occurred so far.[5]

Researchers have also examined the impact on the UK's gross domestic product, compared with the size that the economy would have been expected to reach had there been no pandemic. Even with the extra support spending, one study estimated that the UK lost the equivalent of 19% (£430bn) of its pre-covid gross domestic product across 2020 and 2021.[6]

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BRIEFING

What do we know about omicron sublineages?

Last November WHO designated omicron a variant of concern. With its sublineage BA.2 now widespread, **Elisabeth Mahase** looks at what science has found out about the variant and its three (so far) variations

BA.1 (B.1.1.529.1)

The original SARS-CoV-2 omicron variant is B.1.1.529.1, the version that most people think of when omicron is referred to and that currently makes up more than nine in 10 omicron cases. BA.1 has so far spread to more than 130 countries and is characterised by a significant number of mutations, including 37 on the spike protein.

The World Health Organization says BA.1 is more likely than delta to infect and replicate in the upper respiratory tract, whereas delta targets the lower respiratory tract. This difference may be behind the transmission advantage that BA.1 has shown but could also be the reason for its seeming to lead to less severe disease than delta.

However, although BA.1 infection is generally associated with lower severity, its increased transmissibility has resulted in high numbers of patients being admitted to hospital, putting a big strain on healthcare systems. It is also associated with a 5.4-fold higher reinfection risk than delta.

Current covid vaccines seem to provide strong protection against severe disease and death from BA.1 infection. Early reports indicated that the two dose covid vaccine schedule had reduced effectiveness against milder disease caused by BA.1 than previous variants. Administration of a third "booster" dose was found to provide greater protection.

Looking at treatments, ronapreve (a combination of the monoclonal antibodies casirivimab and imdevimab) has been found to have reduced efficacy against BA.1. Another antibody treatment, sotrovimab, seemed to retain activity against the BA.1 spike protein in laboratory experiments and is likely to be added to the Recovery trial for clinical examination. The antiviral molnupiravir has also been found to remain active against BA.1 in six preclinical studies, although it has not yet been assessed in clinical studies.

BA.2 (B.1.1.529.2)

BA.2 has fewer mutations than BA.1, with 31 on the spike protein. WHO reported that by 30 January it had reached at least 57 countries, while nearly 50 000 cases had been confirmed up to 3 February.

The UK Health Security Agency has reported that across England BA.2 has an "increased growth rate" in comparison with BA.1 and that, although growth rates can be overestimated in early analyses, the "apparent growth advantage is currently substantial." Meanwhile, contact tracing data show that people infected with BA.2 are more likely than people with BA.1 to infect household contacts. The agency has said there are currently no data on the severity of BA.2.

Wendy Barclay, head of infectious disease at Imperial College London, said that much was still unknown about BA.2 but that it did have the same "double whammy ability" as BA.1, with many changes in the spike protein meaning that the antibodies the population has made against vaccines or previous infection were not able to "see the virus very well."

Early investigations showed that BA.3 has 33 mutations in the spike protein, of which it shares 31 with BA.1

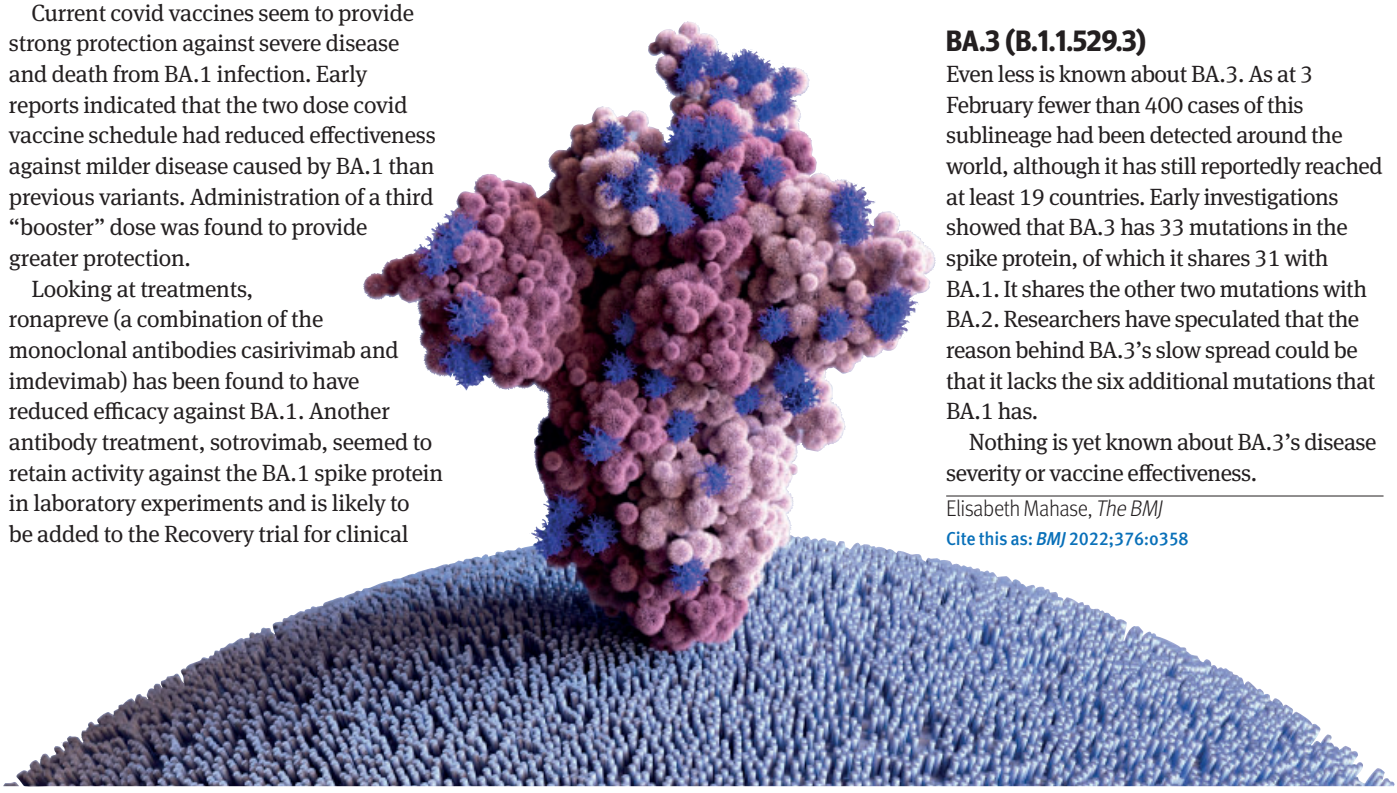
She suggested that BA.1 may have compromised its own ability to infect and reproduce because of the vast number of changes it has accumulated. BA.2, with fewer changes, may have "struck a better balance with the escape from antibodies, while maintaining good transmissibility."

Preliminary investigations by the UKHSA found no evidence of decreased vaccine effectiveness against symptomatic disease for BA.2 when compared with BA.1. At least 25 weeks after two doses, vaccine effectiveness against symptomatic infection was reported as 13% for BA.2 (versus 9% for BA.1). At two weeks after a third booster dose this increased to 70% (versus 63% for BA.1).

BA.3 (B.1.1.529.3)

Even less is known about BA.3. As at 3 February fewer than 400 cases of this sublineage had been detected around the world, although it has still reportedly reached at least 19 countries. Early investigations showed that BA.3 has 33 mutations in the spike protein, of which it shares 31 with BA.1. It shares the other two mutations with BA.2. Researchers have speculated that the reason behind BA.3's slow spread could be that it lacks the six additional mutations that BA.1 has.

Nothing is yet known about BA.3's disease severity or vaccine effectiveness.



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