this week

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JAMES MANNING/PA/ALAMY

"Where's staff strategy in recovery plan?"

Sajid Javid, England's health secretary, visits University College Hospital's proton beam scanner, last week. His recovery plan includes new targets for cancer care

The government has promised to build more surgical and community diagnostic hubs in England and to give patients greater control over their healthcare provider as part of its long awaited recovery plan for elective care to reduce the NHS backlog.

But the targets set out on Tuesday will not be met without the staff to run the expanded services, health leaders have warned.

Andrew Goddard, president of the Royal College of Physicians, said the plan depended on the "recovery of urgent and emergency care, as the two are entwined both with respect to workforce and estate."

He added, "We will also need to build on it with a full plan for recruiting enough new staff to meet patient demand and the steps we'll take to retain existing staff, including flexible and remote working for those returning to practice. Targets help patients to understand what they can expect, but they cannot be met without a supply of clinicians sufficient to meet the demand."

The plan says by March 2025 the NHS will eliminate waits of longer than a year for elective care and that by July 2022 no one will wait longer than two years. By April 2023 this should be reduced to 18 months.

The plan promises the NHS will provide around nine million more tests by 2025 and that clinicians will be able to get instant access to results. Over three years, 17 million more diagnostic tests will be delivered, a rise in diagnostic capacity of a quarter over the three years before covid.

It also promises that three quarters of patients who have been referred urgently by their GP for suspected cancer will have cancer diagnosed or cancer ruled out within 28 days and that by March 2023 the number of people waiting more than 62 days after an urgent referral will be back to pre-pandemic levels. Overall, the plan will deliver around 30% more elective activity by 2024-25 than before the pandemic.

Additional surgical hubs, on top of the 122 operating across England, will be set up to carry out routine operations, so emergency cases do not disrupt operations and cause cancellations or delays.

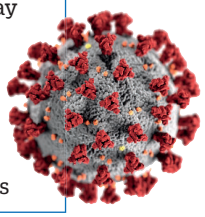
NHS trusts will also receive extra funding to expand capacity and invest in sites, such as modular operating theatres and mobile diagnostic centres for cancer, as part of a £700m scheme that will be split between 870 projects across 180 trusts.

A new digital service for patients will be launched to give those waiting for elective care an estimated waiting time and the

(Continued on page 214)

LATEST ONLINE

- Only a third of children in need accessed mental health support in the pandemic
- Long covid: "Holistic" approach is best, given range of symptoms, say researchers
- Past infection may not protect against future variants, researcher warns



SEVEN DAYS IN

Covid: Vulnerable adult must be vaccinated against parents' wishes, judge rules

The High Court has ruled that a highly vulnerable young adult who lacks the capacity to make his own decisions must be vaccinated against SARS-CoV-2, despite his parents' fears that the vaccine could seriously harm or even kill him.

DC, aged 20, lives in a care home in the north west of England where he is the only unvaccinated resident. He has schizencephaly, microcephaly, cerebral palsy, curvature of the spine, dystonia, intermittent stridor, and pseudomonas of the lungs. He weighs as little as a small child and has several hospital admissions a year for respiratory illnesses.

Judge Simon Burrows accepted that DC's parents, who were not opposed to vaccines in general, had a rational basis for their stance and that they would be "distraught" at his decision. DC's father, a professional risk assessor, although outside the medical or pharmaceutical fields, was particularly concerned about a family history of blood clots.

Burrows said he found the balancing exercise to determine DC's best interests "very demanding." But his main reason for allowing the local clinical commissioning group's application to vaccinate was the positive effect on DC's enjoyment of life. Unvaccinated, he was not allowed to attend events and had to be isolated for 10 days after home visits.

Clare Dyer, *The BMJ* Cite this as: *BMJ* 2022;376:o308

Covid-19

Government writes off £10bn spent on PPE

The government has written off almost £10bn of spending on personal protective equipment that was unusable, above the market price, or not delivered, official accounts showed. Gareth Davies, head of the National Audit Office, said that the Department of Health and Social Care for England had "rapidly increased its risk appetite and adapted its normal processes" in response to covid but was "not able adequately to manage some of the elevated risks, resulting in significant losses for the taxpayer and leaving the department open to the risk of fraud." He said that £3.6bn worth of stock was unaccounted for.

Cancer

Evidence is sought for new 10 year strategy

England's health and social care secretary, Sajid Javid, has called for evidence to underpin an ambitious 10 year cancer plan for England that he hopes will lead to world leading cancer care with earlier diagnoses and innovative treatment to improve outcomes. The plan also aims to boost the cancer care workforce, tackle disparities and inequalities, and improve prevention. "Let this be the day where we declare a national war on cancer," said Javid. "This plan will show how we are learning the lessons from the pandemic and apply them to improving cancer services over the next decade." Anyone can submit evidence up to 11.45 pm on 1 April at gov.uk/government/consultations/10-year-cancer-plan-call-for-evidence.

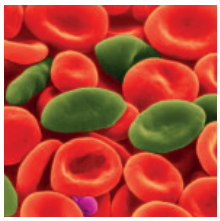
NHS

Public concern about pressure on staff

The public's priorities for the NHS included reducing pressure on staff (37%), increasing the number of staff (36%), and reducing waiting times (35%), found a survey by the Health Foundation with 2102 respondents (with a 58% response rate). It also found that 57% of respondents thought the standard of care provided by the NHS had worsened in the past 12 months. Tim Gardner (below), senior policy fellow at the foundation, said, "The public clearly wants to see the health service supported to recover from the pandemic, not radical changes to the NHS model."

Government was negligent over finance schemes

The government failed to properly supervise two finance schemes it adopted from a company that has now gone into insolvency, leaving the taxpayer out of pocket, concluded MPs on the House of Commons Public Accounts Committee. They criticised government dealings with Greensill Capital that provided the Pharmacy Earlier Payment Scheme (PEPS) to pharmacy contractors and the Employer Salary Advance Scheme, which allowed NHS employees to access their earned salaries ahead of payday. Neither scheme delivered what it promised, and there was no clear rationale for introducing them, said the MPs.



Obesity

NICE recommends weight loss drug for obese adults

Adults who have a BMI of at least 35 and a related comorbidity should be offered semaglutide alongside a diet and exercise plan, NICE has said in draft guidance. A clinical trial found that participants lost 12% more weight on average with the once weekly injectable drug than those who had weight loss coaching only. The treatment will also be offered to people with a BMI between 30 and 34.9 if they have been referred to tier 3 weight loss services or if they have a south Asian, Chinese, black African, or Caribbean family background (BMI threshold reduced by 2.5).

Regulation

London trust must improve sickle cell service

The Care Quality Commission has told North Middlesex University Hospital Trust to make improvements to its services for patients with red blood cell disorders, such as sickle cell disease and thalassaemia, after an unannounced focused inspection last August. The inspection followed a serious incident that had led to the avoidable death of a patient in 2019. The CQC said that the trust gave limited support to its services, staff lacked training, patients experienced delays in treatment, and numerous safety incidents had occurred. In November an inquiry found that many patients in England with sickle cell disease faced substandard care and negative attitudes among NHS staff, and some patients were exposed to blatant racism.

MEDICINE

Net zero

Legal challenge to make strategy stronger by June

The Good Law Project has launched a legal challenge against Kwasi Kwarteng, the business, energy, and industrial strategy secretary, to force his department to make the UK's net zero climate strategy fit for purpose by 30 June. It said the strategy failed to meet duties under the Climate Change Act 2008. Jo Maugham, the project's founder, said, "What we need is a real plan, starting now, for how we get to net zero. To do anything else is to lie to our children."

The UK's green strategy does not meet legal obligations, says the Good Law Project

Afghanistan

UK charity launches Karen Woo award scheme

An award named after Karen Woo (above), a British doctor who was killed by terrorists while working in Afghanistan in 2010, has been launched by the UK Afghan Healthcare Professionals Association and the UCL Hospitals Charity (uclhcharity.org.uk). It offers an annual award, worth at least £1000, which could be used to buy medical supplies, to help a health professional in Afghanistan spend time in the UK, or to enable a UK professional to work in Afghanistan. Narinder Kapur, visiting professor of neuropsychology at UCL, has donated £10 000 to the award and hopes others will help it expand.

Opioids

Hospital admissions in England rise sharply

Opioid related hospital admissions in England rose by 48.9%, from 10 805 in 2008 to 16 091 in 2018, an analysis in the *Journal of the Royal Society of Medicine* found. The rise was 40% higher than the increases for alcohol or illicit drugs. The rise was highest among people over 55 (160%), people living in the most affluent areas (93%), and patients with four or more comorbidities (627.6%).

Menopause

UK consults on HRT as pharmacy medicine

The UK's medicines regulator is consulting on whether the vaginal tablets Gina 10 mg, which contain estradiol to treat dryness, should be made available over the counter for women over 50 who have not had a period for a year. The Commission on Human Medicines has advised it is safe to be made available without a prescription. The consultation is open until 23 February at bit.ly/3sh0lBF.

Gene therapy

NHS makes deal on world's most expensive drug

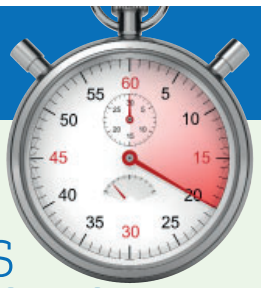
The NHS agreed a "substantial" discount for babies and young children with metachromatic leucodystrophy (MLD) to be treated with Libmeldy, a gene therapy with a reported price tag of £2.8m. MLD usually develops in babies aged under 30 months, leading to loss of sight, speech, and hearing, as well as brain impairment, seizures, and eventually death. Libmeldy, made by UK based Orchard Therapeutics, works by replacing the faulty gene in patients' stem cells, which are then re-injected into the patient.

Cite this as: *BMJ* 2022;376:o330

FOOD POVERTY

The proportion of UK households that experienced food insecurity rose to 8.8% (4.7 million adults) in the past month, up from 7.3% in July 2021

[The Food Foundation]



SIXTY SECONDS ON . . . FOOD ON PRESCRIPTION

YUM! I'LL HAVE STEAK WITH TRIPLE COOKED CHIPS, PLEASE

This is not a restaurant. We're talking about the proposal in the "levelling-up" white paper for general practices to pilot prescribing healthy food to tackle health inequalities and reduce the UK's widening gap in healthy life expectancy.

OH. HOW ABOUT AVOCADO ON RYE?

As I said, this is NOT A RESTAURANT. And neither are general practices the place to help prise the nation from its addiction to fast food and sugar laden drinks, if reactions to the proposal are anything to go by.

DID THE IDEA GO DOWN WELL?

You know when you suck a lemon? The GP and *BMJ* columnist Helen Salisbury called it "disrespectful and demeaning." "Please leave doctors out of this," she tweeted, highlighting that the root of health inequalities is poverty.

OUCH! WHAT'S FOR MAINS?

The campaigner Jack Monroe (below) served up an 11 course retort. The people in greatest need don't have the bus fare or state of mind to engage with GPs, she said, and trying to turn "overworked, underfunded, overstretched" GPs into "ad hoc social workers" won't help.

ANYTHING FOR AFTERS?

Monroe believes the only people likely to benefit are the companies that get contracts. She pointed to Chartwells, which was forced to apologise after its food parcels sparked an investigation in early 2021. Labelled "poverty picnics" by Monroe, £30 parcels contained about £5 worth of items.

SO, WHAT'S A BETTER RECIPE?

Cash first. It's a policy advocated by many organisations working with people in poverty. IFAN (the Independent Food Aid Network) says tackling the root cause of poverty would allow everyone in the UK to buy adequate and nutritious food.

STUFF MOUTHS WITH GOLD?

If you mean adequate benefits, wages that match the cost of living, and cash grants for people in crisis, then yes. IFAN says emergency cash transfers help people afford basic healthcare and more nutritious food, while giving them dignity, autonomy, and choice.

Zosia Kmietowicz, *The BMJ*

Cite this as: *BMJ* 2022;376:o318

(Continued from page 211)

ability to swap to a different provider if they are waiting too long.

On the staffing crisis, the plan says that more than 10 000 nurses will be recruited from overseas this financial year, with particular focus on those with experience in critical care and theatres. However, this is part of the 50 000 extra nurses previously announced. Five thousand support workers will also be recruited this year, while the introduction of new roles, such as anaesthetic associates and first contact practitioners, will be accelerated.

Meanwhile, the NHS will continue to rely on NHS reservists (the volunteer scheme), with the programme now being rolled out nationally from eight pilot areas. Volunteers will be used while "new contingency staffing models" are developed. Additionally, temporary banks will be made "more attractive" by paying staff promptly and offering more permanent roles or development opportunities.

Staff and sites

Commenting on the plan, the NHS Confederation's chief executive, Matthew Taylor, queried how the new surgical and diagnostic sites would be staffed.

"The single biggest barrier to stopping this plan from being achieved is the absence of a fully costed workforce strategy," he said. "The NHS is committed to an ambitious reform agenda and to delivering value for money to the taxpayer, but the backlog of long waits will not be cleared by March 2025, and it will be impossible to carry out nine million more tests and checks if there are not the right number and mix of staff in place."

Richard Murray, chief executive of the King's Fund, agreed, saying, "Without enough staff these targets will remain aspirational numbers rather than real change for patients. To tackle the staffing crisis, government must move beyond repeating manifesto pledges and come forward with a fully funded workforce strategy."

Elisabeth Mahase, *The BMJ*

Cite this as: *BMJ* 2022;376:o343

Michael Gove's reliance that the money will 'trickle down' to those who will benefit is, simply, inappropriate by an order of magnitude
Michael Marmot

J SHAW BAKER/SHUTTERSTOCK

"Levelling up has to focus on health inequalities"

The government's strategy for closing the gap between rich and poor parts of England will need more funding and a greater focus on health inequalities to succeed, experts have warned.

The "levelling up" white paper, published on 2 February, outlines ambitious targets for reducing regional inequalities by 2030 and sets out 12 "missions" across a wide range of areas, including health, education, and living standards.

Targets include narrowing the gap in healthy life expectancy between the best and worst local areas by five years by 2030 and raising overall healthy life expectancy by five years by 2035. The plan also pledges to improve wellbeing in every area of the UK, to close the wellbeing gap between top performing and other areas by 2030, and to increase public investment in research and development outside the south east of England by at least 40% by 2030.

The promise to level up was a key pledge of the Conservatives' 2019 election manifesto. The white paper does not commit substantial new funding and focuses on ensuring funding already allocated is spent effectively. The government's levelling-up secretary, Michael Gove, said the aim was to bring existing initiatives on the policy agenda together and establish a means for measuring progress.

Michael Marmot, director of the Institute of Health Equity and an expert on health inequalities, said additional funding was required. "The £5-6bn currently allocated to levelling up is tiny given the historical scale of the problem," he said. "Gove's reliance that the money he is putting in will 'trickle down' to those who will

UK approves protein based covid vaccine

The UK's regulator has approved a covid vaccine that uses an established technology and so may prove attractive to people who are reluctant to be vaccinated.

Novovax's Nuvaxovid is the fifth covid vaccine authorised by MHRA and the first to be protein based. It was approved by the European Medicines Agency in December.

At the start of the pandemic there was much interest in the Novavax vaccine, but its development and approval have been beset by delays.

A phase III UK trial involving 15 000 people showed the vaccine to be 89.7% effective at preventing symptomatic disease caused by the original Wuhan virus and the alpha variant. A study conducted in the US and Mexico with almost 30 000 people showed the vaccine offered 90.4% overall efficacy against illness and 100% efficacy against serious disease. The incidence of serious adverse events was low in both studies.

Nuvaxovid could have an important role because of its traditional manufacture

A recent phase II study, published as a preprint and not peer reviewed, suggests its protection holds up much better against omicron than that of most other vaccines. It is stable in a refrigerator at 2-8°C, making it easy to distribute.

The UK approval authorises the use of the vaccine in people aged 18 and over for a first and second dose. The manufacturer said it will apply for it to be used as a booster and for adolescents.

benefit is, simply, inappropriate by an order of magnitude. What is needed is a scale of social and financial investment that would take the evidence and put it into practice and target the right areas, not those that need it less."

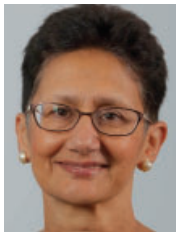
Specific public health pledges include asking GPs to pilot prescribing healthy food, a new tobacco control plan in 2022, and at least 100 community diagnostic centres in England by 2025 to improve early screening.

The BMA's president, Neena Modi, said the paper delivered "less than we hoped," particularly on health. "With limited funding announced, we hope that the proposals to tackle health inequalities are given the priority they need," she said. "The paper focuses on regional inequalities, but we feel that there is a missed opportunity here for support for groups who have poorer health. For example, people from ethnic minority and socioeconomically disadvantaged backgrounds suffer greatly in areas such as maternal and infant mortality, cardiovascular disease, diabetes, and covid and so need well calibrated interventions regardless of where they live."

The government said a separate white paper on health disparities would be published later this year.

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2022;376:o303



This is a missed opportunity for support for groups who have poorer health
Neena Modi

In August 2020 the government agreed to buy 60 million doses of the vaccine. The Joint Committee on Immunisation and Vaccination must still decide how the vaccine will be used as part of the covid vaccination programme.

Paul Heath, principal investigator of the UK arm of the Novavax vaccine trial and director of the Vaccine Institute at St George's University of London, said that although 84% of people in the UK had now had two doses of a covid vaccine Nuvaxovid could still have an important role because of its traditional manufacture. He added, "The vaccine may also be more acceptable to pregnant women, as it uses the same technology as the pertussis or influenza vaccines that they already receive routinely."

The vaccine uses the full length spike protein. Filip Dubovsky, chief medical officer at Novavax, told a briefing that the vaccine contains antibody targets that are common to a wide range of covid variants. "It broadens the immune response. It generates high levels of neutralising antibodies," he said.

Jacqui Wise, Kent

Cite this as: *BMJ* 2022;376:o309

Employers and government must act on racism, says BMA

The NHS has "unacceptable" levels of racism that can't be ignored, the BMA's chair of council has said about the findings of a survey into doctors' experiences.

Chaand Nagpaul said the interim results of a BMA survey highlighted how racist experiences affected doctors' retention, wellbeing, and career progression. "Employers and the government have a duty of care to address the concerns of those who work within the health service," he said. "Decision makers must get their heads out of the sand and act now."

The online survey was open to all doctors and medical students working in medical workplaces in the UK. Three quarters (75.6%) of the 2030 respondents said they had experienced racism at least once in the past two years, and 17.4% experienced racism regularly. It found that 20% of those who had experienced racism reported racist behaviour among patients. One junior doctor of Asian background told the BMA, "Working in A&E was a nightmare: continued racist behaviour from patients and their relatives. Due to this, I have decided not to pursue a career in emergency medicine."

A consultant of "other" ethnic background said, "A patient suggested I can be deported if they suffer post-op complications."

CHRIS J RATCLIFFE/GETTY IMAGES

The survey found that 60% of Asian, 57% of black, 45% of mixed, and 36% of white non-British respondents saw racism as a barrier to career progression, whereas only 4% of white British respondents thought this

Fear of reprisals

More than 70% of doctors who had experienced racism at work did not report it because they had no confidence the incident would be dealt with or they feared they would be labelled a troublemaker. Nearly six in 10 found that when they did report a racist incident it had a negative effect on them.

One consultant of black African background who reported previous incidents said, "No action was taken against the perpetrator. I feel uncomfortable and anxious of reprisals." A consultant of Indian background said, "I was not taken seriously. Emails were ignored. I was branded and suffered work related stress and hypertension. I think of leaving this job every day."

The survey also found that nearly 20% of doctors had either considered leaving or left their job in the past two years because of race discrimination. Nearly 60% of the doctors who had experienced racism said the incident had negatively affected their wellbeing, such as causing depression, anxiety, or increased stress.

The survey found that 59.7% of Asian, 57.3% of black, 45.1% of mixed, and 36.3% of white non-British respondents saw racism as a barrier to career progression, whereas only 4.2% of white British respondents thought this.

The BMA is expected to publish its full report on racism in medicine in the spring.

Jacqui Wise, Kent Cite this as: *BMJ* 2022;376:o289

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THE SURVEY also found that nearly 20% of doctors had considered leaving or had left a job in the past two years because of race discrimination

NEWS ANALYSIS

What is behind ministers' plan for more hospitals to directly employ GPs?

England's health secretary reportedly wants to incentivise more doctors to move into salaried posts with trusts. **Matthew Limb** investigates why

CHRISTOPHER FURLONG/GETTY IMAGES

Last week it was left to health officials to insist that Sajid Javid, health and social care secretary for England, "has no plans to nationalise general practice," after it was reported that he is eyeing a radical shake-up of primary care.

Although the forced removal of GPs' independent contractor status does not seem to be on the cards, Javid is said to be keen for more GPs to be directly employed by hospitals rather than running their own practices and will soon launch a review of primary care to explore how they might be encouraged to do so.

Having hospitals directly employ GPs may help alleviate ministers' long held "frustration" at not being able to exert more control over them, said Beccy Baird, a policy analyst and senior fellow at the King's Fund. But with no policy detail to go on, and no definite signals that the proposed review is linked to new freedoms for the proposed "reform trusts," experts are not yet sure what is driving an extension of this particular model of so called "vertical integration." They can, however, consider the "mixed" learning from places where the model has already been tried.

It's not such a terrible idea that everybody should stay away from at all costs
Beccy Baird, below

"It's not such a terrible idea that everybody should stay away from at all costs, because it's worked in circumstances where there has been a particular issue that needed solving," Baird said. But she added, "It's not likely to work everywhere."

Assessing the evidence

Some hospital berthed models of GP care have had some effect on reducing hospital admissions—in Wolverhampton, for example (box)—and on tackling GP recruitment problems.

Manbinder Sidhu, of Birmingham University's Health Services Management Centre, who has studied vertical integration of general practices with acute care hospitals at three sites in England and Wales, told *The BMJ*, "Where acute hospitals have taken over general practices in England it was because of financial and recruitment challenges: they had to intervene, otherwise the practice would have closed."

Sidhu said that success factors for such vertical integration included good pre-existing relationships between primary and secondary care, but he said there were still "challenges" in understanding each other's different working cultures and gaps in the evidence base. "In the UK we still don't know too much about health outcomes or cost effectiveness," he said. "There are only limited data, and these areas will be the subject of follow-up studies."

Keeping patients out of hospital

As overstretched general practices face unrelenting demand from patients, and hospital waiting lists keep climbing, Javid reportedly sees the model as a way to keep more patients out of hospital.

Better access of GPs to secondary care specialists could potentially improve the management of chronic diseases, which in turn ought to reduce admissions. But Nigel Edwards, chief executive of the Nuffield Trust, thinks it is wrong to frame the problem this way and to focus too narrowly on one organisational model, when other options might be more appropriate.

"It completely distorts what primary care is meant to be doing," he told *The BMJ*. "The overarching goal is to improve the health of the population. And it may be that in the longer term, if you get increased survival, your admissions will go back up again."

Baird said, "If we're really thinking about people living healthier at home for longer, we need to be looking away from a hospital."

She added, "I think a lot of the things that are causing problems in hospitals are not access to general practice but access to things like social care, district nursing, and community services. Prevention is much better done in local communities, pulling general practice closer to local authorities and voluntary sector organisations."

Waning interest in GP partnerships

Experts said it may be tempting for ministers to see hospital provision as one answer to the problem of GP recruitment and a waning interest in practice partnerships, particularly among younger GPs. But Baird warned, "What you gain in salaried doctors you may lose in attracting the kind of discretionary effort you get from partners, things like energy and innovation, because it takes away some of the risks for GPs."

Javid reportedly wants to incentivise GPs to be directly employed by hospitals, and while the detail

remains lacking, analysts do see some potential attractions for GPs.

Edwards noted, "Integrating a pharmacist across eight different GP practices is a major task of change management for which practices don't have managerial capacity."

Support systems

Some GPs may like the routine support systems that hospitals enjoy: human resources and IT, data analytics, process improvement, estates expertise. And that could free up attention for clinical care.

That's in addition to potentially having a smoother route to consultants' advice and guidance to reduce outpatient referrals and closer relationships with hospital specialists.

Edwards said that the offer to GPs may seem like a good one "if they're in some control over what's going on and there is a proper relationship of equals." He added, "That seems to be the story in Wolverhampton, where the hospital has ridden to the rescue a bit, seems to have put some of its own resources in, and used some of its infrastructure and procurement."

Sidhu said that in some areas of the country it can be difficult to replace GPs who leave the profession, and some GPs may prefer salaried roles. But he said more evidence was needed to be able to say whether the government should proceed further with the policy.

International evidence indicated that the vertically integrated systems that have worked best were actually "owned and operated by physicians rather than by hospitals," Edwards said. In the US, many of the hospitals that took over primary care in the managed care "revolution" of the 1980s and 1990s struggled to make it work, he said.

"Differences in risk tolerance and what you think your job is made the cultural alignment very difficult," Edwards said. "I don't think it works as a universal model. It's very different for primary care to have a relationship with a relatively small standalone hospital than it is with much bigger hospitals with multiple sites that don't necessarily relate to a single geography.

"There is more than one way to create vertical integration, and it will vary area by area."

Matthew Limb, London

Cite this as: *BMJ* 2022;376:o315

WOLVERHAMPTON MODEL

The Royal Wolverhampton NHS Trust's vertical integration went live in 2016. It now includes eight general practices serving 50000 patients. GPs and practice staff became trust employees, and the trust provides all corporate services such as human resources, finance, and estates.

A trust spokesperson told *The BMJ*, "We believed that an integrated model could make a real difference and offer solutions to some of the challenges primary care was facing, such as rising demand and a workforce with a high number [of GPs] nearing retirement."

The trust added that there had been "increased primary care input" into developments in secondary care, such as urgent treatment centres, and the project was "still on a journey with lots more opportunities to develop."

A research study on the Wolverhampton model published in 2020 found that pooled rates of emergency department attendances did not alter much after vertical integration. However, there were "statistically significant" reductions in the rates of unplanned hospital admissions—some 888 unplanned admissions were avoided, and 168 readmissions—for a hospital patient population of 67402 a year.

The researchers said that further work was needed to understand the mechanisms involved in this "complex intervention" and to gauge the generalisability of the findings and the model's effects on patients' satisfaction, health outcomes, and GPs' workload.

Specialist surgical mesh centres are not working, MPs are told

The network of specialist mesh removal centres, recommended by the Cumberlege review, are "not working," MPs have been told.

The use of surgical mesh to treat pelvic organ prolapse urinary incontinence was suspended in England in 2018 after years of campaigning by patients' groups. In 2020 the Cumberlege review, *First do no Harm*, recommended that mesh should not be used again until several conditions were satisfied, including the identification and accreditation of specialist centres to deal with complications and removal. There are now eight centres in England and one in Scotland.

Alec Shelbrooke MP, co-chair of the surgical mesh all-party parliamentary group, initiated a Westminster Hall debate as he thought that there had not been enough progress on the Cumberlege recommendations. He told MPs the specialist centres were "not working."

He said, "GPs are unaware of mesh centres and the referral process. Many patients are denied access and are offered physio and pain management instead; they pay thousands of pounds for private care and face extremely long delays for appointments."

ONLY A HANDFUL OF SURGEONS IN THE UK CAN CARRY OUT MESH REMOVAL

Another issue is that only a handful of surgeons in the UK can carry out mesh removal—a procedure described as like removing hair from chewing gum.

Lengthy waiting lists often force women to go private. In Scotland legislation was passed on 25 January to allow women who have paid for private surgery to get their money back. The Scottish government also said it was finalising contracts with Spire Health Care in Bristol to accept referrals .

Kath Sansom, of the patient group Sling the Mesh, told *The BMJ*, "There is nothing special about specialist mesh centres. In some cases, the same surgeons who denied mesh was an issue are overseeing the centres, only to tell women they have nothing wrong with them."

She said it was disheartening the recommendations were either ignored or getting nowhere. "There are long waiting lists. Women are having to jump hoops for psychiatric care and physiotherapy before they can even see a consultant about removal. Many are coerced out of a removal or given a partial removal," she said.

"There is either very little or no aftercare, leaving some women having to go to their local emergency department with dangerous issues like pelvic blood clots or sepsis. There is still no outcome logging after removal to share best practice and no national care pathways, so right now it is a postcode lottery."

Sansom added, "Many GPs don't know the issues or the referral process. The end result is confusion, distress, and anxiety for women."

Jacqui Wise, Kent

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VALERY SHARIFULIN/TASS/GETTY IMAGES

China's Olympic race against covid

The 2022 Winter Olympic Games opened in Beijing on 4 February under a pandemic cloud.

China is seeing rising numbers of cases—up to 46 a day at the time of writing—caused by the omicron variant, putting its zero covid approach under strain. Visitors from other countries must be vaccinated or go into quarantine for 21 days.

China's strict "closed loop" bubble tests games participants every day for SARS-CoV-2 and immediately puts them in isolation if the result is positive. Venues are cordoned off, no one is allowed out of their hotels between events, robots deliver their food, and even rubbish is isolated. Locals have been warned not to help if vehicles being used by the Olympic Games are involved in crashes.

Officially, the country has recorded just 73 cases per million during the pandemic, but, although vaccination rates are reasonable, studies have indicated that the vaccines that are being used in China lack effectiveness against omicron.

Mun-Keat Looi, international features editor, *The BMJ*

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1. **Healthcare workers during the women's 3000 m speed skating race at the National Speed Skating Oval on 5 February**

2. **Staff members in protective suits work at a covid-19 nucleic acid testing site for Olympic athletes in Beijing**

ZHENG YISHUO/GETTY IMAGES

EDITORIAL

Mental health in the criminal justice system

A national review is urgently needed to reverse the decline

The recent joint report by Her Majesty's Inspectorates of Constabulary, Prisons, and Probation highlights that the criminal justice system is seriously failed by mental health services in England and Wales.[1] The report finds poor information exchange at every stage of the criminal justice pathway: mental health services are reluctant to share information on grounds of confidentiality despite it being legal; shortfalls exist in staff training, support, and advice to criminal justice staff; and insufficient attention is paid to mental health in court reports, or no reports are provided. However, the biggest problem by far is access to high quality mental healthcare and treatment, which has worsened since the start of the covid-19 pandemic.

Mental health services have been undermined by years of underfunding because of austerity, no parity of esteem with services for physical illness, and internal ideological battles over the need for inpatient beds[2] and whether patients should be subject to "restrictive" or "coercive" practices.[3 4]

Many people with mental illness in the criminal justice system require hospital beds. For some, other options are not safe. The rapidly reducing numbers of mental health beds and shortfall of 3700 mental health nurses are resulting in patients being placed miles from their homes, poor responses to individuals in crisis, and increased use of the Mental Health Act.[5] The criminal justice system has become the default provider of mental healthcare for people in the system.

The joint inspectorates report[1] shows probation officers are not experts in mental health and are not trained to be. However, they are confronted daily with difficult decisions about people with severe mental health problems. The report describes seriously mentally ill people being referred to a community mental health team on release from prison and being told there was a two year wait for an assessment. This is inappropriate and unethical. Suicide risk is another major concern for probation services. Both men and women in the criminal justice system have far higher rates of suicide than the general population.[6] Despite this, the role of probation services is rarely acknowledged in local suicide plans drawn up by local authorities.

JIM WEST/SPL

NHS mental health services have now largely withdrawn from the criminal justice system

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Jeremy Coid, emeritus professor of forensic psychiatry, Queen Mary University of London

Patchy and disjointed system

Although the report focuses on deficiencies in probation, these apply equally to the police and prisons. NHS mental health services have now largely withdrawn from the criminal justice system.

Prisons are served by a patchy, poorly performing, and disjointed system, funded largely by contracts that the NHS either does not bid for or fails to win in competition with private companies with lower staff costs. Prison healthcare has no parity of resources with the NHS. High prisoner-to-staff ratios and high case turnover mean that screening for mental health problems is ineffective and continuity of care and follow-up in the community cannot be ensured.

Curiously, the report fails to mention forensic mental health provision, calling into question the effect, and indeed relevance, of the service currently responsible for the most serious and high risk offenders. Forensic mental health services receive 25% of the national mental health budget (over £1bn) for 6000 beds, two thirds of which are in the private sector.[2] No data are available for admissions or discharges from these services, or the number of reports prepared for court. However, waiting times for admission often do not meet NHS benchmarking standards,[10] and without integration into a well functioning mental health system with rehabilitation beds, forensic mental health capacity is increasingly occupied by patients who have stayed five years or more.[11]

A national review of this failed system of care is urgently needed to identify how the progressive withdrawal of mental health provision from the criminal justice system can be reversed. The proposed changes to the Mental Health Act designed to control rising compulsory mental health admissions will result in more vulnerable people being criminalised for public protection, increasing pressure on the criminal justice system.

Austerity has made matters worse but is not the only reason the system is failing. Money is available, but only 5% of clinical commissioning groups responsible for funding healthcare for probation clients actually do so.[12]

The principle underpinning the 1992 Reed report on treatment of mentally ill offenders[7] was that high quality mental healthcare is provided by health and social services, in the community where possible, and in conditions of no greater security than justified. Some 30 years later we remain abysmally short of achieving this aim.

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EDITORIAL

HIV and covid-19 in South Africa

The two pandemics must be confronted collectively and globally

Consensus is growing that the omicron variant of SARS-CoV-2 may have evolved during a prolonged infection in someone with a compromised immune system.[1 2] Omicron's likely emergence in southern Africa has raised the question of whether this heavily mutated variant owes its origin to the HIV pandemic, which continues to be a common cause of immunodeficiency in the region.

Around 8 million of South Africa's 60 million population live with HIV, roughly a fifth of all people with HIV globally.[3] A high proportion of people newly diagnosed in South Africa are at an advanced stage of HIV infection by which point the immune system is extremely vulnerable.[4] Many people with advanced HIV in South Africa have started treatment at least once but are not in continuous care or have discontinued treatment.[5] This underscores the complexity of living with HIV where poverty and stigma are often compounded by unaffordable treatment costs and poor access to mental health services.[6 7] Covid-19 has only made these challenges harder, having caused reduced access to routine care and worrying falls in HIV testing, treatment, and prevention.[8 9] Together this has left large numbers of immunocompromised people both more vulnerable to covid-19 and potentially more likely to host mutations of SARS-CoV-2.[1-11]

How should we tackle these synergistic pandemics? The UN's human rights approach has been critical to the effectiveness of responses to HIV and could be constructively applied to covid-19.[12] This involves improving equitable access to all aspects of healthcare, with service users participating in decision making and providers held accountable for high quality care, while simultaneously addressing the social determinants of health, including discrimination and stigma. These concepts could be applied to covid-19 by channelling public health measures (including vaccination and contact tracing) through existing civil society structures and meaningfully involving citizens—especially marginalised groups such as people with HIV—in the process.

LUCAS LEDWABA/ALAMY

Global leaders have the tools to end the health and wealth inequalities that are driving both viruses

Activism

The legacy of South Africa's HIV activism offers a framework on which to model the community engagement that could underpin a human rights based response to covid-19. For two years, the Movement for Change and Social Justice has repurposed strategies developed by HIV activist group the Treatment Action Campaign, which in the 1990s mobilised South Africans with HIV to campaign for their right to health through litigation, protest, advocacy, and human rights education.[13 14] The Movement for Change and Social Justice has delivered key aspects of local public health responses to covid-19 in South Africa, while also advocating for communities and averting stigma. Further empowerment and integration of such civil society groups could transform access to covid-19 vaccination, diagnostics, and treatments in low and middle income settings.

Delivering sufficient vaccines to suppress both transmission and the emergence of variants requires ending "vaccine nationalism," the stockpiling of vaccines for maximal national coverage at the expense of international distribution.[15] A prescient modelling study published in *Science* in August 2021 concluded that "unequal vaccine allocation will result in sustained transmission ... which may result in the emergence of variants with novel antigenicity and/or transmissibility."[18]

The "hoard and boost" approach to variants being taken in many high income countries is as futile as it is unethical. The next variant of concern should be pre-empted by increasing vaccination rates in populations with low levels of immunity and high rates of immunocompromise, rather than tackled after its first appearance in a wealthy country.

An urgent refocus on HIV testing and prevention strategies is required to reverse covid-19's devastating effect on access to primary healthcare. People with HIV also need increased support to access treatment, which should include both specific modifications to routine care, such as dispensing for longer periods, and broader approaches to the determinants of health, such as financial and psychological support.[19]

Moving towards an integrated approach to the two diseases will become essential as health systems must preserve or improve HIV care while accommodating the ongoing covid-19 pandemic.

As the omicron variant closes in on a world entering its fifth decade of the HIV pandemic, global leaders have the tools to end the health and wealth inequalities that are driving both viruses. But while each pandemic continues to fan the flames of the other, neither will end unless both do.

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BRIEFING

What do we know about covid vaccines and preventing transmission?

Vaccines helped change the course of the pandemic by reducing illness and hospital admissions. But **Chris Stokel-Walker** asks what we know about their impact on the virus's spread

The range of vaccines developed in record time by pharmaceutical companies and research laboratories have helped quell the worst effects of SARS-CoV-2. But much of the focus of research has been on effectiveness in preventing infection, illness, and hospital admission. What is less well measured is the impact of vaccination on preventing onward transmission.

Is there evidence vaccines prevent transmission?

Most papers to date (notably, many are preprints and have yet to be peer reviewed) indicate vaccines are holding up against admission to hospital and mortality, says Linda Bauld, professor of public health at the University of Edinburgh, "but not so much against transmission."

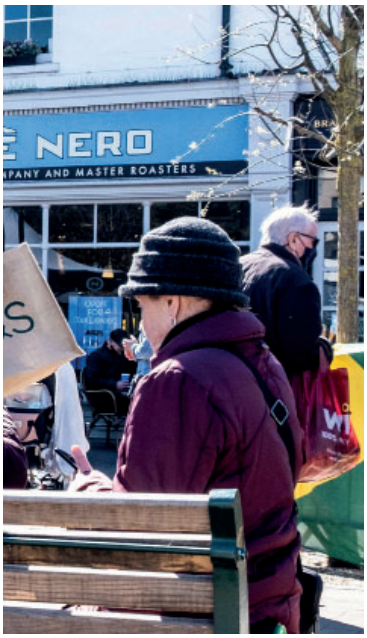
The first weekly covid-19 vaccine surveillance report for 2022 from the UK Health Security Agency (UKHSA) was more positive than Bauld's assessment—but didn't say outright that covid-19 vaccines prevent transmission. "Several studies have provided evidence that vaccines are effective at preventing infection," it states, "Uninfected people cannot transmit; therefore, the vaccines are also effective at preventing transmission."

A study of covid-19 transmission within English households using data gathered in early 2021 found that even a single dose of a covid-19 vaccine reduced the likelihood of household transmission by 40-50%. This was supported by a study of household transmission among Scottish healthcare workers conducted between December 2020 and March 2021. Both studies analysed the impact of vaccination on transmission of the alpha variant of SARS-CoV-2, which was dominant at the time.

A subsequent study, conducted later in the course of the pandemic when the delta variant was dominant, showed vaccines had a less pronounced effect on denting onward transmission, but were still effective.

Policymakers have decided that the game's up on transmission
Linda Bauld

ANDREW MILLIGAN/PA/ALAMY



MARTIN LEE/ALAMY

Damping down on transmission is not an easy thing with omicron
Anika Singanayagam

You shed the same amount of virus with or without having had a vaccine
Paul Hunter

How could vaccines help reduce transmission?

Vaccines aren't preventing onward transmission by reducing the viral load—or amount of SARS-CoV-2—in your body. "Most studies show if you got an infection after vaccination, compared with someone who got an infection without a vaccine, you were pretty much shedding roughly the same amount of virus," says Paul Hunter, professor in medicine at the University of East Anglia. One study, sponsored by the US Centers for Disease Control and Prevention (CDC), found "no difference in infectious virus titer between groups" who had been vaccinated and had not.

Instead, it's the principle that the UKHSA identified above: if you don't get infected in the first place thanks to a vaccine, you can't spread it. Once you're infected, you still can—although what we know about the window when you're most likely to transmit the virus to others has improved.

Does the omicron variant make a difference?

Few studies have looked at the omicron variant, although a report published in January 2022 by the European Centre for Disease Prevention and Control cited a small Danish household study. "People who have completed the primary series of vaccination experienced secondary attack rates (SARs) of 32% in households with omicron and 19% in households with delta. For people who received a booster, omicron was associated with a SAR of 25%, while the corresponding estimate for delta was only 11%. There was an increased transmission for unvaccinated people, and a reduced transmission for booster vaccinated people, compared with fully vaccinated people," summarised the report.

Preliminary data from Japan's National Institute of Infectious Diseases found that patients infected with omicron shed viral particles for longer compared with those infected with other variants. The amount of viral RNA in patients with omicron was highest three to six days after diagnosis or symptom onset. This appears to be two or three days later than other variants.

Hunter said the new data "muddy the waters" on the matter. Vaccine effectiveness against infection, hospital admission, and mortality have all taken a hit when pitted against the omicron variant, and it seems only logical that the impact against transmission would likewise drop.

"The main point of vaccines is not to do with preventing transmission," says Anika Singanayagam, academic clinical lecturer in adult infectious disease at Imperial College London. "The main reasons for vaccines for covid-19 is to prevent illness and death." Therefore, we shouldn't be too disappointed that it's still possible to pass on the virus while vaccinated, she says, "Damping down on transmission is not a particularly easy thing with omicron."

What impact does that have on policy making?

The fact that vaccines are good at preventing serious infection, but less good at preventing transmission makes policy making difficult. The UK has changed its rules on the amount of time those who test positive for covid-19 must spend in self-isolation, first from 10 days to seven, then to five, provided they test negative on a lateral flow test. That decision follows the US, which cut the self-isolation period to five days in late December because "the majority of SARS-CoV-2 transmission occurs early in the course of illness."

"They're recognising that vaccines aren't preventing transmission, and you've got too many people having to isolate," says Bauld. "Policymakers have decided that the game's up on transmission, but that you need a different approach."

Decision makers have a difficult decision, says Singanayagam: they want to enable life to continue as normally as possible—which may mean vaccinated people getting infected with covid because of community or household transmission—while also carefully monitoring that vaccine effectiveness to lower the risk of hospital admission, severe illness, and death is not dented.

Could vaccines become more effective?

Again, first generation covid vaccines were evaluated against reducing hospital admissions and death in the challenging first year of the pandemic. They wouldn't have been expected to generate sterilising immunity and block transmission. But, says Singanayagam, now that we have a suite of vaccines using different approaches, there is some opportunity to think about future jabs for different situations.

"There are avenues to think about the development of vaccines that can have more of an effect on transmission," she says. Those are usually vaccines delivered more locally, such as directly through the respiratory tract, which could tackle the source of major transmission, rather than the lungs, which is where the first generation of vaccines was targeted in order to prevent severe infection. "That's probably the way things will move in the future."

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INVESTIGATION

‘Drug industry is undermining efforts to bring covid vaccine production to Africa’

Why did BioNTech’s representative tell governments that the World Health Organization’s plan to help create manufacturing sites on the continent was doomed, asks **Madlen Davies**

A foundation representing the vaccine maker BioNTech has been accused of seeking to undermine the World Health Organization’s initiative to bring covid vaccine manufacturing to the African continent, *The BMJ* can reveal.

The kENUP Foundation, a consultancy hired by BioNTech, has claimed that WHO’s hub, which is creating a covid-19 mRNA vaccine that African companies can make, is unlikely to be successful and will infringe on patents, documents obtained by *The BMJ* have shown. Instead, they show kENUP promoting BioNTech’s proposal to ship mRNA factories housed in sea containers from Europe to Africa, initially staffed with BioNTech workers, and a proposed new regulatory pathway to approve the vaccines made in these factories. The novel pathway has been described as paternalistic and unworkable by some experts, as it seems to bypass local regulators.

The move threatens the pan-African venture backed by WHO that seeks to scale up African production of lifesaving vaccines from 1% to 60% by 2040. The documents, published for the first time, reveal new details of the proposal from kENUP and BioNTech and their criticism of the WHO venture.

The public approach

WHO’s technology transfer hub, launched in June 2021 and based in South Africa, uses publicly available information to recreate Moderna’s vaccine, to teach companies and scientists across the continent how to use mRNA technology. It will then develop a comparable vaccine, which, if successful in clinical trials and approved by regulators, it will manufacture industrially.

Two South African companies, Afrigen Biologics and the Biovac Institute, have joined a consortium to develop and manufacture the mRNA vaccine, with guidance from organisations including WHO, the Medicines Patent Pool, the South Africa Medical Research Council, and the Africa Centres for Disease Control (Africa CDC). This is part of the wider Partners for African Vaccine Manufacturing project coordinated by Africa CDC, launched last April.

In a document sent to South African government officials after a visit to the country on 11-14 August last year, the kENUP Foundation said that the hub’s activity should be stopped. kENUP’s *Mission Report to South Africa* said, “The WHO Vaccine Technology Transfer Hub’s project of copying the manufacturing process of Moderna’s COVID-19 vaccine should be terminated immediately. This is to prevent damage to Afrigen, BioVac, and Moderna . . .

“Provided that the release from patent cover will be granted by Moderna only during the pandemic, the sustainability outlook for this project of the WHO Vaccine Technology Transfer Hub is not favourable.”

Rumours have been circulating that the mRNA vaccine technology transfer hub intends to infringe patents. This is not the case Medicines Patent Pool statement

The Medicines Patent Pool, which supports the WHO hub, responded in November to claims that the plan would infringe patents. “Unfounded rumours have been circulating that the mRNA vaccine technology transfer hub being established in South Africa intends to infringe patents,” said a press release. “The Medicines Patent Pool, which is responsible for the intellectual property and licensing elements of the hub, wishes to make it clear that this is not the case.”

South African law contains a provision authorising scientists and manufacturers to carry out research and development regardless of patent protection, meaning the hub’s reverse engineering of Moderna’s

What is the kENUP Foundation?

The kENUP Foundation is a public interest foundation, with offices “magnificently overlooking the Grand Harbour” in Kalkara, Malta, its website states.

Its chief executive, Holm Keller (right), was previously chancellor of Leuphana University in Germany and a consultant at McKinsey. Often seen in a yellow scarf, Keller is shown on kENUP’s website meeting government officials and scientists throughout Africa over the past year. Keller has told *The BMJ* that the foundation’s work on bringing mRNA vaccines to the continent is funded by BioNTech.

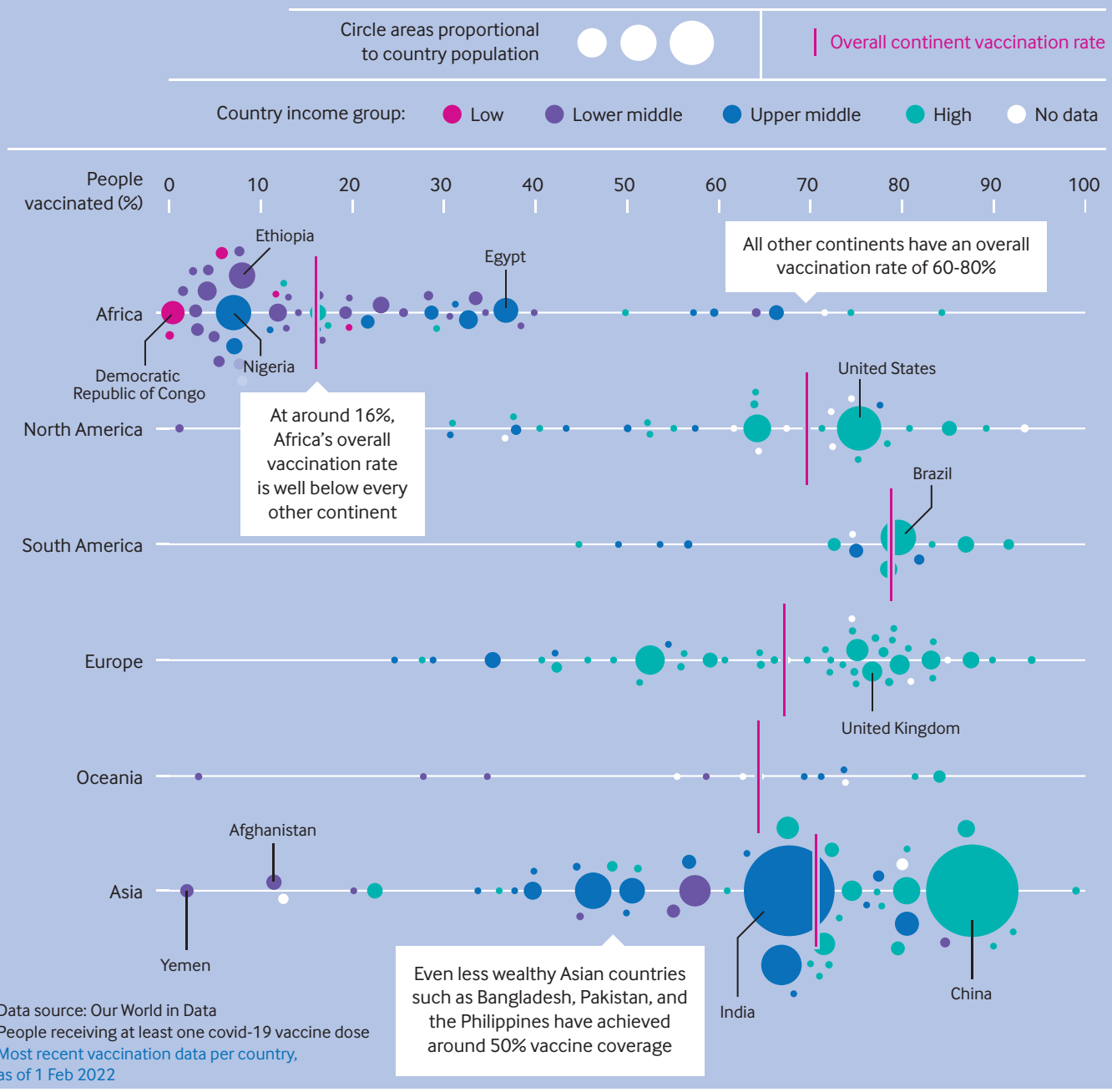
The foundation makes money from its consultancy services and has an affiliated company that invests in healthcare. The EU Transparency Register states that in 2020 kENUP had a total budget of €3.2m (£2.7m). Most of its revenue, €3m, came from consulting, and it estimated maximum costs of €1.25m.

The foundation has worked on projects across a wide range of issues, including healthcare, musicians’s rights, blockchain technology and education. One of its highest profile projects was founding the EU Malaria Fund, which aimed to connect biotech companies making vaccines, drugs, or tests for malaria with funders that could offer loans. After initial plans to create a fund of €500m, the fund gave out €70m and was closed in June 2020 after a year.

Three recipients contacted by *The BMJ* told of their surprise when the fund closed. Stephen Hoffman of Sanaria Inc, based in Rockville, Maryland, received €12.9m to develop its own malaria vaccine, but it expected to receive similar amounts for another two years. “So, you go out on the line and you spend, and all of a sudden there’s no more funding,” he said.

After the fund closed, kENUP launched the Eradicate Malaria project, which is supporting BioNTech to develop an mRNA malaria vaccine to be manufactured in Africa. The EU Malaria Fund said that it had fully complied with all contractual obligations.

Africa's covid-19 vaccination rate still lags behind



Data source: Our World in Data
People receiving at least one covid-19 vaccine dose
Most recent vaccination data per country, as of 1 Feb 2022

vaccine is legal, it added. Moderna has also publicly promised not to enforce its covid related patents during the pandemic and said it was willing to licence its intellectual property after that period. The hub is in talks with Moderna to obtain such a license.

Charles Gore, executive director of the Medicines Patents Pool, told *The BMJ* that the rumours were "ridiculous." He said, "Clearly, somebody has been going around Africa saying that we're going to infringe patents, which is extremely unfortunate since it's completely untrue."

Petro Terblanche, managing director of Afrigen Biologics and Vaccines, a biotech company developing the vaccine for the hub, said that kENUP's activities meant she had to defend her company's work to the South African government, funders, and the media. "I don't understand why kENUP, actively and in many forums, tries to undermine Afrigen's work," she said. "It drains energy that I could have spent making a vaccine."

In January, Afrigen successfully reproduced Moderna's full vaccine, both the mRNA and the formulation—the final vaccine that introduces the active ingredient into the body. It will now experiment with other formulations that are cheaper to produce and don't need to be frozen in storage—a necessity if it's to be given out in many African settings. Afrigen is in talks with two biotech companies to help scale up manufacturing, and it hopes to begin clinical trials in November 2022, Terblanche said.

Ellen 't Hoen, a lawyer and public health advocate, said that BioNTech should be accountable for kENUP's actions. "If you run a not-for-profit foundation and you go around trying to stop people from developing lifesaving vaccines, then I don't know what your agenda is but it smells really bad," she said. "If kENUP is on the BioNTech payroll, then BioNTech should be held accountable for this kind of behaviour."

The kENUP Foundation did not directly address the allegations or answer *The BMJ*'s questions, but it said in a statement that it was "committed to global collaboration in the fight against infectious diseases." It added that it "has always coordinated with important intergovernmental organisations, such as WHO and Africa CDC."

BioNTech also said in a statement that its plans to establish mRNA based vaccine

manufacturing on the African continent "will be done in close alignment with the WHO, the African Union, and the African CDC."

Refusal to share

These initiatives were launched owing to vast global inequities in covid vaccine distribution. By the end of last month 10 billion doses were administered around the world, but only 346 million had been given out in African countries. Booster programmes are under way in Europe and North America despite WHO's pleas for first doses to be prioritised.

It was hoped that Pfizer-BioNTech or Moderna would share technology and know-how with the hub, which could go on to teach African companies, and hubs in other countries, how to make the vaccines. So far both companies have refused. In a statement, a Moderna spokesperson said that trying to accelerate technology transfers could "put at risk" the delivery of its current production lines, with "negative efficiency, safety, and quality consequences."

't Hoen said, "These companies are so reluctant to share the technology because their eye is on the big ship of gold for cancer and other diseases that are very prevalent in high income countries." Both Pfizer and BioNTech argue that sharing the technology would not lead to increased vaccine supplies in the short term and could divert raw ingredients from established manufacturers.

The process of making a covid vaccine would have taken a year with the help of the companies, but without them it will take three, said Martin Friede, coordinator of the Initiative for Vaccine Research at WHO, which is supporting the hub's work. Afrigen and Biovac can manufacture as many as 500 million doses a year, although capacity will increase once other African companies learn to make the vaccine. Friede anticipates bottlenecks from shortages of reagents, glass vials, and trained staff.

In October 2021, five months after the hub was formally announced, Moderna and BioNTech announced their own initiatives. Moderna announced it would spend up to $500m (£370m) to build its vaccine plant in Africa, aiming to make 500 million doses of mRNA vaccines each year. It said it planned to begin filling doses there in 2023 and hoped to make other mRNA products at the facility too.

BioNTech announced it had signed memorandums of understanding with the governments of Rwanda and Senegal to build mRNA production facilities, with construction beginning in mid-2022. BioNTech said the factories would make around 50 million doses of vaccine a year once fully operational, with further factories added until several hundreds of millions of doses could be made.

These companies are so reluctant to share the technology because their eye is on the big ship of gold for cancer
Ellen 't Hoen

Sea containers

kENUP's *Mission Report to South Africa*, sent to the South African government last August, describes BioNTech's initiative. It proposes exporting fully equipped mRNA production lines in a series of sea containers. Made in Europe and staffed initially by BioNTech workers, these sea container factories would create the mRNA, the active ingredient of the vaccine, which would need to be put into vials by another company (a process known as "fill and finish"). The document proposes such a set-up in South Africa.

A second kENUP Foundation document, marked as confidential and sent to South African and European government officials in November, describes a framework to regulate such factories. This "white book" document suggests that to quickly begin producing mRNA vaccines in Africa, a new regulatory pathway should be agreed in which the sea container factories are licensed by the European Medicines Agency (EMA). It claims that this allows them to be fast tracked for WHO prequalification, the global mechanism for ensuring a medicine's safety, efficacy, and quality. The document describes building up local regulatory capacity in the longer term.

But regulatory experts contacted by *The BMJ* said this concept was flawed. Containers can be "useful innovations" for flexible manufacturing and distribution of vaccines, said Prashant Yadav, a senior fellow at the Center for Global Development, but need approval and oversight from local regulators.

Marie-Paule Kieny, who chairs the hub's steering committee as chair of the Medicines Patent Pool and worked for decades on vaccines at WHO, said that it was "pure nonsense" to believe that an EMA licence intended to authorise vaccines used in Europe could apply to those made on a different continent under such different circumstances. "Only somebody who doesn't know how it works can say something like that," she said.

Local regulators are needed to test vaccines before they are released to market, something that European regulators will not carry out for African countries, said Kieny. She described kENUP's proposed regulatory approach as "paternalistic" and advocated more locally owned schemes.

Margareth Sigonda-Ndomondo, who is leading on regulation for Partners for African Vaccine Manufacturing, said her department has had several interactions with kENUP about its white book and it was "not well informed." She rejects the idea that the African regulatory system doesn't have capacity and that another route for approval is needed. "We do have existing systems on the continent," she said. "We have explained to them that all they need to do is to work within the existing initiatives, structures, and systems."

The African Medicines Agency was ratified in 2021 and will harmonise regulation across the continent. South Africa has a laboratory able to carry out the necessary tests, which has been inspected by WHO, hopefully allowing its regulator to approve vaccines by the end of the year, she said. Once it does, it could act as a centre for excellence, supporting other regulators.

Sigonda-Ndomondo added that kENUP and BioNTech could not expect to bring in mRNA factories and expect African regulatory agencies to "give the go ahead without having to go through the scientific review process."

Others are waiting with interest for more granular details on the kENUP and BioNTech proposal. "The real proof of the pudding is going to be, 'Will this vaccine, made in Rwanda and approved through this novel regulatory process, be accepted in Europe?'" said Patrick Tippoo, executive director of the African Vaccine Manufacturing Initiative and head of science and innovation at Biovac. "And if the answer to that is yes, then I would say, maybe it could be accepted in Africa as well."

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