Four experts leave NICE ME/CFS committee

EXCLUSIVE Four members of the NICE guideline development committee for myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) left the group just weeks before the final guideline was due to be published, *The BMJ* has learnt. The departures suggest divisions over the final content, which updates 2007 guidance on diagnosing and managing ME/CFS. Three members resigned, and one was removed.

The draft guidance, published last November, included significant changes to the 2007 recommendations and raised questions about how the evidence shifted so substantially. The 2007 recommendations included interventions such as cognitive behavioural therapy and graded exercise therapy for people with mild or moderate ME/CFS, whereas the draft update cites a “lack of evidence for the effectiveness of these interventions.” The draft also emphasises the potential harms of exercise, based on qualitative evidence from a small number of service users.

NICE received 4000 responses to its update consultation, which it said was “significantly higher” than usual, and it was forced to delay publication by several months, to 18 August, to consider them. The committee also had an unusually high number of patient representatives, prompting suggestions this may have led to more weight being put on patients’ views than on published scientific evidence. The 21 member committee had five lay members rather than the usual two, and a co-opted representative of the ME Association.

None of the three clinicians who resigned at the end of July wished to comment. They were Michael Beadsworth, a consultant in infectious diseases at Royal Liverpool University Hospital; Gabrielle Murphy, clinical lead of the fatigue service at the Royal Free London trust; and Joanne Bond-Kendall, senior physiotherapist at the specialist paediatric ME/CFS service at Royal United Hospitals Bath trust.

Charles Shepherd, honorary medical adviser to the ME Association, announced on 2 August he had been “stood down” because of “continuing conflicts of interest” relating to “providing information and commenting on key issues of concern to the ME/CFS patient community.”

NICE refused to comment on the resignations, but a spokesperson said there were no plans to replace the members or delay publication of the guidance.

Ingrid Torjesen, London

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Charles Shepherd (inset) said he had been “stood down” over conflicts of interest

**LATEST ONLINE**

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**SEVEN DAYS IN**

**White people had lowest life expectancy before pandemic, data show**

White people in England and Wales have lower life expectancy at birth than all other ethnic groups, while people in the black African ethnic group had statistically significant higher life expectancy, data for 2011 to 2014 from the Office for National Statistics have shown.

The analysis was the first in which the ONS has used linked 2011 census and death registration data to produce experimental national estimates of life expectancy and mortality by cause of death and by ethnic group, covering a period before the pandemic. It included 95% of people listed in the census and used self-reported ethnic status.

Julie Stanborough, deputy director for health analysis and life events at ONS, said, “Further research is required. However, these results reveal important patterns in life expectancy and mortality by ethnic group which are complex but consistent with previous studies.”

Cancers and circulatory diseases were a major factor in the differences, accounting for 61% of deaths of men and 53% of women. The analysis found higher age standardised cancer mortality among white men and women than among black and Asian people. It also reported higher mortality from circulatory diseases in Indian, Bangladeshi, and mixed ethnicity men and among Pakistani, Indian, and mixed ethnicity women than among white people.

Gareth Iacobucci, The BMJ  Cite this as: BMJ 2021;374:n1886

**Pay**

**BMA polls consultants on industrial action**

Consultants in England are being surveyed by the BMA on whether they wish to consider taking action over the award of a 3% pay rise. The survey, open until 16 August, will also ask about the effect of the pay offer on consultants’ morale. The results will determine whether the BMA should have a formal ballot. Vishal Sharma, chair of the BMA’s Consultants Committee, said that it was a concern to see reports that the government was suggesting funding the pay rise from within the existing NHS budget and through a potential increase in national insurance contributions.

**Drug pricing**

**Company is fined £100m over thyroid drug**

The Competition and Markets Authority fined the drug company Advanz and its former private equity owners more than £100m for increasing the price of liothyronine tablets by more than 6000% in 2007-17, when the cost to the NHS increased from £600 000 in 2006 to more than £30m in 2016. In 2015 the drug was placed on the NHS’s “drop list” of items that should not be routinely prescribed, meaning that patients had to stop their treatment or buy liothyronine tablets themselves.

**Smoking**

**Charities raise Vectura takeover fears**

The heads of charities such as Cancer Research UK, Asthma UK, and the British Lung Foundation called on Kwasi Kwarteng (below), the business secretary, and Sajid Javid, England’s health secretary, to block the tobacco giant Philip Morris International from buying Vectura, a respiratory drugs company. They warned of a “real prospect” that Philip Morris would use the takeover to “legitimise tobacco industry participation in health debates within the UK.”

**Vaccination**

**Pfizer vaccine’s efficacy declined by 3% a month**

The Pfizer-BioNTech vaccine’s efficacy against SARS-CoV-2 peaked at 96.2% seven days to two months after the second dose and then declined to 83.7% at four months, said a preprint from Pfizer of latest data from the original clinical trial. It showed an average decline in vaccine efficacy of 6% every two months. Trials to evaluate the efficacy of boosters after a longer interval are under way. A booster vaccine in England is expected to be rolled out in September to the most vulnerable people.

**NICE issues guidance on VITT care pathway**

Patients who are acutely unwell with suspected vaccine induced immune thrombocytopenia and thrombosis (VITT) should be referred immediately to the emergency department, said NICE. However, a full blood count should be performed in primary care if the patient is not acutely unwell and if same day results can be obtained. If these blood tests show a low platelet count the patient should be referred to the emergency department.

**England to vaccinate 12-15 year olds from 23 August**

Eligible 12-15 year olds in England will be vaccinated against SARS-CoV-2 from 23 August by primary care network vaccination services, hospital hubs, and school age vaccination services, to ensure they get a first dose before returning to school in September. Eligible children will include those with severe neurodisabilities or underlying conditions resulting in immunosuppression. A letter to GPs from NHS England says primary care networks will need indemnity to vaccinate children but that a contractual agreement will be put in place nationally.

**Drug overdoses**

**Scotland’s drug deaths reached 1339 last year**

Scotland continues to have the highest rate of drug related deaths in Europe, as the latest figures showed the most deaths since records began in 1996. Some 1339 people died from overdoses in 2020, up 5% on 2019, said a National Records of Scotland report, and three times the rate in England and Wales. The Scottish government plans to spend £250m over the next five years to tackle the problem.
MEDICINE

Covid-19

Myopia incidence rises in Hong Kong's children

Researchers estimated that the incidence of myopia among 6-8 year olds in Hong Kong had increased from around 16% before the covid-19 pandemic to around 27% in January to August 2020, which coincided with a reduction in the amount of time children spent outdoors from around 75 to 24 minutes a day and an increase in screen time from around 2.5 hours to seven hours a day. They described their findings, published in the British Journal of Ophthalmology, as “alarming” and warned of the need to “prevent childhood myopia, a potential public health crisis as a result of covid-19.”

Delta worse for pregnant women without a vaccine

Doctors and midwives reiterated their call for pregnant women to get vaccinated against covid-19, as the UK Obstetric Surveillance System has found that this group seems to be becoming more seriously ill as the pandemic progresses. Nearly half (65%) of pregnant women who were admitted to hospital with the delta variant had moderate or severe disease, which compares with 24% admitted in the first wave and 36% with the alpha variant. Of 742 pregnant women admitted with covid symptoms since 1 February 2021 only four had received a single dose of vaccine and none had received both doses.

Wellbeing

Speak-up guardians deal with 25% more cases

The NHS’s 700 or so “freedom to speak up” guardians in England saw 26% more cases in 2020-21 (20 388) than in 2019-20 (16 199), figures showed. Most cases (30%) concerned bullying and harassment, although this proportion was down on last year (35%). Nearly one in five cases (18%) involved an element of patient safety or quality of care, down from 23% in 2019-20. The proportion of cases involving detrimental treatment for speaking up increased in the past year, up from 2.7% in Q1 (April to June 2020) to 3.5% in Q4 (January to March 2021).

A third of trainees are affected by burnout

Of 46 793 trainees in the UK who completed the GMC’s annual national survey (a 76% response rate), 33% said that they felt burnt out from work to a high or very high degree, and 43% found their work emotionally exhausting to a high or very high degree. Charlie Massey, GMC chief executive, said that trainees could not continue to work at such high intensity and that action on workloads was needed. Most trainees (81%) said that they were on course to meet their curriculum competencies or outcomes for 2021 despite disruption from the pandemic.

VACCINES

Northern Europe has administered the highest proportion of covid-19 vaccinations per population at 120%, followed by Western Europe (114%) and North America (110%). Middle and Western Africa have the lowest at 2%.

SIXTY SECONDS ON . . . CUPPING

UP FOR THE CUP?

Some people are. The alternative therapy of cupping—thought to have originated in Middle Eastern and Asian cultures—is popular with Olympic swimmers, with various competitors in Tokyo being seen with dark circles on their bodies. The trend among athletes started with the US swimmer Michael Phelps and others at the Rio Olympics five years ago. Celebrities such as the actor Gwyneth Paltrow and singer Justin Bieber are also fans.

WHAT DOES IT INVOLVE?

Glass, ceramic, bamboo, or plastic cups are used to generate suction on a person’s skin. Negative pressure is created in the cup either by applying a flame to the cup to remove oxygen before placing it on the skin or by attaching a suction device to the cup after it is placed on the skin. The lesser used “wet cupping” pierces the skin and blood flows into a cup.

WHAT DOES THE EVIDENCE SAY?

Scientific evidence of its benefits is lacking. Some studies have been done, but the US National Center for Complementary and Integrative Health says that most of it is of low quality. “Cupping may help reduce pain, but the evidence for this isn’t very strong. There’s not enough high quality research to allow conclusions to be reached about whether cupping is helpful for other conditions,” it concluded.

SO ENTHUSIASTS ARE JUST CUP HALF FULL TYPES?

Perhaps. Phelps may have won five gold medals in Rio, but he’d also won 18 golds at previous Olympic Games before he started doing it, so it’s fair to say that it was probably his athletic prowess that carried him through rather than the cupping.

Gareth Iacobucci, The BMJ

Cite this as: BMJ 2021;374:n1928

Cite this as: BMJ 2021;374:n1919
“Footballers’ dementia risk is linked to position and career length”

The risk of neurodegenerative disease in former professional footballers varies by their playing position and the length of their career—but not by which decade they played in—a landmark study has reported.

The Field (“Football’s influence on lifelong health and dementia risk”) study, led by Glasgow University researchers, found in 2019 that mortality from neurodegenerative disease was more than three times higher than expected in former professional footballers.

Health records
In the latest phase of the work the researchers used data from the health records of around 7676 Scottish former professional footballers and 23 028 matched controls from the general population to look at whether the risk of neurodegenerative disease varied by position, length of career, or playing era.

The study, published in JAMA Neurology, found that the risk among outfield players was almost five times as high as expected. The risk rose with career length, ranging from a roughly doubling of risk (2.26 (1.51 to 3.37); P<0.001) in those with careers of five years or less to around a fivefold increase (5.2 (3.17 to 8.51); P<0.001) in those with careers lasting 15 or more years.

But although head injury management and technology have progressed, the study found no evidence of change in risk in the footballers, whose careers spanned from around 1930 to the late 1990s.

In parallel work led by lead author Willie Stewart, a specific pathology linked to brain injury exposure, known as chronic traumatic encephalopathy, has been described in a high proportion of the brains of former athletes engaged in contact sport.

Gareth Iacobucci, The BMJ
Cite this as: BMJ 2021;374:n1934

MHRA to shed a fifth of workforce in post-Brexit cost cutting drive

The UK’s drug and medical devices regulator is to lose a substantial number of staff as part of a post-Brexit restructuring, The BMJ has learnt.

The Medicines and Healthcare Products Regulatory Agency, which employs around 1200 people in England, could cut its workforce by as much as 20% as part of a transformation programme that will radically reshape how the agency operates, leaked documents seen by The BMJ show. The agency is targeting savings after losing a substantial amount of funding from the European regulatory system after the UK’s exit from the EU.

Voluntary exit scheme
The documents reveal details of a voluntary exit scheme that the MHRA is offering to staff working in vigilance and risk management of medicines, licensing, devices, and inspection enforcement and standards.

A document marked “official sensitive,” seen by The BMJ, said the MHRA’s income is expected to reduce by 15-20% in the next financial year and beyond, while its operating costs will rise by £7-9m a year. It is also making £62m of planned investment to replace legacy IT systems and deliver new capabilities for the future. “To meet [the] income gap through staff savings alone would require around a 20% reduction in our workforce,” the document said.

More robust surveillance
The government’s life sciences strategy has asked the MHRA to become a faster regulator of innovative medicines after Brexit and to propose a new regulatory framework for devices. It is also a response to a safety review into Primodos, sodium valproate, and pelvic mesh by Julia Cumberlege published last year. This recommended the MHRA adopt more robust postmarketing surveillance and adverse events reporting as well as a register of all devices.

But some experts questioned the proposed staff cuts given the importance of the MHRA’s work. Stephen Evans, professor of pharmacoepidemiology at the London School of Hygiene and Tropical Medicine, said Brexit had already meant the MHRA had lost experienced staff and that the agency’s workload could increase after December 2022 if the MHRA was to be totally

Most patients with covid received “good or excellent hospital care”

Most patients admitted to hospitals in England with SARS-CoV-2 in 2020 received good care despite the challenges of dealing with a new disease, concludes a Royal College of Physicians review.

The authors gathered information on the quality of care delivered by 19 NHS trusts, which accounted for a population of almost 10.5 million people exposed to the virus. The organisations dealt with 26 326 cases of covid-19 in 2020. Of those patients, 6389 (24.2%) died with the condition while in their care. Some 510 patient care records were reviewed, of which 425 were identifiable.

A modified version of an established structured judgment review process was used to analyse acute hospital deaths. It found that overall care delivered was judged to have been “adequate,” “good,” or “excellent” for 96.5% of patients. (“Good” or “excellent” care was found for 74.4% of cases.)

In contrast, only 3.5% of the cases involved care
General practice “needs rescue package”

General practice is at “breaking point” and needs an emergency rescue package to ensure staff are supported and patients get the care they need, the Royal College of General Practitioners has said. College chair Martin Marshall said that even before the pandemic the job of GPs was “largely undoable” but that covid-19 had led to “unsustainable” workloads, with an estimated 14 000 GPs expected to leave in the next five years.

The college has produced a five point plan. It calls on England’s health secretary, Sajid Javid, and Amanda Pritchard, the new chief executive of NHS England, to put the plan into action.

Proposals involve increasing efforts to deliver the Tory party’s 2019 manifesto target of securing 6000 more full time equivalent GPs in the next three years, as well as a programme to eradicate bureaucratic burdens and unnecessary workload by 2024, which would allow GPs more time to care for patients and prevent burnout.

Infrastructure

The RCGP also called for improved recruitment and integration of at least 26 000 other members of staff into the general practice workforce by 2024 and ensuring that the general practice infrastructure would be fit for purpose by 2024, to allow GPs to deliver care from modern buildings, using reliable technology.

The final part of the plan is for GPs to be given a strong voice in integrated care systems, to eliminate the waste associated with fragmented services, and in designing care for their communities.

Marshall said the workload pressures in general practice must be “urgently addressed as we move beyond the ‘emergency’ pandemic period and GPs deal with the aftermath of covid in their local communities—including ‘long covid’ and the additional mental and physical health problems it is causing in patients.”

Data show that GP consultations have been rising since last summer and have been above historical levels since the end of April. This situation is set to worsen, as six in 10 GPs say their mental health has deteriorated in the past year. And a RCGP survey found that 34% of GPs expected to leave within five years, meaning that over 14 000 GPs could be lost from frontline care.

Elisabeth Mahase, The BMJ Cite this as: BMJ 2021;374:n1913
EXCLUSIVE INVESTIGATION

**FDA allows drugs without proved benefit to languish for years on accelerated pathway**

Criticisms of the US Food and Drug Administration’s fast track process resurfaced after the approval of aducanumab for dementia. **Elisabeth Mahase** reports on missing efficacy data and vague evidence.

Since the US Food and Drug Administration established its accelerated approval pathway for drugs in 1992, nearly half (112) of the 253 drugs authorised have not been confirmed as clinically effective, an investigation by The BMJ has found. Of these 112 drugs approved in the past 28 years, a fifth (24) have been on the market for more than five years and some longer than 20—often with a hefty price tag, shows The BMJ’s in-depth analysis of FDA data to 31 December 2020.

The accelerated pathway allows drugs onto the market before efficacy has been proved. As part of this approval, however, the manufacturer must conduct post-approval studies—known as phase IV confirmatory trials—to “verify the anticipated clinical benefit.” If these trials show no benefit the drug’s approval can be cancelled.

Further analysis of FDA data shows that only 16 drugs approved through the pathway have ever been withdrawn. Most of these were shown to lack efficacy, but in some cases the confirmatory trials were never done.

Celecoxib (Celebrex), which was given accelerated approval in 1999 for the treatment of familial adenomatous polyposis, was on the market for 12 years before the FDA finally asked Pfizer to voluntarily withdraw it for this indication because the efficacy trials were never done. The BMJ asked the manufacturers of 24 treatments that have been on the market for more than five years whether they had conducted phase IV trials. Six drugs had been withdrawn, approved, or postponed. Of the remaining 18 drugs, relevant trial information was provided for just six. And only four of these had started to recruit patients, while two companies said that they were still in discussion with the FDA over the final study design.

Eleven companies (representing 12 drugs) did not respond to the request, including Sanofi Genzyme, which is responsible for clofarabine (Clolar), a drug for paediatric relapsed or refractory acute lymphoblastic leukaemia that has been on the market for 17 years without a confirmatory trial.

Despite the pathway’s good intentions to accelerate “the availability of drugs that treat serious diseases,” experts are concerned that it is now being exploited, to the detriment of patients—who may be given a drug that offers little benefit and possible harm—and of taxpayers.

Huseyin Naci, associate professor of health policy at the London School of Economics, said, “These products routinely have side effects, but the benefit information is a lot less certain. That’s what we’re concerned about—that we may have drugs on the market that don’t have any benefits but certainly predictably have harms associated with them.”

**All carrot and no stick**

In 2015 a review of the FDA’s expedited pathways by the US Government Accountability Office said that the “data on post-market safety issues and studies were found to be incomplete, outdated, [and] to contain inaccuracies.”

The Institute for Clinical and Economic Review (ICER)—which, like The BMJ, receives funding from Arnold Ventures—dug a little deeper in April 2021, reporting that a lack of “credible threats” to withdraw approval if confirmatory trials were not carried out meant study sponsors had little incentive to do them.

It also highlighted the FDA’s “inconsistent decisions following negative or ambiguous confirmatory data.” The review’s white paper said that, “barring safety concerns, the agency has generally preferred to steer clear of withdrawing approval, even when post-marketing trials do not support a treatment effect on the primary clinical endpoint.”

**Evidence standards are “too low”**

In light of such incidents some medical leaders have argued the FDA’s standards for evidence are too low. When efficacy is not clear the...
FDA uses surrogate endpoints as a substitute for a direct measure of how a patient feels, functions, or survives, and, while benefit may not be measured, a prediction of clinical benefit is expected. In some cases there is a strong indication that the surrogate endpoint predicts meaningful benefit; however, where the situation is less straightforward, inconsistencies and a lack of transparency in decisions have led to serious questions over the standards of evidence being accepted.

Steven Pearson, ICER president and a lecturer at Harvard Medical School in Massachusetts, said, “Sometimes we just don’t really know how well the surrogate outcome correlates with future patient outcomes. That’s where there’s always going to be some judgment about whether that seems reasonably likely.

“But there’s really very little transparency around how these decisions are being made. There’s no kind of compendium that the FDA returns to look at to try to calibrate its thinking and to make it more transparent to outside observers. So, it feels a bit ad hoc, and certainly to some people’s eyes it feels like what it takes to be reasonably likely is almost meaningless now—it seems very, very small.”

Another problem is that even when confirmatory trials are carried out many use the same surrogate endpoints that were used in the pre-approval trials, rather than clinical outcomes. This means that no real understanding of efficacy is gained.

Naci said, “I think regulators across the board need to really raise the bar for using surrogates in general. Regulators really need to think very carefully about what would constitute a valid surrogate and whether companies can actually provide that level of evidence.”

The current process—which allows drugs to be on the market with such a low evidence base— sends the wrong signals to other drug companies, which will assume that they can also gain approval with little evidence, he said.

Rachel Sachs, an associate professor of law at Washington University in St Louis, Missouri, said, “There are some instances where the companies really do seem to be taking advantage of the accelerated approval pathway and are using it in a way that makes it harder to get at the truth about whether these products really are safe and effective.”

Can the process be reformed?

Despite the concerns raised, all experts who spoke to The BMJ agreed that the accelerated pathway was still useful and could be truly beneficial to patients, although some changes were needed. One effective reform could be for confirmatory trials to be designed, agreed, and even started as part of the approval, and the FDA needs to be stricter in enforcing its own rules.

Sachs said, “One important piece of the puzzle is for the FDA itself to be tougher on these companies, to hold them to the bargain that they have agreed to, and to take action when the company has not met their obligations. “Knowing that it is difficult to take these products off the market should be a factor in whether they think about granting accelerated approval in the first place.”

Other suggestions in the ICER’s white paper include strengthening the selection of surrogate endpoints, regulating the price of accelerated drugs, and regularly re-reviewing approvals to ensure they continue to justify the risk-benefit trade-off.

Pearson told The BMJ, “I’m not shy in saying that some of [the suggested modifications] would just take the FDA a little bit closer to the way that the Europeans manage these things, where even the term conditional approval sends a different signal than accelerated approval.

“We could move the needle and get the true goal of accelerated approval, which is still a very viable one, [but] get it done in a way that really is more beneficial for patients in the long run.”

An FDA spokesperson said that the agency was “committed to working with sponsors to ensure that confirmatory studies are completed in a timely manner. . . . We expect sponsors to commit all resources needed to move trials forward as effectively as possible, with the aim of completing trials as soon as is feasible, while assuring the quality of the data and the robustness of the results.”

Elisabeth Mahase, The BMJ
Cite this as: BMJ 2021;374:n1898
The Royal College of General Practitioners has launched its first online exhibition, to mark the many changes in the profession since the first British women pioneers began to take formal medical qualifications 150 years ago.

“Women at the Heart of General Practice” showcases the experiences of female GPs and the wider practice team throughout history, including the discrimination and prejudice many women encountered, the rise in the number of female GPs, as well as the challenges they face today, including the gender pay gap.

Amanda Howe, RCGP president, said, “Women have had a long and contested route into fulfilling their potential as doctors. I am proud that the RCGP has created this exhibition, which shows us some of the history and context of this journey and allows us to celebrate the contribution of women GPs to the profession and patient care.”

To see the exhibition visit bit.ly/RCGPshow

Alison Shepherd, The BMJ

Cite this as: BMJ 2021;374:n1932
1. Amanda Howe, current RCGP president
2. Katharine Annis Gillie, a founder member of the RCGP, its first female chair, and first female president. Portrait by Mimi Winter
National food strategy and health

Healthier diet environments, but a missed opportunity to tackle poverty

It is not easy to eat well in the UK. Less healthy food is cheap,1,2 heavily promoted,1,3 and available everywhere.4 Our food problem is huge: around 15% of all years of life lost are due to poor diet,5 one quarter of adults experience food poverty each year,6 and agriculture accounts for 10% of greenhouse gas emissions. Against this backdrop, the second part of the government commissioned National Food Strategy was published on 15 July. Together with part 1, published in 2020,7 the population health aspects of the strategy focus firmly on changing the environments in which we make food decisions. The media’s initial response to the strategy focused on proposed taxes on salt and sugar sold for use in processed foods. The prime minister soon expressed his opposition to “extra taxes on hardworking people,” but this is a misunderstanding. The intention is not to increase prices to consumers but to encourage manufacturers to reformulate.

The soft drinks industry lev provides a blueprint. By setting taxable thresholds for sugar content, the levy achieved large scale reformulation,8 reducing the amount of sugar purchased in soft drinks but not the overall volume of soft drinks purchased.11 However, manufacturers appeared to reformulate only to meet the “targets” set by the taxable thresholds. The new proposals for salt and sugar taxes go further and have no target thresholds for content, so should incentivise ongoing salt and sugar reduction by manufacturers.

Evidence is growing of the health harms of ultra-processed foods,12 but it remains unclear whether these arise from the processing methods used or from high concentrations of harmful ingredients such as salt and sugar.

Jean Adams, programme leader, MRC Epidemiology Unit, University of Cambridge jma79@medschl.cam.ac.uk

Opposition to public health regulation across the food industry may be starting to fracture

Tackling poverty

Part 1 of the strategy concluded that economic poverty and that reducing food poverty requires attention to the broader welfare system. Part 2 also recognises the health and social harms of food poverty and makes several proposals to expand food subsidies. But it ducks the issue of welfare, which it considers outside the strategy’s remit. This is disappointing, particularly in view of the impending withdrawal of the £20 (£23; $28) a week rise in universal credit introduced in response to the pandemic. Furthermore, as the suggested household incomes for eligibility for food subsidies are not linked to inflation, any gains may quickly be eroded. The same is true for the salt and sugar taxes.

While the strategy is framed as the start of a policy journey, various other ideas could easily have been introduced at this stage, including a ban on marketing unhealthy food through sports sponsorship and more explicit targets. Diet and obesity policy in the UK has too often floundered, partly because of the absence of targets and appropriate monitoring systems.8 The new strategy includes several recommendations for improving monitoring, but it is left to government to define the targets for the strategy’s health recommendations. Bold targets can be used both to inspire and to assess progress.

Our food problems will not be solved without buy-in from food companies. Voluntary agreements with the food industry have largely failed,14 and mandatory regulation is probably the only way to achieve large scale change. The extent of that buy-in is currently unclear: the strategy includes positive comments from industry, and these are reflected in responses from some supermarkets, but industry bodies quickly denounced proposed taxes on sugar and salt.15

The previously united opposition to public health regulation across the food industry may be starting to fracture.16 Or maybe it was politically expedient for the strategy to praise, rather than criticise, industry. Either way, the narrative that even parts of the food industry support strong regulation may help bring those politicians on board who are concerned about an industry backlash.

Education and training

General practitioners prescribing fruit and vegetables attracted attention, but that recommendation actually described referral to broader education and training on food and cooking skills. This is one of the few educational recommendations in a strategy focused on structural change. However, evidence that training in cooking skills improves dietary health is equivocal at best,17 perhaps because it remains hard to put skills into practice until the food environment improves. The proposal for a pilot “community eatwell” programme reflects this uncertainty.

The government has committed to responding to the National Food Strategy with a white paper within six months. If it fails to take this opportunity to kickstart radical change it risks overwhelming the NHS and failing to reach its climate targets.

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Find the full version with references at http://dx.doi.org/10.1136/bmj.n1865
Drug treatment services are broken, says review

More money, more trainees, and greater accountability are urgent priorities

In announcing the second part of her drugs review, focusing on prevention, treatment, and recovery, Carol Black said that the current system in England was “broken and wanting.” She is right.

Funding for treatment and prevention has fallen, perhaps most worryingly for children aged 11 to 15, among whom drug use has increased by over 40% since 2014. Other indicators of a broken system are the increasing numbers of drug users repeatedly in and out of prison and the growing number who are homeless and rough sleeping. Drug use is an important driver of social inequalities.

Drug use affects many areas of people’s lives so responsibility is fractured across numerous government departments. Even within the health sector, responsibility for managing drug related harms cuts across primary care, mental health, and public health. The skills and responsibilities needed to do this well should be embedded within all these and other specialties.

Hollowed out system

In 2012, the UK Health and Social Care Act moved responsibility for commissioning drug and alcohol treatment services to local authorities, leaving them vulnerable to big reductions in funding as a result of cuts to local authority budgets and resulting in a demoralised and deskilled workforce—handling bigger caseloads with less training and supervision and unable to provide the full range of treatment options. The number of higher training posts in addiction psychiatry across England has fallen by 58%, from 64 in 2011 to just 27 in 2019, leaving some regions without a single trainee.

Black’s latest report—published on 8 July—makes 32 recommendations, including the formation of a central drugs unit. The new unit would sit within the Home Office but have a clear brief to hold all government departments to account in delivering a new national outcomes framework focused on reducing demand for illegal drugs. The report also recommends more funding for treatment for drug users, rising each year to an extra £552m in the fifth year. Critically, this new funding would be ring fenced within local authority budgets. The report calls for the Department of Health and Social Care (DHSC) to develop a national quality standard for commissioning and ensure strong local partnerships for delivering services, including aligning or pooling local organisational budgets.

It also proposes that the DHSC develops a workforce strategy and sets targets for the number of professionally qualified staff required for effective treatment services. The Academy of Medical Royal Colleges is asked to set up a centre for addictions, modelled on the Australasian Chapter of Addiction Medicine.

The report further recommends a regional funding mechanism for high cost, low volume services such as inpatient detoxification. There is also a strong focus on improving pathways between drug treatment services and the criminal justice system, treatment and prevention in young people, and promoting drug-free communities with housing support and work placements to increase employment.

Black’s first report published in February 2020 has already resulted in an additional £80m for prevention and treatment of drug misuse. Alcohol misuse was outside the scope of both reports, despite treatment services for alcohol dependence and drug misuse often being combined. People with alcohol dependence risk being ignored, benefiting only from funds “left over” from drug services.

Integrated commissioning

Treatment services remain the responsibility of local government despite repeated calls for their return to the health sector. Black’s recommendation on integrated commissioning will help, however, along with ringfenced funding and an increased emphasis on the quality of commissioning and accountability.

Urgent action is now required to increase the number of training posts in addiction psychiatry. The proposed new centre for addictions is an exciting prospect but will need commitment and cooperation from professional bodies such as the Royal College of Psychiatrists and Health Education England to make it work.

Black’s report is comprehensive, intelligent, and nuanced. It is also ambitious and calls for concerted implementation effort across local and national government, the NHS, other treatment providers, and the healthcare professions. Drug users desperately need the same standards of healthcare as people with other chronic health conditions to ensure they can move quickly towards meaningful, lasting recovery.

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The past year has been stressful because getting hold of a medical professional has been very difficult,” says Vicky Small, a patient with restrictive cardiomyopathy. She would usually see a cardiologist twice a year, but first her appointment in June 2020 was cancelled and she was then told that her January 2021 appointment would be postponed until January 2022.

Small, aged 46 and from Bournemouth, says that she put her foot down because she hadn’t been feeling well. She had an echocardiogram in hospital and a video consultation from home, which resulted in her cardiologist changing her medication. However, it was only at a routine check-up a few weeks later that her GP spotted that her heart rate was alarmingly low, and her medication was halved.

Continuing to feel unwell, with an erratic heartbeat, Small had to call NHS 111 when she couldn’t get through to her busy general practice.

She was taken by ambulance to hospital, where she had further tests and her medication was changed again. “If it hadn’t been for a check-up at my GP surgery the problems wouldn’t have been picked up, because I hadn’t seen a cardiologist in person since 2019,” she says.

Missing routine appointments
Small’s story is typical, and for some patients the consequences of missing routine appointments have been far more serious, with Public Health England reporting more than 5800 excess deaths from heart and circulatory diseases in England from 21 March 2020 to 26 February 2021. About half of these cases have covid-19 mentioned on the death certificate—so a large proportion of the extra deaths may not have been caused directly by the virus but as a consequence of disruption to routine treatment and care.

An analysis by the British Heart Foundation in February found that the pandemic had had a huge impact on services for people with cardiovascular disease and a growing backlog of people waiting for treatment. About 371000 heart procedures and operations were performed in England in 2020: a 22% drop from 2019, when more than 473000 were carried out. These include coronary artery bypass, heart valve, and congenital heart disease surgery, as well as stents or balloons to open blocked arteries and procedures to treat heart valve disease, such as transcatheter aortic valve implantation.

Recent figures from NHS England show that 242181 people were waiting for invasive heart procedures including surgery at the end of this May—the highest number for May on record. More than 52484 had been waiting for longer than 18 weeks. The number of people waiting for over a year decreased in May, to 4252 from a peak of 5248 in March, but the figure is still 152 times higher than before the pandemic.

All aspects of care have been affected: for example, the number of people who took part in cardiac rehabilitation in the UK fell by about a third as the pandemic first hit.

Virtual cardiovascular medicine
All areas of medicine, including cardiovascular care, have seen huge increases in telemedicine in the past year, and this is likely to continue.

Simon Ray, president of the British Cardiovascular Society, tells The BMJ, “We have found that a significant proportion of patients with general cardiology problems can be dealt with in a virtual consultation. “These are not suitable for more complex problems, or for people who have English as a second language, but around 70-80% of straightforward appointments don’t have to be face to face.”

The pandemic has also stimulated increased ability to organise virtual multidisciplinary team meetings and to work collaboratively with multiple institutions, he says, as institutions have worked together well during the pandemic, particularly in London.

The forthcoming Getting It Right First Time report on cardiology, from an NHS improvement programme designed to improve care quality by reducing unwarranted variations, will reflect this by recommending that cardiac services be delivered as part of functional networks, with a cardiac surgical centre at the apex.

Ray says, “A network structure means that resources are used to the best advantage and will make it much easier to respond to any future pandemics.”

Simon Kendall, president of the Society of Cardiothoracic Surgeons,
tells The BMJ of “a real need for centres to have dedicated cardiac surgery level 3 [intensive care] beds.” He says, “Even before covid-19 the cancellation rate for surgery because of a lack of level 3 beds was too high. There is also an onus on professionals to use these intensive care beds better through implementing ERAS”—enhanced recovery after surgery pathways, which is an evidence based approach aiming to help patients recover more quickly after surgery, including through exercise and healthy eating.

Shahed Ahmad, NHS England’s national clinical director for cardiovascular disease prevention, tells The BMJ, “Throughout the pandemic the NHS has prioritised cardiovascular disease prevention, including distributing thousands of blood pressure monitors to clinical commissioning groups for people to use at home and send their readings to their GP, and community pharmacies have been trialling free blood pressure checks for those aged 40 and above.”

When heart surgery stopped

During intense periods of the pandemic, only the most urgent cardiac surgery was carried out. “Basically, heart surgery stopped for the month of April 2020,” says Kendall.

Procedures slowly started to resume through the summer, and cardiology departments were getting back on top of waiting lists by last November, he says, “But our waiting lists were a lot smaller because fewer people were presenting to their GP and cardiologists. Overall, we did 30-50% less work last year than we usually do.”

Then in January 2021 heart surgery virtually stopped again all around the country, but particularly in London, the West Midlands, and the north west. Kendall says that these areas are coming out of that now but have a backlog of patients on the waiting list.

“We are expecting all the patients who didn’t come forward last year to come forward this year,” he says. “There is a very significant amount of unmet demand that will become apparent in the coming years.”

Cardiology services were also shut down in the first wave of the pandemic, but in later waves, except in some areas of the country such as London, they were able to offer levels of activity closer to normal.

Ray explains, “With the benefit of hindsight, I think shutting down most cardiac surgery and elective cardioiology happened too quickly, and we could have carried on doing quite a bit of elective and semi-elective activity in some areas of the country.” He also notes a lack of agility in getting services up and running again at the end of the first wave. “Cardiac nursing staff or theatre staff were still working in covid wards when the demand for those services was declining,” he says.

During the pandemic’s first wave acute cardiovascular deaths increased, and about half of the additional deaths occurred in the community, suggesting delays in patients seeking help. Research published in the Lancet found that hospital admissions of patients with acute coronary syndromes in England had fallen 40% by the end of March 2020, with about 5000 fewer admissions than would be expected. By the end of May admission rates had partially recovered after awareness campaigns by medical societies and the British Heart Foundation, but they remained below expected levels.

Barbara Casadei, one of the Lancet study’s authors and British Heart Foundation professor of cardiovascular medicine at Oxford University, tells The BMJ, “We found a decrease in admissions for acute coronary syndrome all over the country, irrespective of age and comorbidity, not just in frail patients and in areas with high rates of covid-19.” She says that this may be partly driven by the government promoting the message, “Stay at home. Protect the NHS. Save lives,” as well as by people’s worries about going to hospital for fear of exposure to SARS-CoV-2.

The immediate pressure from covid may be lessening, but the backlog of cardiovascular care continues to grow. And it’s not clear how “long covid” will affect cardiovascular services in the next few years, says Ray: doctors will need to ensure that their cardiovascular patients are kept well informed of plans and future delays in care as we begin to emerge from lockdowns.

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Even before covid-19 the cancellation rate for surgery because of a lack of level 3 beds was too high

Simon Kendall
Patient safety is ultimately the responsibility of health and social care institutions. With regard to employment practice, these institutions have a duty to employ only workers whose presence would not place patients at unnecessary risk. Frontline care roles should not be offered to people unwilling to be vaccinated against high risk infections. This applies not only to direct employment but also to contract and agency staff.

The situation is less clear where existing staff are concerned, as employers have responsibilities not only for their patients but also to their staff. These include obligations of non-discrimination and ensuring reasonable working conditions. But healthcare staff, too, have responsibilities. They should, for example, be willing to modify their practice in the interest of patient safety. If hospital chefs refuse to comply with new safe food preparation guidance, they have no good reason to expect to continue to be employed. So too in frontline healthcare roles, staff are rightly required to modify their practice in the light of evidence about patient safety.

Low risk from vaccination
Where might vaccination against a new infectious disease fit into this? In terms of personal morality, the low risk from vaccination means that health workers whose unvaccinated status poses a risk to patients have an obligation to accept vaccination. They have what is sometimes referred to as a “duty of easy rescue.” Although covid-19 vaccines confer less than 100% protection and are available under emergency approvals, the evidence of impact on patient safety and of low risk of adverse effects is sufficient to establish this duty, other than in exceptional cases such as where the risk of serious health implications that vaccination poses to an individual staff member is high.

But should health and care workers be compelled to accept vaccination? There are many things staff should arguably do on moral grounds that it would be wrong for employers to require as a condition of continued employment, such as being welcoming and friendly to all patients. Legitimate compulsion, then, requires further justification: what are employers’ responsibilities in relation to existing unvaccinated staff and the safety of patients?

Employers should certainly actively promote vaccination, establish a culture in which vaccination is expected, and make it as easy as possible for employees to be vaccinated. They should also move staff who are reluctant to be vaccinated, or those with a medical contraindication, to roles where the risk to patients is low. Ideally, this should be done immediately for all unvaccinated staff. There may, however, be some situations in which an immediate reallocation would create greater risk than the continued presence of the unvaccinated care worker. Transitions of this kind require careful, responsible management and can take time. In such situations a formal risk assessment should be undertaken and a plan put in place for the safe and timely reallocation of staff. The fact that there will be times when moving staff would put patients at greater risk—where, for example, recruitment is difficult—is not a justification for doing nothing.

Obligations to patients
What should happen when all reasonable alternatives have been explored but it is still not possible to swiftly ensure that patients are cared for by vaccinated staff? At this point, for employers to meet their obligations to patients they should make it mandatory for all remaining frontline staff without a serious medical contraindication to be vaccinated. A plan should be put in place to move those in whom it is contraindicated to other roles as quickly as possible. Any such plan should consider whether an individual staff member might leave if required to be vaccinated and assess whether this would put specific patients at serious risk of harm. Where there is clear evidence that this is the case a temporary, time limited delay—perhaps of up to two months—accompanied by a structured plan of action may be appropriate.

Although health and social care institutions are ultimately responsible for the safety of patients, it is worth repeating that the low levels of risk involved mean there is a strong argument for considering the vast majority of health and social care staff to have a personal moral obligation to accept vaccination against infectious diseases that put their patients at significant risk of serious harm.
New English law will make vaccination a condition of employment for care home workers, following similar moves in Italy, France, and Greece for healthcare staff. Michael Parker argues this is reasonable as institutions have a duty to protect patients; but Helen Bedford, Michael Ussher, and Martine Stead worry that such a blunt approach is unnecessary and could be counterproductive.

**Freedom of choice**
We consider that mandatory vaccination is “a blunt instrument to tackle a complex issue”: it is not necessary, acceptable, or the most effective way to achieve high uptake, and it raises serious ethical issues about freedom of choice. Although it can be argued that freedom of choice does not trump protecting patients and home care residents, mandatory vaccination could be counterproductive.

In England, covid vaccine uptake among adults in the general population, and among staff in NHS and older adult care homes, is generally high: 87%, 90%, and 87% of these respective groups have been vaccinated with at least one dose, although the accuracy of the data on care home workers has been questioned. However, uptake varies geographically and between sociodemographic groups, with lower uptake or intended uptake (hesitancy) among some minority ethnic groups also reported.

Of concern, a large study of healthcare workers reported that those in patient facing roles, including nurses, nursing associates, and midwives, were more likely to be hesitant. Health and social care workers are obviously not immune to vaccine concerns or susceptibility to misinformation. As with the general population, exploring the reasons for vaccine hesitancy among these workers is fundamental to informing interventions to improve uptake.

**Initiatives to improve vaccine uptake**
Hospital trusts have reported successful initiatives to improve staff vaccine uptake, which address the main reasons for hesitancy. These include improving access and providing support for booking vaccine appointments; providing evidence based information in various formats and languages, including regular question and answer sessions in online webinars; and drop-in sessions where concerns are acknowledged and dealt with non-judgmentally.

An “active listening” approach to providing information, while recommending vaccination, builds trust—a key factor in vaccine acceptance. Importantly, vaccine advocates and ambassadors involved in these initiatives were mainly from minority ethnic groups. Staff reported that vaccine confidence among more senior colleagues, particularly clinicians, was influential. Since healthcare workers, together with the NHS, are the public’s most trusted source of information about covid vaccine, such strategies may also help to improve vaccine confidence among the wider population.

In the context of concerns about suboptimal vaccine uptake, mandatory vaccination can seem a straightforward solution, requiring less resource than other interventions, but it has downsides. Notably, it may risk increasing resistance to vaccination by damaging trust in the government and other organisations. This is of particular concern among ethnic minorities, who are over-represented among health and social care workers, have been disproportionately affected by covid-19, are less likely to trust government sources of information, and are more likely to be vaccine hesitant.

In a recent public consultation, 47% of care home workers did not support mandatory vaccination. There are reports of staff threatening to leave rather than be forced to be vaccinated, which is a particular concern owing to shortages in NHS and care home staff. Although this does not seem to have been borne out in Australia, where flu vaccine is mandatory for some health and social care staff, enforcing vaccination risks damaging the morale of an already pressured essential workforce.

To maximise uptake, mandatory vaccination should be the last resort when other measures have failed. But vaccine uptake is generally already high in health and care workers, and it can be improved with less extreme measures. The UK already has highly successful vaccine programmes across the life course without recourse to compulsion; introducing such a coercive practice now, even if only for specific groups, represents a slippery slope that is best left untrodden.

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PATIENT COMMENTARY

Protect patients, with staff exemptions only for medical reasons

A covid vaccine should be mandatory for all care workers, says Michael Mittelman

More than 50 US medical organisations—including the American Medical Association—are calling for compulsory covid vaccination of healthcare staff. Many US healthcare settings already have such a policy, but many allow exemptions for religious, philosophical, or other reasons.

I have a rare kidney disease, three transplants, and other chronic conditions. People like me, at high risk from covid-19, must be protected by and from the staff caring for us. All patients and staff could have their exposure to SARS-CoV-2 reduced if all healthcare workers who have direct contact with patients were required to get a covid vaccination, with exemptions only for medical reasons. Not being able to trust the healthcare worker treating me, or the person bringing me a meal, breeds anxiety as covid variants spread.

Ken Sutha, a Stanford University paediatric nephrologist and also a transplant recipient, told me, “I worry about my patients’ exposure to covid-19 by unvaccinated healthcare workers. Young children may be ineligible for vaccination or might not mount a full response due to their anti-rejection medications. As a transplant recipient myself, I also worry about my own risk of exposure and the possibility not only that I might spread the virus but also that I might serve as an incubator for developing new variants due to my own immunosuppression if I were to be infected.”

Covid-19 vaccination is mandatory at Stanford, but staff can opt out for a plethora of reasons.

New York City’s healthcare workers must be vaccinated or undergo weekly testing instead. But only 60% of the city’s public hospital workers are vaccinated, and weekly testing is not good enough: I could get sick from a person who tested negative yesterday but would test positive today.

Employers should make vaccination as easy as possible for staff. Staff who are medically ineligible should be required to work away from patient facing roles. As a patient who needs care in multiple settings, I hope that mandatory vaccination rules become universal, with only medical exemptions permitted. It would alleviate some of my anxiety in receiving care.

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COMMENTARY

Don’t blame social care workers for government failures

Staff leaving because of compulsory jabs will increase NHS pressures, says Nadra Ahmed

Covid has left social care providers battling for survival. Staff, like our NHS colleagues, work on the front line, but there was no cry to “keep them safe,” no “protective shield” around our services. In return for staff’s dedication, the prime minister blamed excess deaths in care homes on poor infection control, which outraged the sector.

Less than three months after vaccines became available the government consulted on making vaccination a condition of employment in care homes. Despite majority opposition the government has pushed ahead with this policy.

Our sector supports people at their most vulnerable, and we share the ambition to have a fully vaccinated workforce. In England, already over 87% of staff and 95% of residents are vaccinated at least once. London’s figures are much lower, however.

Even vaccinated staff can carry the virus, as can unvaccinated visitors including loved ones and healthcare workers. All health and care services and staff coexist to support patients and clients. Our workforce could leave and take jobs in the NHS, while social care residents could access treatment from healthcare workers who may be unvaccinated. It makes no sense.

This legislation targets an exhausted and anxious workforce as the cause of the spread of infection, such that their employment conditions must be amended. But where is the consideration for alleviating anxieties about adverse effects from new vaccines? It is not an ultimatum that staff need.

Care homes have a growing staffing crisis, with over 112 000 vacancies and the need for an additional 500 000 care workers in the next decade or so. The most dangerous assumption is that staff who walk out will be easily replaced: if staff who have not yet had a vaccine were to leave—potentially an additional 13%—care services would be unsustainable.

This policy highlights that social care is always seen as the problem, never the solution. Chronic underinvestment has directly affected the sustainability of services, which has been further eroded by the pandemic. The unintended consequence of this legislation will be greater pressure on the NHS if we cannot staff our services.

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