Researcher sues Roche over Tamiflu claims

A UK epidemiologist and Cochrane Collaboration researcher is suing the drug company Roche in the US, claiming it defrauded federal and state governments by falsely claiming that its antiviral drug oseltamivir (Tamiflu) could be a powerful tool in mitigating a flu pandemic.

Tom Jefferson is suing as a private whistleblower for $1.5bn (£1.1bn), roughly the amount the US public health authorities spent on their pandemic stockpile of oseltamivir. The stockpile is maintained today, though recent purchases have involved generic versions, as Tamiflu’s main patent expired in 2016.

Should Jefferson win, he would be awarded up to 30% of the money recovered, with the rest being returned to public coffers.

Jefferson’s Cochrane acute respiratory infections group was engaged by the UK government to review the effectiveness of oseltamivir in 2009, after an outbreak of virulent type A influenza H1N1. The group realised that many assumptions about oseltamivir were based on papers whose underlying data had not been published. Having been refused the detailed trial data from Roche they began a campaign—much of it conducted in The BMJ—and the data were finally released in 2013.

The group’s 2014 report, the first Cochrane review ever to be based on full clinical study reports rather than journal articles, concluded that oseltamivir could reduce the duration of flu symptoms and reduce the proportion of symptomatic cases among infected people. But it did not find evidence that the drug reduced transmission or respiratory complications, citing the poor design of the studies. These are vital criteria for any pandemic treatment or prophylaxis.

Jefferson argues that Roche “originally produced Tamiflu to meet the demands of seasonal influenza, but was not satisfied with the revenue it produced,” and so “embarked on a fraudulent campaign to convince the United States to add Tamiflu to its Strategic National Stockpile.”

He told The BMJ, “I believe Roche misrepresented that Tamiflu could stop the spread of an influenza pandemic—when the evidence doesn’t show the drug can even stop viral transmission, let alone prevent complications or deaths.”

A company spokesman said, “Roche has complete confidence in the safety and efficacy of Tamiflu. It plans to vigorously defend itself against these allegations.”

Owen Dyer, Montreal
Cite this as: BMJ 2020;368:m314
SEVEN DAYS IN

Esketamine: NICE doesn’t recommend it for treatment resistant depression

An esketamine nasal spray may not be available for NHS patients with treatment resistant depression because of uncertainties over its clinical and cost effectiveness.

In draft guidance NICE reviewed the effectiveness of esketamine in combination with a selective serotonin reuptake inhibitor or serotonin-norepinephrine reuptake inhibitor for adults who had not responded to at least two antidepressants in a moderate to severe depressive episode. It said that while current evidence indicated that the treatment “may be more effective at relieving the symptoms of depression than placebo and an oral antidepressant,” it was unclear how much benefit esketamine provided over other treatments as they “have not been compared directly.” It added that “the available evidence did not include psychological therapies.”

The spray, sold as Spravato by Janssen, was approved by the US Food and Drug Administration last March and by the European Commission in December despite concerns over limited evidence and the risk that patients could misuse or become addicted to the drug.

“It is unclear if any improvements will be maintained after a course of treatment and whether this will improve someone’s quality of life. Therefore, the costs of possible repeated courses of esketamine are unknown, as are the costs of providing the clinic service,” said NICE in its guidance, which is under consultation until 18 February.

Elisabeth Mahase, The BMJ  Cite this as: BMJ 2020;368:m329

Assisted dying
Belgian doctors stand trial in landmark case
Three Belgian doctors (two GPs and a psychiatrist) are accused of unlawfully killing a 38 year old patient by poisoning almost 10 years ago, in the country’s first criminal case involving assisted dying. The trial focuses on conditions in the 2002 legislation that must be fulfilled before a request for assisted dying can be acted on. It also highlights possible gaps in the law and the many emotions that patients, their families, and medical professionals may experience when involved in such a procedure.

Heart screening
Study shows executive programmes are unjustified
US “executive screening programmes” offer expensive cardiovascular testing even though the tests are not justified and often not covered by insurance, said a report published in JAMA Internal Medicine. Leading US medical centres offer “executive screening,” at prices ranging from $995 (£760) to $25 000, to wealthy people who can pay out of pocket for tests not covered by insurance. Professional organisations do not usually recommend the tests for people without symptoms, and no evidence shows they reduce deaths from heart disease.

Immigration policy
UK offers leading scientists fast track visa entry
The government announced a new fast track visa scheme to attract scientists, researchers, and mathematicians. The Global Talent route, open from 20 February, will not cap the number of people able to come to the UK. For the first time, UK Research and Innovation will endorse applicants from the scientific and research community. The prime minister, Boris Johnson (below), said, “As we leave the EU I want to send a message that the UK is open to the most talented minds in the world.”

Pensions
BMA calls for end to delays
The BMA’s GP committee urged NHS England to step in to resolve “unacceptable” delays that have seen only a quarter of GPs in England provided with a record of their pension contributions for the tax year starting 2017. The committee’s chair, Richard Vautrey, said in a letter to NHS England’s chief executive, Simon Stevens, “It [the delay] is leaving the majority of GPs without the relevant information to be able to make an assessment as to whether or not they are likely to face an annual allowance charge in any given year.”

Health inequalities
Poverty status is linked to worse care, says study
People living in England’s most deprived areas seem to receive the worst quality of healthcare in various types of services, health experts concluded in new research. Examples of inequality included having to spend longer in hospital emergency departments and having worse experiences when making appointments with a GP. Research from QualityWatch, a joint programme of the Nuffield Trust and Health Foundation, involved looking at 23 measures of healthcare quality to see how these were affected by deprivation.
MEDICINE

Public health

Trump moves to lower school nutrition standards

Donald Trump’s administration announced plans to roll back school food nutrition standards introduced under the Obama administration, by cutting the required levels of fruit and vegetables while allowing more hamburgers, pizza, and chips. The changes affect programmes that feed breakfast and lunch to about 30 million children, 22 million of whom are from low income families.

Car smoking ban has worked, study suggests

The proportion of teenagers exposed to secondhand tobacco smoke fell by 72% in England after a law to ban smoking in cars carrying children was introduced, a data analysis showed. The study, published online in the journal Thorax, examined 15 318 responses from the Smoking, Drinking and Drug Use (SDDU) surveys from 2012, 2014, and 2016. The proportion of children exposed to secondhand tobacco smoke in England was 6.3% (2012) and 5.9% (2014) before the ban took effect and 1.6% after it came into force, representing an absolute reduction of 4.1% and a fall of 72% from the period before the ban.

Meningitis

UK cases fall after infant vaccination programme

The UK’s infant vaccination programme against group B meningococcal disease resulted in a significant reduction in cases of the disease in young children, research from Public Health England reported in the New England Journal of Medicine. However, an Australian study published in the same journal found that, while the meningitis B vaccine also worked in teenagers, it did not provide herd protection against the meningococcal bacteria and so would protect only those who were immunised.

Regulation

CQC reinspect care homes after “duplicate” reports

The Care Quality Commission will reinspect dozens of care and nursing homes, after an internal audit found that reports contained “duplicate material.” The regulator found evidence of duplication in 108 reports, and 68 care homes will be reinspected. The remaining 40 will be republished with the duplicate material removed. Seventy eight reports involved material from two members of the public, whom the CQC called “experts by experience.” A further 30 involved a specialist adviser, who was a frontline worker.

Online GP service is fined for providing care illegally

An online GP service was ordered to pay more than £18 000 after admitting to providing an unregistered online GP service for 14 months. The court heard that the Bury based Medical Specialist Company also dispensed prescription drugs by mail from 1 April 2017 to 14 June 2018.

RESEARCH

The National Institute for Health Research announced a £58.7m research investment to protect the public from antimicrobial resistance, air pollution, and infectious diseases. The funding will come from 14 NIHR Health Protection Research Units

SIXTY SECONDS ON... MINIMUM UNIT PRICING

YOU MEAN BANNING CHEAP BOOZE?

In a manner of speaking. The policy to control the price of alcohol and stop the sale of very cheap alcoholic drinks was introduced in Scotland in May 2018. As a result, no drink can be sold at less than 50p per unit of alcohol. The policy aimed to reduce the sale and consumption of high strength, low cost products that cause the most health harms.

JUST THE TONIC?

NHS Health Scotland’s first analysis of alcohol sales in supermarkets and off licences over the full year since the policy was launched shows a 3.6% drop in the volume sold (in terms of units of pure alcohol), mostly cheap beer, strong cider, and spirits.

SO, THE MINIMUM PRICE IS RIGHT?

Not necessarily. It seems that people are prepared to spend more on alcohol, and sales have started to creep up. NHS Health Scotland has also published a study suggesting that the policy is not having much of an impact on children and young people.

DO CHILDREN BUY OR DRINK ALCOHOL?

Some do. After interviewing 50 teenagers aged 13-17 years who had consumed alcohol before and after May 2018, the researchers found little effect on their level of drinking or choice of drinks. Many of the favoured drinks cost more than 50p a unit, and where the price had risen most continued drinking it anyway because they could still afford it.

HOW, THEN, CAN TEENAGERS BE PERSUADED TO DRINK LESS?

Good question. The study found that price was only one factor influencing their drinking habits. Others included getting older, changes in tastes, and changes in personal circumstances such as friendship groups. Future research findings from NHS Health Scotland might give us a clue.

COULD THE POLICY BE CANCELED?

The Scottish parliament will review it in 2023, informed by NHS Health Scotland’s evaluation. Children and teenagers are just one group being looked at, and it’s possible the policy may benefit other groups, such as older people drinking at home.

Ingrid Torjesen, London

Cite this as: BMJ 2020;368:m328

Cite this as: BMJ 2020;368:m320
Babylon Health holds talks with “significant” number of NHS trusts

The digital provider Babylon Health is in talks with a “significant number” of hospital trusts in England as it seeks to expand its service in the NHS, the company has told The BMJ.

Babylon’s managing director for NHS services, Paul Bate, said the company wanted to spearhead a “fundamental transformation” in the way people accessed healthcare. His comments came as Babylon announced a major 10 year partnership with Royal Wolverhampton NHS Trust, a large acute care and community service provider that also runs 10 general practices, to deliver “joined-up” digital care to the city’s population.

The service, which is expected to go live later this year, will allow patients in the city to access primary, secondary, and community care through an app that lets them book video or face-to-face consultations, access their medical records, use Babylon’s AI symptom checker, and create personalised care plans.

Fundamental transformation

Ahead of the announcement, Bate told The BMJ, “We’ll be working with a wider number of trusts as well as in primary care in 2020. The aim is for Babylon would continue to look for

Diagnosis delay is killing patients with acute aortic dissection

Around 20% of patients with acute aortic dissection die before reaching hospital, and 50% die before reaching a specialist centre, shows an investigation by the Healthcare Safety Investigation Branch.

Hospital activity

The report on delayed recognition of AAD analysed hospital activity and other national datasets and found that it may occur in around 4.5 per 100,000 of the population a year, equal to around 2500 cases a year in England.

It showed that a delay in diagnosis occurs in around 16-40% of cases and is more likely if patients walk in to hospital or if doctors suspect there is a cardiac cause for chest pain.

The report said hospitals must improve diagnosis and management of aortic tears, and has tasked the royal colleges of radiologists and emergency medicine to create a standard process for suspected cases. AAD is a rare cause of chest pain but requires rapid treatment. As the most common symptoms are generalised chest and back pain, and it is not easy to identify on X-ray images, clinicians can miss the condition.

Five hour wait

The review was initially sparked by the case of a 54 year old patient who went to an emergency department after experiencing severe chest pain at the gym. After a five hour wait for a confirmed diagnosis, the patient died while being transferred to a specialist centre for surgery.

In response to the findings, HSIB has recommended that the royal colleges’ review “develops, deploys, and evaluates a national evidence based process to detect and manage patients with acute aortic dissection presenting to emergency departments. The process should form part of a wider strategy for managing non-cardiac chest pain in the emergency department.”

Elisabeth Mahase, The BMJ

Cite this as: BMJ 2020;368:m304
opportunities to expand the GP at Hand service but that it also wanted to work with hospitals to deliver integrated care.

“There are a significant number of trusts that have asked us about that [replicating the work with UHB] and who we will work with, because the model does work,” he told The BMJ.

The partnership deals show that Babylon’s ambitions extend beyond the UK primary care market, which it entered in 2017 by partnering with an NHS general practice in London to launch GP at Hand, which now has more than 70 000 registered patients and is expanding to Birmingham and Manchester.

Bob Morley, a GP and executive secretary of Birmingham Local Medical Committee, said, “I’d assume the [UHB] deal is a very successful deal for Babylon, in which case it would be inevitable that Babylon would wish to do this elsewhere. There’s no doubt there will be an ever growing proportion of NHS funding spent on the commercial digital sector.

“What the end result will be for general practice, the wider NHS, and, of course, its patients remains to be seen.”

Gareth Iacobucci, The BMJ
Cite this as: BMJ 2020;368:m266

Orthopaedic patients recalled amid unnecessary operation fears

More than 200 patients of an orthopaedic surgeon who practised at a private hospital where the rogue breast surgeon Ian Paterson worked have been recalled amid concerns that they may have had inappropriate or unnecessary operations.

Spire Parkway Hospital has recalled 217 patients of Habib Rahman for independent investigation of shoulder manipulation procedures carried out under general anaesthetic.

Rahman works in the NHS as a consultant orthopaedic surgeon for University Hospitals Birmingham NHS Foundation Trust. It confirmed it had not recalled any of his NHS patients.

The medical practitioners tribunal service placed interim conditions on his practice last July requiring him to work only for the Birmingham NHS trust and to have a clinical supervisor.

**No medically justifiable reason**

Paterson, an NHS consultant who performed breast surgery at Spire’s Parkway and Little Aston hospitals, was jailed for 15 years in 2017 for carrying out “extensive, life-changing operations for no medically justifiable reason.” His sentence was deemed unduly lenient and was increased to 20 years by the Court of Appeal.

The latest Spire recall came just days before the independent inquiry that was set up to look at the circumstances around Paterson’s malpractice was due to report. A spokesman said Spire had restricted Rahman’s shoulder practice in September 2018 before suspending his practising conditions on his practice last July requiring him to work only for the Birmingham NHS trust and to have a clinical supervisor.

**Habib Rahman worked at the same hospital as Ian Paterson who was jailed for 20 years**

The death of a baby boy seven days after his emergency delivery at a hospital hit by a maternity care scandal was “wholly avoidable,” a coroner has ruled.

Assistant coroner Christopher Sutton-Mattocks ruled that neglect was partly to blame for Harry Richford’s death at Queen Elizabeth the Queen Mother Hospital in Margate, Kent, in 2017. The coroner heard that Harry was born by emergency caesarean section not crying or moving, and was left for 25 minutes before “panicking” staff helped him to breathe.

Sutton-Mattocks said the baby’s parents, Sarah and Tom Richford, were “grieving for a child they believe should not have died.” He added, “I agree with them.”

He criticised East Kent Hospitals University trust for characterising the death as “expected,” so the coroner was not informed. Only the persistence of Harry’s family led to the inquest, he said.

The failings did not reach the threshold of unlawful killing, he added. But there were failures, some from people who lacked experience for the positions they filled.

**Unannounced CQC inquiry**

Just before the end of the inquest, the CQC carried out an unannounced investigation into the trust’s maternity services but has not yet decided whether to prosecute for failing to provide safe care.

At least seven preventable baby deaths may have occurred at the trust since 2016, a BBC investigation found. In 2015 the trust asked the Royal College of Obstetricians and Gynaecologists to carry out a review, citing “concerns over the working culture.” The BBC said the college’s report found poor team working, with consultants who were “doing their own thing rather than following guidelines.”

Paul Stevens, the trust’s medical director, said, “We wholeheartedly apologise for our failings in Harry’s care and accept the coroner’s conclusion and findings.”

Responding to the wider concerns a trust spokesman said, “We are reviewing our service with leading maternity experts to make sure we are doing everything we can to make rapid improvements to maternity care.”

Clare Dyer, The BMJ
Cite this as: BMJ 2020;368:m309

**Baby’s death at Margate hospital was “wholly avoidable,” says coroner**

Clare Dyer, The BMJ
Cite this as: BMJ 2020;368:m326
China coronavirus: what do we know so far?

Elisabeth Mahase reports on the facts that have been emerging on the new pneumonia-like illness

Is it similar to SARS or MERS?
The virus is a type of coronavirus, a family that includes the common cold, severe acute respiratory syndrome (SARS), and Middle East respiratory syndrome (MERS). MERS was first identified in Saudi Arabia in 2012, and around 34% of people reported as infected with the virus have died (858 of 2494 cases). Its R0 is less than one. The SARS outbreak of 2002-03 led to 8098 identified cases and 774 deaths (9.6%). It has an R0 of 2-5.

Where did it start?
The initial source of 2019-nCoV is still unknown, but the first cases were linked to a seafood market in Wuhan, capital of Hubei province. The market was closed on 1 January in efforts to contain the outbreak.

How many confirmed cases?
As at 28 January 4520 confirmed cases and 106 deaths had been reported in China (including Macau). Most cases (2714) are in Hubei province, where the outbreak began. Thailand has reported 14 cases; Hong Kong eight; the US, Taiwan, and Australia five each; Singapore, Japan South Korea, and Malaysia four; France three; Canada and Vietnam two; and Nepal, Cambodia, and Germany one.

Can it spread person to person?
Yes, human to human transmission has been confirmed, and there have also been unconfirmed reports that the virus may spread before symptoms show. WHO said that the preliminary R0 (reproduction number) estimate is 1.4 to 2.5, meaning that every person infected could infect between 1.4 and 2.5 others. However, MRC Centre researchers have more recently estimated that, on average, each person infected 2.6 others.

Is the death rate?
The case fatality rate of 2019-nCoV infection has fluctuated as the numbers change. On 23 January WHO estimated it at 4% (17 of 557 cases). Peter Piot, professor of global health and director of the London School of Hygiene and Tropical Medicine, said, “The good news is that the data to date suggest this virus may have a lower mortality than SARS, we have a diagnostic test, and there is greater transparency. That is essential, because you cannot deal with a potential pandemic in one country alone.”

What were the SARS lessons?
Diana Bell, from the University of East Anglia’s School of Biological Sciences, said that after SARS there was an emphasis on wildlife trade as a “major dual threat to human health.” However, she said that the warnings have clearly not been heeded.

But Paul Hunter, professor in medicine at UEA, thinks there has been some improvement. He said that Chinese authorities had been “much more open about the outbreak, investigated the infection much more rapidly and thoroughly, and shared that information with the international community.

“As a result, neighbouring countries should be able to prepare well in advance of any cases that may arrive on their shores.”

What action has China taken?
Travel bans on several cities near Wuhan have been imposed, affecting more than 41 million people during Chinese New Year preparations. Michael Head, senior research fellow in global health at the University of Southampton, called the restrictions “unprecedented” and raised concerns over the effects on people inside the quarantine zones. “Will they have enough food to eat? How are emergency cases going to be treated? Will the hospitals have any medicines left? These are all questions China will be considering right now,” he said.

How are other countries doing?
Many countries, including the UK, have implemented screening at borders or on flights from the affected region in China. However, people may be infected but not have symptoms. A diagnostic test has been developed, and countries are quarantining and testing suspected cases. In the UK people who have been to Wuhan in the past 14 days and have developed respiratory symptoms are being advised to phone NHS 111.

What’s the advice for health staff?
NHS staff are being told to ensure they take an accurate travel history from all patients with acute respiratory infections. GPs are being asked to identify possible cases, isolate the patients immediately, and seek specialist advice.

Is this a global emergency?
WHO met on 3 January to determine whether the situation should be deemed a public health emergency of international concern but decided against it. However, the committee is expected to reconvene this week to reconsider the situation. Many believe it’s only a matter of time that an emergency is declared.

Cite this as: BMJ 2020;368:m308

Michael Head, senior research fellow in global health at the University of Southampton, called the restrictions “unprecedented.”

Many believe it’s only a matter of time that an emergency is declared.
New panel to set out how NHS can achieve net zero emissions

NHS England is establishing an expert panel to set out how the service can get to “net zero” on greenhouse gases ahead of the 2050 national target, the first major health service to do so.

The panel will examine changes that can be made to cut the NHS’s carbon footprint by looking at its supply chain and energy use. It will submit an interim report in the summer, and the final report is expected in the autumn, ahead of the COP26 climate change summit in Glasgow in November.

The causes of air pollution and climate change are often the same, and both contribute to rising pressure on health services. Last month a group of 175 doctors and health professionals wrote to the Times newspaper saying that air pollution was directly adding to current pressures in emergency departments.

Simon Stevens, NHS England’s chief executive, also announced the launch of a national campaign, For a Greener NHS. Supported by the UK Health Alliance on Climate Change, the campaign will encourage staff to cut emissions, energy use, and waste and will look at phasing out oil and coal boilers and increasing the use of LED lighting and electric vehicles.

Stevens said, “With almost 700 people dying potentially avoidable deaths due to air pollution every week, we are facing a health emergency as well as a climate emergency.”

A new NHS standard contract will advise hospitals to reduce carbon emissions from estates and switch to less polluting anaesthetic gases, better asthma inhalers, and more active travel by staff.

The expert panel’s chair, Nick Watts of University College London, said, “Everyone who works in healthcare has a responsibility to take action on the health emergency posed by climate change, and I encourage all NHS staff to join the campaign to feed in their ideas and help drive this forward.”

Initiatives

Doctors and other staff are encouraged to share ideas and evidence of hospital initiatives with the panel at www.england.nhs.uk/greenerNHS.

Some trusts are taking steps to reduce their carbon footprint. For example, Barts Health saved 2200 tonnes of CO₂, a year across six sites through Operation TLC, which involved turning off equipment such as printers and photocopiers, switching off lights, and closing doors to keep in heat.

Newcastle upon Tyne was the first trust to declare a climate emergency. It planted 100 trees at Freeman Hospital and created a wellbeing garden, reduced plastic use, and successfully trialled bicycle couriers.

Manchester University trust has encouraged staff to change how they travel to work by introducing a car club, subsidised hybrid bus shuttle services, and initiatives to encourage cycling.

Katherine Henderson, president of the Royal College of Emergency Medicine, said, “The air pollution and increased frequency of adverse heat events caused by the burning of fossil fuels lead to higher rates of respiratory and cardiovascular diseases and mental health crises, all of which will increasingly impact on the already stretched emergency care system.”

Jacqui Wise, London

Cite this as: BMJ 2020;368:m310

In the UK healthcare is responsible for 5.4% of the country’s net emissions, says a report from the NGO Health Care Without Harm

FIVE MINUTES WITH . . .

Rosena Allin-Khan

The A&E doctor, London MP, and Labour deputy leader candidate talks about her political priorities

“I am a doctor first. I didn’t become an MP to stop being a doctor. Working shifts in the emergency department also helps me form coherent, evidence based arguments. I see the effects of austerity every time I do a shift, and I can talk about that with real legitimacy. An emergency waiting room is like a microcosm of society. When I’m working I can see the impact of cuts not just on our NHS but on the wider community, on education, on housing.

“I decided to become an MP because through my work, both in the NHS and in places of conflict and postwar areas, I could see that not all life is valued equally. The morning after the last election, I decided to run for deputy leader because I felt like a door had closed on a future generation who are growing up in poverty like I did, and that nothing would get better unless we fought for it.

“As deputy leader I would do what I do as a doctor when someone comes to see me and they need a diagnosis. I would listen to what they have to say, take a thorough history, and do tests if I need to, before I work out how to fix them.

“I’ve started travelling around the country, talking to people about why they voted the way they did. It’s the rebuilding process through listening.

“In terms of health, I want to ensure our NHS isn’t privatised. Boris Johnson has said the NHS is not on the table for a US-UK trade deal, and I’m going to hold him to that. At the same time, our social care system is on its knees, and I want to put extreme pressure on the government to produce the social care green paper that we have been waiting for for so long. I will push for a real parity of respect for our elderly people.

“I want people to know that politics is for everyone. One thing I’ve learnt in this job is that MPs respond to pressure. People should not feel that their voices do not matter.”

Rosena Allin-Khan is a junior doctor who works in the emergency department at St George’s Hospital, Tooting, London. She was elected as an MP in the 2016 by-election.

I WILL PUT EXTREME PRESSURE ON THE GOVERNMENT TO PRODUCE THE SOCIAL CARE GREEN PAPER

Rosena Allin-Khan, The BMJ

Cite this as: BMJ 2020;368:m292
Chinese premier rallies medics in coronavirus fight

China’s premier, Li Keqiang, visited the Wuhan Jinyintan Hospital this week to support the health workers tackling the outbreak of the novel coronavirus in the area. Li—head of the Communist Party’s central committee leading on the outbreak—arrived in Wuhan on 27 January to inspect and direct the prevention and control efforts. He spoke to frontline medical workers at the hospital in central China’s Hubei province.

A report from Imperial College London warned this week that uncertainty over the severity spectrum of the coronavirus, and whether people with mild symptoms could efficiently transmit the virus, meant that it was currently “unclear” whether the outbreak could be contained within China.

The researchers said that controlling the situation would require “successful detection, testing, and isolation of suspect cases with the broadest possible range of symptom severity,” and they called for efforts in these areas to be as “extensive” as the capacity of health services allow.

Tom Moberly, The BMJ

Cite this as: BMJ 2020;368:m343
GPs condemn new network specifications

Back in July when primary care networks (PCNs) got off to a flying start, I warned of two key risks to this good beginning. The first was that these emergent PCNs would get overburdened with too many commitments, and the second that some commitments might look sensible in theory but prove too hard to implement in practice.

These risks exist because of the multiple challenges to which primary care networks are meant to be the answer: firstly, to stabilise general practice given the current workforce and morale crisis; secondly, to bridge a gap in the evolving reformed structure of the NHS by acting as the principal link between general practice and the rest of the health and care system; and, lastly, to deliver key elements of the long term plan through a set of new service specifications.

Unrealistic expectations

In December, NHS England and NHS Improvement released five of these new service specifications for consultation, setting out requirements for enhanced services for care homes, structured medication reviews, services to support early cancer diagnosis, and plans for personalised care and anticipatory care. General practitioners responded with widespread condemnation. Social media is full of GPs threatening to pull out of PCNs and the associated contract, a striking turnaround given the fanfare around its launch this time last year. The BMA’s General Practitioners Committee has now formally rejected the contract package and draft service specifications and called for a special conference of local medical committees to discuss PCNs. How has this happened, and what is the way forward?

The aims of the specifications look reasonable and seem to have been written by people who understand the subject and the evidence, at least as a basis for consultation. Where they slip up is the required call on general practice resources during the current deep capacity crisis. There is, of course, a commitment to increase capacity through more GPs and other staff, including pharmacists and physiotherapists. This promise of more staff in the future (when the specifications will really bite) is theoretically sound but risky. It assumes that new staff will be found and that the organisational challenge of developing new teams is quickly solved. Pent-up demand for access may also consume most or all of planned increases in capacity. For many GPs the specifications were also very detailed and prescriptive and left little room for local priorities.

An analysis may exist somewhere showing that this new supply will be enough to improve access to primary care, deliver the service specifications, and make the working life of GPs acceptable again. But, if so, it’s not in the public domain. Tired, overworked GPs see only that the service specifications will increase their workload.

Richard Murray, chief executive, King’s Fund, London R.Murray@kingsfund.org.uk

Tired, overworked GPs see only that the service specifications will increase their workload

Lack of capacity means that PCNs are being set up to fail

EDITORIAL

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Find the full version with references at http://dx.doi.org/10.1136/bmj.m258

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EDITORIAL

Boost for sustainable healthcare

Cochrane joins the fight against waste, corruption, and futility in healthcare

At the preventing overdiagnosis conference in Sydney, Australia, in December 2019, Cochrane launched a new group, “sustainable healthcare.” It seemed particularly appropriate in a city blanketed by thick yellow smoke from the bush fires that raged around it.

The group will have the potential to bring together issues of futility and waste within biomedicine; corruption in the production and governance of biomedical research; exploitation of planetary resources and the resulting climate change; the burgeoning costs of biotechnical healthcare across the globe; and the threat this represents to universal health coverage. This is an enormous agenda of interconnected issues that exacerbate each other in a series of increasingly vicious circles.

Too much medicine

The BMJ is one of a growing number of journals, organisations, researchers, clinicians, patients, and citizens drawing attention to the problems posed by overscreening, overtesting, overdiagnosis, and overtreatment. Modern medicine has been a powerful force for good. However, because of humanity’s shared reverence for that success, combined with the increasing financial rewards from the industrialisation of healthcare, almost everyone has been slow to recognise that medicine also has great power to harm.

Professional and political hubris has allowed a now vast screening industry to move away from the invaluable principles established by Wilson and Jungner back in 1968— including that a condition’s natural course from any latent phase to evident disease should be adequately understood. Now, ever increasing numbers of healthy people are being labelled as having life threatening diseases that do not subsequently seem to progress. These labels cast shadows of fear across the lives of individuals and families.

Screening and preventive treatments are also given to frail elderly people who have little chance of benefit in the face of their inevitably diminishing life expectancy. Diagnostic thresholds seem to be constantly lowered, despite the diminishing likelihood of treatment benefit for people who are only mildly affected and mostly have no symptoms. Waste and futility are everywhere, generating huge profits and driving corruption alongside the concealment of vested interests, both professional and financial.

In 2019, a report by EvaluatePharma (which claims to provide “accurate, transparent commercial intelligence” for the drug industry) declared: “There is significant optimism around the launch of new technologies and the approval of the first cell and gene therapies, resulting in prescription drug sales being forecast to reach $1.18tn.” This sum of money can only be realised by continuing and intensifying the medicalisation of life and society, and by persuading all of us to consume ever more medicines and other healthcare technologies.

Environmental harm

The carbon footprint of the drug and health technology industries has received remarkably little attention, but the global drug industry alone has been estimated to be 55% more emission intensive than the automotive industry. Furthermore, every medicine produced ultimately ends up in the global ecosystem with as yet unknown implications for natural habitats. Rivers in all regions of the world are now contaminated with many medicines.  

In the face of these overwhelming challenges, what can the new Cochrane group offer? Its existence is a recognition of the importance of this concatenation of issues and provides vital support for the increasing number of researchers working (often against fierce opposition) to quantify the harms being caused to patients, citizens, and the environment globally. The importance of this support and validation cannot be underestimated. Beyond that, the new group offers opportunities for networking within and across all relevant disciplines, identifying new research topics, remaining vigilant about research standards, and widely disseminating research findings.

In his 2015 book Island Home, Australian writer Tim Winton argued: “The gospel of perpetual economic growth carries in its train the salvation promise of a life bigger and better for everyone. But this greater good is often mythical. The actual experiences of believers rarely bear out the claims of their faith. Even so, many adherents cleave stubbornly, fearfully to orthodoxy… Challenging this mindset has traditionally been the work of loons, heretics and Luddites.” No longer. Now it is also the work of Cochrane.

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Brexit is done. The UK has left the European Union, in a process that will be difficult to reverse and that a powerful majority government intends to progress at full tilt.

But this won’t make any immediate difference: a standstill “transition” will keep almost every law and process in place. So what real changes will affect doctors and others working in the NHS? When? And is it too late to influence what they might be?

The crucial date looks set to be this December, when the transition period ends. At that point the UK moves from being closely enmeshed in the EU to formally relating to it only through one or more trade and cooperation agreements—or none. Before then, agreements will need to be ratified by parliaments across Europe, so negotiation will have to happen in a few months this summer.

As one of the most globalised aspects of healthcare, drugs and devices will be strongly affected. The Department of Health and Social Care for England’s top civil servant told MPs in 2018 that two thirds of UK medicines came from or through the EU.

Lighter regulatory burden
Within the single market, many regulatory processes need to happen only once for products to be sold across Europe, including the UK. This lighter regulatory burden means drug prices are probably 5% or more below what they otherwise would be, and new products are introduced months earlier than in a medium sized market such as Canada.

Recognising this, Theresa May’s government aimed for the UK to continue to participate in the European Medicines Agency, which gives out single approvals for many cutting edge new medicines across the EU. But this was always difficult to square with her commitment to leave the wider single market. This government, with its emphasis on divergence, will find this an even tougher ask—if it can be persuaded to try at all.

Even within the limits of trade deals such as those the EU has across the world, though, there is still a lot to play for. It has agreements with many countries to recognise each other’s inspections of drug factories, removing a layer of bureaucracy from trade. The EU has an agreement with Australia to mutually recognise the assessment of medical devices.

Every barrier avoided matters. Since the referendum we have seen how price pressures, in this case due partly to the lower value of sterling, seem to be exacerbating shortages of generic drugs. The sharp shock of extra trade friction could still threaten a “no deal” type of disruption to NHS supplies on the day transition ends.

These are sensitive issues to negotiate, with patient safety and what the EU sees as the “integrity of the single market” at risk. It will take tremendous effort to cover them in a six month dash for the finish line.

Similar concerns exist at an earlier stage in the introduction of new treatments: clinical trials. After years of criticism of a bureaucratic system that drove research away, the EU is about to introduce a more streamlined approach. This will involve a single online portal to submit applications, and one approval process, led by one member state.

Not being part of this will make the UK a less attractive place to carry out trials, because adding a UK arm to an EU trial will mean many extra hoops to jump through. The government seems to be actively planning for this, with its recently announced Medical and Medical Devices Bill, described, without detail, as “removing unnecessary bureaucracy for the lowest risk clinical trials.”

It makes sense for the UK to try other ways to be competitive as a place for science if we are shut off from the EU system. But we need to be honest about whether this will fully compensate and be careful about implications for safety and trust.

The UK’s chances of remaining part of the EU’s science framework programmes should be much better. These multiyear initiatives fund many innovative international life science projects, such as the recently awarded research contract for gene based diagnostics to be led by Imperial College London. There is a well established associate member status. But Switzerland’s access to this was suspended during wider debates about the country’s relationship with the EU. It is idealistic to imagine that health and science would not be part of a game of trading favours in the intense disputes to come over issues such as fisheries, competition rules, and agriculture.

Many potential disputes stem from the EU’s goal of a “level playing field” to stop the UK undercutting its industries after it becomes a competitor. Two issues here are the Working Time Directive, seen by some doctors as a restrictive curse and by others as a valued protection for the lowest risk bureaucracy for the lowest risk.

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Brexit will mean big and often difficult changes. But exactly how big is only now about to be decided—very, very quickly. The leaders of the medical profession will need to be prepared to fight their corner as UK interest groups begin to struggle against each other and against the EU for the most favourable deal possible.

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Why are US doctors testing young women needlessly?

Every year millions of teenagers undergo invasive gynaecological exams, most against medical guidance. Kim Painter reports

Most teenage girls do not need pelvic examinations or cervical cancer screening tests, but many in the US get them anyway, new research shows.

Each year between 2011 and 2017 about 1.6 million girls and women aged 15 to 20 underwent unnecessary smear tests to screen for cervical cancer, and 1.4 million had pelvic examinations that weren’t needed, shows the study, published in January in JAMA Internal Medicine.

These practices are out of line with guidelines of major US medical groups, which have set 21 as the starting age for cervical cancer screening since at least 2012. Guidelines on pelvic examinations, which many US doctors learnt as a standard practice to screen for a range of gynaecological problems, have evolved in recent years, but no group recommends their routine use in healthy teenagers.

In the UK cervical cancer screening starts at age 25, and pelvic exams (vaginal exams) are recommended only in women with symptoms such as abnormal bleeding and pain.

The new findings show how medical practice often lags behind evidence and guidelines, the researchers say. Potential harms include extra costs and follow-up tests but also “fear, anxiety, embarrassment, discomfort and pain,” the researchers write.

Old habits?

“I suspect it’s really just old habits that haven’t changed,” says study coauthor George Sawaya, a professor of obstetrics and gynaecology at the University of California San Francisco.

The findings point to broader problems with “learning how to unlearn” outdated practices, says Melissa Simon, vice chair for clinical research in the department of obstetrics and gynaecology at the Northwestern University Feinberg School of Medicine, Chicago.

Simon, who wrote an editorial on the new study, says that despite the lack of medical justification many insurers cover the questionable exams. The estimated cost nationally, according to the study: $123m (£94m) a year.

The study included 3410 women aged 15 to 20 who were enrolled in the National Survey of Family Growth from 2011 to 2017. Participants were asked about smear tests and pelvic examinations “where a doctor or nurse puts one hand in the vagina and the other on the abdomen.”

Nearly 23% of the participants reported undergoing a bimanual pelvic examination and 19% a smear test in the previous year. After looking for medical explanations—such as pelvic examinations in pregnant or symptomatic women—the researchers found that more than half of the pelvic examinations and nearly three quarters of the smear tests were potentially unnecessary. That would translate to millions of unneeded tests nationwide.

Inconsistent guidance

While US guidelines on cervical smear testing are consistent, those on pelvic examinations are not. The American College of Physicians says the examinations have no value as a screening tool for cancers or infections. The US Preventive Services Task Force says evidence is insufficient to recommend for or against the practice. The American College of Obstetricians and Gynecologists also says evidence is lacking but urges doctors and patients to engage in shared decisions concerning examination.

A first visit to a gynaecologist is a golden opportunity to start that conversation and build trust, says Catherine Cansino, a coauthor of the current guidelines of the American College of Obstetricians and Gynecologists. She is an associate clinical professor of obstetrics and gynaecology at the University of California, Davis.

Believing, incorrectly, that a pelvic examination is needed to get most forms of birth control or to test for sexually transmitted infections “may discourage a girl or woman from coming to the doctor,” she says.

One small study in Obstetrics and Gynecology found that 13 of 30 young US women interviewed about their first pelvic examinations felt “poorly prepared.” One participant said she “was not sexually active or anything like that” and experienced “a lot of anxiousness, nervousness” about an internal examination.

Others praised sensitive care. One, who had been sexually abused, said, “The first time I went to the gynecologist when I was 19, I had just recently retrieved the memories of my assault, and so I’m really glad actually that I didn’t have a pelvic exam at that first encounter.”

Susan Bewley, professor emeritus of obstetrics and women’s health at King’s College London, says, “It’s just obvious to us that routine vaginal examinations are unnecessary. In the NHS we pull the stops out if people have symptoms. We don’t waste well women’s time, money, and effort, and [risk] anxiety doing an unpleasant, invasive form of ineffective screening.”

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Mobile attackers with bladed weapons, firearms, or explosive devices are currently a significant global threat to the public and emergency responders. The risk of chemicals, vehicles, and fire used as weapons adds further complexity to such attacks.

Recent attacks have killed many people: more than 9800 terror attacks occurred worldwide in 2018, resulting in 22,980 deaths. Some of these people might have survived had the medical response gained access to them earlier. Emergency services face the problem of how to provide medical care to casualties in an area deemed under direct threat, known as the “hot zone.”

Although many of the armed police responding in the hot zone are also trained to provide some lifesaving medical care, they are the same armed officers who are trained to first locate and stop the attackers—delaying their focus on medical interventions until the threat is controlled. The resulting therapeutic vacuum of medical intervention can last for minutes to hours.

We believe that the UK should adopt standard military practice in these attacks and enable armed police to give “care under fire,” alongside management of the immediate threat. Appropriately trained medical officers should also be integrated with the police in the hot zone: this happens in France, as seen in the Paris terror attacks in 2015. These steps would tackle many of the areas that currently encourage this potentially lethal therapeutic vacuum in the UK.

The “hot zone” in a terror attack is one that poses a credible and continuing threat to life, including attackers with weapons. The “warm” zone is an area where the attackers are not believed to be present but a threat remains, and the “cold” zone is far enough from the threat to be considered safe.

Analysis and suppression of the threat and the declaration of these zones are led by the police. By working closely with police commanders, other agencies adapt their response, aiming for rapid treatment and extrication of patients. The hot and warm zones are often dynamic, rapidly changing in size or location as the incident evolves, as exemplified by recent attacks with mobile and multiple attackers. Unknown numbers and locations of attackers—and continual, potentially confusing, intelligence updates—also complicate the situation.

The term “therapeutic vacuum” was coined in the 1960s to describe the lack of prehospital advanced medical care for people in road crashes. The specialty of prehospital emergency medicine has evolved such that helicopter emergency medical services and ground based prehospital critical care teams are now standard in many countries. They deliver not only technical medical interventions but also decision making and medical leadership.

In the UK, however, these teams are currently not trained to work in high threat environments. Instead, the police are the only emergency service deployed in the hot zone, and, even then, initially only armed police. As mentioned, these officers are the same officers whose mission is to locate and confront the threat. So, while they are trying to stop the killing, no one is trying to save the lives of those casualties trapped in the hot zone.

The therapeutic vacuum was raised last year in the chief coroner’s report on action to prevent future deaths after the inquests arising from the fatalities in 2017’s terror attack at London Bridge and Borough Market. The report suggested improved training of police medics to be analogous to battlefield first aid. UK soldiers provide medical care while dealing with the immediate threat—a concept known as “care under fire.” He also urged action to tackle the problem posed by hot and warm zones.

A national review of joint operating procedures between ambulance, fire, and police services since the London Bridge
attack has dealt with some of these challenges in principle, but plans are yet to be tested.

Evidence is limited on the potentially preventable causes of death from terror attacks. The literature, predominantly military in origin, indicates that haemorrhage is the leading cause of prehospital death in 91% of military cases in Iraq and Afghanistan, and airway compromise is associated with 8%.

Emerging civilian data show the causes of death in US active gunman events, which point to lung injury (without any major vascular compromise) as the most likely cause of potentially preventable death. More data are required to cover all mechanisms of attack, but skills to adequately manage pneumothorax and ventilatory failure may be required earlier than in the cold zone, where it is currently provided in the UK.

The timing of interventions is critical if they are to save lives. Minimal data are available on the exact timings of deterioration and intervention. Although dating back to the mid-1960s, the most detailed database available is that of the Wound Data and Munitions Effectiveness Team. These are meticulously collected data from 7801 US casualties from Vietnam documenting all causes, injuries, timings, and interventions. These data showed that 62% of deaths occurred in the first 30 minutes (26% within five minutes). To deal with any of these preventable deaths the interventions need to be performed by people who can rapidly access the casualties.

Catastrophic external haemorrhage can be controlled with tourniquets, junctional wounds with haemostatic dressings, and pressure bandages, and airways can be opened by simple manoeuvres. All of these interventions can be provided by appropriately trained bystanders or first responders, such as police officers who may be present. For example, a passing ENT surgeon at the Westminster Bridge attack in 2017 opened a patient’s airway, allowing him to start breathing again after the initial effects of hyperacute head injury.

The UK has made improvements in the joint emergency services’ response to a marauding terrorist attack, including new operating principles that allow unarmed police responders into the hot zone and non-specialist ambulance responders into the warm zone, depending on the nature of the threat and method of attack. Simple care procedures that can be carried out by police officers, which form part of the “care under fire” concept, include tourniquets and rapid patient positioning for postural airway management.

All armed police in the UK are trained to apply tourniquets, blast bandages, and chest seals, to open airways, insert airway adjuncts, and to provide bag valve mask ventilation and administer oxygen. Some of the teams use these skills daily. However, in current training on marauding terrorist attacks, medical interventions are taught to be delivered only by armed police after the threat is neutralised. If this takes hours and the hot zone remains “hot,” no one is available to provide medical care to these casualties except for uninjured bystanders, because the armed police are not using their medical skills at this stage.

Meanwhile, patients with penetrating torso injuries, for example, have a high chance of internal non-compressible haemorrhage requiring rapid identification and extrication to hospital.

In an evolving terror attack it may be impossible to rapidly locate and neutralise or contain the mobile threat, and so police may not be able to immediately evacuate casualties. Even where evacuation becomes possible, however, some patients remain clinically trapped at the scene because of the nature of their injuries. For example, those with blunt injuries from an associated mobile vehicle attack may not be easily moved from the hot zone without potent analgesia.

Current triage systems allocate patients into broad groups commonly described as priorities 1, 2, and 3. But reports from
The coordination between the RAID forward medical commander and police commanders who train and work closely together, along with the movable warm zone corridor, is key to their success. In the incident at the Bataclan concert hall in Paris, two RAID doctors entered with police cover and triaged all casualties (about 100) from the orchestra pit while the intervention plan was coordinated. All live casualties were evacuated within 30 minutes of RAID entering the theatre and 30 minutes before the terrorists were killed. Had evacuation been delayed until after police intervention, as happens in the UK, it would have been three hours before any medical care was delivered. Only 1.4% of casualties evacuated from the Bataclan later succumbed to their injuries, compared with around 10% in historical military data.

In the US, integrated public safety rescue task forces, which include paramedics and firefighters, can rapidly deploy into warm zones behind the initial law enforcement response. Other warm zone integrated rescue response models include the “protected island” or “protected corridor,” allowing medical personnel to access and stabilise wounded people quickly. Sometimes, however, a rescue task force may not be available or appropriate. In these instances a “police rescue” by initial responders has occurred, for example, at the San Bernardino gunman event in California in 2015. Police provided immediate tactical emergency casualty care and evacuated casualties either to a collection station on the edge of the cold zone or directly to hospital, avoiding delays in treatment and evacuation.

In Australia, the Lindt Café siege in Sydney in 2014 precipitated improvements to the management of casualties in the hot zone and better integration between the police and healthcare services. A national, multi-agency drive to increase awareness and capability to respond effectively beyond the cold zone led to the development of the Australian Tactical Medical Association and increased medical skills for some police medics, and senior paramedics are now embedded with the Police Tactical Group in Sydney.

Internationally, there are examples of senior medical professionals embedded or working closely with police to ensure appropriate advice and decision making, communication with medical resources in warm and cold zones, and coordination of more rapid treatment and extrication of casualties from hot zones.

The recent terrorist events in the UK have been of a significant scale but have not tested the country’s resources to the extent of much larger events abroad. These relevant lessons from domestic and international events must be learnt and adopted into UK practice. The dying process does not wait for a warm or cold zone to be in place or for the threat to be completely suppressed. Trained and untrained bystanders may provide immediate and simple lifesaving interventions. Empowering bystanders is a repeated lesson from these international events.

People who die in these situations predominantly do so in the hot zone. The strategy to improve outcomes is to identify potentially reversible pathology and ensure that medical providers at the appropriate level, whether police medics, paramedics, or doctors, can access the patients to provide the required intervention.

Alternatively, the casualties need to be evacuated in a timely manner. A forward senior medical officer integrated with the police response is key to this dynamic decision making and can increase the fluidity of the tactical medical response. To achieve this in the UK, the current system needs further development.

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