this week

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JACK TAYLOR/GETTY IMAGES

Medical cannabis to be prescribed

The case of Alfie Dingley, who needs medical cannabis to control his epilepsy, was one of several that caused Sajid Javid to commission a review of UK drugs legislation

Medicines derived from cannabis will be available on NHS prescription from specialist clinicians for patients with an exceptional clinical need from the autumn, the government announced last week.

A clear definition of what constitutes a cannabis derived medicinal product will be developed by the Department for Health and the UK Medicines and Health Products Regulatory Agency. Products meeting the definition will become schedule 2 under misuse of drugs legislation, allowing them to be prescribed. Other forms of cannabis will stay under strict schedule 1 controls.

The home secretary decided to reschedule the products after receiving advice from experts through a two part review he commissioned on 19 June. Sajid Javid said, "Recent cases involving sick children made it clear to me that our position on cannabis related medicinal products was not satisfactory. That is why I set up an expert panel to advise on licence applications in exceptional circumstances.

"Following advice, I have taken the decision to reschedule cannabis derived medicinal products, meaning they will be available on prescription."

In the first part of the review England's chief medical officer, Sally Davies, concluded there was evidence that medicinal cannabis had therapeutic benefits. The Advisory Council on the Misuse of Drugs carried out the second part of the review, considering the appropriate schedule, based on the balance of harms and public health requirements. It recommended that products meeting a clear definition of what constituted a cannabis derived medicinal product should be placed in schedule 2 of the Misuse of Drugs Regulations 2001.

In the meantime, clinicians will continue to be able to apply to the independent panel on behalf of patients wishing to access these products. Javid also confirmed licence fees for applications will be waived.

Ian Hamilton, a lecturer in mental health at the University of York, said, "This appears to be a very conservative decision by the home secretary, as he could have opted for a lower schedule. Unfortunately this adds to the lack of credibility, as everyone knows that opiates and cannabis pose different risks yet they are now both schedule 2 drugs."

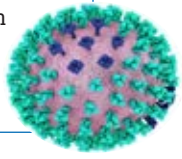
▶ ESSAY, p 138

Ingrid Torjesen, London

Cite this as: *BMJ* 2018;362:k3290

LATEST ONLINE

- Increase support for doctors being investigated after an unexpected death, says MDU
- GP lead is struck off after conviction for sexual assaults on patients
- Lack of public health resources leaves London vulnerable to pandemic, BMA warns



SEVEN DAYS IN

Protestors return Ebola care medals

Around 20 aid workers who were honoured for their work in west Africa during the 2014-15 outbreak of Ebola disease have returned their medals as a protest against the "hostile environment" policies introduced in the NHS.

The workers are calling for the repeal of the October 2017 regulations that enforce immigration checks and upfront charging of 150% before immigrants and foreign visitors from outside the EU can access NHS healthcare. They also want to see the removal of charges for pregnant women, newborns, and children as a priority.

An assessment by the humanitarian organisation Doctors of the World earlier this year found that pregnant women were particularly at risk and were deterred by the threat of antenatal care charges, with almost two thirds of those surveyed yet to access antenatal care at 10 weeks of pregnancy.

GP registrar Harriet Burn (pictured left, with Labour peer Alf Dubs), said, "It's hypocritical to be rewarded for providing healthcare overseas only to be prevented from treating vulnerable people at home. Even by the government's own estimates, the cost benefit of charging in these cases is minimal and will likely be outweighed by the administration cost and the expensive emergency care that patients end up needing when they are excluded from receiving earlier preventive care."

Zosia Kmietowicz, *The BMJ* Cite this as: *BMJ* 2018;362:k3243

Childhood obesity

Severe obesity in 10-11 year olds hits record high

Some 4% of children in school year 6 were severely obese in 2016-17, up from 3.2% a decade earlier. Public Health England's analysis of the National Child Measurement Programme found that the prevalence of excess weight, obesity, overweight, and severe obesity was higher in the most deprived areas than in the least deprived. The trend is happening at a faster rate in year 6 than in reception (ages 4-5).

Assisted dying

Falklands votes in favour of assisted dying motions

The Legislative Assembly of the Falkland Islands backed a motion that terminally ill residents should have the right to die at the time and place of their choosing, subject to robust legislation and safeguards. A second motion stated that, if assisted dying legislation is introduced in the UK, the Falkland Islands would consider adopting it. Both motions passed by four votes to three, with one abstention. Earlier this year Guernsey voted against a similar proposal that would have created the first such regime in the British Isles.

Radiology

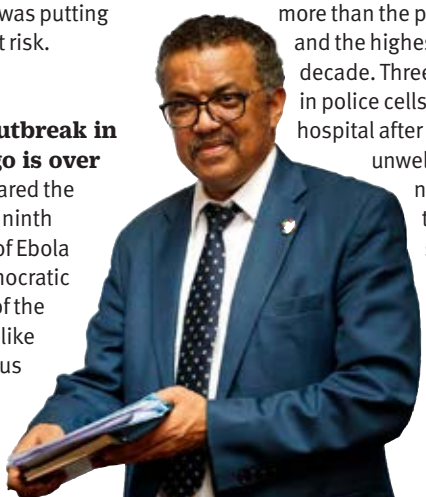
Regulator urges targets for reporting patient results

The Care Quality Commission called for national standards for the time it should take for patients to receive their results from radiology examinations, after it found "significant variation" in reporting times throughout hospitals in England. It inspected three NHS trusts—Worcester Royal Hospital, Kettering General Hospital, and Queen Alexandra Hospital in Portsmouth—and found serious delays in reporting on radiology examinations that had led to backlogs. Inspectors also identified images that had been reported on only by non-radiology clinicians who were not adequately trained to do so, which was putting patients at risk.

Ebola

Latest outbreak in DR Congo is over

WHO declared the end of the ninth outbreak of Ebola in the Democratic Republic of the Congo. Unlike the previous outbreaks this affected four separate locations, including an urban centre with river connections to the capital and to neighbouring countries and remote rainforest villages, prompting concerns that the disease would spread. WHO's director general, Tedros Adhanom Ghebreyesus (below), urged the country's government and the international community to build on the positive momentum generated by the quick containment of the virus.



Custodial health

Deaths in custody are highest for a decade

Some 23 deaths occurred in or shortly after police custody in 2017-18, the Independent Office for Police Conduct's annual report showed—nine more than the previous year and the highest number for a decade. Three people died in police cells, five died in hospital after becoming unwell in custody, nine were taken ill at the scene of arrest and died in hospital, four were taken ill while in a police vehicle, and two died after being released from police custody. Mental health and links to drugs or alcohol were common factors among the people who died.

"Groundbreaking" scheme aims to cut prison drug use

A three year pilot programme to tackle illegal drug use in prison by helping inmates to fight their addiction and by tightening security to shut down supply is already making progress, the government announced. Healthcare workers have been drafted in to support recovering offenders as part of the £9m pilot at HMP Holme House in County Durham, which began in April 2017. The scheme aims to help prisoners transition from custody to community by arranging appointments for drug and alcohol treatment, financial and accommodation advice, and family engagement.

MEDICINE

Child health

NHS launches action plan to cut stillbirths

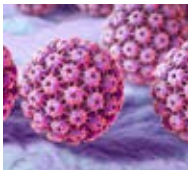
Around 600 stillbirths could be prevented each year if maternity units adopted national best practice, NHS England said. An independent evaluation published on 30 July found that improvements, such as better monitoring of a baby's growth and movement in pregnancy and better monitoring in labour, saved 160 babies' lives in 19 maternity units. Stillbirths fell by a fifth in units where guidance had been implemented. Best practice guidance is now being introduced across the country.

Dearth of new consultants in the community

Vulnerable children may fall through gaps because of an "extreme shortage" of newly qualified paediatric consultants in the community, the Royal College of Paediatrics and Child Health warned. It found just 9.6% of newly trained paediatricians took up a consultant post in community child health—the specialty responsible for assessing children for abuse and for treating conditions including attention deficit/hyperactivity disorder and obesity. This compares with recruitment rates of 65% in general paediatrics and 27.7% in specialist paediatrics such as neonatology.

HPV

Boys in England to be vaccinated



The vaccine against the human papillomavirus (right) is to be made available to boys aged 12-13 in England from next autumn, after the Joint Committee on Vaccination and Immunisation recommended extending the current programme. Until now only girls, and some men who have sex with men, have been offered the vaccine.

Former soldiers and other service personnel will be offered improved care under a new GP scheme

Primary care

GP clinics aim to be "veteran friendly"

General practices in England are signing up to become "veteran friendly" under a national scheme designed to improve medical care and treatment of former members of the armed services. The initiative, backed by NHS England and the Royal College of General Practitioners, aims to offer support to ex-military personnel who may face additional challenges in civilian life. It was devised by Mike Brookes, a North Yorkshire GP who served in Iraq.

Listed patients rise as number of surgeries falls

NHS Digital data showed 59 178 163 patients registered at general practices in England on 1 July, up three million from five years ago. In that time the number of general practices fell by 11% from 8053 to 7148. List sizes also increased: in July 2013 the largest proportion of practices (23.1%) had 2000-3999 registered patients, but in July 2018 the largest proportion (19.3%) had 4000-5999. These totals are higher than the population owing to patients still being registered when they die or emigrate, as well as patients not completing the census.

Cite this as: *BMJ* 2018;362:k3341

MEASLES

The New York City Department of Health and Mental Hygiene spent almost $395 000 and more than 10 000 personnel hours responding to **58** cases of measles in the 2013 outbreak, and most patients were unvaccinated. That's the equivalent of **$6800** per case

[JAMA Pediatrics]

SIXTY SECONDS ON . . . KIDNEY STONES

OUCH!

You can say that again. The discomfort of kidney stones passing through the ureter has been compared to birth contractions, with pain radiating across the lower abdomen and groin. The stones can also cause pain in the testicles and scrotum, as well as nausea, frequent peeing, and pain on urination.

WHAT CAN PATIENTS TAKE FOR THAT?

They can't have pethidine or an epidural, but NICE recommends non-steroidal anti-inflammatory drugs or intravenous paracetamol—and opioids if neither of these help. Alpha blockers and oral nifedipine can help some people pass some small stones.

BUT THEY'VE HIT ROCK BOTTOM. HOW LONG WILL THE PAIN LAST?

Not for much longer if latest draft guidelines from NICE are followed. If a doctor suspects a patient could have a kidney stone, they should order a computed tomography scan within 24 hours. If stones are confirmed, the pain is persisting, and the patient is unlikely to pass the stone, they should be offered treatment with shockwave lithotripsy (SWL) within 48 hours of diagnosis.

STONE ME!

This is NICE at its finest. It is good for patients—they are treated promptly without complex surgery, and there's less risk of postsurgical complications. If left untreated, ureteric stones can lead to loss of kidney function, which is far more expensive to treat. The NHS also benefits—SWL can generally be delivered on a day case basis.

SOUNDS LIKE JOINED-UP THINKING

There's more. Andrew Dickinson, consultant urologist at Plymouth Hospitals NHS Trust and chair of the NICE guidance committee, is also concerned about patients' mental health. "Waiting times for treatment are increasing," he said. "This is why offering shockwave lithotripsy is important for both a patient's health and mental wellbeing."

WOW! THERE MUST BE A DOWNSIDE

Indeed there is: not all hospitals are set up for the service yet.

IS THIS ADVICE SET IN STONE?

Not yet. The consultation on the guidance closes on 29 August.

Zosia Kmietowicz, *The BMJ*

Cite this as: *BMJ* 2018;362:k3190

School mental health plan "inadequate"

The Royal College of Paediatrics and Child Health has expressed disappointment in government plans for an army of new mental health staff to work with schools and colleges in England from next year.

Max Davie, the college's officer for health promotion, said the initiative was an inadequate response to mental health needs of children. "It takes a number of teams working collaboratively and inclusively to provide patients with the best possible outcomes," he said. "We need all professionals who work with children and young people to be trained in mental health so they can identify problems at the earliest opportunity."

Under the plan, published on 25 July by the Department of Health and Social Care in response to the consultation on the green paper for young people's mental health, seven universities will offer "education mental health practitioner" courses from January. The first staff trained will begin working in "trailblazer" areas by the end of 2019, ultimately totalling as many as 8000 staff.

The trailblazers, made up of NHS bodies and schools, local authorities, and local organisations, will pilot the teams and test how they work with other services. The teams will cover at least 20% of the population by March 2023.

Matt Hancock, England's health secretary, said, "By creating a dedicated new workforce in schools, we will support each and every child in fulfilling their potential."

Ingrid Torjesen, London

Cite this as: *BMJ* 2018;362:k3253

"All those working with children need to be trained in mental health"

Bawa-Garba's suspension was right, appeal court told

The decision to suspend Hadiza Bawa-Garba for 12 months rather than strike her off the medical register after a conviction for gross negligence manslaughter was "humane and balanced," her barrister has told the Court of Appeal.

Because that decision was overturned by the High Court, the NHS lost a "young and talented" paediatrician, said James Laddie QC.

Bawa-Garba, 41, a junior doctor specialising in paediatrics, was found guilty of manslaughter by a jury for contributing to the death of 6 year old Jack Adcock from sepsis at Leicester Royal Infirmary in 2011. She was denied permission to appeal the manslaughter conviction because none of her grounds for appeal were "arguable."

A medical practitioners tribunal, which took account of systemic failures at the hospital, decided to suspend her from practice rather than strike her off. But the GMC appealed the decision, and the High Court ruled that she should be struck off.

Laddie told three senior judges that doctors had been "baffled and angered" by the High Court ruling. It was agreed that Bawa-Garba posed no risk to the safety of patients.

Lightning rod

In a courtroom crowded with doctors supporting Bawa-Garba, Laddie said that her case had been "something of a lightning rod for the dissatisfaction of doctors and medical staff in this country."

The High Court ruled last January that the tribunal had impermissibly gone behind the jury's verdict in deciding Bawa-Garba's level of culpability and that she had to be struck off to maintain public confidence.

Laddie said the ultimate question was whether, as the High Court had concluded, the only sanction was erasure. The court had failed to appreciate that it was not just the jury's verdict that was important but the sentencing remarks of the judge and the suspended sentence, he added. Had the court conducted that exercise, it would have

Trial of Viagra to combat fetal growth restriction is halted after baby deaths

A Dutch trial using sildenafil (Viagra) to try to correct fetal growth restriction has been halted after 11 babies subsequently died.

An interim review by an independent committee of the STRIDER trial, which had randomly assigned 183 pregnant women to take sildenafil or placebo, showed that lung complications were more common in babies whose mothers were given the drug. Of these women, 17 had babies with lung problems, 11 of whom have since died, while three in the placebo group had lung problems and none died.

Amsterdam University Medical Centre said the adverse consequences happened after birth. All of the women in the study had been approached, and almost all had now been contacted to tell them whether they had been in the active or control group.

Suspended activities

On other measures sildenafil had shown no benefits, so the decision to stop recruiting and close the trial was straightforward. Canadian and Australian groups responsible for other arms of the trial have been contacted and have also suspended activities.

The UK arm, led from the University of Liverpool, reported in February that sildenafil was ineffective at prolonging pregnancy or improving outcomes. But these results did not show any rise in adverse side effects, except for a deterioration of blood flow in fetuses whose mothers were taking sildenafil.

Calling it "potentially worrying," the team, led by Zarko Alfirevic, reported that this might have been a chance finding and offered no plausible explanation. It recommended extreme caution in any future studies that use a dose higher than 75 mg of sildenafil a day.

The Dutch arm of the trial, due to run until 2020 and to recruit 350 women, used the same dose as in the UK—75 mg daily,

appreciated the case was at the lower end of the culpability spectrum.

Jenni Richards QC, for the BMA, said her submissions were made in the interests of the profession. She said the tribunal had judged that suspending Bawa-Garba would satisfy public confidence, but the court reached the contrary conclusion: that public confidence necessitated erasure. "How does one undertake the assessment of maintaining public confidence in the profession, and whose role is it to undertake the assessment?" she asked.

She argued that public confidence must relate to an ordinary, intelligent, well informed citizen; that the tribunal has a right to all evidence, whether it was shown to a jury or not; and that the judgment about public confidence must be reached on the facts of the individual case, with no presumptions.

In addition, she contended that insight, remediation, and risk have an important role to play; that the tribunal must be allowed to take into account other public interest considerations, such as the interest in returning a competent doctor to practise; and that determining public confidence is pre-eminently a matter for the tribunal.

Ivan Hare QC, for the GMC, said it accepted erasure was not the only sanction available. But what the tribunal did was to go behind the jury's determination of culpability. The tribunal must have taken a different view of the seriousness of Bawa-Garba's culpability than a jury, which was not permitted under GMC rules.

The judges reserved judgment, which is not expected before September.

Hadiza Bawa-Garba (third right) with supporters outside the Royal Courts of Justice, London

Speaking outside court, Bawa-Garba said, "I'd like to apologise wholeheartedly once again to Jack's family for my role in Jack's death. I am truly sorry and will live with this for the rest of my life." She said she was "overwhelmed with gratitude" for the support she had received and added, "I hope I will be given the opportunity to do what I enjoy, which is looking after sick children."

Clare Dyer, *The BMJ*

Cite this as: *BMJ* 2018;362:k3260

taken as three 25 mg doses. The hypothesis was that intrauterine growth restriction might be improved by sildenafil, a drug that causes blood vessels to relax, potentially enhancing blood flow to the placenta. Previous studies had provided some supporting evidence.

Neither the babies' birth weight nor gestation length were improved significantly in the UK arm of the trial.

The leader of the Dutch trial, Wessel Ganzevoort, told a Dutch newspaper he was shocked by the deaths. "We wanted to show that this is an effective way to promote growth of the baby," he said. "But the opposite happened."

An external inquiry is likely, but there is no evidence to suggest that it was poorly conducted.

Nigel Hawkes, London

Cite this as: *BMJ* 2018;362:k3247

Pay rise for doctors in England is revealed

A one year pay rise of 1.5% for consultants, 2% for trainees, 3% for specialty doctors, and a backdated 2% for GPs has been announced. Matt Hancock, secretary of state for health for England, set out the proposals in response to a Review Body on Doctors' and Dentists' Remuneration (DDRB) report.

He said the award would be worth between £1150 and £1550 for consultants, £1140-£2120 for specialty doctors, £1600-£2630 for associate specialists, £532-£924 for junior doctors, and around £1052 for a salaried GP with a median income of £52 600.

The DDRB had recommended a 2% minimum increase for all salaried doctors in the UK and a 2% increase for GP partners.

Hancock said that from 1 October consultants would receive a 1.5% increase on their basic pay. He froze the value of clinical excellence awards (CEAs) and said 0.5% of the consultant pay bill would be targeted at a new performance pay system. The DDRB recommended CEAs should rise in line with the 2% it recommended for consultants' pay.

Hancock said he was committed to "negotiations on a multi-year agreement incorporating contract reform for consultants to begin from 2019-20." Negotiations for a new consultant contract have been ongoing since 2013.

Trainees will receive a 2% rise in basic pay plus increased flexible pay premiums, which will be extended to histopathology trainees, as well as those in general practice, emergency medicine, and psychiatry.

Anthea Mowat, chair of the BMA's representative body, said, "It is truly astonishing that the government has chosen to ignore the already insufficient recommendations of its own independent pay review body." She added that the BMA would be considering its next steps.

Abi Rimmer, *The BMJ*

Cite this as: *BMJ* 2018;362:k3236

THE DEAL: one year rise of 1.5% for consultants, 2% for trainees, 3% for specialty doctors, and a backdated 2% for GPs

Babylon app will be "regulated to ensure safety"

EXCLUSIVE The Department of Health and Social Care has sought to assuage concerns over the regulation of Babylon Health's GP at Hand app, after the Glasgow GP and *BMJ* columnist Margaret McCartney raised the issue with MPs.

Self diagnosis apps or symptom checkers, such as the one available to patients who join the GP at Hand service, are becoming increasingly popular. McCartney outlined her concerns about the app to Sarah Wollaston, former GP and the chair of the health select committee, who wrote to the then health secretary, Jeremy Hunt, about the issues raised.

McCartney was worried that it missed symptoms, generated a high rate of false positives, and that regulators (the Care Quality Commission, the Medicines and Healthcare Products Regulatory Agency, and the Advertising Standards Authority) considered the app to be outside their regulatory remit.

In Hunt's written response to Wollaston, sent on 3 July—a week before he was appointed as foreign secretary—he set out details of an "overarching programme of work . . . to ensure that the regulatory environment for technological innovations in health and care strikes a balance between ensuring the delivery of safe and effective care and not stifling innovation."

Independent evaluation

Hunt's letter, seen by *The BMJ*, highlighted the actions being taken to ensure that the app was safe. These included an independent evaluation of GP at Hand in 2017, a further clinical review currently assessing the safety and safeguarding aspects of the service, and an "ongoing process of assurance" from NHS England.

A code of conduct is also being developed, to which digital providers will have to adhere before they can provide care in the NHS. Hunt wrote, "This will include model management for clinical decision support in partnership with MHRA [Medicines and Healthcare Products Regulatory Agency], FDA [US Food and Drug Administration], BSI [British Standards Institution] and others."

He said a cross departmental legal team was testing how the regulatory system would deal with "a range of potential scenarios" presented by new models of care such as GP at Hand: "Where it is found that there is a gap in the regulatory model, risk based 'fixes' are being evaluated. Such scenarios include where diagnostic software misses symptoms."

Digital developers must also answer questions about the clinical safety of their products before they can be approved by the NHS Apps Library, while Public Health England and NICE are working on a way to classify digital health tools using an assessment of "risk versus evidence," Hunt added.

Careful assessment

But McCartney said that she did not consider it sufficient to examine issues after the event."We should be proactive and test new diagnostic technology in safe, limited situations, with independent trials and careful assessment," she said.

"It has taken decades to achieve the acceptance that, for example, drug companies shouldn't be allowed not to publish clinical data they don't like, and that independent scrutiny is essential. Yet we are repeating

"We should test new diagnostic technology in safe, limited situations, with independent trials" Margaret McCartney

Life support can be removed without a court ruling

Doctors will no longer need to seek court approval to withdraw artificial feeding and hydration from all patients in a permanent vegetative or minimally conscious state, the UK Supreme Court has ruled in a landmark judgment.

Ruling in an appeal case against the withdrawal of life support for a 52 year old man, five justices in the UK's highest court concluded unanimously that court applications weren't needed where families and doctors agreed that withdrawal was in the patient's best interests.

The judgment will provide clarity for doctors looking after the thousands of patients with what are characterised as "prolonged disorders of consciousness" who are being kept alive by clinically assisted nutrition and hydration.

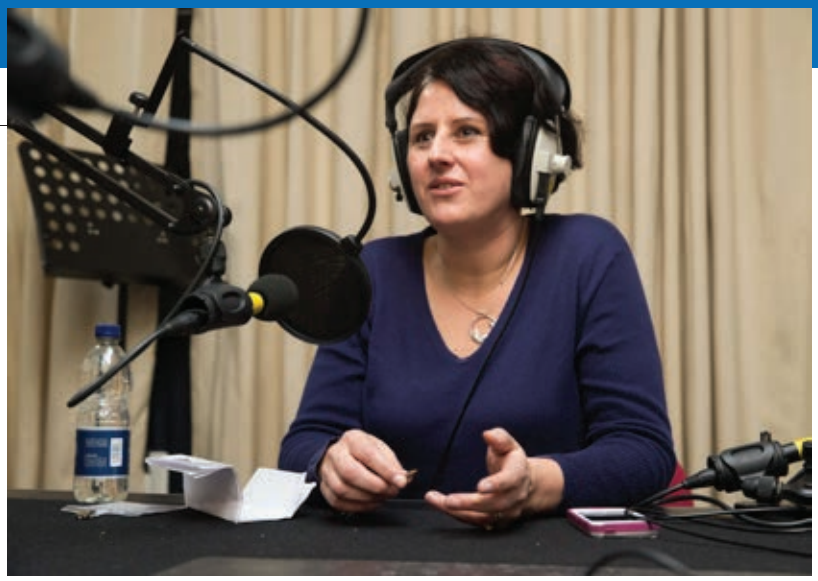
Common law

Lady Black, giving the judgment, said neither the common law nor European human rights law required every case to go to court.

The case concerned a patient known only as Y, who in June 2017 had a cardiac arrest and sustained severe cerebral hypoxia, resulting in severe brain damage. Doctors agreed that he would not recover consciousness.

He had been an active man, and his wife, adult children, parents, and siblings agreed he would not want to be kept alive, given the prognosis. The High Court ruled that it was not mandatory to take his case to the Court of Protection as his doctors and family were in agreement. The official solicitor, who represents people who lack capacity, appealed to the Supreme Court.

It was agreed that the treatment would be continued pending the appeal, but Y died in December from acute respiratory sepsis. The Supreme Court decided the



Margaret McCartney is concerned that regulation is not yet sufficient to protect patients

our mistakes with technology, with interventions available that haven't been adequately tested but are being heavily promoted."

In his first speech as health secretary on 20 July, Hunt's successor, Matt Hancock, revealed that he used GP at Hand, which he said "works brilliantly for me."

He acknowledged concerns that "the algorithms sometimes throw up errors." But he added, "Emphatically the way forward is not to curb the technology: it's to keep improving it and—only if we need to—change the rules so we can harness new technology in a way that works for everyone: patient and practitioner.

"I want to see more technology like this available to all, not just a select few in a few areas of the country."

In a statement a Babylon spokesman said, "As senior clinicians and scientists, we take our responsibilities to provide safe and effective care extremely seriously.

"Creating services that are available any time, anywhere at the touch of a smartphone button is core to what we do, but even more important is the ongoing testing, quality improvement and external assurance that we undertake to ensure the clinical safety of all elements of our work."

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2018;362:k3215

appeal should go ahead because of the general importance of the issues.

Since a House of Lords judgment in 1993 in the case of Tony Bland, a Hillsborough disaster survivor, it was assumed that cases where patients were in a persistent vegetative state had to go to court for approval. But Black said that the law lords in that case had not created a legal requirement but had recommended that this should happen "as a matter of good practice."

The Mental Capacity Act 2005 provided protection for doctors who act in the reasonable belief that a patient lacks capacity and that the action is in the patient's best interests, she noted. The act's code of practice has contradictory provisions on whether application to the court is mandatory.

A study has shown that the average persistent vegetative state case that goes to court takes about nine months and costs the NHS about £122 000 in legal costs and care. Black noted the risk that a requirement to go to court might "lead in some cases to inappropriate treatment continuing by default."

However, she added, "If it is apparent that the way forward is finely balanced, or there is a difference of medical opinion, or a lack of agreement from those with an interest in the patient's welfare, a court application can and should be made."

"A requirement to go to court might lead in some cases to inappropriate treatment continuing by default"
Lady Black

Clare Dyer, *The BMJ*

Cite this as: *BMJ* 2018;362:k3332

FIVE MINUTES WITH . . .

Malik Nedam Al Deen

The paediatrician and Syria Relief manager explains the need for a field manual on blast injuries in children

"Thousands of children across the world's conflict zones experience blast injuries every year as a result of air strikes and other explosive weapons. When they reach medical facilities, there will be few, if any, doctors with expertise in paediatric surgery to treat them.

"The first health professional who treats a child is unlikely to have any expertise in paediatric surgery; they may not even be a doctor. In some crisis situations, dentists have had to intervene and do some small surgical interventions. There are books on emergency medicine that these health professionals can refer to, but these are very general and wide ranging. They contain limited information on the treatment of blast injuries and they are certainly not focused on the treatment of children. When treating a child everything needs to be adjusted—the amount of intravenous fluid, drug dosages, even the stitches.

"ITS PRIMARY AIM WILL BE TO EXPLAIN STEP BY STEP HOW TO STABILISE THE CHILD"

"Acting on a request from doctors providing care in Syria, Save the Children and Imperial College London are working with doctors with expertise in relevant disciplines and experience in conflict zones as part of the Paediatric Blast Injury Partnership to develop an easy to follow manual to support health professionals specifically managing blast injuries in children.

"The field manual gives practical advice on the entire continuum of care, from point of injury to treatment to rehabilitation and mental health support. Its primary aim, however, will be to explain in a step-by-step fashion how to stabilise the child before they are transferred to someone with more expertise, and how to treat life threatening and life changing blast injuries if treatment is needed immediately.

"If there is an airstrike or an explosion, medical staff can refer to this manual to at least stabilise the child at the beginning. Sometimes they can't save the limb, but sometimes they can save the life."

Ingrid Torjesen, London

Cite this as: *BMJ* 2018;362:k3305

THE BIG PICTURE

Doctors demand inquest for Chinese bodies

This gruesome image is of one of more than 20 dead Chinese men whose skinless bodies are on display in Birmingham this month. UK doctors are demanding a coroner's inquest into the causes of death of all the men, claiming that they are "unknown" and possibly "unnatural."

The doctors have launched a petition demanding that Louise Hunt, Birmingham's coroner, investigate the bodies in the NEC this month. The petition states that the organisers of Real Bodies: The Exhibition have been unable to provide any information regarding "consent or cause of death, merely stating [the bodies] were unclaimed." It adds that there are suspicions the men died as prisoners.

David Nicholl, a consultant neurologist at City Hospital Birmingham, who was one of the signatories of an open letter to Hunt, told the BBC, "I am looking for the coroner to investigate any suspicions surrounding their death as the bodies are now within her jurisdiction."

Imagine Exhibitions, the company behind the touring show, which received similar protests when it opened in Australia last year, dismissed the allegations as "fake news." A spokesman added that the cadavers were legally provided by a Chinese medical university, where hospitals determined them to be "unclaimed corpses" that were "certified to have died from natural causes."

Alison Shepherd, *The BMJ*

Cite this as: *BMJ* 2018;362:k3329

HEAD TO HEAD

Does evidence based medicine adversely affect clinical judgment?

yes

Standardisation aims to improve outcomes; clinical judgment aims to improve health. The two goals are clearly distinct

Michel Accad, cardiologist, San Francisco
mfa@alertandoriented.com

Consider Dr Smith, a conscientious physician who keeps abreast of the medical literature and is attentive to the individual needs of her patients. Smith is well respected by her colleagues for the wisdom of her decisions.

For example, when she sees a patient with chest pain that is unlikely to be ischaemic, Smith rarely orders a stress test. She knows that the risk of a false positive result outweighs the possibility of diagnosing coronary disease.

Sometimes, however, Smith may deviate from that practice. She believes that, under certain circumstances, after considering all alternative courses of action, it may turn out to be in a patient's best interest to disregard the objective evidence on stress tests. Can Smith be said to practise evidence based medicine (EBM)?

At first glance, proponents of EBM seem willing to answer in the affirmative and grant Smith her decisional prerogative. For example, a well established definition of EBM is "the conscientious, explicit, and judicious use of best evidence in making decisions about the care of individual patients." Judicious use of best evidence implies that evidence is subject to judgment. Depending on the circumstances, a physician can choose to apply or ignore the evidence even if the evidence is "best." Judgment rules. Case closed.

But this lenient interpretation runs the risk of trivialising EBM. After all, what's the point of calling attention to the importance of the evidence if that evidence can be discarded willy-nilly by the clinical judgment of the doctor? Isn't EBM meant as a safeguard against the reasoning errors of physicians?

To defend the importance of EBM, its architects feel compelled to backpedal. They specify that "good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough." Evidence, then, is a check against clinical judgment gone awry.

Something's amiss

Unfortunately, the proposition doesn't hold up. How can evidence be a check on judgment when judgment is obviously required to appraise the quality of the evidence and its relevance to the patient at hand? Something's amiss.

What's amiss is that EBM's professed respect for clinical judgment is, at best, only wishful or, at worst, simply disingenuous. A clue to that effect is provided by US EBM guru David Eddy, originator of the term "evidence based," who recently remarked that the movement arose primarily from a desire to standardise care, not to individualise it.

Eddy's point is obvious when we consider the institutions and organisations that have embraced EBM: national health systems, private healthcare payers, regulators, drug companies, public health departments, and disease specific interest groups have all taken a keen interest in EBM precisely for its ability to formulate standards of care—that is, clinical guidelines—and to encourage, reward, or even oblige doctors to practise in accordance with those standards.

But practising according to standards is antithetical to practising according to clinical judgment: standardisation can only identify best practices for an "average patient" under average conditions. Clinical judgment is personal and seeks to decide what is best for this specific patient at this specific time. Standardisation aims to improve outcomes; clinical judgment aims to improve health. The two goals are clearly distinct.

EBM's bias

EBM may claim to reduce cognitive bias, but it introduces a bias of its own: the tendency to treat according to population norms rather than personal needs, a "groupthink" of sorts. Standardisation informed by EBM, then, will necessarily deny Dr Smith the freedom to care for her patient on the basis of her judgment. It is no longer judgment that rules but evidence that decides.

EBM's adverse influence on clinical judgment is not unexpected. Early critics pointed out its internal contradictions: individual decision making cannot be based on general evidence, and clinical judgment cannot be specified by methodological formalities.

EBM may claim to have been hijacked or corrupted, but it contains within itself the seeds of its own demise. The confused premises on which it is based can only confuse the clinical judgment that it claims to assist.

For practical and theoretical reasons, says **Michel Accad**, evidence based medicine is flawed and leads to standardised rather than excellent individualised care, but **Darrel Francis** argues that it protects patients from seemingly rational actions that cause more harm than good

no

We overestimate our ability to understand biology well enough to personalise tests and treatments beneficially

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Imagine that an electrician comes to your house to repair a washing machine that repeatedly breaks down. She adjusts a screw deep inside the machine. How would you feel to learn that this adjustment had never been found to reduce recurrence of breakdowns? And that it had multiple consequences whose net effect was unknown?

Evidence based medicine expects doctors to choose among tweaks that have been found to do more good than harm; not just among tweaks that they or their institution like to do for financial reasons or to feel good about themselves.

Draw of autonomy

The greatest pleasure in life is freedom to do what one wants. Inevitably we doctors dislike the straitjacket of EBM restricting our freedom to treat patients with water (because we like the sound of homeopathy) or diagnose their diseases by feeling the bumps on their head (because we read about it in a magazine). It is annoying to be limited to things that somewhere, somehow, someday, genuinely worked.

Can't we be trusted to spot a nonsensical therapy or diagnostic test? No. Humans are easily fooled, and doctors are—for now—human. The real danger is not obviously nonsensical ideas but seemingly logical ones. Only recently, our profession believed that physical and mental disorders arose from imbalance of the four humours—blood, yellow bile, black bile, and phlegm. A patient with disordered blood would obviously improve with bloodletting. Years of experience of patients recovering after thoughtful, personalised bloodletting were confirmation of efficacy. Today's experts in homeopathy and astrology quite rightly give level C (proof by expert consensus) or level B (proof by non-randomised observations) recommendations for their techniques (using the terminology used in cardiology).

We are all trapped in our bubble of beliefs

Neither the medieval believers in humours nor the modern homeopaths and astrologers are amenable to the suggestion that their mechanistic world view is nonsensical. However, this should not make us smirk with smug superiority but heighten our awareness that we, too, are trapped within our bubble of beliefs. Consensus of beliefs does not automatically make them correct.

EBM protects our patients not from nonsensical therapies but from rational ones that cause more harm than good. The human body is incomprehensibly complex. Unlike complex computer software, in which each component has precisely specified behaviours designed to fit together in a manner comprehensible by human software engineers, human biology underwent natural selection for providing a competitive edge, rather than for ease of describing. Moreover, even the language we use in medicine is almost incapable of describing dependence on more than one variable, never mind thousands. For example, how does a doctor describe non-mathematically the dependence of z on x and y in the relation $z=(x+10)(y+10)^2$?

We consistently overestimate our ability to understand biology well enough to personalise tests and treatments beneficially. Personalisation may be harmless fun and even increase the placebo effect, but we should be under no illusion that we have done anything useful.

Some people criticise EBM for failing to curtail the overuse of therapies in fee-for-service systems such as in the US. However, EBM is only a framework for thinking and cannot stop doctors responding to incentives. (The clue is in their name, after all.)

My favourite example of the need for EBM, even for astute clinical scientists, was inadvertently provided by a friend, a veteran of many guideline writing committees, who said: "We are not treating many HF [heart failure] patients who would benefit from CRT [cardiac resynchronisation therapy] simply because there are no scientifically evidence based guidelines telling us to. I have used CRT successfully in patients with narrow QRS [complex], and so have many others. The medical literature supporting this belief is increasing with observational studies and anecdotal cases of success in several thousands of these patients."

He went on to lead a randomised trial. Unfortunately, the large effect found was an 80% increase in mortality.

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ESSAY

The case for medical cannabis

Legal restrictions have impeded research, says **M P Barnes**, but evidence shows cannabinoids may have benefit in several indications and calls for legislation to support building the evidence base

Cannabis has been used as a medicine for thousands of years. The earliest recorded use dates back to 4000 BC in China. In the 19th and 20th centuries it was used around the world to treat migraine, and neuropathic and musculoskeletal pain, and in childbirth.

In the UK, cannabis was made illegal in 1928 but doctors could prescribe it up to the introduction of the Misuse of Drugs Act in 1971. Cannabis is currently a Schedule 1 drug under the UK Misuse of Drugs Regulations 2001, which means that it is deemed to have no legitimate use or medicinal value. It also remains a Schedule IV drug under the UN Single Convention on Narcotic Drugs treaty of 1961—along with heroin—for substances "particularly liable to abuse and to produce ill effects" which are "not offset by substantial therapeutic advantages."

The cannabis plant contains more than 100 cannabinoids and many terpenes, flavonoids, and other components. The two most studied are tetrahydrocannabinol (THC) and cannabidiol (CBD). THC gives the recreational "high" but CBD does not—to some extent it counteracts the psychoactive effect of THC.[1]

CBD is unscheduled and legally available as a nutritional supplement in the UK, whereas THC is scheduled and illegal, although there are two formulations that can be prescribed in the UK: nabiximols (Sativex), a natural product with about a 1:1 ratio of THC to CBD, is available as an oromucosal spray and licensed in the UK for resistant spasticity in multiple sclerosis; and nabilone (Cesamet), a synthetic cannabinoid that mimics THC and is used for chemotherapy induced nausea and vomiting.

Although the benefits of cannabis have been known for centuries, only recently has a scientific rationale been suggested

Epidiolex (a pure form of CBD) has recently been approved by the Food and Drug Administration in the US for the treatment of seizures associated with Lennox-Gastaut and Dravet syndromes.

Endocannabinoid system

Although the benefits of cannabis have been known for centuries, only recently has a scientific rationale been suggested. In 1990, Matsuda and colleagues described a cannabinoid receptor in humans,[2] now called the CB1 receptor. Later a CB2 receptor was also identified.[3] These receptors are present throughout the central nervous system and in peripheral tissue, including the immune, reproductive, and gastrointestinal systems, as well as the heart, lungs, and bladder. The system, including

KEY MESSAGES

- Cannabis has many medicinal properties, which are increasingly recognised worldwide
- It seems a relatively safe product, with a good risk:benefit profile
- We need much more research to understand the merits of different strains, different THC to CBD ratios, different modes of ingestion and dosages
- Such research should be facilitated by legalisation for medical use; recent moves in the UK to reschedule cannabis based medicinal products represent real progress, but many questions remain

PATIENT PERSPECTIVE

Greg de Hoedt

UK is a hostile environment for patients who use cannabis to live with their conditions

As a 30 year old with Crohn's disease, I have lived my entire adult life dependent on drugs, both legal and illegal. I have learnt what works best to keep my symptoms under control and provide me with a good quality of life.

In 2010 I was told I needed major surgery and chemotherapy or I would live two to five years before dying from malnutrition associated with short gut syndrome. For me this wasn't an option. The side effects of chemotherapy can include all the symptoms of Crohn's amplified, and potential impotence, leukaemia, and death. I was a mess.

Pharmaceutical drugs such as immunosuppressive azathioprine and the anti-inflamatory mesalamine nearly killed me, causing vomiting, and foaming at the mouth. I had worse diarrhoea with blood and mucus than my Crohn's had ever given me.

Cannabis, however, drops my bowel movements from 20 a day to one or two; it takes away my nausea and chronic pain; and it gives me back the ability not only to want to eat food again, but also to enjoy it.

My medical regimen starts the moment I wake up. I vaporise four 50 mg doses of terpene rich cannabis oil to help my bowel function properly. This is repeated every three to four hours. I take between 200 mg and 400 mg of cannabis oil orally in capsules two to three times a day, depending on my gut comfortability and my body's chronic pain level. Between dosing oil, I will also vaporise a variety of homegrown cannabis flowers, some to give me more energy to complete physical tasks and others to help slow my mind by curbing the constant release of cortisol. Daily I will consume between 600 mg and 2000 mg of cannabinoids.

Flare-ups return because of a lack of access to high quality cannabis—well grown buds with a high resin content, the resin being the part that contains tetrahydrocannabinol (THC) and cannabidiol (CBD). Globally, high THC cannabis is referred to as sensimilla

the natural precursors and the metabolic pathway, is now termed the endocannabinoid system.

The phytocannabinoids (THC, CBD, and more than 100 others) found in the natural cannabis plant can mimic the effects of the endocannabinoid receptor ligands and also interact with other neural transmission systems.[4]

Evidence of efficacy

There is surprising evidence of efficacy, given the drug has been illegal in most countries for many years. Certainly, more studies are needed, particularly regarding the efficacy of different strains of the plant, ratios of THC to CBD, different methods of ingestion, and whether the whole plant is more efficacious for medicinal purposes than individual cannabinoids. In brief, the evidence for key conditions is as follows.

Pain

Several reviews have assessed the efficacy of various cannabinoid preparations for the management of chronic pain. One review found eight studies and concluded there was "moderate quality" evidence of efficacy against placebo to support the use of cannabinoids.[5] My non-peer reviewed paper for the all party parliamentary group on drug policy reform found overall good evidence (defined as at least two class 1 studies supported by other class II, III, or IV evidence) for pain relief in several conditions, including arthritic, neuropathic, and cancer pain, and with several products, including the natural plant as well as nabiximols and synthetic cannabinoids.[6]

Spasticity

There is also evidence, sufficient to satisfy licensing authorities in the case of Sativex, for the use of cannabinoids in spasticity. Most work has been in the context of nabiximols but other treatments have been studied.[7]

Nausea and vomiting in chemotherapy

A recent Cochrane systematic review of 23 randomised controlled trials confirmed the anti-emetic properties of "cannabinoids." Patients were five times more likely to report complete absence of vomiting against placebo. The authors did not find superiority of "cannabinoids" (undefined) when compared with conventional therapy.[8]

Chemotherapy patients using cannabinoids were five times more likely to report complete absence of vomiting against placebo

Epilepsy

Recently evidence from published studies has shown that a pure CBD product (Epidiolex) has efficacy in the management of the drug resistant childhood epilepsies, Dravet and Lennox-Gastaut syndromes.[9 10]

The case of Alfie Dingley and other children,[11] whose epilepsy responded to full extract cannabis oils containing

("without seed" in Spanish); in the UK it is dubbed "skunk" and demonised by the press, politicians, and the public. It is hypocrisy that the Home Office licenses GW Pharmaceuticals to produce cannabis in the UK, including the original high THC skunk strain.[1] The Dutch company Bedrocan's flagship herbal cannabis is also 19% THC and less than 0.1% CBD. Scientifically speaking, skunk is medical cannabis.

THC and CBD get all the attention, but a strain's terpene profile can modulate the effects of the cannabinoids. Over eight years' experimentation I've found four plant strains that I grow myself that work better for my symptoms than any cannabis I can buy illegally—but I had to break the law by growing hundreds of different seeds to identify which ones to keep. Other growers hold genetic copies in case I am raided by police who would destroy plants in my home.

Visiting the US allowed me a patient's perspective of how appropriate and efficacious the different states' schemes were. The right to grow and find what is correct for the patient is fundamental, and providing facilities like testing laboratories to enable patients to speed up the process is a necessity. There is no reason the UK cannot regulate medical cannabis similarly.

If I had waited for the UK government to enact laws that suit my needs, I would be dead. I am alive because I have refused to obey an unjust law

If I had waited for the government to enact laws that suit my needs, I would be dead. I am alive because I have refused to obey an unjust law. We cannot wait, we need the right to grow freely. While the Home Office has said that it will allow medical cannabis licences, the condition list and licence fee prohibits access to most patients like me.[2] We do not deserve to be classed as criminals and certainly shouldn't have to live in fear of police raids because we grow cannabis to stay alive.

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CBD and THC, shows that the matter is complex and that some children seem to respond maximally to a combination of low dose THC and higher dose CBD. Clearly more studies will be needed once other cannabinoid preparations are available.

Studies have also shown that cannabis may have therapeutic use for anxiety,[12] sleep disorders, appetite stimulation in the context of chemotherapy, fibromyalgia, post-traumatic stress disorder, and some aspects of the motor symptoms of Parkinson's disease, as well as for the management of agitation in dementia, bladder dysfunction, glaucoma, and Tourette's syndrome.[6] Other indications are often cited anecdotally but so far lack a firm evidence base.

Side effects

In the appraisal of any "new" drug, a risk-benefit analysis is needed. For cannabis side effects generally depend on the amount of THC in the product. Varieties available for recreational use with very high THC (commonly called "skunk" in the UK) can cause serious mental health problems.[13] In medicinal cannabis, however, lower THC levels, often combined with CBD, which counteracts the effects of THC, are usually recommended. Certainly, in the short term, products with predominant THC can have effects such as dizziness, euphoria, drowsiness, dry mouth, confusion, somnolence, and fatigue, whereas these effects are generally not the case in pure CBD products or full extract oils high in CBD, where the effects are usually mild and well tolerated.

There is legitimate concern about cannabis's link with schizophrenia or psychosis. The evidence suggests a likely causal link between cannabis use (particularly with high THC) and psychosis among people who already have psychotic symptoms or a family history of schizophrenia or other psychosis.[14] Clearly, we need better understanding of the relation between cannabis use and psychosis if the drug is to be more widely available.

Dependency on cannabis is around 9% of users, usually those using a high THC product, which compares with about 15% for alcohol and 32% for tobacco.[15]

LEGAL PROGRESS

Cannabis's illegal status has impeded research. This is changing in many countries. Indeed, cannabis for medical use is legal in 29 US states and in

- Australia
- Austria
- Belgium
- Canada
- Croatia
- Czech Republic
- Denmark
- Germany
- Israel
- Italy
- Malta
- The Netherlands
- Portugal
- Spain
- and 26 other countries.

Laws vary from simple decriminalisation to full legal medical use.

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Cannabis varieties with predominant THC can impair psychomotor performance and cognition (and driving) in the short term but there is conflicting evidence on whether there are neurocognitive deficits in the long term and these are probably only for heavy use of THC products in people who start using at a young age.[16]

Alternative drugs for the main indications should also be considered. As an example, severe pain is often treated with opioids, and the problem of opioid addiction and death, either deliberately or accidentally, is a substantial social issue. No death has ever been reported from an overdose of cannabis. Prescription of cannabis can lead to less opioid use and cessation of opioids.[17] Reduction of mortality from opioid death after introduction of medical cannabis has now been demonstrated in the US.[18]

Given the limited evidence, an analysis of the benefits and risks of cannabis leads to the conclusion that in various formulations it is both an efficacious product in some indications and is reasonably safe.

Availability

In the past few weeks the UK government stance has changed from one of insistence that cannabis should remain a Schedule 1 drug to an acceptance that it has medicinal value. The chief medical officer's report[19] concluded that there was "conclusive evidence of the therapeutic benefit of cannabis based medicinal products for certain conditions and reasonable evidence of therapeutic benefit in several other conditions."

The recommendation was that "the whole class of cannabis based medicinal products be moved out of Schedule 1." As a result the home secretary asked the Advisory Council on the Misuse of Drugs to consider the matter. It recommended that medicinal products derived from cannabis be rescheduled, and the home secretary agreed. He has asked the Department for Health and Social Care and the Medicines and Health products Regulatory Authority to define what constitutes a cannabis derived medical product. Only those products would be rescheduled (to Schedule 2). In the interim, a panel has been established for applications to be made for consideration of a special licence.[20]

While this is real progress, many questions remain unanswered. Not least, who will be able to prescribe what, and for what conditions. Will the government, for example, allow only those products that have been subject to a clinical trial to be prescribed? If so, this would disadvantage those people (such as Alfie Dingley and tens of thousands of others worldwide) who would and do benefit from full extract cannabis oils, which have not yet been through a trial process.

A big hurdle is likely to be the licensing of a plant product. UK drug approval generally focuses on a single compound, rather than the whole variety of cannabinoids as well as the terpenes and flavonoids in the cannabis plant. In addition, there are many different strains of cannabis plant with varying proportions of THC and CBD. The product can be ingested in many ways, with wide variations in bioavailability. It would take decades for each type and variety of cannabis to go through the current clinical trial system, and in the meantime thousands of people with disabilities in the UK are deprived of a potentially useful and relatively safe medicine.

Other countries have resolved this by developing alternative licensing systems. Many jurisdictions, both in the US and elsewhere, control the quality of cannabis by approving specific suppliers and monitoring quality. The final cannabis product is often available only through licensed pharmacies with the appropriate medical recommendation.

Of course, we need more research into the efficacy and side effects, the most beneficial type of cannabis, and the best mode of ingestion for particular conditions, and best dosage. Much work needs to be done, and facilitated by legalisation. It is certainly time that we moved beyond "reefer madness" to a more enlightened use of a plant that has so much potential benefit for tens of thousands of people in the UK.

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EDITORIAL

Over to you, Mr Hancock

However long you have got, please use it wisely

There is no guidebook for new secretaries of state for health, and their approaches have often differed substantially. Some have decided to be radical, while others have had to spend time restoring relationships and bringing a period of calm. Sometimes there have been big policy shifts, even within the same government—such as when Jeremy Hunt followed the chaos created by Andrew Lansley, or the more market sceptic John Reid followed Alan Milburn.[1]

The extent to which Matt Hancock has discretion to choose how he will approach the role is limited. Whether or not it will be enough, most of the job of squeezing out more funding for the NHS has been done. A difficult 2018-19 remains, with providers having major financial deficits, winter approaching, and most targets going in the wrong direction.

The health secretary's most important task is to end the painfully long wait for an acceptable system of social care

Confused accountability

The national structure of the NHS is widely recognised to be a mess, with confused accountability, and the prime minister has indicated there could be new legislation to sort out some of the confusion. But it would be a challenge for a new secretary of state to take this on, even in a much less fractious political environment. Since 1974, the NHS has had a habit of large reorganisations that distract from delivery for up to two years, and which are then declared unfit not long after. The new health secretary might want to ask some tough questions about the value—or potential for harm—of how such change will be approached.

There are, however, several other areas where he can and should act. He has already commented on the importance of valuing NHS staff, and hopefully he will be able to rebuild some of the bridges that were damaged during the junior doctor dispute. Serious shortages in hospital and community staffing and in general practice demand urgent attention, along with the related issue of burnout. These problems need rapid solutions framed within a high quality strategy, but there are few clear signs of progress. As some of the responsibility lies with arm's length bodies such as Health Education England, this is an area where firm action by the secretary of state could make a real difference.

Political strength

Hancock's most important task is to end the painfully long wait for an acceptable system of social care in England. Political strength and courage will be required to secure a long term solution given current financial and legislative constraints, but Hancock has already written about an insurance based option and is aware of the need to move forward.[5] Whether he can marshall the necessary political will to make progress or simply ducks the problem as others have done for the past 20 years remains to be seen.

Hancock has a keen interest in digital technology and has the opportunity to make advances in this area. The current vogue is for artificial intelligence and patient apps,[6] but he might be better advised to pursue less eye catching but more important initiatives such as getting current systems within the NHS to work better together and overcoming persistent barriers to safe sharing and secondary use of NHS data. Without this basic infrastructure, the more exciting developments will fail.

Finally, Hancock could use the change of leadership to rethink how the NHS is managed more generally. A system of targets and upward reporting mixed with intrusive regulation was the method of choice under Hunt and seems to have long ago reached the point where the costs outweigh the benefits.

All the above assumes that he is in place long enough to find his feet and negotiate a difficult role, and that political turmoil and the potential effect of a no-deal Brexit—including the withdrawal of the prime minister's £20bn funding pledge—doesn't torpedo what small scope he may have to shape a better NHS.

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EDITORIAL

Managing blood pressure in older adults

Age alone is no barrier to treatment

In a recent paper in *The BMJ*, Liv and colleagues reported the results of a large cohort study investigating the link between blood pressure and mortality in community dwelling Chinese people with a mean age of 92 years.[1] Studies of very elderly people are challenging and rarely performed so these data are of particular interest. Both high and low systolic blood pressure were linked to an increase in mortality (a "U shaped curve" relation).

The finding that low systolic blood pressure predicts increased risk of death is consistent with many other epidemiological studies in older people. Although low blood pressure may in itself cause harm, it is also likely to be a marker of ill health, with systolic blood pressure falling for up to two years before death.[2] Any link between high systolic pressure and mortality has been much less consistent in later life.

How should these data influence decisions on use of antihypertensive drugs in very elderly people? Here we must be mindful of the fact that observational data have serious limitations. Randomised controlled trials remain the gold standard for informing treatment decisions, and a substantial body of such evidence exists to guide treatment of hypertension in older adults.

Evidence says aim low

In a Cochrane review and meta-analysis of randomised trials of treatment of hypertension in people aged over 60, antihypertensive drugs reduced cardiovascular morbidity and both total and cardiovascular mortality.[6] People older than 80 have also been shown to benefit from drug

The priorities for older people with hypertension can vary greatly

treatment of high blood pressure, although there are fewer data in this age group. In the hypertension in the very elderly trial (HYVET), people with sustained systolic blood pressure >160 mm Hg were randomised to antihypertensive drugs or placebo. Treatment reduced systolic blood pressure from a baseline 173 mm Hg to 143 mm Hg (compared with 158 mm Hg on placebo), leading to a decrease in stroke, heart failure, and total mortality.[7]

The Systolic Blood Pressure Intervention Trial (SPRINT) found benefits from targeting a systolic blood pressure <120 mm Hg in participants with mean age of 68 years and systolic >130 mm Hg[8]; in a prespecified subgroup of people aged over 75 intensive antihypertensive treatment achieved a mean systolic of 123 mm Hg and led to a substantial reduction in cardiovascular events and total mortality compared with standard care with mean systolic pressure of 135 mm Hg.[9] There was a penalty associated with intensive treatment—an increase in adverse events including hypotension, syncope, acute kidney injury, and electrolyte disturbance, seen across all trial participants.[8]

Consider overall health

The most recent 2017 American College of Cardiology/American Heart Association Task Force guidelines (including the evidence from SPRINT)[10] recommend a target systolic blood pressure of <130 mm Hg for ambulatory community dwelling people older than 65.

However, for some, such as people who are very frail or have complex comorbidity or limited life expectancy, antihypertensive drugs are likely to be irrelevant or harmful. Clinical judgment, patient preference, and a team based approach to assess risks and benefits should be used in decisions regarding intensity of treatment and choice of antihypertensive drugs.

What should be done for older people with low systolic blood pressure? Evidence is limited, but it seems reasonable to avoid prescribing medicines likely to further reduce blood pressure. For those taking antihypertensive drugs, the risks and benefits associated with reducing or stopping treatment are also unclear.[11] However, it is sensible to reduce or stop antihypertensives in patients with adverse effects, such as syncope or acute kidney injury associated with low blood pressure.

Shared decision making is particularly important when considering preventive treatments for very elderly people. The priorities for older people with hypertension (and their carers) can vary greatly. For some, the option of taking antihypertensive drugs for longer term gain will be attractive. Others look for faster and more noticeable benefit from any medicine taken, with clear improvement of symptoms and enhanced quality of life. The clinician's role is to support patients navigating this decision, in line with their individual preferences.

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