Surge in knee and hip surgery refusals

Increasing numbers of patients seeking knee or hip surgery are finding the NHS won’t fund the operation, an investigation by The BMJ has found.

In 2017-18 exceptional funding requests for 1675 procedures (1188 for knee surgery and 487 for hip surgery) were turned down by clinical commissioning groups, show the data obtained under a freedom of information request. This was a 45% increase from 2016-17, when 1155 requests were rejected (766 for knee and 389 for hip surgery).

Funding requests have been in use since the 2000s to limit cosmetic and fertility procedures. But under financial pressure, some CCGs use them more widely. GPs refer patients to specialists as normal, but there is no guarantee that a recommended treatment will be funded. Instead the GP has to submit a funding request, and a CCG panel decides if it will grant it. The BMJ’s latest analysis shows stark variation across England in how CCGs apply the restrictions. For example, Buckinghamshire had 1298 requests for knee surgery last year and rejected 18%, while Doncaster had only 24 requests and rejected all but one.

Ian Eardley, senior vice president of the Royal College of Surgeons, said, “Hip and knee surgery has long been shown to be a clinically and cost effective treatment. We are appalled CCGs are effectively requiring thousands of patients to beg for treatment.”

The NHS performed almost 200 000 hip and knee surgeries in 2016-17.

Graham Jackson, co-chair of NHS Clinical Commissioners, said it was right to follow clinical evidence to try to reduce unwarranted variation. But he admitted some CCGs may be overzealous in imposing criteria because of financial pressures.

Commissioners said that the winter crisis (when elective procedures were effectively cancelled), ongoing financial pressures, and CCGs’ efforts to reduce unwarranted clinical variation had all contributed to the rise in knee and hip surgery refusals.

Julie Wood, chief executive of NHS Clinical Commissioners, said, “The money has in effect run out, and CCGs have got to find ways of delivering greater efficiencies. “We have to be very honest and upfront. It needs to be a conversation with the public about what the NHS should be providing.”

NHS England declined The BMJ’s request for a comment.

See more on the investigation, p 88

Gareth Iacobucci, The BMJ
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Ian Eardley, of the Royal College of Surgeons, said he was “appalled CCGs were effectively forcing thousands of patients to beg for treatment”
Adrenaline doubles risk of brain damage

A randomised trial of use of adrenaline in patients who have a cardiac arrest outside hospital leaves paramedics with a dilemma. More patients were alive 30 days after their hearts had been restarted with adrenaline, but the risk of serious brain damage almost doubled, show the findings, reported in the New England Journal of Medicine.

Speaking at a London briefing, the trial’s lead author, Gavin Perkins of Warwick University, said it would need a broader consideration of the findings by bodies such as the UK Resuscitation Council to make any guideline change. Adrenaline has been used for many years by ambulance crews if cardiopulmonary resuscitation and defibrillation have failed. It was introduced after animal experiments showed that it did restart the heart but has never been subjected to a randomised controlled trial. Observational studies have reported higher rates of return of circulation but worse neurological outcomes.

The trial involved nearly 8000 patients in five English ambulance services. About 30 000 people have a cardiac arrest outside hospitals in the UK every year. Of these, it is believed that 15-18% are given adrenaline.

NICE recommendations

Drug recommended for severe eosinophilic asthma

Benralizumab (Fasenna) should be an option for people with severe eosinophilic asthma whose symptoms are not adequately controlled with standard treatments, NICE said in draft guidance. The drug is cost effective for people who have had at least three exacerbations in the past year and who have a blood eosinophil count of ≥400 cells x 10⁶/L and when the biological treatment mepolizumab is not appropriate. AstraZeneca agreed a discount on the list price of £1 955 for a 30 mg prefilled syringe.

Patients to benefit from dye to show brain tumours

All patients with a brain tumour who could benefit from 5-aminolevulinic acid (5-ALA) before surgery should have it, NICE said. The dye shows tumour cells glowing pink under ultraviolet light and helps surgeons distinguish them. The guidance also recommends targeted radiotherapy to reduce the risk of damage to the rest of the brain, but it doesn’t recommend tumour treating fields for high grade glioma as they are not cost effective.

Discount on neuroblastoma drug results in deal

NICE recommended dinutuximab beta (Qarziba) for treatment of high risk neuroblastoma (below), after an agreement with EUSA Pharma to discount the average list price of £1 52 200 for the NHS. Dinutuximab beta will be given to those who have at least partly responded to first stage chemotherapy followed by myeloablative therapy and stem cell transplantation.

The potential survival gain is substantial, although uncertainty remains about the drug’s long term benefits, said NICE.

Hernia

Patients left in pain and at risk of complications

More than half (57%) of England’s CCGs require patients with a hernia to have a period of watchful waiting or to prove they have a history of incarcerated hernia, or that their hernia is increasing in size from one month to the next, before allowing them to have surgery, a report from the Royal College of Surgeons and the British Hernia Society has found. David Sanders of the British Hernia Society said such policies were not acceptable, as they denied patients improvements in quality of life.

Workforce

Grenadian graduates to train in NHS

Up to 100 graduates a year from St George’s University Medical School in Grenada are expected to join foundation training in the NHS in England this autumn, HEE announced. After completing the foundation course the trainees are expected to enter specialty training in psychiatry or general practice in areas of the country with acute staff shortages, especially the Midlands, the East, the North, the South West, and Yorkshire and the Humber.

Brexit

May: Money will help fund NHS

The government has said the UK “will allow free movement for skilled workers” after Brexit, although it has given few details about how this will apply to NHS staff. In an introduction to the Brexit white paper released on 12 July, Theresa May (below) suggested that leaving the EU would release money “for domestic priorities—in particular our long term plan for the NHS.” The government is also requesting a special accord so that UK researchers can continue to participate in research EU funded programmes.

Research misconduct

Academics who raised concerns face threats

Two Liverpool University academics who alleged research misconduct at University College London studies into transplanted tracheas seeded with the patient’s own stem cells have been threatened with a lawsuit. Patricia Murray and Raphael Lévy have received a lawyer’s letter from Videregen, a company seeking to commercialise the research and is planning two clinical trials with UCL. It claims the complaints have threatened its future. It offered not to proceed with litigation against Liverpool University if it dissociates itself from the allegations.
MEDICINE

Digital GP
CCG blocks expansion of service to Birmingham
Clinical commissioners have rejected a request from GP at Hand to subcontract its digital service from its London base to a site in Birmingham, because of patient safety concerns. The service, run by an NHS general practice in Hammersmith in partnership with the technology company Babylon, operates from five physical clinics in London. The proposed Birmingham clinic would allow patients to see a GP at the location if they chose to. But Hammersmith and Fulham CCG rejected the proposal after Birmingham and Solihull CCG issued a formal objection.

Women’s health
Doctors challenge Trump during UK visit
The Royal College of Obstetricians and Gynaecologists and the Faculty of Sexual and Reproductive Healthcare wrote to Theresa May urging her to raise the issue of the so-called Mexico City Policy with US President Donald Trump when she met him last week. The policy prevents organisations that receive US federal funding using any of their financial resources to provide, inform about, or advocate access to abortion care. The policy has seriously damaged family planning programmes in many countries, increasing the risk of unintended pregnancies and unsafe abortions, the organisations said. Protesters, including Rachel Clarke, a specialty doctor in palliative medicine, who carried the placard above, gathered outside Blenheim Palace in Oxfordshire, where a dinner with the president was taking place.

Rheumatoid arthritis
Goal is remission or low disease activity, says NICE
New NICE guidance says that adults with rheumatoid arthritis (above) should start treatment with a single conventional disease modifying anti-rheumatic drug (DMARD) rather than a combination, as recommended previously, because effectiveness is the same. The aim of treatment should be remission or low disease activity if remission can’t be achieved. A second DMARD can be added if escalating the dose of a single DMARD fails to reach the new treatment goal, and steroids can be used until the DMARD starts to take effect.

CHD
Nine in 10 people with coronary heart disease in the UK have at least one other condition, most commonly high blood pressure (56%), followed by diabetes (26%), stroke (14%), heart failure (13%), and dementia (5%).

[British Heart Foundation]

SIXTY SECONDS ON…

PROBIOTICS

FRIEND OR FOE?
Companies selling probiotic foods refer to them as having “friendly” bacteria. But just how friendly they are has been questioned in research showing that randomised trials often fail to report adverse effects. More than a third of the 384 trials studied gave no information on harms, and only 2% adequately reported adverse events.

GETTING TO THE GUTS OF THE ISSUE
The past few years have seen growing interest in the potential health benefits of modifying the microbiota—the 100 trillion microbes, mostly bacteria—that inhabit the gut. Best thought of as a virtual organ, this teaming micro-community has a role in many aspects of health, including immune, metabolic, and neurobehavioural traits.

HARD TO SWALLOW?
You may believe that the issue is not exactly mainstream medicine, but probiotics (live bacteria that, “when administered in adequate amounts, confer a health benefit”) are now among the most studied interventions in neonatal medicine, particularly in reducing the risk of eczema and asthma. The EU Clinical Trials Register lists 41 trials with probiotics, ranging from treating antibiotic-related diarrhoea in care homes to preventing bloating in women with irritable bowel syndrome.

CHALLENGING THE GUT INSTINCT
There’s a widespread belief that such a “natural” approach must be safe. So much so that many infant formulas are now supplemented with probiotics and prebiotics (fermented products that help gut bacteria thrive) with the aim of shifting the microbiota to match that of a breastfed infant. But the potential for adverse effects in the wider use of prebiotics, probiotics, and symbiotics (a mix of pre- and probiotics) as health interventions is less clear.

ABOVE ALL DO NO HARM
“We cannot broadly conclude these interventions are safe without reporting safety data,” cautioned the review authors. “An evaluation of the benefit-risk balance should always be included in trial reports,” they concluded, calling for urgent international effort to achieve this.

Susan Mayor, London
Cite this as: BMJ 2018;362:k3134
GPs’ view—A source of extra work

The BMJ’s analysis shows that GPs are increasingly having to make requests on behalf of their patients for knee and hip replacements. There is also a sharp rise in the number of requests being turned down.

The figures show that in 2017-18 Wiltshire CCG rejected 62 of 194 (32%) exceptional funding requests for knee surgery and 28 of 108 (26%) requests for hip surgery. This compared with 32 of 59 (55%) requests for knee surgery and 12 of 27 (44%) for hip surgery rejected in the previous year.

Desperately short of clinical time

Helena McKeown (below), a GP and vice chair of Wiltshire Local Medical Committee, said the process of applying for funding placed strain on GPs and their patients. “It’s a source of extra work for GPs at a time when we are desperately short of clinical GP time,” she said.

In 2017-18 Rotherham CCG budgeted for a 25% reduction in the number of hip and knee replacements it commissioned as it sought to save money. But in September 2017 it reported overactivity, with 177 procedures carried out in the first three months of 2017-18, against a forecast of 138. Across the year Rotherham received 32 exceptional funding requests for knee surgery, 28 (88%) of which it rejected. It also received 11 exceptional requests for hip surgery, all of which were rejected.

Greater consistency

Rotherham has applied thresholds for referring patients for hip and knee surgery since 2016, and it is now developing policies with other local CCGs in South Yorkshire to ensure greater consistency. Like Rotherham, several of these CCGs rejected a high proportion of exceptional funding requests for hip and knee surgery last year.

GP Neil Thorman, medical secretary of Rotherham LMC, said that while the motivation for imposing thresholds was financial, the CCG had been “as fair and objective as they could have been” and had engaged with local GPs.

The BMJ investigation: Hip and knee surgery as funding pressures grow

The BMJ has found that nearly 1700 requests for knee and hip surgery were rejected in England last year. Gareth Iacobucci investigates

The BMJ’s analysis shows that the proportion of funding requests for hip and knee surgery rejected by CCGs remained broadly static last year at around 10%. But there were more rejections, because the number of funding requests increased substantially, by 56% for knees (from 6894 to 10755) and 46% for hips (3704 to 5414).

A major concern is the disparity uncovered across the country, with CCGs acting independently to restrict access to procedures to balance their books.

Ananda Nanu, the British Orthopaedic Association’s president, said that some CCGs had imposed “draconian” restrictions. “Access to healthcare in different parts of the country seems to be determined not by clinical factors or by patient factors but by how the money is to be spent,” he said.

To eliminate what it describes as “unwarranted variation” in activity, NHS England is consulting on nationwide proposals to stop funding 17 procedures it considers are clinically ineffective, including knee arthroscopy for patients with osteoarthritis. The initiative follows work to reduce GPs’ prescribing of low value medicines. NHS Clinical Commissioners, which helped draw up the plans, said that the initiative may eventually look at hip and knee replacements too.

The NHS is also considering, as part of its Elective Care Transformation Programme, whether the locally driven approach to hip and knee surgery commissioning needs to be reviewed to create more standardised thresholds across England. Nanu said he was concerned that moves to standardise access may lead to stricter thresholds if cost savings were prioritised. “The key question is: do you take everybody up to the highest common factor or do you take everyone down to the lowest common denominator?” he said.

Clinically appropriate threshold

But NHS Clinical Commissioners’ co-chair Graham Jackson said that consensus should be possible if policies were clinically led and based on sound evidence. “There are cases where we have put joint replacements in people that have not improved their outcome, cost money, and created morbidity,” he said.

“If you use knee replacement as an example, we should be able to standardise that to a clinically appropriate threshold,

Funding requests increased substantially, by 56% for knees (from 6894 to 10755) and 46% for hips (3704 to 5414)

Surgical trainees face longer training periods

The restrictions on hip and knee procedures are having a negative effect on orthopaedic surgery training, consultants report.

The British Orthopaedic Association’s president, Ananda Nanu, said that at a recent meeting of training directors half said they had moved a trainee, considered moving them, or extended the training period because of the lack of training opportunities.

“It’s a huge problem,” he said. “In certain areas there has been a complete moratorium on hip and knee surgery for several months.”

Patrick Williams, the British Orthopaedic Trainees Association’s education representative, said that during a recent placement he had carried out fewer than a quarter of joint replacements he needed to complete his training. In the longer term, he said, higher treatment thresholds could have “very long reaching effects” if trainees aren’t able to carry out simple procedures.

“Replacements are likely to become more complicated because patients are seen later,” he said. “Some consultants will say, ‘It’s a harder one, you do it,’ but others will say, ‘This one’s a bit tricky; you’d better not.’ That would have an effect on training and potentially on patient outcomes.”
whether its a BMI threshold, an activity measure, [or] a quality of life issue. There may be CCGs which are then overlaying something on top, but that's the challenge, because of the fact that there isn't enough money in the system.”

Jackson said that all clinicians had a responsibility to avoid using NHS funds inappropriately. “It’s not about pitching different parts of the service against each other. It’s coming to collective consensus about what the right thing to do is,” he said.

In May doctors in London attacked draft NHS plans to refer patients with osteoarthritis for a knee or hip replacement only if there was a “substantial impact on quality of life.” And last year the Royal College of Surgeons criticised three CCGs in Worcestershire for plans to raise the eligibility threshold, using the Oxford hip and knee score system, for patients requiring replacements.

Evidence is emerging that more patients are choosing private hip and knee surgery because of NHS restrictions and longer waiting times.

Spire Healthcare, one of the largest providers of private healthcare in the UK, saw a 12% rise in revenue from all self paying patients in 2017.

Certain areas have seen a particularly high surge in patients paying for care. Spire Little Aston Hospital, near Sutton Coldfield in the West Midlands, reported a 60% growth in patients paying for orthopaedic procedures in 2017.

In the company’s most recent annual statement, chief executive Justin Ash, said he expected these trends to continue this year. “It is clear to all UK healthcare stakeholders that demand for healthcare provision by the independent sector will continue to rise rapidly as the NHS remains severely financially constrained, and waiting lists and rationing, especially for elective work, continue to grow,” he said.

### Are More Patients Going Private?

Patients have to be prepared to give up their identity and clinical info to a panel, not all of whom are clinical. Some patients feel that this is a price they are not prepared to [accept] and so don’t pursue exceptional funding, she warned.

John Kell, head of policy at the Patients Association, said that exceptional funding requests shouldn’t be needed to access “well established and highly effective interventions such as hip or knee replacements.” He added, “Patients shouldn’t be forced into making a ‘hail Mary pass’ such as trying to use a mechanism that’s intended for something else to access relatively basic care.”

### Largely Accepted

But Neil Thorman, a GP and medical secretary of Rotherham LMC, said the conditions for referral in his area had largely been accepted by patients. “When it’s explained to patients that there might be less invasive, safer, or more conservative way of managing the problem it’s unusual for them not to be willing to try those before moving forwards,” he said.

Gareth Iacobucci, The BMJ

Cite this as: BMJ 2018;362:k3002
Jury awards $4.7bn damages against Johnson and Johnson in talcum cancer case

A jury in Missouri has ordered Johnson and Johnson to pay $550m (£415m) in compensatory damages and $4.14bn in punitive damages to 22 women who claimed its talcum powder caused them to develop ovarian cancer.

The lawsuit was brought by 22 women from across the US, six of whom have since died. More than 9000 US customers have lodged suits. Most claim damages for ovarian cancer, but some allege that using the product led them to develop mesothelioma.

The award is by far the biggest yet against Johnson and Johnson in litigation relating to talcum powder and the first case in which plaintiffs alleged that asbestos in the powder caused their disease. “We hope this verdict will get the attention of the J&J board and will lead them to better inform the medical community and the public about the connection between asbestos, talc, and ovarian cancer,” said Mark Lanier, the lawyer for the 22 women.

“The company should pull talc from the market before causing further anguish, harm, and death from a terrible disease.”

“Unreasonable”
In his summing up, Mr Justice Grammond said, “Health Canada’s decision in this case is unreasonable, because it entirely disregards one of the main purposes of Vanessa’s Law, namely to improve clinical trial transparency.

“Health Canada cannot ignore that parliament intended to make clinical trial data public”
Mr Justice Grammond

“A federal court judge said it was “unreasonable” for Health Canada to impose a confidentiality requirement as a condition for the disclosure of data, and ordered the agency to release it without any further reconsideration.

The case is the first time that the Canadian courts have been required to interpret and apply legislation introduced in 2014 which empowered the government to disclose information concerning drugs to certain persons. The legislation is known as Vanessa’s Law, after 15 year old Vanessa Young, who died from a heart attack in 2000 after taking the prescription drug Prepulsid.

“The evidence in the case was simply overwhelmed by the prejudice of this type of proceeding,” the company said in a statement.

Canadians ordered to release unpublished Tamiflu data

The Canadian government has been instructed to release unpublished clinical trial data relating to Tamiflu, Relenza, and three human papillomavirus vaccines immediately, in a landmark ruling hailed as a “major victory” for transparency.

The case was brought by Peter Doshi, assistant professor at the University of Maryland and associate editor of The BMJ, after Health Canada refused his request to obtain unpublished information relating to Tamiflu, Relenza, Gardasil, Gardasil 9, and Cervarix because he would not sign a confidentiality agreement.

A Health Canada spokeswoman said, “We are reviewing the decision and will continue to move ahead with the plan to make clinical information on drugs publicly available to better protect the health and safety of Canadians.”

A Health Canada judge said it was “unreasonable” for Health Canada to impose a confidentiality requirement as a condition for the disclosure of data, and ordered the agency to release it without any further reconsideration.

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“Johnson and Johnson remains confident that its products do not contain asbestos and do not cause ovarian cancer. Every verdict against Johnson and Johnson in this court that has gone through the appeals process has been reversed and the multiple errors present in this trial were worse than those in the prior trials.”

The company pointed to research from the Nurses’ Health Study, the Women’s Health Initiative observational cohort, and the Sister Study (2003-9), which it said “found no association overall between talc use and ovarian cancer.”

However, a simplification of the Nurses’ Health Study did find an association between talc use and the most aggressive, invasive ovarian tumours. Follow-up research extended those findings while suggesting that risk was linked to particular gene mutations. Other researchers studying that cohort found an association between talc and risk of endometrial cancer.

The American Cancer Association and the UK ovarian cancer charity Ovacome call the evidence for a link between talcum and ovarian cancer inconclusive.

WHO’s International Agency for Research on Cancer lists talcum as a class 2B chemical that is “possibly carcinogenic.”

No association

The Sister Study found no association between cancer and talcum use but noted that users were more likely to practise vaginal douching, which was quite strongly associated with ovarian cancer risk.

Three suits against Johnson and Johnson over talcum and mesothelioma have ended in the past three months, one with a mistrial and two with jury awards against the company of $11m and $25.75m.

Owen Dyer, Montreal

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Test for M genitalium or risk a new superbug, doctors warn

Sexual health experts have warned that the sexually transmitted infection Mycoplasma genitalium could become a “superbug”—resistant to first and second line antibiotics—if new guidelines are not fully implemented.

Draft guidelines from the British Association for Sexual Health and HIV (BASHH) recommend diagnostic testing for M genitalium, which, if left untreated in women, can cause pelvic inflammatory disease and infertility. It is often misdiagnosed as chlamydia and treated as such, which encourages antimicrobial resistance.

However, a BASHH survey of 125 public health commissioners found that only one in 10 were making provisions for testing in their 2019 budget. Another survey of 169 sexual health experts found 83% did not routinely test for it in symptomatic patients, and 60% cited a lack of funding or resources.

Peter Greenhouse, a Bristol based sexual health consultant, warned, “Mycoplasma genitalium is rapidly becoming the new ‘superbug’: it’s increasingly resistant to most of the antibiotics we use to treat chlamydia. The guidelines will help, but unless we get funds to regularly test for it, we’ll be in the dark about the true risks of long term complications.”

M genitalium, with a prevalence estimated at 4–38% among those attending sexual health clinics, is more prevalent than gonorrhoea.

Jacqui Wise, London

Cite this as: BMJ 2018;362:k3060

FIVE MINUTES WITH . . .

Robert McKinley

Keele’s medical education research director on why GPs should earn the same as hospitals to train students

“W e have estimated that there needs to be a funding increase of around £31m a year for general practices to train medical students. If we don’t get funding sorted out we risk a catastrophic collapse of undergraduate general practice teaching in England and Wales. Northern Ireland and Scotland are facing similar problems.

“Without the funding, practices will start to withdraw from providing teaching. If medical schools then ask for the same level of teaching from a smaller number of practices then that places an increasing burden on those practices and things will start to snowball. In May and June 2017 we collected data from 50 GP practices, with two practices in almost every English medical school area. Those data demonstrated that on average it costs the same amount to provide teaching as it did in hospitals.

“We have worked out that practices needed £38 000 to train a student for 37 weeks a year. On average, however, the amount universities pay varies from £22 000 a year up to £34 000 a year. We found one medical school that was paying the equivalent of £8 000 per student, per year. There was an almost fourfold variation in the amount paid.

“This meant that some medical schools struggled to provide students with four weeks of meaningful training in general practice, whereas in Keele we provide them with 24 weeks. We also found that 12 medical schools in England were curtailing their GP training programmes because they couldn’t recruit enough practices. Some made fewer demands because they knew that if they asked any more of practices, they wouldn’t teach. Some increased the number of students who would go out to a practice.

“We know that graduates from medical schools where students spend more time in general practice are more likely to go into the specialty. We also know that positive experiences in general practice can change students’ minds.”

Robert McKinley is director of medical education research and scholarship at Keele University Medical School

Abi Rimmer, The BMJ

Cite this as: BMJ 2018;362:k3120

“SOME SCHOOLS STRUGGLED TO PROVIDE FOUR WEEKS OF MEANINGFUL GP TRAINING”
The Beth, an old fashioned cradle-to-grave hospital serving a town on the Yorkshire edge of the Pennines, is threatened with closure as part of an NHS efficiency drive. Meanwhile, a TV documentary crew eager to capture its fight for survival follows the daily struggle to find beds on the Dusty Springfield geriatric ward, and the triumphs of the old people’s choir. Thus the scene is set for Allelujah!, Alan Bennett’s first new play in five years, which is described by director Nicholas Hytner as “The History Boys with 80 year olds.”

The 84 year old playwright has long been a champion of the NHS, writing in 2009 about how it saved his life after he was diagnosed with an aneurysm in his abdomen. Praising the staff at University College London Hospital, who were involved in his seven hour surgery, he said: “The NHS is an institution dear to the heart of the public and which defines what it is to be British.

“Any patient who had what I had and who opts to pay for private treatment has got to have more money than sense. The NHS does it better than the rest and its achievements should be trumpeted.”

The play, which features dance routines choreographed by Arlene Phillips, stars Deborah Findlay, Samuel Barnett, and Sacha Dhawan (standing, far left).

Allelujah! is at the Bridge Theatre, London SE1, until 29 September; boxoffice@bridgetheatre.co.uk

Alison Shepherd, The BMJ

Cite this as: BMJ 2018;362:k3146
Decriminalise abortion in the UK

Outdated laws obstruct reflective choice and best care

The recent decisions to liberalise abortion laws in the Republic of Ireland and the Isle of Man\(^1\) have put pressure on Theresa May to consider decriminalising abortion in the UK. Although she believes “that a woman should be able to access safe, legal abortion,”\(^2\) she has not yet acted to initiate amendment of the 1861 Offences Against the Person Act—perhaps in fear of Northern Ireland’s anti-abortion Democratic Unionist Party (DUP), on which her minority government depends.

The UK 1967 Abortion Act was introduced to provide a legal defence against the criminal law passed in 1861, but that law remains on the statute book. The abortion act still requires two doctors to predict the grounds for termination permitted under the 1967 act can feel to the medical practitioner like an invitation to overstep clinical competence—a kind of clinical contortion. Applying the law as it stands, we can at best inform a woman conscientious attempts to apply the law impedes advances in safe medical abortion practice, including the trend away from paternalism towards patient centred services and services that are nurse led or delivered using telemedicine.\(^3\)

Finally, the law is out of step with those in many other European countries and with UK social values.\(^4\)-\(^7\) The UK Supreme Court recently ruled that abortion legislation in Northern Ireland—where abortion is prohibited even after rape or in cases of fatal fetal abnormality—is incompatible with the European human rights convention.\(^8\)

A blunt tool

Criminalisation is a blunt tool. Conscientious attempts to apply the grounds for termination permitted under the 1967 act can feel to the medical practitioner like an invitation to overstep clinical competence—a kind of clinical contortion. Applying the law as it stands, we can at best inform a woman of what the law requires, inquire sensitively whether she believes it to be fulfilled in her case, explore doubt conscientiously, inform her of risk, and trust her response. At worst, the veiled threat of being forced to continue an unwanted pregnancy can place women on their guard and undermine any reflective process.

The law is left either coercive (as in Northern Ireland) or impotent (as in the rest of the UK), but it does reduce stigma and improve quality of care and access.\(^9\)-\(^11\) Third, UK abortion law impedes advances in safe medical abortion practice, including the trend away from paternalism towards patient centred services and services that are nurse led or delivered using telemedicine.\(^12\)

To champion reform would be a memorable act of leadership and courage by Theresa May

Neither case is it conducive to best clinical practice. Concern that abortion should be a reflective not a heedless process is justified, though not the only issue at stake. But criminalisation does not support reflectiveness.

Futuro UK law could support conscientious reflection in abortion care more effectively by guaranteeing women access to the resources they need to make the ethical and practical choices that are theirs to make and live with. Resources currently used to “police” choice and access\(^15\) could be reallocated to offering counselling services to women who are ambivalent or whose abortion request signals a wider life crisis, and to ensuring immediate access to effective post-abortion contraception. That way, ineffective, unjustified, and unpopular attempts to constrain women’s reproductive choices would be replaced with active support to ensure that each woman makes the right choice for her circumstances.

Right now, the UK prime minister has an opportunity to champion evidence based reform of an outdated, ineffective, and unpopular law, with the backing of health professionals and public opinion in Great Britain and Northern Ireland. To do so, despite the political threats made against her, would be a memorable act of courage and leadership.

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Find the full version with references at http://dx.doi.org/10.1136/bmj.k2928
New uses for old drugs

Low cost generics are an untapped source of therapeutic innovation

Cost constraint is a major concern for health systems globally. High unmet needs, increased demand because of demographic change, and the rising prices of new drugs conspire to exacerbate financial strains. Of these three factors, only drug pricing is amenable to influence in the short to medium term. Drug repurposing—the use of existing licensed drugs for new medical indications—has the potential to help reduce costs.

Many candidates for repurposing are widely used low cost generics. For example, the Repurposing Drugs in Oncology project has identified more than 230 licensed non-cancer drugs with data supporting anti-cancer activity, of which over 75% are off patent. As the drugs are already in routine clinical use for other purposes early phase clinical trials can be bypassed, saving time and money.

Something old, something new

The potential for repurposing extends to all areas of medicine, with much activity in oncology, neurology, psychiatry, and infectious diseases. Several drugs are already being used for new indications, including the repurposing of propranolol for infantile haemangioma, thalidomide for multiple myeloma, and topiramate for migraine prophylaxis.

Propranolol, a widely used non-selective β blocker, shows evidence of activity against a wide range of malignancies, including angiosarcoma, a rare soft tissue sarcoma for which current treatments produce response rates of 25-40%.

Another example is epilepsy, which affects 65 million people worldwide. Current antiepileptic drugs fail to suppress seizures in a third of patients. The Prescribable Drugs with Efficacy in Experimental Epilepsies (PDE3) project has identified 173 drugs licensed for other conditions that have antiepileptic efficacy in animal models. Research investment is now needed to develop the most promising candidates further.

However, there are specific financial disincentives to repurposing generic drugs. Investment is required to prove efficacy and to extend the licence of the drug for the new indication. While a commercial sponsor with a patent on a product might invest in the hope of realising a return on investment, there is less to gain from repurposing a generic drug. A generics manufacturer who invests in repurposing risks seeing competitors benefit from any increase in sales.

Other barriers include restrictions on who is able to apply for label extensions—for example, applicants must hold a marketing authorisation for the drug in question.

Given these obstacles, drugs that are promising candidates for repurposing risk being bypassed in favour of more expensive new drugs or ignored altogether, to the detriment of patient health and the public purse. This is a global problem, but the effects—and potential benefits—are greatest in low and middle income countries, where the costs of newer medications are especially onerous.

Attempts at a legislative solution stalled in the UK when the off-patent drugs bill failed to win government backing in 2014 and 2015 despite widespread parliamentary and public support. In response, a drug repurposing group was convened, moderated by the Association of Medical Research Charities with the support of the Department of Health and Social Care, to look at non-legislative solutions. This group recently published recommendations to tackle the problem of incentives.

Create incentives

Specifically, it proposes amending the tax credit rules for research and development so that generics manufacturers have more incentive to license generics for new indications. Crucially, this scheme was designed to ensure that newly licensed repurposed drugs would not be subject to price hikes, which would undo the benefits of public investment. The report also recommended the creation of a UK “catalyst fund” to supply the necessary investments.

These recommendations are welcome. Additionally, European research funders should be more willing to support repurposing trials for drugs that do not have patent protection. Many valuable repurposing leads have come from serendipitous discovery thanks to careful observation and reporting by treating clinicians—this is to be encouraged. Clinicians may further facilitate repurposing by supporting clinical trials and trial applications when they occur. Finally, we ask scientists, citizens, doctors, and patients to join forces in support of repurposing old drugs for new indications.

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This is how many doctors hospitals really need

The Royal College of Physicians (RCP) has developed the first recommendations for safe medical staffing levels in UK hospitals. It urges NHS trusts to measure their workforce against these “indicative” standards (see visual summary, right) to guard against shortages that pose risks to patients.

College registrar and president elect, Andrew Goddard, says there is “staggering” variation in the numbers of doctors per bed in the UK but no clear tally of how many doctors, nurses, or other healthcare professionals are needed in the acute medical setting at any point in time.

“Everybody’s been afraid to measure it, because they haven’t known what to compare it to. This is the first time that anybody’s actually put a standard down to say, ‘This is what we think we should have. Let’s now measure against it to see what we do have,’” he says.

After Mid Staffs

Five years ago, in his final report on Mid Staffordshire NHS Foundation Trust, the chair of the public inquiry, Robert Francis, recommended that “minimum safe staffing and skill mix levels should be drawn up by the National Institute for Health and Care Excellence (NICE) and policed by the Care Quality Commission (CQC).”

Since then, attempts to develop such levels have had mixed fortunes and have focused on nursing; although both Wales and Scotland have introduced safe staffing legislation, the RCP’s work is the first to suggest hard figures.

Guidance on Safe Medical Staffing, published on 13 July, sets out the number of hours that different levels of clinicians (including physician associates and advanced nurse practitioners as well as doctors) need to be present in various hospital settings. When practicable, it also estimates the number of posts needed to deliver that type and volume of care safely.

Francis tells The BMJ this approach is “encouraging,” although he would have liked to see patient involvement in the work. “The challenge has always been to find an evidence base to justify any numbers for staff-patient ratios and so on,” he says. “This does seem to me to be a laudable attempt to do that at least for the medical team … and it’s something that’s been conspicuously absent in the nursing field.”

Indicative not absolute

The RCP’s recommendations now need to be “drawn together” with the work that has been done on safe nursing staffing, Francis says, “so that you have an overall pattern of what is needed in the ward.”

The RCP says there is much variation in the way that individual medical wards function and the calculations provide indicative rather than absolute staffing numbers. It says staffing should be based on “80% of maximum activity” and that the modelling assumptions take account of the estimated 30-70% of medical time spent on indirect care such as leadership and management.

It points out that the out-of-hours workload of the medical registrar on call is “inappropriately onerous, with implications for patient safety.” It argues that services must always support training and that an increase in consultant delivered care may be limiting opportunities for trainees to acquire experience in decision making.

EXAMPLE OF RECOMMENDED SAFE STAFFING LEVELS

RCP president elect Andrew Goddard explains this by describing a patient with pneumonia being admitted to hospital and arriving first in the acute medical unit (AMU). He says it will take an average tier 1 clinician an hour and a quarter of their time to do all the tests, take the blood samples and history, do an examination, request radiography, and be on hand to arrange any further investigations.

“So that’s how we come up with the figure that says if you’ve got 10 patients in that setting you’re going to need 15 hours of tier 1 time,” explains Goddard.

“And in the report we’ve looked at an average AMU take of 45 patients and say you’ll need six to eight tier 1 doctors to do that—an estimated 13 posts. We’ve tried to say to a trust, this is how many doctors you are going to need to employ to provide this number of hours.

“You’ve got to remember that’s not necessarily the number of doctors you’re going to have on the ward or the unit at that particular time, but to cover that number of patients in that setting, given that some doctors will either be off shift or taking time off in lieu or for sick leave, annual leave, study leave, paternity leave, etc.

“One of the reasons we feel like we’re understaffed at the moment is because we haven’t taken those calculations into account.”

“This is ground breaking. There was no standard to compare with previously”

Andrew Goddard, RCP
Safe medical staffing levels

This graphic presents new estimates of the person hours needed, by different levels of medical staff, for safe medical care in UK hospitals. The recommendations are based on a report from the Royal College of Physicians (July 2018).

**Tier 1: Junior**
- Competent clinical decision makers
- Foundation trainees
- Core medical trainees
- General Practice Vocational Training Scheme trainees
- Acute Care Common Stem trainees
- Physician associates
- Advanced nurse practitioners
- Other healthcare professionals with equivalent capabilities

**Tier 2: Registrar**
- Senior clinical decision makers
- Experienced trainees who are at the end of core medical training or other equivalent training
- Specialist or specialty registrars in higher medical training programmes
- Year 3 trainees in internal medicine
- Specialty and associate specialist doctors
- Trust doctors

**Tier 3: Consultant**
- Expert clinical decision makers
- Specialty and associate specialist doctors with higher levels of competencies, qualifications, and experience—often above threshold 2

**ASSESSMENT AND ADMISSIONS TEAM**

To assess 10 patients
- Medical staffing for patients who present acutely to hospital with medical problems

**Model 1**
- Consultant led care, without an immediate consultant presence in the emergency department and acute medical unit but with consultant led post-take ward rounds
- Tier 1: 15 hours
- Tier 2: 9.5 hours
- Tier 3: 4.5 hours

**Model 2**
- Care partly delivered by consultants, with consultant presence and early involvement in the emergency department and acute medical unit
- Tier 1: 15 hours
- Tier 2: 7 hours
- Tier 3: 6.5 hours

**DAYTIME WARD TEAM**

For 30 bed medical ward
- Similar medical staffing is needed for wards that have lengths of stay of 4 days and 6 days

**Monday to Friday**
- Staff time required per week
- Tier 1: 71 hours
- Tier 2: 30 hours
- Tier 3: 20.5 hours
- Tier 3: 24.5 hours

**Weekends**
- Staff time required per day
- Tier 1: 8 hours
- Tier 2: 2 hours
- Tier 3: 2 hours

**ON-CALL TEAM**

Day and night
- Staffing for emergency medical care for inpatients who are covered by the on-call team

**Tier 1**
- Per 16 hour on-call period for every 100-120 beds covered
- 16 hours

**Tier 2**
- Dependent on hospital size

**Small hospitals**
- May be able to combine with leading the medical assessment and admissions team

**Medium hospitals**
- Require a separate, dedicated tier 2 medical registrar to provide on-call cover of the wards for 12 hours of greatest activity every day, with another medical registrar leading the medical assessment and admissions team

**Large hospitals**
- Need a separate dedicated tier 2 medical registrar to provide on-call cover of the wards 24 hours a day
THE RECOMMENDATIONS EXPLAINED

These safe staffing benchmarks are a necessity, not a pipedream, say RCP president Jane Dacre, president elect Andrew Goddard, and cardiologist Rhid Dowdle, who chaired the guidelines working group.

Why was the report needed?
“We are heading for a real workforce crisis and we need to have national solutions,” says Dacre. The college says the number of doctors coming through the system has “flattened” because of caps in medical student numbers and on visas for overseas doctors.

“Patient care is now jeopardised by staff shortages and low morale,” she says. “We recognise that the complex issue of safe medical staffing will not be resolved at a stroke but this guidance is a significant step towards that objective.”

How long has this work taken?
Two years, but the seeds were sown much earlier, says Goddard. In 2010, an RCP snapshot survey indicated how many junior doctors there were on NHS wards. “What became clear was that nobody collects those data and that there’s a huge variation,” Goddard says.

Although NICE guidance covers safe nursing levels, it has not produced similar for medical staffing. “We thought that’s a space we have to go into,” says Goddard. “This is ground breaking. No one previously has had any standard to compare with, to understand whether the number of medical professionals they’ve got working in different wards within the hospital is right.”

What was the working party’s brief?
The group of 23 experts was asked to define benchmarks for safe staffing levels for different clinical situations (see visual summary, p 97). Dowdle says this meant analysing workload and working patterns to come up with a set of recommendations. “We started to examine what people do, how they should do it, how long it took and therefore how many people were needed.

“We tried to be sensible; we didn’t document best practice but what we thought was safe care,” says Dowdle.

What were the methods?
Focusing on four areas of hospital activity, the experts calculated the time needed to provide care from clinicians, whom they grouped into three tiers according to levels of knowledge, experience, and responsibility.

The working group says it is no longer appropriate to speak of work being done by specific grades of doctors, and the model reflects how the medical workforce has been evolving and “broadening out.”

Dacre says, “What’s happened over the past few years, quite appropriately, is that other clinical staff have been able to pick up jobs that traditionally might have been done by doctors. One of those groups is physician associates. [The RCP hosts the Faculty of Physician Associates.]

“We’re all clinicians and we work in teams and are codependent, and that’s because medicine is more sophisticated and complicated. So, how we reach those numbers can be quite flexible.”

Goddard says the tiered classification of medical professionals aims to make the analysis “future proof. So whatever the future looks like in how care is delivered in hospital, this is the measure of what is safe and effective care.”

How many hospitals are likely to be meeting the new standards?
“We don’t know,” stresses Goddard. “It may be there are some places that have reached this standard easily and others may be a long way behind it. But until we actually start to measure against this standard it’s impossible to say.

“This is very much about setting a bar, so then we can measure against that bar and then start to talk about what is achievable [and] what’s not achievable.”

“One of the biggest arguments for not looking at this is that it’s too complicated and too difficult. We’ve got to stop that and try to see where we are.”

How long will it take to know how trusts are measuring up?
“I’d be disappointed if we didn’t have a reasonable idea after a year,” says Goddard. “There are 180 odd trusts in England, so we need to start in a selection of those.

“We hope people use this as a yardstick and over the next year or two begin to work with the CQC, NHS Improvement, and hospitals and healthcare systems to look at how many staff there are; then we can begin to think about how we help places where they are understaffed.”

How should the guidance be used?
Dowdle says, “We’ve produced a template which trusts can use if they want to assess where they are with their staffing. We suggest if your trust has concerns about your staffing, or if there are adverse events being reported, these can be used to trigger an audit. From that, they can use our indicative numbers to work out roughly what their workforce levels should be.

“The key thing about this document is it’s not the definitive product; it isn’t the end of the process—it’s the start. Our recommendations must be validated in action by people doing audits.

How could regulators use the benchmarks?
Goddard says he believes the CQC would see it as a “positive” step that hospitals were looking at them. But could they consider taking action if trusts aren’t measuring up? “We’re nowhere near that point, because we don’t know where everybody is,” he says.

What are the cost implications?
Goddard says that if trusts were found to be terribly understaffed this would affect costs. But he says alleviating staff shortages mitigates other costs. “Let’s not forget we spent £3bn last year on locums.

“The NHS already spends a lot of money trying to fill rota gaps and shortages and a lot of money trying to sort out problems when something’s gone wrong with patient care that could be prevented by having adequate staffing levels.”

Matthew Limb, freelance journalist, London
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Making online GP services safer

Nick Renaud-Komiya examines how digital primary care providers are responding to critical findings in the Care Quality Commission’s first inspections

In March, the Care Quality Commission (CQC) published the findings from its first programme of inspections into companies that provide digital primary care services. Critics of these commercial services seized on the finding that 43% of the 35 providers inspected since November 2016 were deemed not to be meeting safety standards by February.

However, safety was also the area where the healthcare regulator saw the greatest improvement over the inspection period, according to its report (86% were not fully compliant at their first inspection)—and the changes the providers are making offer insight into the development of this growing sector.

Ruth Rankine, the CQC’s deputy chief inspector of general practice, says, “Patients being supported online deserve the same standards of quality and safety as they would see in more traditional healthcare settings, and we are happy to be working with the sector to tackle challenges around this and promote innovation.”

Demand versus opposition

The companies, which typically charge for each use or have a monthly fee, offer services ranging from video based medical consultations to home delivery of prescription medicines and sexual health treatments.

Thirty seven online healthcare companies are registered with the CQC. Although audited figures on the use of their services are scarce, the evidence suggests that there is a demand. The CQC has reported that Push Doctor, for example, which offers video GP consultations through a smartphone app, was providing roughly 10,000 consultations a month with a team of 72 GPs in March 2017.

Richard Vautrey, chair of the BMA General Practitioners Committee, accuses the digital providers of fragmenting care—“cherrypicking” healthier, younger patients away from traditional, list based general practices. He adds: “Patients would inevitably rather be safe using these services through their own general practice, which has full access to their medical records and can provide follow-up face-to-face consultations when necessary.”

Out of the 35 providers inspected by the CQC between November 2016 and February 2018, 16 were re-inspected within this period at least once, with 14 showing improvements against some of the regulator’s safety criteria.

Communicating with NHS GPs

One such provider is The GP Service, a London based online consultation platform linked to a group of community pharmacies. This February it had 1500 registered patients. Its first CQC inspection in July 2017 found it was not meeting all the criteria for communicating information about a patient’s treatment to their registered GP.

Although information was regularly shared, inspectors noted a lack of evidence that a recorded policy was in place should a patient refuse permission to share treatment information with their GP.

This concern, resolved by the time of a subsequent inspection in February, is one that founder and chief executive, Hiren Patel, stresses is subject to continual development. “In any scenario the patient always gets asked if they would like us to share the information with their NHS GP. If they get around to the consultation and the doctor feels that information [should be] shared with a GP, that doctor can refuse to prescribe the treatment if a patient refuses to allow the doctor to share the information,” says Patel.

A similar approach has been adopted by Nationwide Pharmacies, which provides doctor consultations alongside a drug ordering service. It is another provider considered to have made the journey from not providing safe care by the CQC to meeting requirements. “In some instances, we may not provide a prescription if we do not have the doctor’s details and permission to contact their doctor,” explains David Harrison, the chief executive of the High Wycombe based company.

“When we do have a patient’s permission to contact their doctor, we have installed an automated letter system that keeps the patient’s regular GP updated with any medicines we have prescribed their patient,” he adds.

Patient verification

After its first inspection, the CQC also told The GP Service that it wished to see more evidence of
rules for checking patient identity—essential for safeguarding vulnerable users, correctly monitoring long term conditions, and ensuring appropriate prescribing.

“We were in the process of integrating a ‘know your customer’ (KYC) check system when we were first inspected. It went live two days after the first inspection,” Patel says.

KYC systems are commonly used by financial institutions to verify customers’ identities by cross checking information provided by users with national databases. While The GP Service had previously asked all patients for photo identification, its KYC system was an improvement in ensuring patients were who they said they were.

Push Doctor was also found to have improved its identity verification systems between March and August last year, particularly with regard to guarding against the risk of consulting and prescribing medicines to children.

Its founder and chief executive, Eren Ozagir, insists that the company’s GPs have never had any problems related to inadvertently treating patients aged under 16. He also shows some frustration at a perceived difference in the standards applied by the CQC to online GPs and bricks and mortar practices with regard to patient identification.

“Parents who go to a traditional GP surgery are not asked to present the birth certificate of the child every time the child attends the surgery. But in digital they are. That can be quite difficult in terms of accessing the care that the parent deems the child needs,” says Ozagir.

**“If you engage with the regulator rather than heckle, then together we can get this done”**

Eren Ozagir, Push Doctor

**Oversight**

Providers who spoke to The BMJ also described CQC requirements to better record decision making processes to show how quality improvement was being implemented.

Patel says that The GP Service’s relatively small size meant that, although key figures in the business, including the chief technical officer and medical director, met regularly, there were not always official minutes documenting these meetings. And Ozagir says that Push Doctor changed the format in which it collected data, to adhere to CQC rules.

The CQC’s regulatory practices are not without their critics among private digital healthcare providers. Last December, Babylon launched a legal challenge to prevent the CQC’s publication of a report into its services. The company, which provides app based consultations, including through the NHS partnership GP at Hand, said it had a “duty” to point out the regulator’s “shortcomings,” though it withdrew the challenge weeks later.

However, other providers broadly support the approach the watchdog has taken. “My experience with the regulator has been that if you engage, rather than heckle, then together we can get this done,” Ozagir said. “Support the regulator, be open and they respond much better to that, because they know what they’re dealing with. We respect general practice as it is today and we want to contribute to it, but we all need to go on a journey together.”

**Patients would rather be safe using these services through their own GP**

Richard Vautry, BMA

**SAFETY CONCERNS**

The Care Quality Commission’s first programme of inspections of 35 private online primary care services identified six main safety concerns:

**Antibiotic prescribing**

Some clinicians were found to have lowered the threshold at which they prescribed antibiotics because the remote nature of care made it difficult to carry out the clinical assessments usually done when seeing patients in person.

**Information sharing**

Although many services routinely asked for patients’ permission to share the details of their consultation with their registered GP, this wasn’t always recorded. In some cases, even after the patient’s consent was given, information was not shared.

**Monitoring long term conditions**

Providers did not always monitor patients with asthma, especially those ordering reliever inhalers; overprescription of these inhalers is an important indicator of poor asthma control.

**Identity verification**

On first inspection some providers were found not to have any systems to verify identity and would ask for verification only if patients gave contradictory responses to questions.

**Consent and capacity**

Several online providers did not have procedures in place to assess a patient’s mental capacity during consultations. Inspectors also identified a lack of understanding of the Mental Capacity Act 2005 among some providers.

**Safeguarding**

Some companies did not have a named safeguarding lead. Where providers had up-to-date policies to safeguard people from abuse, they were not always tailored to the online environment.