Surge in exceptional funding requests

The number of exceptional funding requests that doctors in England are making on behalf of their patients for treatments such as cataract removal, hip and knee replacements, and mental health interventions has increased markedly, an investigation by The BMJ has found.

Richard Vautrey, deputy chair of the BMA’s General Practitioners Committee, said that the figures were a sign that clinical commissioning groups were under increasing financial constraint. “There is undoubtedly more pressure on CCG budgets and attempts to reduce referrals and costs, and the greater use of individual funding requests (IFRs) may be one way some are trying to do this,” he told The BMJ.

Doctors made 73,900 IFRs to CCGs last year, a 47% rise from 2013-14, when they made 50,200, data collected by The BMJ under a freedom of information request show. In just the past year the number of requests rose by more than 20%, from 60,400. Just over half (52%) the requests made in 2016-17 were approved, but even patients who are granted access to treatment may have waited months for it.

IFRs, which first emerged in England in the 2000s, are made by GPs or consultants for treatments that are not routinely funded in their area. Local panels decide which to approve. Most are for cosmetic procedures or fertility treatment. But GPs in some areas are now being told to apply for exceptional funding for a wider range of treatments.

Chiltern and Aylesbury Vale CCGs in Buckinghamshire recently told doctors that all referrals for hip and knee surgery must go through an IFR process.

Stephen Cannon, vice president of the Royal College of Surgeons, said the move was a misguided attempt to save money. “These CCGs are unfairly and unnecessarily prolonging the time patients will spend in pain, possibly immobile and unable to carry out daily tasks or to work,” he said.

Vautrey urged NHS England to set clear guidelines on which treatments should require an IFR. “It’s clearly unfair for patients to be subjected to this postcode rationing, and it also adds further to GPs’ workload,” he told The BMJ.

Julie Wood, chief executive of NHS Clinical Commissioners, said that CCGs had to make “difficult decisions” on funding services. “Unfortunately the NHS does not have unlimited resources,” she said.

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구로인용: The BMJ

LATEST ONLINE

- Women in Northern Ireland to get free abortion on NHS in England
- Practice that suspended GP who later died by suicide criticised by coroner
- NHS bosses soften cost cutting plans after concerns
Junior doctors say rota gaps are affecting training

A third of junior doctors think that they have lost opportunities for learning because of gaps in rotas, a survey by the UK General Medical Council has found.

Initial findings from the GMC’s 2017 national training survey, which received 53,335 responses from UK doctors in training (a 98% response rate), revealed that 32% disagreed or strongly disagreed with the statement, “In my current post, educational/training opportunities are rarely lost to gaps in the rota.”

The survey also received responses from 24,577 trainers (a 54% response rate), 27% of whom said that they thought rota gaps had affected doctors’ training.

The questions on rota gaps were included in the survey for the first time this year, and as a result it was important to treat the results with caution, Charlie Massey, the GMC’s chief executive, said. “However, the results do reflect the concerns that have been raised previously by doctors in training,” he added, “and they suggest rota issues are affecting some doctors’ access to education and training.”

The GMC survey also found that over half (54%) of UK trainees worked beyond their rostered hours daily or weekly. However, this proportion was lower than in 2016, when it was 59%. The proportion of trainees who reported that their working pattern left them short of sleep on a daily or weekly basis also fell slightly, from 24% in 2016 to 22% in 2017, as did the proportion describing the intensity of their work as heavy or very heavy, down from 43% in 2016 to 41% in 2017.

Abi Rimmer, BMJ Careers

Cite this as: BMJ 2017;358:j3226

Prison health

Scale of mental health problems is unknown

Urgent action is needed to tackle record rates of suicide and self harm in prisons under pressure from staffing and funding cuts, the National Audit Office said. It warned that, although ministers had ambitious plans for improving prisoners’ mental health, they did not know how many people in prison have mental health problems or how much the government spends. Amyas Morse, NAO head, said, “Consequently, government do not know the base they are starting from, what they need to improve, or how realistic it is for them to meet their objectives. Without this understanding it is hard to see how government can be achieving value for money.”

NHS finance

“NHS tax” could bridge funding gap

A ringfenced tax funded by a rise in national insurance could raise £16bn over the next five years, a think tank said. The Institute for Public Policy Research said that an “NHS tax” should be channelled to sustainability and transformation partnerships to help them close the NHS funding gap. It also advised a law change to enable STPs to pool budgets and commission locally.

Genomics

CMO wants lab service centralised

Genomics medicine must evolve from a “cottage industry” to become a centralised service to realise its full potential in improving diagnosis and management of patients with rare diseases and cancer, said England’s chief medical officer, Sally Davies (below), in her annual report. Genomic services are currently delivered by 25 regional laboratories, but Davies believes that three centralised ones may be needed to enable use of the latest technology. “The technology is changing every 18 months to two years, [so] it is best for quality, speed, and cost to use the latest,” she said.

Regulation

EU proposes NPS ban

The EU council and parliament reached agreement on a planned reform of the legislation on new psychoactive substances (NPS) that are used as alternatives to illicit drugs. A proposed amendment to regulations was tabled in response to the risks to public health and safety stemming from the rapid expansion of NPS in Europe and worldwide. The changes aim to streamline the procedure for assessing the potential negative effects of NPS and deciding on a possible ban.

BMA conference

GPs should use “black alert”-style warnings

GP clinics should use a system similar to hospital “black alerts” to indicate when they have reached their maximum capacity, the BMA said. Delegates at the BMA’s annual representative meeting last week voted in favour of urging the BMA to construct such a system “with or without government cooperation.”

Stop sharing patient details with immigration

The BMA will urge the UK Department of Health to stop sharing patient details with the Home Office. Delegates voted to oppose the practice of sharing patients’ administrative details, including their addresses, without their GP’s knowledge. Jackie Applebee, a GP in east London, said that NHS Digital had handed over the confidential patient records of more than 8,000 people, “leading to over 5,500 people being traced by immigration enforcement.”

Pregabalin must be made controlled drug

Pregabalin should be reclassified as a controlled drug to tackle widespread problems of misuse and addiction, delegates said. They called on the BMA to “lobby the appropriate authorities to make pregabalin a controlled drug.” Pregabalin is currently prescription only.
TRANSPARENCY

MORE DOCTORS DISCLOSE DRUG COMPANY PAYMENTS

Nearly two thirds of UK doctors and other healthcare professionals chose to disclose payments made to them by drug companies in 2016, up 10 percentage points from 2015. The industry paid a total of £454.5m to work with UK healthcare professionals and healthcare organisations in 2016, said Disclosure UK, a website run by the Association of the British Pharmaceutical Industry. This was up 25% from 2015.

GOOGLE DEEPMIND TRIAL FAILED TO COMPLY WITH LAW

The Information Commissioner’s Office ruled that the Royal Free NHS Foundation Trust in London did not comply with the Data Protection Act when it provided patient details to Google’s DeepMind programme. The trust provided personal data on around 1.6 million patients as part of a trial to test an acute kidney injury alert, diagnosis, and detection system. But an ICO investigation found several shortcomings in how the data were handled, including patients not being adequately informed that their data would be used in the test.

HONOURS

DOCTORS ARE COMMENDED FOR BRAVERY IN TERRORIST INCIDENTS

BMA commended Wijesuriya for running “not towards safety but towards danger,” while Daley had “behaved with courage, dedication and professionalism.”

BURNOUT

“Grit” helps doctors avoid burnout

High levels of “grit” or resilience are associated with lower levels of burnout in UK doctors, a study in the Postgraduate Medical Journal found. The correlation was found among different groups of doctors: consultants recorded significantly higher levels of grit than trainees, but it was low among GPs, who, as a group, had the highest levels of burnout. The authors said that the protective role of grit may be lost at very high burnout levels.

ALLEGED RHINITIS

The number of people seeing their GP for hay fever rose 50% in the past year. In the week ending 25 June, 37568 visited their GP with hay-fever-like symptoms. In the same week in 2016 this was 25097

[ROYAL COLLEGE OF GPs]

THE CEP

THE WHAT?

You know, the CEP. Close friend of the STP, the IFR, and the RRT. It’s the capped expenditure process—another lovely phrase straight from the NHS Acronym Referral Site for England (ARSE).

VERY AMUSING. BUT WHAT DOES IT ACTUALLY MEAN?

According to a letter sent to trusts and clinical commissioning groups in Cheshire, it’s a way of ensuring that “those geographies that are significantly out of balance now confront the difficult choices they have to take.”

I’VE FED THAT INTO MY JARGONOMETER—WE’RE TALKING CUTS, AREN’T WE?

Well, the health and social care sector regulator NHS Improvement would prefer to call it prioritising resources, or ensuring that organisations stay within their financial envelope. But if you insist on using such vulgar terminology then yes, we’re talking about cuts.

BUT I THOUGHT THE AGE OF AUSTERITY WAS OVER?

Not in the NHS, I’m afraid. Some 14 areas have been “selected” to take part in the cost cutting process. Five of the areas are in London, which, according to documents seen by the Guardian, have been asked to make savings of £183m.

WHAT KIND OF COST SAVINGS ARE THEY PLANNING?

The usual—delaying non-urgent operations, rationing treatments, and closing wards.

THIS IS TERRIBLE! WE MUST FIGHT THIS

After a barrage of criticism, NHS Improvement has reined in the plans. Jim Mackey, chief executive of NHSI, has written to the areas involved saying that any plans will be viewed as proposals only at this stage and that “patient choice” must be taken into account.

PHEW, GLAD IT’S ALL OVER. I CAN SLEEP EASY NOW

Not really, NHS finances are still Full of Underlying Cost Deficits (FUC...you get the picture).

Anne Gulland, London

Cite this as: BMJ 2017;357:j3189

Cite this as: BMJ 2017;358:j3234
MHRA issues new guidance on metal-on-metal hips

All patients with metal-on-metal hip implants are advised to have blood tests and either plain radiographs or scans, under new guidance by the Medicines and Healthcare Products Regulatory Agency (MHRA).

Concerns have been repeatedly raised about these devices, and the regulator previously recommended in 2012 that symptomatic patients or those with particular types of implants should undergo tests.

Over 50,000 UK patients have had metal-on-metal hip replacements fitted. The MHRA said that the majority currently have well-functioning hips but that some patients will develop progressive soft tissue reactions to the wear debris generated by the hips, and not all will be symptomatic.

So far only DePuy, the manufacturer of one type of implant, is paying the costs of follow-up investigations and revision procedures in patients who have one of its ASR implants.

As tens of thousands more patients need follow-up with potential early revision procedures, the cost to the NHS is likely to be substantial. The BMJ has learnt that the tariff for a revision procedure has been cut by almost £3,000, which is likely to place extra financial pressure on trusts, and some providers that carry them out for the NHS are questioning whether they should continue to do them. The Department of Health and NHS England were contacted for comment but had not responded by the time of publication.

**Safety fears**

Back in 2012 The BMJ questioned the safety of metal-on-metal hips and specifically warned that total hip replacements with a large diameter head and hip resurfacing in women and in smaller men carried higher risks of failure.

This latest guidance builds on those concerns by advising that all patients who have had a metal-on-metal hip replacement should be reviewed. However, the frequency of the blood tests and the type of imaging required will depend on patients’ sex, whether they have symptoms, and the type of hip replacement used.

Neil McGuire, MHRA clinical director of medical devices, said, “The clinical advice we have received indicates that patients will likely have the best outcomes if these problems are detected early, monitored, and treated if necessary.”

The MHRA also told The BMJ that it is reviewing available information about long-term systemic effects of the ions released from metal-on-metal hips. The agency said that it was “aware that there has been some limited research carried out looking for an association with cardiac failure and that the scientific literature contains a small number of case studies of some patients with very raised metal ions who have developed systemic symptoms, in relation to a rapidly wearing hip.”

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Senior trainees will be balloted on new consultant contract, says BMA

Senior trainees, as well as all consultants, will be balloted on proposals for a new consultant contract, the BMA has said.

Delegates at the BMA’s annual representative meeting (ARM) in Bournemouth on 29 June voted in favour of a motion which said that “all consultants, [BMA] members on the specialist register, and junior doctors of year 3 specialty training and above should be balloted on the new consultant contract proposals.”

The motion was passed by 116 votes to 89 (57% for the motion, 43% against).

Earlier this year, consultants voted against automatically holding a collective ballot of consultants and senior trainees on a new contract. At the BMA’s consultants’ conference in February, delegates voted against a motion calling on the association’s Consultants Committee neither to approve nor accept any new contract “without balloting appropriate branches of the BMA membership.”

**Voice for members**

Proposing the motion at the ARM, Latifa Patel, a year 4 specialty trainee in paediatrics, said, “Our greatest asset in negotiations with the government remains our membership.”

“As such, we owe it to ourselves, the membership, to ensure that each and every voice is [heard]. As we reach a consultants’ contract which our committee are proud of, why wouldn’t we mobilise our members? Why wouldn’t we give a voice to our members?” Patel added.

Tom Martin, an ear, nose, and throat consultant, also spoke in favour. “Those who are not yet consultants may well be those who have to work under these conditions for the longest time,” he said. “I think that they must be given a voice.”

David Rouse, chair of the BMA’s North Thames Junior Doctors’ Committee, spoke against. He said that there was a need to be “practical and pragmatic” about the issue. “We need to think about where this leads,” he said. “If you vote for a ballot, and the ballot fails, then what? Are you willing to push for strike action?”

Vishal Sharma, one of the BMA’s consultant contract negotiators, also spoke against the motion, saying there had not yet been any decision to forgo a ballot. He said that the possibility of providing individual consultants with the option of choosing whether or not to move onto the new contract was currently under consideration.

Tom Moberly, The BMJ

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Cite this as: BMJ 2017;358:j3246
An investigation by The BMJ has shown stark local variation in the number of exceptional funding requests that doctors in England are having to make on behalf of their patients, and the types of treatment being restricted.

The analysis shows that the overall number of individual funding requests (IFRs) received by clinical commissioning groups in England increased by 47% in the past four years.

But there is substantial variation around the country. For example, Rushcliffe Clinical Commissioning Group in Nottingham received no IFRs last year, while Chiltern CCG in Amersham, Buckinghamshire, processed nearly 3800.

The proportion of IFRs being approved increased slightly in the past four years from 43% (20 515/47 626 with data available) to 52% (35 222/68 051). But the sharp increase in the overall number of requests means that thousands more patients are being turned down for funding each year, while many others are forced to wait for their treatment while their request is considered.

Again, there is much variation in how many requests are approved. Southern Derbyshire CCG received just 14 requests last year for procedures such as cataract surgery but approved none. In contrast, Stafford and Surrounds CCG processed 2123 requests, including 764 for skin excision, 232 for cataracts, and 163 for hip or knee replacement, but approved them all.

IFRs are made by GPs, consultants, or other health professionals for treatment and are not routinely funded in their area. CCGs decide which treatments are subject to IFR, and host panels of lay people, GPs, and other clinicians to decide whether to fund treatments. Doctors’ leaders told The BMJ that the increase in the requests and the wide variation in access was discriminating against patients in some parts of the country.

One patient whose request for treatment for rheumatoid arthritis has to be resubmitted as an IFR every six months told The BMJ that the process was slow, stressful, and painful (see p 49).

The findings come against a backdrop of unprecedented financial pressures in the NHS. NHS Clinical

### How The BMJ Carried Out Its Investigation

The BMJ sent freedom of information requests to each of England’s 207 clinical commissioning groups. It asked each group to disclose the number of IFRs it had received in each of the past four years, the number of requests that it approved, and the three most common treatment categories in which IFRs were submitted. A total of 192 CCGs (93%) had responded in time for The BMJ’s deadline. Of these, 10 responding CCGs did not supply figures as their IFR process is overseen by neighbouring CCGs, and 13 supplied incomplete data that could not be included in the results.
WHAT’S CAUSING THE INCREASE IN IFRs?

The overall rise in IFRs seen over the past few years is largely down to stricter enforcement of rules on what treatments CCGs will fund.

In 2015-16 Aylesbury Vale CCG and Chiltern CCG in Buckinghamshire decided not to pay providers for activity if the referring doctor did not follow their policies and submit IFRs where necessary. The move led to a fivefold increase in the number of IFRs over two years (from 1226 in 2014-15 to 6400 in 2016-17). Recently, the CCGs decided that all referrals for hip and knee surgery must be done through an IFR.

Strict enforcement

Christine Campling, a GP and executive lead for elective care for Aylesbury Vale and Chiltern CCGs, told *The BMJ* that stricter rule enforcement was needed because “a huge number” of procedures were going ahead despite being listed as requiring prior funding approval—to the tune of £1.7m a year.

“From that, we realised a) that we couldn’t afford that activity and b) that there’s no point having policies if they are not going to be practised,” said Campling.

“We ramped up our contractual challenges on IFR procedures, so that unless the providers could prove why there was a very good reason why an IFR had not been obtained, they wouldn’t get paid for the procedure. It helps to reduce the amount of clinical variation in what happens to patients.”

Campling said she was very aware that some patients may be disadvantaged and delayed by having to seek funding for their care, and the CCG has tried to make allowances for them. For example, although the Buckinghamshire CCGs’ default policy is for patients who need joint replacements to go through IFR, the CCG permits patients with severe rheumatoid arthritis to bypass this process with a letter from the consultant rheumatologist to another clinician.

But Campling said that the group’s IFR policy “has absolutely proved cost effective.” If we took our foot off that pedal and allowed patients to have operations without having to hit thresholds, then, we know that in other CCGs [which are not enforcing it] their activity has gone up,” Campling told *The BMJ*.

In other areas, stricter enforcement has accompanied changes to how IFRs are classified. Three CCGs in south Staffordshire (Stafford and Surrounds CCG, South East Staffordshire and Seisdon Peninsula CCG, and Cannock Chase CCG) now direct requests for procedures of “low clinical value” as determined by the CCGs to their IFR team. As a result, the number of IFRs in the three CCGs rose from 416 in 2014-15 to 7000 in 2016-17.

Hips and knees

Between 2013-14 and 2016-17 the number of IFRs for hip and knee surgery rose from 49 (0.2% (49/22 669 of the total number of IFRs with available data)) to 899 (3% (899/30 166)), indicating that these procedures are becoming increasingly difficult to obtain on the NHS.

In Buckinghamshire, two CCGs, Aylesbury Vale and Chiltern, recently issued guidance stating that all referrals for hip and knee surgery should go through an IFR process (see left).

Service commissioners say that such policies reduce clinical variation and are guided by evidence. But though evidence now advises against some specific procedures such as knee arthroscopy for patients with degenerative knee disease, surgeons argue that policies such as Buckinghamshire’s are too draconian and are denying patients treatment that could benefit them.

Stephen Cannon, vice president of the Royal College of Surgeons, said, “Hip and knee replacements are some of the most clinically effective and economical treatments available on the NHS. Unfortunately, patients needing hip and knee surgery have misguidedly become soft targets for NHS savings.”

THE 10 MOST COMMONLY REQUESTED TREATMENT AREAS THROUGH IFRs IN 2016-17

<table>
<thead>
<tr>
<th>Category</th>
<th>Requests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excision of skin</td>
<td>6079</td>
</tr>
<tr>
<td>Cosmetic and aesthetic surgery</td>
<td>4426</td>
</tr>
<tr>
<td>Varicose vein surgery</td>
<td>2058</td>
</tr>
<tr>
<td>Plastic surgery</td>
<td>1889</td>
</tr>
<tr>
<td>Fertility treatment</td>
<td>1151</td>
</tr>
<tr>
<td>Mental health</td>
<td>1150</td>
</tr>
<tr>
<td>Cataract removal</td>
<td>1034</td>
</tr>
<tr>
<td>Carpal tunnel surgery</td>
<td>952</td>
</tr>
<tr>
<td>Hip and knee surgery</td>
<td>899</td>
</tr>
<tr>
<td>Breast surgery</td>
<td>786</td>
</tr>
</tbody>
</table>

Source: IFRs made to 155 CCGs

A GP’s VIEW—“IT IS VERY DISCONCERTING FOR THE PATIENT”

CCGs in the north east of England had some of the highest numbers of IFRs last year and some of the highest year on year increases in requests received.

Neil Morris, medical director of Newcastle Gateshead CCG, said that the rise had largely been driven by giving more guidance to clinicians on when to refer for so called limited value procedures. He said that it was necessary for the CCG to have “an honest discussion” with doctors and patients over which treatments to prioritise, given financial pressures.

“One of my IFR [patients] had knee problems. They had had a meniscus partially shaved, which resolved the problem five years ago. The patient came to me and said, “It is exactly the same on the other knee as I had five years ago. I was helped: I did it through the IFR.” As the GP, I did x ray the knee first, because [the CCG] would return it if I didn’t do that. It wasn’t anything to do with joint degeneration. I did the IFR, and what happens? They refused to do it. So what does the patient do? Either they put up with their symptoms, or they have to go privately. I don’t think that’s fair.”
A patient’s view—“The process doesn’t make sense to me”

HELEN COLE, from west London, was given a diagnosis of rheumatoid arthritis 11 years ago. For the past two years Cole has been treated successfully with rituximab after she was switched from other tumour necrosis factor inhibitors that were not working. But to receive rituximab her consultant has to submit an IFR every six months and wait for a panel to approve it. All the requests have been approved so far, but Cole said that the uncertainty over whether her treatment could continue was “stressful,” while delays in getting the drug meant there have been gaps in her treatment that have left her in pain.

“Last time was the longest wait for me—10 weeks. That’s a long time to be living with a flare, and the potential joint damage. I had a lot of pain in my joints and really big problems with fatigue. It can be really challenging day to day,” she told The BMJ.

Cole is critical of the IFR process as it requires her to reach a certain level of pain before being judged eligible to receive funding for treatment.

“The process doesn’t make sense to me. The whole point of treating a disease like rheumatoid arthritis is to try to keep it under control at all times, stop it from flaring, and stop permanent long term damage to joints. But you almost have to flare to get the funding.

“This treatment works. There isn’t anything else they could give me. It just seems like a waste of the rheumatologist’s and the panel’s time. I’m sure there is an unbelievable amount of paperwork behind the request.”

“I had a lot of pain in my joints and really big problems with fatigue. It can be really challenging day to day

“It is assumed these policies have been put in place to reduce the number of hip and knee replacements performed and thereby save money. Patients needing surgery will cost the NHS more, in physiotherapy, pain medication, and other support, while they wait to find out if they can be referred,” said Cannon.

Cataracts

As commissioning budgets have become increasingly stretched in recent years, some CCGs have restricted access to cataract surgery by imposing thresholds for referral that are based on visual acuity.

The BMJ’s investigation found that the total number of IFRs for cataract removal in England rose from 359 (1.6% (359/22 669 of the total number of requests with available data)) in 2013-14 to 1034 (3.4% (1034/30 166)) in 2016-17.

These requests were concentrated in three CCGs in Staffordshire, which in 2015-16 increased the remit of its IFR department to include so called procedures of low clinical value, including cataract surgery.

Mike Burdon, president of the Royal College of Ophthalmologists, said that asking doctors to submit IFRs for cataract surgery amounted to inappropriate rationing.

“There should not be any impediment to access for what is a highly effective procedure that can seriously transform quality of life,” he said. “My concern is that there is no longer equality of access to cataract surgical care across the country.”

Mental health

The data show a consistently high number of mental healthcare requests through IFR between 2013-14 and 2016-17. This is despite a government push to improve access to mental health treatments over this period.

In some areas of the country mental healthcare was the most commonly requested treatment area under IFR last year. This included Wakefield CCG, which processed 122 requests for mental health services such as autism diagnosis, treatment for attention-deficit/ hyperactivity disorder, psychiatry, and counselling in 2016-17, but approved only eight.

“Many requests that were declined were signposted to make a referral into a suitable service already available,” said a spokeswoman for Wakefield CCG.

The spokeswoman added that the rise in the number of IFRs was due to “increased understanding and awareness” of mental health conditions among patients. But she insisted that patients had “timely and necessary access” to psychological therapies and that the CCG had responded to demand by commissioning a new diagnostic and treatment service for autism.

Gareth Iacobucci, The BMJ

Cite this as: BMJ/2017;358:j3190

Find the full version with references at http://dx.doi.org/10.1136/bmj.j3190

bmj.com Visit the online version to find out what the top three IFR requests were in your area last year
Medical leaders celebrate the ascent of woman

What glass ceiling? From left to right: Sue Bailey, Kate Lovett, Carrie MacEwen, Nicola Strickland, Jane Dacre, Suzy Lishman, Clare Marx, Lesley Regan, Fiona Godlee, Parveen Kumar, Helen Stokes-Lampard, Neena Modi

The BMJ’s editor in chief, Fiona Godlee, gathered together an unprecedented number of female medical leaders earlier this week in celebration of the fact that eight royal colleges are now led by women.

The senior women are Sue Bailey, chair of the Academy of Medical Royal Colleges; Jane Dacre, president of the Royal College of Physicians; Parveen Kumar, chair of the BMA’s Board of Science; Suzy Lishman, president of the Royal College of Pathologists; Kate Lovett, dean of the Royal College of Psychiatrists; Carrie MacEwen, chair elect of the Academy of Medical Royal Colleges and former president of the Royal College of Ophthalmologists; Clare Marx, president of the Royal College of Surgeons; Neena Modi, president of the Royal College of Paediatrics and Child Health; Lesley Regan, president of the Royal College of Obstetricians and Gynaecologists, Helen Stokes-Lampard, chair of the Royal College of General Practitioners; and Nicola Strickland, president of the Royal College of Radiologists.

Unable to make the meeting were the chief medical officers...
Neither the BMA nor the GMC has had a female chief executive or chair; the *Lancet* has not had a female editor in chief; and the Academy of Medical Sciences has never had a woman as president.

The ascent of female leaders reflects demographic change in the profession. The latest GMC figures show that the male-female split on the medical register as a whole is 54.5% to 45.5%. But in the GMC’s latest survey of trainees those figures are reversed: 55.9% of respondents were women and 44.1% men.

In other areas of medicine women are yet to achieve equal status. A report by the Exeter Business School said that just 25% of medical directors are women, and the latest data from the Medical Schools Council show that just 18% of professors are women. Godlee said, “Having so many women in senior leadership positions in medicine is something to be celebrated and will benefit female and male doctors as well as patients. However, we must not be complacent: gender equality is something we must continue to strive for.”

Anne Gulland, London

Cite this as: BMJ 2017;358:j3250
A 10 month old baby lies in the intensive care unit at London’s Great Ormond Street Children’s Hospital, kept alive by a mechanical ventilator and fed by a tube. Unable to breathe unaided or move his arms and legs, he has epileptic seizures which, because he is unable to move, can be detected only by electroencephalography. His brain has severe damage.

Doctors at the hospital believe they can do no more for Charlie Gard, a baby with an exceptionally rare inherited disease, infantile onset encephalomyopathic mitochondrial DNA depletion syndrome (MDDS). Caused by mutations in a gene called RRM2B inherited from both his parents, the condition leads to severe depletion of mitochondrial DNA in his tissues. The clinicians treating him think that he is in the final stage of the disease and that they are no longer serving his best interests by keeping him alive.

But Charlie’s parents, Chris Gard and Connie Yates (right), refuse to give up. They found a professor of neurology at a mainstream medical centre in the United States who was willing to give him nucleoside therapy, an experimental treatment that has never been given to a patient with the RRM2B form of MDDS. And they raised more than £1.3m through crowdfunding to take him there. Some 18 people around the world with a TK2 mutation, a less severe type of MDDS, have had some benefit from nucleoside therapy, but the condition had not affected their brains.

Nucleoside treatment
Back in January, the doctors treating Charlie had considered trying nucleoside treatment themselves and had drafted an ethics committee application. But after Charlie had several seizures, his parents were told that he had severe epileptic encephalopathy and that the treatment would be futile. Cue the start of a legal battle.

All the treating clinicians and the experts who gave evidence in the High Court agreed that the treatment, which cannot reverse existing brain damage, would not benefit Charlie. Even the US professor of neurology who gave evidence by telephone link conceded during the court hearing that Charlie was unlikely to benefit from the therapy, given his severe encephalopathy. But he added, “I would just like to offer what we can. It is unlikely to work, but the alternative is that he will pass away.”

Battles between parents and hospitals over children’s treatment are nothing new and hit the headlines regularly. But the fight over Charlie’s treatment is unprecedented, both legally and in its coverage on social media. It has involved seven judges in three courts in the UK and seven more at the European Court of Human Rights in Strasbourg, which agreed that undergoing experimental treatment would “continue to cause Charlie significant harm.”

Keeping Charlie alive
On 11 April the High Court in London ruled that it would be in Charlie’s best interests to come off the ventilator, to have only palliative care, and not to have nucleoside treatment. But the declarations were put on hold through unsuccessful forays to the Court of Appeal, UK Supreme Court, and Strasbourg.

FEATURE
Law, ethics, and emotion: the Charlie Gard case

The fight over a terminally ill baby’s treatment has been unprecedented, legally and in the social media coverage. After the European Court of Human Rights ruled he should now be allowed to die, Clare Dyer considers where it leaves doctors’ presumptions about a child’s best interests.
The law says that doctors cannot be required to provide treatment that they consider to be against a patient’s best interests. Yet the successive stays have obliged doctors to continue keeping Charlie alive for months on artificial ventilation, against what they believe to be his best interests.

On 19 June, to enable the Strasbourg court to consider the case urgently, the UK Supreme Court extended the stay again “with considerable hesitation” until midnight on 10 July. “We three members of this court find ourselves in a situation which, so far as we can recall, we have never previously experienced,” said the court’s deputy president, Lady Hale. “By granting a stay, even of short duration, we would in some sense be complicit in directing a course of action which is contrary to Charlie’s best interests.”

She added, “Every day since 11 April 2017 the stays have obliged the hospital to take a course which, as is now clear beyond doubt or challenge, is not in the best interests of Charlie. The hospital finds itself in an acutely difficult ethical dilemma.”

Rights to private and family life

The case has challenged the established view that a judge, in weighing up parents’ and doctors’ conflicting views on treatment, must simply decide what is in the child’s best interests. That was the traditional path the case followed in the High Court. But when it went to the Court of Appeal, the parents’ new legal team, led by leading human rights lawyer Richard Gordon QC, mounted a new argument.

He contended that where the parents are proposing a viable treatment elsewhere, the state cannot interfere unless this puts the child at risk of significant harm. Withholding treatment when the parents have a legitimate contrary view favouring an alternative treatment would involve interference by the state “on a massive scale,” he argued. The courts rejected the argument.

During this legal process, Charlie’s doctors continue, as they must, keeping him alive, providing treatment that they believe is futile and causing him suffering. During a discussion last month at Serjeants’ Inn Chambers in London, led by several of the barristers in the case, David Hicks, interim medical director at the hospital, asked: “Where does this leave the doctors at Great Ormond Street? My colleagues feel in a completely invidious situation. They are now required to provide treatment to a certain date which they do not agree with, while at the same time being told that they can’t be directed to give treatment, according to the law.

“They feel that they are at risk of being reported to their regulator, the General Medical Council, for changing treatment, sustaining treatment, or avoiding treatment… They’ve experienced delay after delay in being able to do what they feel is the right thing in Charlie’s best interests.”

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When “patient centred” is not enough: the challenges of collaborative health

Sweeping technological, economic, and social changes are taking some of the power out of doctors’ hands and they will have to alter their behaviour to retain public trust, writes Michael L Millenson

A quarter of a century ago, researchers proposed “patient centred care” as a conceptual framework that “consciously adopts the patient’s perspective” about what’s important in interactions with providers and institutions.

Today, technological, economic, and social changes are moving healthcare in directions unanticipated by the patient centredness pioneers. It’s not that patient centredness no longer pertains; rather, it’s being subsumed under these larger forces reshaping 21st century medicine. I suggest “collaborative health” as an umbrella term framing how clinicians should respond.

The Victorian parliamentarian and novelist Edward Bulwer-Lytton declared, “A reform is a correction of abuses; a revolution is a transfer of power.” Patient centred care began as a correction of abuses, a response to patients being treated like “imbeciles and inventory.” Decades later, what’s claimed to be patient centred still too often reflects a paternalistic attitude, ironically expressed by comedian Stephen Colbert in a different context in 2015: “See what we can accomplish when we work together by you doing what I say? It’s called a partnership.”

In contrast, collaborative health describes a shifting constellation of collaborations for sickness care and for maintaining wellbeing that is shaped by people based on their life circumstances. The result is not reform, but a transfer of power in which the traditional system loses some control. That system often will often be part of wellbeing and care relationships—providing patient centred, person-centric, or collaborative care—but other times (and not by choice) it will be excluded.

Though the role of the doctor is in flux, there remains great value in professional expertise rooted in ethical and legal traditions

Dissolving old boundaries
The digital health domain provides some of the most visible evidence of this shift. Increasingly, people can find, create, control, and act on an unprecedented breadth and depth of information. For example, according to its website the for-profit patient network and research platform PatientsLikeMe has amassed more than 520 000 patient profiles for more than 2700 conditions, filtering data reported by patients through analytical tools in an independent online collaboration.1

Although most PatientsLikeMe users are American, participation in this and similar platforms will grow as the digital divide continues to diminish. In 2015, more than half of adults in 21 emerging and developing countries reported using the internet or owning a smartphone (rising to 87% in 11 advanced economies).2 In 2017, an estimated 8.4 billion objects were part of the “internet of things” (sensors and web connectivity in everyday objects).3

People can increasingly “integrate data from diverse aspects of life—financial, medical, home automation—and control what to share with whom,” the web’s creator, Tim Berners-Lee, has said. And they can decide whether that sharing necessitates real world partners, such as their doctor.

Much attention has been paid to the emergence of “e-patients.”4 As significant, however, are efforts by private and government organisations bearing financial risk for medical costs. These efforts can be relatively rudimentary: the NHS, for example, provides an online repository of vetted diagnostic and health management apps. But organisations can also play an important part in proactively engaging vulnerable populations, who otherwise risk being left out of patient driven initiatives.

Consider a vendor placing biometric sensors in the home of an older person wishing to “age in place.” The sensors transmit information to a computer centre, where algorithms flag potential problems—for example, a change in toilet habits could mean a possible urinary tract infection. When an alert is triggered, a clinician from the company (not the family doctor) contacts the person. This collaboration may involve just the family and vendor. But it could also involve another party with an interest in the person’s wellbeing—for example, a US retirement community or an Italian municipal government.5

Beyond technology’s glitter
Finally, the collaborative health umbrella covers activities that may have little or no consumer e-health element. Chronic disease is implicated in 60% of all deaths globally,6 prompting more intense attention to the socioeconomic factors that affect health. The result has been an upsurge in interventions by organisations that bear financial risk for medical costs. Their purview has expanded both to areas once thought to be reserved for clinicians, such as drug adherence, and to the work of social service organisations.

In the US, for example, some health plans have been helping members with food, shelter, and even finding a job. The motivation may be less Matthew 25:36 (“I was naked and you clothed me, I was sick and you looked after me”) than mammon (lower medical costs). Yet whatever moral message this may send, sick people are being looked after (particularly if they’re at risk of getting expensively sicker) in collaborations outside the traditional clinical and public health infrastructure.
THREE CORE PRINCIPLES

Shared information
Opening the complete electronic health record for patients to read, comment on, and share improves their ability to manage their health. Moreover, by making sharing the default, the profession sweeps away a critical information asymmetry and has a moral standing to demand that corporations and governments practise similar transparency with the “big data” they collect. That’s imperative at a time when half of consumers are willing to share health data with Apple, Samsung, Microsoft, or Google. At the same time, the profession will have to be much better at communicating information.

Shared engagement
Collaborative health is multidirectional and multidimensional. For example, a paediatrician related how parents of a baby with a rare condition referred him to a Facebook group where families exchanged stories. What he learnt there shaped the eventual clinical decision. Collaboration also means accommodating varying engagement preferences. Elsewhere, I’ve suggested that clinicians adopt an approach which encourages active exchange of ideas and the explicit negotiation of differences. This flexibility fits those who may want or need the doctor to guide prevention or care, those in the do-it-yourself health movement, those who prefer shared decision making, and those whose preferences may shift because of illness or a new life situation. It’s also a model that sometimes allows one partner to say, “I want you to decide.”

Shared accountability
This may pose the greatest challenge. Hierarchies have clear lines; shared power is more complex, particularly among diverse individuals and organisations. For example, a device company offers consumers a diabetes management app developed with an artificial intelligence company. Who is accountable for that individual’s health, and what role does the doctor play?

Important questions related to ethical and legal responsibilities for care continuity, communication, privacy, and security remain. However, adopting an explicit collaborative health framework that acknowledges the presence and power of traditional and non-traditional actors—not just “providers” and “patients”—allows and encourages the raising of these kinds of questions.

Cops and docs
Analogous trends in crime prevention reflect the influence of the same larger societal forces driving collaborative health. In the US, UK, and elsewhere, data driven analytics and decision making are being used to prevent crime in much the same way those strategies are being used to prevent acute illness. Interventions with a healthcare counterpart include “hot spotting” (timely identification of extreme patterns in data), home visits, and focusing on frequent users. Some crime prevention and healthcare strategies even engage the same groups, such as churches, and, for both, their collaborations may at times exclude the professionals who have historically served as the public face—that is, the police officer or family doctor.

To be clear: prevention has limits. We’ll always need cops to catch bad guys and medical professionals to minister to those coping with what Susan Sontag famously called the “night side of life” in the “kingdom of the sick.” All of us are vulnerable, and the core values of competence and compassion for people in need remain unchanged.

What the collaborative health concept provides, however, is a framework for understanding how the traditional and non-traditional will coexist and interact in a healthcare ecosystem with new players and relationships. Pieces are already in place: the Australian Coles supermarket chain collecting health and fitness data; a US wellness firm combining genomic, clinical, lifestyle, and behavioural data with predictive analytics and health coaching; the German Agency for Self Help Friendliness aiding hospitals in collaborating with patient groups formed by the chronically ill. All these take place alongside doctors treating heart attacks, trauma, and children with earaches, and “digital natives” dabbling at home in “do-it-yourself” health.

Control issues
These emerging collaborations promise better health, better healthcare, and more individual autonomy. Already, interactive and personalised web technologies are empowering “citizens” (the European Commission’s word) “to manage their own health” and “contribute to modern, efficient, and sustainable [national] health systems.” Although the process of biomedical actors becoming more active in tackling social problems is often seen as medicalisation, that characterisation only partially fits here.
disruptive changes under way, how we as a society shape those changes remains crucial. Particularly critical is the professional response. Three core principles of explicitly and voluntarily sharing power—in the forms of information, engagement, and accountability—should guide medical practice in this new environment (box).

Greener pastures, not higher fences
An aphorism popular in some sections of the US system goes this way: “Greener pastures, not higher fences.” It suggests doctors should embrace, not resist, the changes needed to make their practices more attractive to patients and to maintain their trust.

Are physicians willing to create a “greener pasture” of true collaboration in diverse wellness and sickness relationships? Will they accept sometimes being cut out entirely until we call upon them? If so, nine out of 10 of us want our doctor as a partner.²¹ Or will doctors seek to maintain the high fences of professional privilege, resisting revolution and holding ever tighter to incrementalism?

In the information age, “the magic, mystery, and power of the profession may be somewhat diminished,” one informatics pioneer observed, but the opportunity to “bolster the cognitive and moral pillars” of professional identity will grow.²² Mutual trust is the foundation upon which those pillars must rest. Taking concrete actions to implement shared information, engagement, and accountability are critical to building that foundation. The Quill and Brody model, as well as the collaborative deliberation model suggested by Elwyn and colleagues,²³ are good places to start.

Though the role of the doctor is in flux, there remains great value in professional expertise rooted in ethical and legal traditions.²⁴ As economic, technological, and social changes give rise to new networks of collaborations, we the citizenry (your sometime patients) need you at our side, both for our sake and to counteract others’ economic or political agendas. Accepting a less central role may feel at first as if collaborative health is shrinking the profession’s importance. In reality, accepting true partnership will profoundly expand the profession’s influence in the days to come.

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COMMENTARY Iona Heath

Information without wisdom

This is the dystopian future: health-related data are to be harvested from a huge variety of digital sources, including biometric sensors attached to individual bodies. This information is then fed back to the supposedly autonomous person and can be used to trigger algorithms and offer possibilities for remedial interventions.¹

Technology is remarkably seductive and may delude us into thinking that the human condition is changing faster than it really is. Big data, biometric sensors, and the vaunted promise of e-health have undoubted contributions to make to contemporary healthcare but fall far short of delivering the moral core of medicine that has always been the relief of suffering. Despite all its cleverness, big data and biometric sensors cannot access the lonely subjective experience of the fearful and distressed individual in the face of the threat of disease and death.

The whole process is profoundly normative, always looking for deviations from the mean to define abnormality and a need for action. The biologically normal is a broad and accommodating phenomenon, but big data will be interpreted within arbitrarily set limits. From experience, these limits will likely be narrowed in the financial interests of companies eager to maintain their place in the healthcare market. The likelihood of false positives is enormous and further medicalisation inevitable.²

T S Eliot was prescient: “Where is the knowledge we have lost in information?”³ Let alone the wisdom?

Medicine cannot afford to leave wisdom to be considered only by humanist scholars and writers. In his profoundly wise book Mortality, Immortality and Other Life Strategies, the late Zygmunt Bauman describes ‘the primacy of individual mortality among the constituents of the human predicament’⁴ and posits the whole of human culture as a gigantic ongoing effort to give meaning to human life in the face of intolerable and unavoidable finitude of death. For Bauman the current obsession with monitoring fitness and health is a futile attempt “to redefine the unmanageable problem of death . . . as a series of utterly manageable problems.”⁵ We deny death but also the dying, whose care is an essential part of medicine within which big data and e-health have nothing to offer. This is no coincidence because the proponents of e-health also seem to draw only a minimal distinction between the currently well and the currently sick and yet these categories demarcate fundamentally different needs and experiences of healthcare systems.

Any healthcare professional who has been seriously ill knows that information rarely reduces the fear that is intrinsic to all illness, beyond the self limiting and trivial, and that it can often aggravate fear by suggesting a range of possibilities that might not have come to mind without the information. Too much contemporary healthcare exacerbates fear systematically in the interests of profit and reputation⁶ but there may be much worse to come. Recent history suggests that the latest wave of technological innovation will work more in the interests of the medical-industrial complex than in those of the distressed and suffering individual.

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Judging the benefits and harms of medicines

Only trustworthy evidence will earn the public’s trust

How should society judge the safety and efficacy of drugs? This was the question posed by England’s chief medical officer, Sally Davies, in February 2015. Citing controversies about oseltamivir (Tamiflu) and statins, as well as growing disquiet about overmedication by doctors and conflicts of interest among researchers, she feared an erosion of public trust and asked the Academy of Medical Sciences to undertake a review. In June that same year, editorialists in The BMJ called on the academy to recommend “simple practical improvements that would address legitimate concerns.” The academy has now published its report. Does it deliver?

The academy confirms that there is a problem. Its survey found that only one in three members of the public trusts the results of research. In response to this finding, which the chair of the report, John Tooke, called “startling,” the academy has produced a wide ranging report that says many of the right things. But the overall result is disappointing. The academy report includes welcome calls for researchers to involve patients and be more transparent (see box of recommendations on bmj.com), but its main focus is better communication with patients and the public. It offers few new or concrete suggestions to tackle what the UK’s Science and Technology Committee identifies as a crisis in reproducibility of research and an upward trend in misconduct and mistakes.

Missed opportunities

The BMJ has been closely involved in issues that triggered the report and continues to campaign on them. What does the report say about these issues, and what could it have said? A “detailed account” of the statins saga sticks to the version presented in various places by the Cholesterol Treatment Trialists collaboration. The report says that future controversies could be prevented through better communication and, among other things, better access to data. But the debate about statins in people at low risk has not gone away, and the anonymised trial data remain inaccessible. The academy could have put its weight behind calls for an independent review of the evidence, similar to the review on breast cancer screening commissioned by the UK’s cancer tsar in 2012.

The report makes far less of the controversy around oseltamivir, despite this being perhaps the best illustration of why the public and professionals cannot trust the published evidence. The academy could have used its position to hold Roche accountable for withholding data, undermining public trust, and wasting public money. It could also have made concrete proposals for better independent research during future pandemics.

Optimism bias

As for overmedication, this has many causes. Most relevant to judging the benefits and harms of medicines is the optimism bias afflicting the medical literature. Poor science, research misconduct, and publication bias all contribute to the systematic exaggeration of benefit and understatement of harm. Communicating this overoptimistic view more effectively will only compound the problem. But the academy’s priorities seem to be to reassure patients and the public so that they will take their pills, and to collaborate closely with industry to develop more. It would have been good to see the academy acknowledge the avoidable harm and cost caused by overmedication, and to propose possible solutions and avenues for further research into the problem.

The report looks to funders and the next research excellence framework to incentivise better research and publication practices. But the academy could also lead by example. Its nearly 1200 fellows comprise a sizeable swathe of the UK’s medical science leadership. They could be required to declare their competing interests on the academy website. They could also publicly commit to involving patients in their research, making their data shareable, sharing their data on reasonable request, running their own research teams in ways that promote reliability and transparency, and publishing their research in full, in a timely manner, and in open access journals.

Status Quo

The academy had an opportunity to show leadership and independence. But its report says little to unsettle the status quo, suggesting it was not the right group to take on this task. By contrast, the Evidence Manifesto initiative (evidencedefine.org/manifesto/) leaves no room for doubt that there is a crisis in our evidence base and sets out an agenda for radical change. We hope that the UK science and technology committee will pick up its inquiry into research integrity, which was postponed for the general election. As Carl Heneghan, director of the Centre for Evidence Based Medicine in Oxford, said at the recent Evidence Live conference, there is a problem with the E in EBM. If we want the public to trust the evidence, we must make the evidence trustworthy.
Is psychiatry becoming more coercive?

The rising trend is damaging for patients, unsupported by evidence, and must be reversed

More and more people are being subjected to coercive psychiatric interventions, even within well resourced mental health systems. The term coercion has a broad definition in mental healthcare,1 but here we focus on the use of force or compulsion. In England, the rate of involuntary psychiatric hospital admission has increased by more than a third in the past six years.2 In Scotland, the number of detentions has increased by 19% in the past five years.3 More than half of admissions to psychiatric hospitals in England are now involuntary, the highest rate recorded since the 1983 Mental Health Act.1

The use of coercion in mental healthcare is a global phenomenon. As well as involuntary admission, coercive measures include forced administration of medication, involuntary confinement in isolation or seclusion, and manual or mechanical restraint.1

Expansion of institutions

The increasingly coercive culture in mental healthcare is also evident from a renewed trend towards institutionalisation of mentally ill people.4 The marked expansion of “protected” housing (secure housing, with restricted freedoms) for people with mental illness in the community and increase in the number of forensic psychiatric beds in many European countries are indicative of this trend.5 New types of secure mental health facilities are also emerging, replicating some of the functions of old style asylums. In Italy, for example, a new law in 2012 required the development of secure residential facilities for people with mental disorders considered “socially dangerous.” Legislation such as this, disguised as innovation, represents a backwards step.6

Our prisons are also increasingly used to manage and contain mentally ill people. There are now over three times more mentally ill people in jails and prisons in the US than in hospitals, and 16% of them have serious mental illness.7 In the UK, 15%-25% of the prison population reportedly has a psychotic illness.8

More generally, psychiatric practice, even in seemingly unrestrictive settings, is undergoing a cultural shift towards greater coercion. This is shown by the advent of compulsory treatment in outpatient settings and in the community. Community treatment orders are now “a feature of most developed mental health services,”9 although there is little evidence that they offer any benefit.10 The use of such orders in England has increased every year since their introduction in 2008.11

Risk management has become a central tenet in the care of mentally ill people. Clinical practice seems no longer driven by the needs of the individual but by risk assessments, often of dubious validity.11

Psychiatric facilities are increasingly relied upon, instead of prisons, for long term detention of people who have committed sexual or other violent crimes. For example, use in England of the controversial diagnosis “dangerous and severe personality disorder” to detain people in psychiatric hospitals because of their perceived risks to others is an ill conceived attempt to hide preventive detention behind the veneer of respectability provided by a mental health context.14

In the US, so called sexual predator laws15 allow serious sexual offenders to be detained indefinitely in mental health treatment facilities after they complete prison terms. Although society has the right to be protected, using healthcare facilities to detain people for punishment rather than treatment, is inconsistent with basic medical ethics.

Counterproductive

This cultural shift in psychiatry, which prioritises risk management over individual health and social needs is likely to be counterproductive. The stigma associated with mental illness will increase as care becomes more coercive. Further social exclusion of people with mental illnesses is inevitable if we continue to conflate the concept of dangerousness with poor mental health. Those who might benefit from psychiatric care are likely to delay or avoid contact with health services for fear of losing their liberty and compromising their basic rights. Collaborative and person centred care leading to recovery is an aspiration of most modern mental health services. This aspiration is entirely inconsistent with the increase in compulsion and involuntary care across much of psychiatry. As three commentators recently concluded, “It would be more humane, just and effective to implement alternatives that serve to reduce experienced and actual coercion, promote the wider involvement of people in their care, and potentially improve outcome.”16

Further social exclusion of people with mental illnesses is inevitable if we continue to conflate the concept of dangerousness with poor mental health

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