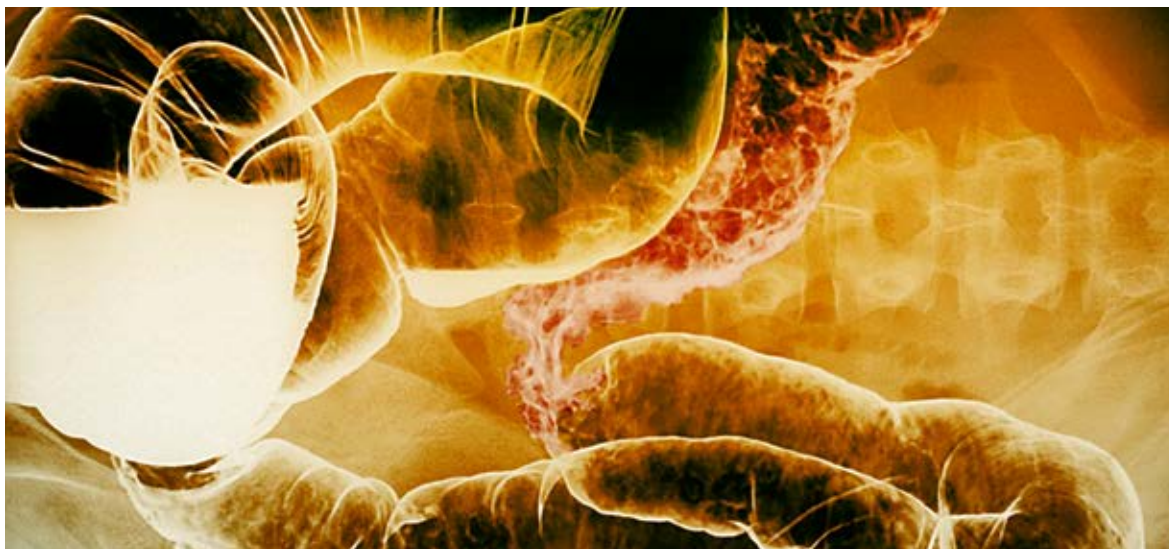


# this week

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## Infliximab biosimilars halve costs

Infliximab “biosimilars”—biological therapies engineered to work in the same way as the monoclonal antibody drug infliximab (marketed as Remicade)—are safe and effective and could halve the cost of inflammatory bowel disease (IBD) treatment, a report by the Royal College of Physicians has found.

Use of these drugs could cut the cost of an annual course of treatment from around £10 000 to around £5000, it said.

Given their reduced cost, clinicians should use biosimilars as first line treatment for appropriate patients with active IBD and should consider switching those currently being treated with Remicade, said the report. An estimated one person in every 250 in the UK has IBD.

Only a fifth of patients were receiving infliximab biosimilars (Inflectra and Remsima), the audit found, prompting the authors to say that the NHS could save £3m a year if all patients being treated with a monoclonal antibody received a biosimilar.

Ian Arnott, author of the report and consultant gastroenterologist at Western General Hospital in Edinburgh, told *The BMJ* that the savings the NHS stood to make if every suitable patient were treated with biosimilars were “potentially massive.”

And, when adalimumab (Humira) comes off patent next year, there will be further opportunities to save money, he added.

“Some clinicians felt that there was no direct evidence that biosimilars worked in IBD, and so were reluctant to use them. But if a clinician is going to treat a patient with Remicade, there is no reason why they shouldn’t give them a biosimilar instead,” said Arnott. “There are no additional contraindications. It’s a win-win.”

The report, which looked at the use of biological therapies for treating ulcerative colitis and Crohn’s disease, draws on a UK audit of 2722 adults and 278 children who were newly treated with these drugs in the 12 months to February 2016.

It showed that a third of adults and 17% of children with ulcerative colitis in 2016 were treated with these drugs, compared with 17% and 12%, respectively, in 2015.

Biological therapies are safe and clinically effective, with few side effects, the audit found. Only one in 10 adults and one in 20 children said that they had had side effects.

Some concern has arisen that biological therapies increase the risk of cancer, but this audit found no cancers.

Caroline White, London

Cite this as: *BMJ* 2016;354:i5084

**A side view of organs affected by Crohn’s disease. Biosimilars are reportedly safe for patients who are suitable for treatment with a monoclonal antibody**

### LATEST ONLINE

- New way to define disease is needed to reduce overdiagnosis
- Side effects are under-reported in peer reviewed journals
- The UN’s Ban Ki-moon leads talks on antimicrobial resistance



# SEVEN DAYS IN



Women from the protest group Femen demonstrate against FGM in 2014

**Women from the radical protest group Femen demonstrate against FGM in 2014**

## MPs and doctors clash over FGM reporting

An influential committee of MPs has called for harsher penalties, beyond the existing professional disciplinary sanctions, against health professionals who do not report cases of female genital mutilation (FGM) to police.

In its latest report on FGM, the House of Commons Home Affairs Committee repeated its predecessor committee's call in 2014 to make intentional or repeated failures to report such abuse a criminal offence.

Although reporting FGM to police became mandatory in October 2015, MPs noted that they "heard that some healthcare professionals just did not accept that mandatory reporting should be their responsibility."

Healthcare professionals are also obliged to report cases of mutilation discovered through clinical examination. The MPs said that they were "alarmed by reports that some clinicians are ignoring the requirement to record data on the basis that they do not recognise its purpose," and urged NHS employers and the royal colleges to "take a hard line against such attitudes."

Geoff DeBelle, officer for child protection for the Royal College of Paediatrics and Child Health, said, "Doctors take every case of child abuse extremely seriously and follow guidance for reporting, so for the Home Affairs Committee to claim that some clinicians are ignoring their duty to record data on FGM is untrue and insulting. We would therefore like to hear promptly from where this information arises."

Clare Dyer, *The BMJ* Cite this as: *BMJ* 2016;354:i5038

## General practice

### RCGP campaign aims to attract more doctors

The Royal College of General Practitioners launched a new



"Think GP" video and guide, which aims to attract more doctors to general practice by dispelling the myth that only hospital doctors have exciting and

challenging roles. The college predicted a shortfall of 9940 GPs by 2020 and said that 594 general practices are at risk of closure, which could compromise patient safety.

### Capita fails to deliver key support services

A BMA survey of local medical committees showed serious failures in a range of areas Capita now oversees as part of its contract with NHS England to run primary care support services. These include serious

problems in managing patient records; delays in providing funding to practices for GP trainees; failures in maintaining supplies to general practices such as prescription pads, fit note certificates, and syringes; and delays and mistakes in recording NHS pension payments to GP locums.

## Malaria

### UK troops will continue to receive mefloquine

UK doctors will still be allowed to prescribe the antimalarial drug mefloquine to British troops but only if they carry out a face to face risk assessment and provide evidence that they offered suitable alternatives, the Ministry of Defence said. The policy change was prompted by a House of Commons report into the use of mefloquine (Lariam) in British military personnel. The drug has been linked to adverse reactions, including psychosis. (doi:10.1136/bmj.i5030)



## Social care

### Nearly 80000 staff could be lost owing to Brexit

Nearly 80000 workers who provide care services for elderly and disabled people could lose their right to work in the UK as a result of its referendum decision to leave the EU, research by the charity Independent Age and the International Longevity Centre UK showed. Of almost 84000 migrants from the European Economic Area in the social care workforce, around 78000 do not have British citizenship.

### Social care funding cuts put strain on NHS

Six consecutive years of cuts to local authority budgets mean that 26% fewer people now get help, which puts significant strain on the NHS, said a report by the King's Fund and the Nuffield Trust. It noted "unacceptable" burdens on unpaid carers and said that more older people who have difficulty with basic living activities are getting no support, adding that the biggest sign of cuts was "the rapid growth in delayed discharges from hospital." (doi:10.1136/bmj.i5021)



## Weekend effect

### Public inquiry urged over Hunt's excess weekend mortality claims

A group of prominent doctors and scientists, including Stephen Hawking (above) and Robert Winston, called for an independent inquiry into claims by England's health secretary, Jeremy Hunt, over excess deaths in patients admitted to NHS hospitals at weekends. In a letter to the *Guardian* newspaper the group accused Hunt of "cherry picking" research. "Of the eight 'studies' cited by Hunt, only four are independently peer-reviewed," they wrote. "Three use data from the same population and are not independent, with just two from the last decade. The remainder are not peer-reviewed ... being opinion pieces, the lowest form of clinical evidence." (doi:10.1136/bmj.i5040)



# MEDICINE

**Infant feeding guidelines have moved away from advising parents to delay introducing allergenic food**



## Patients

### **Patients should be more involved in care decisions**

The National Institute for Health and Care Excellence joined forces with NHS England, the General Medical Council, universities, and other organisations to get patients more involved in decisions about their care. The Shared Decision Making Collaborative hopes to promote a move away from “top-down” medicine towards a culture where clinicians and healthcare professionals work with patients to choose the most appropriate tests, treatments, and support packages.

### **Dementia strategy fails to reduce antipsychotic prescribing**

Introducing a national dementia strategy, including recommendations to limit inappropriate use of antipsychotics, has failed to reduce prescribing of these drugs in residential care homes in England, showed results from the first study to assess the impact of the policy published in *BMJ Open*. The National Dementia Strategy was launched in the UK in 2009 and recommended that any prescribing of antipsychotics in people with dementia should be reviewed at least monthly. But in the four years since the strategy there has been no fall in prescribing rates and no move to prescribe newer second generation antipsychotics.

## Food allergy

### **Introduction into infant diet may cut allergy risk**

Introducing eggs or peanuts early into infants' diet is associated with a lower risk of developing egg or peanut allergies, said a systematic review in *JAMA*. The review found “moderate certainty” evidence that introducing eggs at 4 to 6 months was associated with reduced egg allergy and that introducing peanuts at 4 to 11 months was associated with reduced peanut allergy when compared with later introduction. (doi:10.1136/bmj.i5099)

## Screening

### **Screening cuts cervical cancer deaths by two thirds**

Screening for cervical cancer at least every 5.5 years is associated with a 67% reduction in stage IA cervical cancer and a 95% reduction in stage III or worse cervical cancer when compared with minimal or no screening, showed a study in the *British Journal of Cancer*. Using information from England's cervical screening programme, the researchers estimated that it currently prevents 70% of cervical cancer deaths but that it could prevent 83% if all eligible women attended screening regularly. (doi:10.1136/bmj.i5026)

Cite this as: *BMJ* 2016;354:i5096



## QUIT RATES

England has 14.6 million former smokers, twice the number of current smokers (7.2 million)



MARK HILL/ALAMY

## SIXTY SECONDS ON... SEX EDUCATION



### **OH NO, MISS, NOT MORE SEX EDUCATION?**

Yes, parents around England will be rejoicing at the news that the education secretary, Justine Greening, is considering compulsory sex education for all secondary school children. This comes just a few months after her predecessor, Nicky Morgan, declared the opposite despite pleas from the parliamentary education, health, home affairs, and business select committees, as well as children's charities.

### **BUT IT'S SO EMBARRASSING, MISS**

And not just for the students. A recent *BMJ Open* paper investigating young people's views on sex and relationships education found that teachers were awkward and embarrassed when delivering it.

### **AND THE BOYS ALWAYS MUCK AROUND**

But that's because they're masking their anxiety. Young men think that they ought to be sexually experienced so disrupt the class to hide their lack of experience.

### **AND WHY ARE THE LESSONS SO BORING?**

Because schools fail to acknowledge students' sexuality and have adopted a “no nonsense” approach. Lessons are overly

biological, with sex presented as a “scientific activity.” They also focus on unwanted pregnancy and sexually transmitted infections and cast men

as sexual predators, while ignoring the information needs of gay, bisexual, or transgender students.

### **SO WHAT SHOULD BE COVERED?**

Students wanted group discussions, confidentiality, and skills based lessons and demonstrations.

### **BUT MY PARENTS SAY THAT TEACHING ABOUT SEX WILL ENCOURAGE ME TO TRY IT**

A 2008 US study showed that young people whose sex education focused on sexual abstinence were at greater risk of pregnancy or sexually transmitted infections than those who had more comprehensive sex education.

Anne Gulland, London Cite this as: *BMJ* 2016;354:i5070

# Doctors could be asked to declare private income, NHS England says

**"It's not an attempt to curb private work by consultants ... Let's have some transparency here," said Malcolm Grant, chair of NHS England**

Doctors could be asked to declare how much they have earned from private practice, under proposals set out by NHS England.

The plans were included in a wider NHS England consultation on proposals designed to strengthen the management of conflicts of interest, which was published on 19 September.

Under the proposals, clinical staff would be required to declare their earnings from private practice and state whether they earned less than £50 000, less than £100 000, or more than £100 000. This information would then be included on their employers' register of interests.

The proposals also said that clinical staff should not initiate conversations about private work with patients when they were undertaking NHS work, or accept financial incentives from private providers.

The consultation also included proposals requiring doctors to refuse all gifts from patients and foreign dignitaries that were worth more than £50, and to decline all gifts

from suppliers except when they were "low cost branded promotional aids" worth less than £6. All NHS staff who received hospitality from the pharmaceutical or other industries worth more than £25 must declare it, the proposals said.

Malcolm Grant, chair of NHS England, who led the group that worked on the proposals, said, "We have a responsibility to use the £110bn healthcare budget provided by the taxpayer to the best effect possible for patients, with integrity, and free from undue influence. Spending decisions in healthcare should never be influenced by thoughts of private gain."

Speaking to the *Times* newspaper about doctors' payments for private work, Grant said, "It's not an attempt to curb private work by consultants ... Let's have some transparency here. Much of what goes on in these communities is almost under the radar."

Commenting on the consultation, Clare Marx, president of the Royal College of Surgeons, said that clear



guidance for NHS staff on managing potential conflicts of interest was long overdue. "Patients rightly have a huge amount of trust in the medical profession, and this guidance will help doctors to think about any potential conflicts of interest and help them to act appropriately at all times," Marx said.

## Having a named GP does not improve continuity of care



Since April 2014 general practices in England have had to offer all patients aged 75 or over a named accountable GP to take responsibility for ensuring the delivery of relevant health and social care. But the initiative seems to have had no effect on continuity of care, a study published in *BMJ Open* has found.

### 1 STUDY METHOD

The study included 255 469 patients from 200 general practices in England. The researchers compared having a named accountable GP for patients aged just over 75 with usual care provided for patients aged just under 75, over a nine

month period. Continuity of care was measured using the "usual provider of care" index, defined as the proportion of a patient's general practice contacts that were with the GP seen most frequently.

**2 UPTAKE** Within three months of the new policy almost 80% of patients aged 75 to 85 had been assigned a named accountable GP.

**3 FINDINGS** Patients with a named accountable GP did not experience statistically significant differences in continuity of care or in the number of GP contacts from those who had usual care without a named GP.

**4 CARE** Nor did having a named accountable GP lead to clinically significant changes in referrals to specialist care or in the number of common diagnostic tests such as blood pressure and HbA<sub>1c</sub>.

**5 LIMITATIONS** The researchers acknowledged that the benefits of having a named accountable GP might be realised only over periods longer than nine months, but they said that they were unable to study the effects over a longer period, as the policy was expanded to all patients from April 2015.

Jacqui Wise, London

Cite this as: *BMJ* 2016;354:i5048





Keith Brent, BMA consultant committee chair, said: “All consultants are dedicated professionals who in the vast majority of cases work beyond their contractual hours. Under the terms of the consultant contract, if a doctor wishes to undertake private work, they have to first offer extra time to

the NHS. Consultants, like all other senior NHS staff, are also required to make an annual declaration of substantial conflicts of interest in accordance with legislation.”

Competing interests: *The BMJ*'s editor, Fiona Godlee, is a member of the conflicts of interest taskforce.

Abi Rimmer, *BMJ* Careers

Cite this as: *BMJ* 2016;354:i5101

## Doctors work more unpaid hours

Some doctors are working an extra five weeks a year for no extra money owing to relentlessly growing demand and understaffing, the Royal College of Physicians has said.

The college published a report on 21 September in which it made several stark warnings about the extreme pressures currently on the NHS.

The report was based on the latest national data for the NHS and drew on the experiences, views, and concerns of consultant and trainee physicians surveyed for the college. It painted a picture of an NHS struggling to cope under the increasing pressure of rising demand at the same time as inadequate funding, with resulting workforce pressures threatening patient safety.

Doctors were regularly working longer than their contracted hours, it

said. Although this had long been a trend for consultants, six of 10 doctors in training worked longer than their rostered hours on a daily or weekly basis, said the college. This meant that, on average, specialty trainees worked an extra five hours a week—the equivalent to each trainee working an extra five weeks every year.

Most doctors in training (80%) reported that their job caused them excessive stress, with three quarters going through at least one shift a month without drinking enough water and more than a quarter (28%) having worked four shifts a month without a meal. Consequently, the report said, 95% of doctors in training reported poor staff morale as having a negative impact on patient safety.

Adrian O'Dowd, London

Cite this as: *BMJ* 2016;354:i5092

## FIVE MINUTES WITH...

### Caroline Gannon

The paediatric pathologist made national news when she quit her job in Belfast this month

**T**he media have portrayed my resignation [from Belfast's Royal Victoria Hospital] as mainly about abortion, but it's also about stillbirths. In

Northern Ireland all stillbirths have to be reported to the coroner. If the parents consent, he [the coroner] may go along with a consented autopsy, keeping him informed of the results, or he may decide to order an autopsy, in which case the parents' consent is not required.

“Cases have to be reported to the coroner since the attorney general [for Northern Ireland] convinced the Court of Appeal in 2013 that a stillborn baby was ‘capable of being born alive’

and therefore that its death could be considered a form of ‘child destruction.’ We have potentially criminalised 120 families a year.

“There is a fundamental mismatch between the standards of a PM [postmortem examination] ordered by the coroner and the standards expected by the Royal College of Pathologists. With a coroner's PM I can't do the PM to the standard the college expects me to. I am permitted only to identify

the cause of death. Families are not finding out the information they need for future pregnancies.

“More worryingly, I'm hearing of cases where parents may be told, ‘You may as well sign a consent form or the coroner will order a PM.’ This isn't valid consent: this is coercion, and it's illegal. The thought that I could have done an autopsy where the family has been bullied horrifies me.

“Termination for fatal fetal abnormality (FFA) is not permitted in Northern Ireland, so women whose scan shows a fatal anomaly who choose to end the pregnancy because of FFA may go to England. It means that access to an autopsy to confirm the diagnosis is difficult. This impacts on future pregnancies and is discriminatory—these women aren't getting the follow-up they need or that other women have access to.”



**CAROLINE GANNON, THE THOUGHT THAT I COULD HAVE DONE AN AUTOPSY WHERE THE FAMILY HAS BEEN BULLIED HORRIFIES ME**

Clare Dyer, *The BMJ*

Cite this as: *BMJ* 2016;354:i5093



## Junior doctors' strikes: BMA responds to your questions

**Ellen McCourt**, chair of the BMA's Junior Doctors Committee, answers questions from *The BMJ's* readers and junior doctors about the upcoming strike action in England

### What would it take for the BMA to call off the five day strike planned for October?

Ellen McCourt: "Future action is still avoidable. Put simply, we have repeatedly said we will call off further action if the government puts a halt to its plans to force junior doctors to work under a contract they rejected because they don't believe it is good for the future of patient care or the profession."

### What specifically in the wording of the current contract document does the BMA want to see changed?

"We know that junior doctors still have significant concerns with the contract, including the impact it will have on those working less than full time—a majority of whom are women—and the impact it will have on junior doctors working the most weekends, typically in specialties where there is already a shortage of doctors. These are just two areas we want to work with the government on."

"The contract has a crucial part to play in how attractive medicine remains as a profession and the NHS's ability to recruit to certain specialties in particular. It is vital that we get it right, rather than rush it through."

### Why does the BMA think that three sets of five days of strike action, as opposed to less disruptive forms of action, will be successful in improving the contract agreement?

"After junior doctors rejected the government's proposed contract in July, the BMA made repeated attempts to work constructively with the government to address junior doctors' outstanding concerns, but genuine efforts to resolve the dispute through talks have been met with an unwillingness to engage from the secretary of state. This is despite a pledge from him that his door is always open."

"With just weeks before the first group of doctors is moved onto the imposed contract—a contract that will be in place for many years and will have a direct impact on patient care and on whether we can attract and keep enough doctors in the NHS—junior doctors feel they have no other option but to take further action. The urgency of the timeline is in the government's hands: they have chosen to impose this contract from October."

"We have made it absolutely clear that this action is avoidable. All the government has to do is start listening to junior doctors' concerns and stop the imposition."



**"Future action is still avoidable"**  
—Ellen McCourt

**Many junior doctors on social media say that they did not support the contract but do not support strike action and would like a new ballot on the issue of strike action. What would you say to them?**

"Throughout this dispute the BMA has reflected the views of junior doctors. Junior doctors across England rejected the proposed contract. After this we sought feedback from junior doctors to gauge what their remaining concerns with the contract were and what action, if any, they wanted to take next. It was clear that junior doctors felt that their outstanding concerns were being ignored by the government and were prepared to take escalated industrial action."

"During this dispute we have seen the profession unite in an amazing way, with thousands of junior doctors turning out on the picket lines to support each other. It is because of their action that we were able to make progress with the government, but eight days of constructive negotiations, brought to an end purely because of a political deadline, is not enough. This contract will affect a generation of doctors and their patients and should not be rushed through to a political timeline."

**What should a junior doctor who does not support the new contract, but does not want to go on strike for five days, do?**

"Junior doctors who wish to express their views to the Junior Doctors Committee can contact their regional JDC or email





jdccchair@bma.org.uk. It is the choice of individual junior doctors whether or not to take part in the industrial action. This is not an easy decision for any doctor. Their choice will be respected by their colleagues.”

**What other issues, not directly to do with the new contract, are contributing to the strength of feeling among junior doctors? What would the BMA like to see done about these issues?**

“The government has said that a new contract is needed to deliver more seven day services, when the Department of Health’s own documents show that the NHS does not have a plan as to how it will staff or fund further seven day services.

“Already our hospitals are chronically understaffed, and our NHS is desperately underfunded. Concerns have repeatedly been raised by NHS staff and NHS leaders about rota gaps across the NHS, GPs are at breaking point, and we’ve seen hospitals in Chorley, Grantham, and Stafford that have been forced to close A&E departments or limit access because they don’t have enough staff to deliver safe care.

“Stretching an already overstretched service is not the right thing to do for the future of the NHS or for the patients it serves. If the government wants to make more services available across seven days, then it needs to urgently address how it will staff and fund them rather than continue to mislead the public and brand doctors—who already work round the clock, seven days a week—as a roadblock to their plans.”

[Cite this as: BMJ 2016;354:i5113](#)

## GMC relaunches test for overseas doctors but experts still concerned

The General Medical Council has relaunched its test for international medical graduates wishing to work in the UK, with the aim of making it more rigorous and reflective of real life practice. But one of the researchers whose work led the GMC to overhaul the test has warned that the revised examination will still not assess overseas graduates to the same level as UK graduates.

The first students sat the updated Professional and Linguistics Assessment Board (PLAB) test on 7 September.

The exam was updated after a review commissioned by the GMC recommended that candidates should not be able to resit the test several times. The review also recommended that the exam should test candidates on ethical and professional principles.

There was concern that the pass marks for the PLAB test were too low, after two *BMJ* research papers found that candidates sitting the examination were not meeting equivalent standards to UK doctors.

### Researchers’ concerns

Chris McManus, professor of psychology and medical education at University College London and coauthor of the *BMJ* paper that urged PLAB pass marks to be raised, said that time was now needed to see how the new examination works out. “And of course that requires evidence,” he said, adding that when a new test for all UK and international medical graduates replaces PLAB it should “automatically provide equivalence of standards with UK graduates, which is the difficult thing to ensure using PLAB.”

McManus’s coauthor, Richard Wakeford, fellow of Hughes Hall at the University of Cambridge, said that the

new PLAB test was still set at a lower level than equivalent UK qualifications.

He said that many of the questions were available to doctors who paid to attend exam preparation courses in the UK and internationally. “And the Part 1 pass mark is still not increased from a ‘cut score’ [the lowest mark to be attained to pass an exam] to compensate for test inaccuracy, as are, for example, the MRCGP [membership of the Royal College of General Practitioners] examinations.

“This is important, as part 1 measures the key matter of clinical knowledge. The current (to me) unacceptably low passing standard results in large numbers of international medical graduates being accepted into UK training programmes who will fail their specialist examinations to a greater degree than their UK counterparts—resulting in expensive arguments about differential performance.

“The real problem, in my opinion, is that Health Education England needs the resultant workforce but is unwilling to pay for the essential and substantial pre-training of international graduates before entry to the respective training programmes. In my opinion, the level of PLAB as a whole just needs enhancing,” he said.

In a statement, Niall Dickson, chief executive of the GMC, said, “Making sure that doctors who practise here can do so safely with the right skills and competence is absolutely central to what we do. This improved test will help make sure doctors are reaching the high standards we require to practise safely in the UK.”

Anne Gulland, London

[Cite this as: BMJ 2016;354:i5104](#)







## Beyond Bedlam

The Wellcome Collection's new exhibition, *Bedlam: the Asylum and Beyond*, opens with this large scale installation, *Asylum*, by the Czech artist Eva Kotátková, which explores the tensions between protection and restraint of psychiatric patients.

The 2014 work tries to capture the institutional constraints but also the alternative modes of communication envisioned by the patients. In the words of the artist, "Asylum presents a collection of fears, anxieties, phobias, and phantasmagorical visions of patients and children suffering from communication difficulties or struggling to fit within social structures, a chaotic archive of inner visions."

The installation, inspired by the artist's conversations with patients at the Bohnice psychiatric hospital in Prague, emphasises the fact that although the exhibition focuses on one historic psychiatric institution, the Bethlem Hospital in London, it is about patients' experience of psychiatric care and how it has evolved in the UK and Europe since the days of the "madhouse." Some days, unannounced, performance artists hide under the plinths of the installation and stick out their heads or an arm or a hand.

Wellcome Collection co-curator Bárbara Rodríguez Muñoz adds, "At a time when the marketplace of treatment and support options is so broad, but often inaccessible, the exhibition both interrogates and reclaims the idea of the asylum as a place of sanctuary and care."

The guest curator, the author and historian Mike Jay, says, "Preserved in popular imagination as 'Bedlam', the Bethlem Royal Hospital, which has treated psychiatric patients since the mid-18th century and is still a functioning hospital and part of the South London and Maudsley NHS Foundation Trust, is perhaps the oldest institution of its kind in the world and has witnessed the entire history of mental illness and psychiatry. Its story is the perfect focus for the Wellcome Collection to explore how medicine, art, and culture define mental illness, and the big questions it raises about the individual and society."

*Bedlam: the Asylum and Beyond* runs at the Wellcome Collection in London from 15 September 2016 to 15 January 2017 (<https://wellcomecollection.org/bedlam>). A parallel exhibition curated by Sam Curtis, *Reclaiming Asylum*, is held at the Bethlem Gallery, from 21 September to 11 November 2016 (<http://bethlemgallery.com/event/reclaiming-asylum>).

Sophie Arie, *The BMJ*

Cite this as: *BMJ* 2016;354:i5115

"The installation was inspired by the artist's conversations with patients at the Bohnice psychiatric hospital in Prague"



Timothy Evans, 62, is national director of clinical productivity at the Department of Health, consultant in thoracic medicine at the Royal Brompton Hospital, and professor of intensive care at Imperial College London. His previous roles include medical director, deputy CEO, and director of research and development at the Royal Brompton and vice dean of the Faculty of Intensive Care Medicine, the specialty in which he practised for 30 years. As academic vice president at the Royal College of Physicians he led the Future Hospital Commission, and he was founding editor of the *Future Hospital Journal*.

## BMJ CONFIDENTIAL

# Timothy Evans Cutting variations in practice

### What was your earliest ambition?

To be a pilot—stymied by Shinobu Ishihara [Japanese ophthalmologist who created the Ishihara test to detect colour blindness].

### Who has been your biggest inspiration?

Leslie Turnberg, professor of medicine at Manchester when I was a first year clinical student, is definitely one. A great clinician, teacher, academic, and former president of the Royal College of Physicians, he still speaks out for patients.

### What was the worst mistake in your career?

To think that I could be academically productive, practise intensive care and thoracic medicine, and be a medical director and deputy CEO simultaneously.

### What was your best career move?

My latest one (it always is).

### Bevan or Lansley? Who has been the best and the worst health secretary?

Alan Milburn was arguably the most forward thinking of my time. There's plenty of competition for the worst.

### Who is the person you would most like to thank, and why?

Paul Bramley, for his professional and personal example and for convincing me as an 18 year old that I could read medicine, having undertaken arts A levels.

### To whom would you most like to apologise?

My wife and four children, for missing Christmases, birthdays, parents' evenings, sports days, and (one) millennium celebration (I was living in the hospital in case the computers crashed and the ICU shut down).

### If you were given £1m what would you spend it on?

Durham University Military Scholarships, enabling wounded or injured veterans to obtain a degree.

### Where are or were you happiest?

Living as a pre-registration house officer in Manchester Royal Infirmary and as a senior house officer in hospitals in Sheffield and London (1979-82), coming to realise what a fantastic privilege it is to be a doctor and, specifically, to manage acutely (and later, critically) ill patients.

### What single unheralded change has made the most difference in your fields?

Effective UK training schemes in intensive care medicine (clinical) and the techniques of cell and molecular biology (research).

### What is your guiltiest pleasure?

A week's holiday taken on my own each year, doing whatever I want.

### What personal ambition do you still have?

To work with Tim Briggs to maximise the value patients get from the NHS, by engaging with clinicians to reduce unwarranted variations in specialty practice, thereby improving productivity in English hospitals.

### What is your pet hate?

Physicians who tell patients, "I don't know what's wrong with you, but it's not your (insert organ of specialisation)," before sending them back to their GP.

### Do you have any regrets about becoming a doctor?

Fewer, since I gave up weekend and night working last year.

Cite this as: *BMJ* 2016;354:i5059



# Co-creating health: more than a dream

The slow march towards true partnership with patients, which *The BMJ* champions, is progressing

It is three years since *The BMJ* launched a strategy to “walk the talk” on patient partnership.<sup>1</sup> Its key components include patient review of research papers, requiring authors to invite patients to help shape their educational articles, and new patient led content. ([www.bmj.com/campaign/patient-partnership](http://www.bmj.com/campaign/patient-partnership)). We reported on progress a year ago.<sup>2</sup> Since then, with the help of patient authors, our patient reviewers, and patient panel members we have continued our ambitious quest towards coproduced content. Each section of the journal now has a target for patient involvement, and we are refining a series of research projects, including an evaluation of the strategy’s impact.

In some areas, progress has been slower than we would like. One is to realise our pledge to the #PatientsIncluded campaign to involve patients in all conferences we co-run and sponsor. But it is good to see that the campaign’s call to include patients in all forums discussing their health and wellbeing is increasingly being heard, as the linked analysis by Chu et al shows (p XXX).<sup>3</sup> Patients’ views on being invited to the conference table vary from enthusiastic<sup>4-6</sup> to sceptical.<sup>7</sup> This is not surprising. It is hard to ensure that patient participation is more than tokenistic. Conference organisers need to start with appointing patients on to the committees that steer events.

## Research involvement

Involving patients in setting research priorities has potential to reduce waste in the research enterprise,<sup>8</sup> and *The BMJ* now requires all authors submitting research papers to include a statement detailing if and how they included patients in their work. Pharma companies regularly invite patients to meetings, and many have patient groups to inform research and development. The imperative now is to identify and disseminate best practice so that patient involvement in drug



**Encouragingly, shared decision making is beginning to show modest signs of moving from policy imperative to routine practice**

research and development delivers outcomes that patients value.<sup>10,11</sup>

Many organisations and foundations who fund research already embrace patient involvement and public engagement, including the Patient Centred Outcomes Research Institute, the National Institute for Health Research, and the Canadian Institutes for Health Research. Here too the challenge is to identify and implement meaningful partnership, and to assess its effect<sup>13</sup> on improving healthcare through better targeted research funding, outcomes that matter to patients, and a more patient oriented research agenda.

## Delivery of care

Patient involvement in strategies to improve the design, delivery, and quality of care has become routine in some settings, although “involvement” usually falls well short of partnership. The value of patient feedback is also limited since quantity of data has trumped quality.<sup>15</sup> A more manageable volume of higher quality data, combined with timely and personal interaction and feedback would be preferable;

PatientOpinion.org.uk, an online way of giving feedback to NHS trusts, is a good example.

Encouragingly, shared decision making is beginning to show modest signs of moving from policy imperative to routine practice.<sup>16</sup> There is also a move towards partnership in undergraduate medical education.<sup>17</sup>

Employing patient leaders to drive engagement and partnership within the formal structure of the health service is the next logical step, and in July *The BMJ* heard from pioneer David Gilbert, who is the first patient director in the NHS. His experience at the Sussex Musculoskeletal Partnership and the response to it should surely encourage other services to follow suit.<sup>19</sup>

Patients and their organisations have clear views on their role in coproducing health and wellbeing.<sup>20</sup> The new digital technologies, medical devices, and apps they are being encouraged to use could help advance partnership as well as promote self management. The promise of open access to fully integrated electronic health records also needs to be realised, and the conversations patients have in their online communities must be brought closer to the conversations currently conducted among health professionals. Health professionals should also give higher priority to patient partnership in routine clinical practice. The development of new patient oriented quality indicators to encourage and reward those who do will help.<sup>21</sup>

Meanwhile, in the rarefied world of medical publishing, it’s good to see other journals following *The BMJ*’s lead.<sup>22</sup> The growing support for a new charter for journals on #PatientsIncluded<sup>23</sup> will, we hope, spur others to follow suit.

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● ANALYSIS, p 444

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# Data sharing: lessons from Copernicus

Copernicus and Kepler shared their data, and so must we

**T**o understand the workings of science, pick up a copy of *De Revolutionibus Orbium Coelestium*.

Published with great reluctance by the astronomer Nicolaus Copernicus in 1543, the book puts forth a compelling argument for a heliocentric universe. Turn the pages and you will see the book is filled with data. Whose data? Copernicus relied on the data collected by others in addition to his own to formulate his revolutionary theory. Publication of these data subsequently allowed Johannes Kepler to identify discrepancies, which led to his innovative proposal in 1605 that the planets moved in an ellipse (rather than in a circle), an idea that he had previously assumed to be too simple for earlier astronomers to have overlooked. Of course, Kepler presented his data at the same time as he published his conclusions. By contrast, Tycho Brahe (who opposed Copernicus) famously withheld his astronomical data from Kepler because he knew they could be used to confirm Copernicus's heliocentric model.

The same principles apply to progress in medicine. Pick up an important book or paper published in the 18th, 19th, and early 20th century; thousands of data points are described or plotted assiduously by the authors in an effort to show

**Those who propose delays or a complicated process should understand that they may be perceived as losing whatever credibility scientists and physicians still have**

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their work and support a hypothesis or conclusion. We can return to these papers again and again to discover patterns that never occurred to those who originally made the observations.<sup>1</sup>

Now look at the medical literature in the 21st century. We no longer publish our data; instead, we present truncated summaries in the hope that readers will believe our conclusions without seeing the raw observations. Rather than present the data we have, we put forth only the analyses that we like people to see, and we expect readers to trust that we have presented a comprehensive and unbiased compilation of the important findings. Alas, even the most trustworthy researchers are not so insightful as to see all that is meaningful in their work or motivated to report every data point that may be at odds with their conclusions.

## Seeing is believing

When evaluating applications for approval of new drugs, many regulatory agencies demand that the sponsor provide all the raw data of a clinical trial for a complete and independent examination. Not surprisingly, regulatory review often identifies meaningful methodological concerns and data discrepancies, both of which influence decisions about drug approval.<sup>2</sup> Readers cannot possibly glean this information from the published manuscript of a clinical trial.

Furthermore, although we extol the virtues of peer review, reviewers never have access to the raw data; they are simply asked to judge the reasonableness of the data presentation and interpretation. Thus, reviewers are easily fooled. As long as an author is persistent, even the most flawed trials eventually are published in the peer reviewed literature. There is an obvious reason for this: the number of journals is so large that their combined capacity far exceeds the quality of the

material that deserves to be published.

It is no wonder that many clinicians have stopped reading the medical literature. There are too many papers, and most do not contain data that we can examine or validate. There are too many opportunities to be misled. So we tune out, and as a result, even the most compelling and clinically important results are often ignored.<sup>3</sup>

Researchers can help to solve this problem by showing our work. Yet, surprisingly, when asked to place their data in the public domain, some investigators rebel, as they did recently in the *New England Journal of Medicine*.<sup>4,5</sup> Why the reluctance? Do these investigators believe that the time and effort that they spent to generate data allows them an exclusive licence to perform analyses and write papers? If so, they act as if the data belong to them.

Data in clinical trials are generated as part of a social contract by which patients (by signing consent) participate in studies for the potential benefit that they can provide to society without the expectation of individual benefit.<sup>6</sup> Researchers who collect the data and report their findings at scientific meetings and in the medical literature are privileged to do so; these databases are not items that they own or can sell. Patients who sign consent do so for the general good; they do not participate to generate information so that it can be hoarded to support the academic careers of a few investigators.

So we need to collectively agree on what we are debating when we argue the merits of data sharing. We are not talking about whether or when to do it; we are not talking about being paid or taking credit. We only need to agree on how to do it—quickly, easily, reliably, and respectfully.<sup>7</sup> Those who propose delays or a complicated process should understand that they may be perceived as losing whatever credibility scientists and physicians still have.

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## The Karolinska Institute case: notes on a scandal

An investigation has concluded that Sweden's Karolinska Institute (KI) and University Hospital should not have hired the Italian surgeon and researcher Paolo Macchiarini (pictured) and that he should not have performed three transplants using artificial tracheas coated with stem cells. Two patients died and one is still in intensive care. Between 2010 and 2015, six reports of suspected research misconduct have been filed against him.

Swedish authorities have sacked the institute's board following a series of highly critical reports. On 5 September a separate external inquiry examined Macchiarini's recruitment, and whether his research was documented and evaluated.

Those of us who work at KI are not surprised by the criticism, and on most points we agree. We need to improve research documentation, pay attention to formal regulations, and improve recruitment processes. We need to be better at following up our research as well as our researchers. And we are concerned about how the case might affect the collaborative climate between healthcare providers and academia.

Something has been missing in the discussions. Yes, there are descriptions of the fact that Macchiarini was well



liked by many, that he was able to create strong enthusiasm for his ideas, and that he was well published.

The history of the Macchiarini case is being written as we speak, and the ultimate question needs to be further discussed: Given academia's "fixation on excellence"—what type of true organisational learning is necessary in order to increase our ability to detect the cheaters among all of us other narcissists?

Clara Hellner Gumpert, dean of research education at Karolinska Institutet 2008-2011  
This is an edited extract of a blog post. Read the full post at [bmj.co/macchiarini](http://bmj.co/macchiarini)

### PAOLO MACCHIARINI ON THEBMJ.COM

21 November 2008

Patient makes good recovery after transplant of a bioengineered airway

• [BMJ 2008;337:a2676](#)

23 March 2010

British boy receives trachea transplant built with his own stem cells

• [BMJ 2010;340:c1633](#)

11 July 2011

Novel polymer used in first artificial windpipe shows promising future

• [BMJ 2011;343:d4419](#)

23 October 2013

Five year results show success of first tissue engineered trachea transplant

• [BMJ 2013;347:f6365](#)

12 February 2016

Nobel official resigns in wake of storm over Italian surgeon

• [BMJ 2016;352:837](#)

1 September 2016

Italian surgeon should never have been hired by Karolinska, inquiry concludes

• [BMJ 2016;354:i4754](#)

8 September 2016

Swedish government sacks entire Karolinska Institute board over Macchiarini

• [BMJ 2016;354:i4894](#)

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# Can researchers still promise control of participants' data?

After a five year battle, patients with chronic fatigue syndrome have forced researchers to release data from controversial research into treatment of the condition. But trial participants never consented to this. **Nigel Hawkes** reports



Walking was the most commonly taken up exercise by the PACE participants undergoing graded exercise therapy

**T**he consent agreements researchers make with patients participating in trials will have to be rethought, experts have warned, after researchers were forced by a court ruling to release data from a controversial trial despite not having obtained the participants' authorisation to do so.

Queen Mary University of London said this month that it has released the data from the PACE trial (a randomised evaluation of pacing, graded activity, cognitive behaviour therapy, and specialised medical care for chronic fatigue syndrome<sup>1</sup>) to a patient who had requested it under the Freedom of Information Act. The university had long battled against the request, citing concern that the participants could be identified if the data were released.

Frances Rawle, head of corporate governance and policy at the Medical Research Council, says that it will now be necessary to rethink how consent forms for future trials are drafted if it is no longer possible to assure participants that data will not be shared.

"People who run trials have to say what will happen to the data they collect, so we'll have to look very carefully at the wording of consent forms," she

says. "As things stand they are no longer consistent with the Freedom of Information Act."

If people have to be told that data may be shared, even if only after anonymisation, it could affect recruitment for trials, she said.

## Questions over the data

The PACE trial, which was published in the *Lancet* in 2011,<sup>1</sup> included 641 patients and remains the most important research to date into treatment for chronic fatigue syndrome (also called myalgic encephalomyelitis). But patients and experts have challenged the trial's methods and its influential finding that cognitive behavioural therapy and graded exercise therapy are more effective than adaptive pacing therapy or specialist medical care. Activists and charities that represent patients favour adaptive pacing, which involves a gradual increase in activity aiming to improve people's capacities over time, and reject psychological treatments.

Alem Matthees, who made the freedom of information request, had, like many patients, questioned the research methods and the original findings, saying the researchers had not analysed the data as set out in the original trial protocol.

## LANDMARK TRIBUNAL RULING

In August a tribunal rejected Queen Mary's argument that to release the information would risk identifying patients who had participated in the PACE trial.<sup>5</sup>

The PACE trialists, led by Peter White, professor of psychological medicine at the university, had answered critics who have made legitimate scientific points and shared the data with other research groups. But they had been unwilling to share them more widely. A total of 37 freedom of information requests were made, many successfully rejected by Queen Mary under section 14 of the act, which covers vexatious applications.

But when Matthees, a patient with chronic fatigue syndrome from Perth in Western Australia, made a request in March 2014, Queen Mary did not play the vexatious card. Instead it rejected the request under section 40, which relates to the protection of personal data, and section 41, information provided under a duty of confidence. It also attempted to invoke section 22A, which was written into the act in 2014 to protect medical trial data from improper use. However, this did not come into force until October 2014, some months after Matthees had made his request, and the

commissioner ruled it could not apply retrospectively.

That left the personal data issue. The commissioner found that anonymisation of the data would be an adequate safeguard. In doing so he disregarded the editor of the *Lancet*, Richard Horton, who argued that there was "a fairly small, very vocal and very damaging group of individuals who have, I would say, actually hijacked this agenda and distorted the debate so that it actually harms the overwhelming majority of patients. This community actively seeks to identify and attack those who are associated with the PACE trial."

The *Lancet* has since had nothing to say about the ruling.

Queen Mary took the case to a tribunal, which ruled that if the university was prepared to share data with other researchers it was tacitly acknowledging that anonymisation is effective and dismissed as "implausible" claims made by data security expert Ross Anderson, a professor at Cambridge University, that anonymisation could be broken by linking different databases. By a majority of two to one—the lay member dissenting—the tribunal ruled that Matthees should get the data he asked for. After mulling it over, Queen Mary agreed to comply.





**Vincent Racaniello and 41 other experts criticised the original trial results published in the *Lancet***

Experts have also questioned the published results. Former editor of *The BMJ*, Richard Smith, called for the release of the data in December 2015, accusing the researchers, along with Queen Mary, of “defending the indefensible.”<sup>2</sup> And earlier this year, 42 experts wrote an open letter calling for a third party review of the data.

Vincent Racaniello, professor of microbiology and immunology at Columbia University in New York, who organised the open letter, said the decision of the tribunal was “a victory on multiple fronts: for patients seeking the proper therapies, but also for transparency in science and the need to have data available for review by others.”

#### **What patient information was released?**

Matthees has been sent what he asked for, Queen Mary says, but it has not been posted on the university’s website. This is not obligatory, though most government departments do post freedom of information releases on their websites. The data are now in the public domain, and Matthees can make them available if he wishes. It was not possible to contact Matthees before this article went to press. Anybody else who wants the same data can now apply to Queen Mary for them.

What Matthees sought was a spreadsheet listing the baseline and 52 week follow-up data for all trial participants, including their physical function scores, their fatigue scores (in two forms), whether they were still classified as having chronic fatigue syndrome by the Oxford caseness classification at 52 weeks, participant and doctor related impressions of overall health, and walking distances.

This is by no means all the trial data. “There are about 3000 variables in this trial and we’ve released 12,” says White. “These are the primary outcomes and two secondary outcomes, plus some other things. It’s a limited release because that’s what he asked for.”

#### **New analyses**

Matthees told the commissioner he wanted to analyse the data using the original 2007 protocol. One of the principal complaints of critics is that the protocol was changed after data started to come in and that if this had not been done, different conclusions would have been drawn.

White says these changes were made before any data were examined, were ratified by the trial steering committee, and reported in the 2011 *Lancet* paper.

To anticipate any analysis that Matthees plans, the PACE team published its own this month.<sup>3,4</sup> What is the result of going back to the 2007 protocol? “It makes not a ha’porth of difference,” White says. “Cognitive behavioural

therapy and graded exercise therapy are still statistically significantly better than pacing or specialist medical care.”

The patient advocacy organisation #MEAction and others have claimed, however, that these new analyses show only a third as many patients improving as the *Lancet* paper found. “They’re not comparing like with like,” White says. “They are comparing one measure with a completely different one—it’s apples and pears.”

Nigel Hawkes, freelance journalist, London

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**We need a culture of open data, in which researchers engage with all reasonable criticism, whether from academics or patients.**

Simon McGrath, patient

**We were concerned for the rights and welfare of trial participants and were ethically bound to act in our patients’ best interest**

Peter White, lead researcher

See full commentary on [overleaf](#)

## RESEARCHERS' VIEW by Peter White

### Releasing patient data from the PACE trial

We have received many requests over the past five years to release the patient data collected in the PACE trial, and Richard Smith, former editor of *The BMJ*, suggests that we have made “a serious mistake” in not always releasing data. Data requests often cite the importance of transparency, giving other scientists the opportunity to investigate our data, as well as changing customs in science where data sharing is increasingly encouraged.

These are important issues, and we entirely support the principles behind sharing scientific data. We have already shared data from the trial many times, when there have been sufficient safeguards in place before doing so.

Although discussed in a *Nature* article by Lewandowsky and Bishop earlier this year, the central issues of patient consent and the need for pre-specified analysis plans are rarely mentioned in debates about open data, and this is especially important to consider in the context of clinical trials.

The reason we have been unable to release data to some who request it is that trial participants did not give consent for the public release of their data when they entered the trial.

The two data requests mentioned by Smith were from a member of the public, using the Freedom of Information Act, and from a researcher who has said that he would make the data publicly available once received. We were concerned for the rights and welfare of trial participants and were ethically bound to act in our patients' best interest. We have also followed both our university guidance and that of the UK Medical Research Council, which funded the PACE trial, regarding data sharing.

Few people in medical research, to our knowledge, include an agreement as part of the consent that a patient's individual data, even “anonymised data,” can be released to anyone who requests it. How many patients would take part in medical research if they knew that their data could be made publicly available afterwards? We fear that having such an agreement as part of the consent to participate in a clinical trial would put off a significant number of potential participants, particularly if the trial was of treatments of a stigmatised illness, such as CFS.

In our opinion, this issue is a threat to medical research into such conditions and has not received the attention it deserves, although the recent section 22A amendment to the Freedom of Information Act provides some protection for current ongoing research.

As we move into an era of greater openness in scientific research, the issue of how we balance the need for data sharing, patient confidentiality, and ongoing recruitment into clinical trials will require careful consideration.

Peter White is professor of psychological medicine at Queen Mary University of London

Trudie Chalder is professor of cognitive behavioural psychotherapy at King's College, London

Michael Sharpe is professor of psychological medicine at the University of Oxford and a consultant psychiatrist

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## PATIENT VIEW by Simon McGrath

### This shows why trials need patient scrutiny

Like all patients, what I want most from clinical research is treatments that work, not ones that merely look good on paper. As *The BMJ* has pointed out, patients are often faced with over-hyped treatments and an incomplete research base biased towards positive results.

So, well informed patients should have the right to query research findings, and researchers should be willing to engage constructively and transparently with patients who challenge them.

Most aspects of my own illness, ME/CFS (chronic fatigue syndrome), are contentious, so there's all the more reason to ensure that trial data are properly scrutinised. In ME/CFS, the PACE trial of cognitive behaviour therapy and graded exercise dominates the research landscape, so its findings matter—not least because of their influence on treatment guidelines around the world—but the findings are contested.

For years, patients have pointed out that the modest gains in subjective outcomes in this non-blinded trial were not matched by objective gains and that key analyses specified in the study's original protocol were altered drastically once the trial was under way. Thresholds for “recovery” were lowered so far that 13% of patients already met the revised threshold for recovery of physical function before therapy.

Unfortunately, the trial authors have tended to dismiss rather than engage with the central issues. This led one patient to submit a freedom of information request for data that would allow the key outcomes to be analysed using the various thresholds specified in the trial's original protocol. Queen Mary University of London, which holds the data, refused the request, but the Information Commissioner over-ruled it and, despite the university's £245 000



appeal to a tribunal, the order to release the data was upheld. The tribunal determined that there was a strong public interest in data release.

Despite this progress, however, I'm deeply frustrated and saddened. Frustrated because, for many years, researchers and the medical establishment would not engage with patients who made the same criticisms—simply because, it seems, they were patients. And I'm saddened that an attempt to establish the truth about the effectiveness of the main interventions recommended for my disease ended up in a courtroom.

These issues are relevant well beyond ME/CFS and PACE. Researchers are not infallible, and their research reports are not the incontestable truth. Patients with any illness should be allowed to scrutinise findings from any clinical trial about their health. Disease strikes patients from all walks of life, including many who have or acquire the skills to competently assess research and who can contribute effectively to the science. We need a culture of open data, in which researchers engage with all reasonable criticism, whether from academics or patients.

Simon McGrath had an all too brief career in charity fundraising before becoming too ill to work in 1995.

Read this blog in full and others at [bmj.com/blogs](http://bmj.com/blogs)