



**We have Margaret Thatcher to thank for the modern scourge of worklessness**  
Des Spence, p 41



## I'm a patient: show me the trial data

**Alex Lomas** is taking a biological drug for Crohn's disease, and he wants to know why the maker is trying to prevent disclosure of trial data that may well affect him

I have an obsession with data. I have instruments in my house so I know how hot each room is and to warn me if the fridge door has been open for too long. I record my weight and blood pressure using devices connected to the internet so that I can monitor long term trends. I use my smartphone to track how much walking and exercise I do.

I was diagnosed with Crohn's disease about 20 years ago, when awareness of inflammatory bowel diseases was not as high as it is today.<sup>1</sup> The treatment decisions made at the time of my diagnosis had unfortunate side effects for me as a teenager. High doses of prednisolone led to Cushing's syndrome, and I was mercilessly teased about my appearance at school. With time came a reduction in the dose of steroids required, but I had to take them throughout my 20s, and control of my symptoms was still inadequate.

As a patient with Crohn's disease, I take an active interest in my day-to-day health, but I also routinely scan news media and journal sites for new treatments and for changes to current best practice in the management of my condition. I often arrive at appointments with my consultant armed with PDFs printed from the *BMJ*, the Cochrane Collaboration, and the National Institute for Health and Care Excellence (NICE) to discuss the latest trials and treatment options. Yes, I'm afraid I'm one of those patients.

Three years ago my consultant suggested a new course of treatment with adalimumab (Humira), an anti-TNF $\alpha$  monoclonal antibody. My local primary care trust approved this new drug, which costs £352 per injection, and which I administer myself by injection each fortnight.<sup>2</sup> Since I started taking adalimumab I have the least symptoms since diagnosis. I am no longer taking steroids; I have started to recover from 15 years of side effects; and I spend less time in clinical care and off work on sick leave.

However, anecdotes are not the foundation of evidence based medicine, and nor are they a rational basis for evaluating the cost of a treatment. On 1 April 2013 responsibility for commissioning transferred from my primary care trust to the local clinical commissioning

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group, bringing into sharp focus the question of whether the NHS is getting value for money in continuing my treatment.

Equally importantly, I want to be able to evaluate the benefits and risks of these costly pharmaceuticals with which I inject myself regularly. Biologicals are relatively new, and have failed spectacularly in clinical trials.<sup>3</sup> Who knows what 20 or 30 years of data from clinical use might bring? The most recent Cochrane review of biologicals looked at nine studies, and, although it found that they were effective, it noted that none of the trials allowed for an assessment of long term adverse

events nor had any trials been undertaken that compared efficacy among the available biologicals.<sup>4</sup> My consultant recently told me that no trials had been done to determine what the minimum effective dose of adalimumab was, nor would there likely ever be; a drug company has no interest in showing you can take less of something.

Part of NICE's approval for the use of adalimumab in treating Crohn's disease was the recommendation that a register of patients being treated with biologicals be set up to track long term outcomes and relapse rates after withdrawal of treatment, something patient groups welcomed.<sup>5</sup> Unfortunately it seems that such registers are fragmented, with registers of patients with rheumatoid arthritis held independently from registers of patients with inflammatory bowel disease, or are still at pilot stage.<sup>6</sup>

As a patient, I need clinicians to interpret trial data and systematic reviews of new and existing treatments so we can come to appropriate decisions about my treatment, but what if even experts don't get to see the whole picture? How can we even know what trials are being run?

I was therefore dismayed to learn that Abbvie, the maker of adalimumab, are seeking a legal injunction to prevent the European Medicines Agency from disclosing trial data submitted during the drug's approval process.<sup>7</sup> With such a new drug, it is vital that all data, whether it's good news or bad, are made available so that I, my consultant, and the care commissioning group can make informed decisions about the efficacy and cost effectiveness of treatments.

As the drug industry and medical profession as a whole move towards the registration of all trials, and the publication of all trial data—in no small way thanks to the All Trials initiative ([www.alltrials.net](http://www.alltrials.net))—this decision by Abbvie is a backwards step and is offensive to trial participants, patients, and the wider public who ultimately pick up the tab.

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References are in the version on [bmj.com](http://bmj.com).

Cite this as: *BMJ* 2013;346:f2336



FROM THE FRONTLINE **Des Spence**

## Thatcher's legacy

Rats on the streets during the bin collectors' strike, the Green Goddesses, wildcat strikes, flying pickets, block votes, "one out all out," restrictive work practices, double digit inflation, a three day week, and a winter of discontent. The 1970s in the UK were a time of national crisis, with undemocratic and out of control trade unions.

The Tories won the 1979 election: working class people had voted for change. The Thatcher government crushed the unions' power, but the price was broken communities, public disorder, and mass unemployment. England's industrialised north and Scotland paid the heaviest price, while the south east and London experienced economic renewal. Thatcher was a saviour to some, a political savage to others. Thatcherism set off a cascade of consequences: the current deregulation of the NHS is simply her unfinished free market business.

There is another Thatcherite legacy: worklessness. In the 1980s and 1990s



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unskilled middle aged men were haemorrhaged from heavy industry, with no hope of work in the new service based economy. So GPs were encouraged to redefine the unemployed as "sick" to get the unemployment figures down. We colluded, because this meant some improvement in meagre benefits for patients. This worklessness doubled between 1985 and 1995, to more than two and a half million people, but varied hugely by region. Today in areas of Glasgow 17% of the working age population is deemed too sick to work, eight times more than in Hampshire.<sup>1</sup> (These figures do not include people officially deemed unemployed.) This huge difference can be explained only as a social phenomenon; it cannot reflect true variation in disease or disability.

Worklessness is a modern medical scourge. With 1.8 million children living in workless households,<sup>2</sup> it is associated with poor child development and schooling, behavioural issues, unhappiness, and increased risk of being a NEET ("not

in education, employment, or training") at age 18.<sup>3</sup> Worklessness is bound to poverty and premature death.<sup>4</sup> It is worklessness that has created the chasm of inequality, leaving millions of children in poverty. These are society's new precariat, and society's elite are unwilling or unable to tackle this pernicious sickness. But welfare reform must happen.

Welfare reform is not about paying down the national debt but saving the mental and physical welfare of millions of marginalised people. And today there is a public consensus for change.<sup>5</sup> Breaking the cycle of worklessness will take Thatcherite conviction, steely leadership to see it through, and a willingness to be disliked.

Worklessness and welfare are a national crisis, and reform must not be for turning.

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References are in the version on [bmj.com](http://bmj.com).

Cite this as: *BMJ* 2013;346:f2382

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THE BIGGER PICTURE **Mary E Black**

## The messianic cockroaches of sexual health

Sexually transmitted diseases will always be with us. We have only one antibiotic left to hold multi-resistant gonorrhoea at bay. Every three cases of HIV infection we prevent will save the NHS a million pounds in the cost of treatment. Within living memory, lack of contraception and backstreet abortions devastated women's health in the UK, and this is still the case in some parts of the world.

Sexual health providers and advocates are like messianic cockroaches: you just cannot get rid of them and they will survive anything, which is just as well as the current so called reforms have certainly made a mess. The sexual health service commissioning framework is an elaborate patchwork across clinical commissioning groups, local authorities, and the recently renamed NHS England, placing commissioners and providers

into new and ever more complex relationships. Meanwhile patients keep turning up to genitourinary medicine clinics expecting to get what they have been told they will get: free confidential services, available wherever they choose. Behind the scenes, local authorities are mostly in agreement on the cross boundary charging needed for this, but if those agreements break down we will have problems.

Take HIV prevention. We know that London's approach badly needed a shake-up. The old patterns of HIV prevention missed out key groups, such as ethnic minorities. A new generation has different patterns of sexual behaviour. The internet and social media have changed the way people meet and how they get their information and advice, so simply churning out leaflets will no longer be enough. We need a coordinated



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approach throughout the city, but the budget for HIV prevention is now split across all the local authorities, so a new set of alliances needs to be built. This will take time and effort and will need to include the widest range of sexual health advocates. We need to be smart, fast, and connected.

But opportunities exist. In other parts of the world I have been one of only a few people interested in sexual health services, with a paucity of actual services or funding. This isn't the case in London, which has a combative army that will refuse to stand down. It may not be quite sure where to march right now, but if we stick to basic principles and find allies in the new bodies and in local authorities we should be able to ride out this storm.

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Cite this as: *BMJ* 2013;346:f2362

