

# THIS WEEK

## EDITORIALS

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## Data sharing will pay dividends

*As public pressure builds for drug companies to make more results available from clinical trials, the industry should not forget that it relies on collective goodwill to test new therapies.*

Readers of *Nature* who are familiar with recent controversies surrounding clinical trials and medical practice may find it bizarre that anyone could be “surprised and concerned to discover that information is routinely withheld from doctors and researchers about the methods and results of clinical trials”, as stated in a UK government report last week.

After all, campaigning doctors have warned for years that pharmaceutical companies have in the past concealed data that reflected poorly on their drugs. Regulators — notably the London-based European Medicines Agency — have pushed for more information to be released into the public domain. And the drug industry itself has moved to open its private data vaults, albeit not by as much or as quickly as campaigners would like.

The ‘surprise’ and ‘concern’ at this well-chronicled behaviour of big pharma comes in a report from the UK Parliament’s Committee of Public Accounts, a cross-party group with the remit to scrutinize whatever public-expenditure topic catches its eye. The report focuses on the antiviral drug Tamiflu (oseltamivir) — used to treat influenza — which the UK government and others have stockpiled at great expense owing to concerns about pandemic flu.

Independent scientists who want to investigate whether Tamiflu works have struggled to find all the information they need, in part because its manufacturer Roche, headquartered in Basel, Switzerland, held back some details of trials. The company says that it has now released all its Tamiflu data, and researchers are working their way through them, but the case has become a high-profile example of the need for greater openness in biomedical science.

The report made headlines in the United Kingdom and, according to campaigners, vindicated their position. Its call for the UK government to improve the availability of clinical-trial information is also in line with initiatives elsewhere.

For instance, the European Medicines Agency is already pushing forward plans to release the clinical-trial data that drug companies submit to it when seeking approval for their products. Legal action taken against the agency by two aggrieved companies has slowed progress. But in December, the body again stated its “firm commitment to pursuing the objective of full transparency regarding clinical trial data”.

Meanwhile, the European Union is overhauling its clinical-trial legislation. Final agreement is some months away, but it seems likely that pharmaceutical firms will eventually be required to upload at least a summary of all their trials to a publicly accessible website.

The two major drug-industry associations in Europe and North America have also moved towards openness. Their joint policy on access to clinical-trial data came into force at the start of this year, adding to promises made by individual companies such as Glaxo-SmithKline, Sanofi and Roche to share more data on their drugs.

Yet critics — notably the AllTrials campaign group — say that the industry is not going far enough. Their main complaints are that

transparency initiatives are not retrospective and do not require the inclusion of data from older trials, and that some in industry want to act as information gatekeepers, determining which researchers have a genuine need for their expensively assembled data sets. These campaigners deserve credit for raising the issue and for their perseverance in pushing for change.

The industry is at a crossroads. As the UK committee’s report shows, concern over the behaviour of pharmaceutical firms is growing.

**“Recent history is full of examples of the public turning against businesses with essential roles.”**

Any anger over the industry’s perceived underhand tactics when it comes to data transparency could spread from the vociferous — but small — community of politically active medics and policy campaigners to the wider public.

Drug companies perform a vital function for society in fighting disease and preserving public health. But recent history is full

of examples of the public turning against businesses with essential roles. From banks and energy firms to the oil industry, an increasingly networked and ethically aware public is now capable of dramatic and damaging pushbacks against disliked companies.

It may be true that the worst practices of big pharma are behind it, but shades of that bad attitude linger. And past misdeeds have a habit of coming back to bite. Drug companies must remember that they need the public and its goodwill to test their medicines in the first place. They may have to release more information than they would like, but if they do, it will safeguard the trust and support of the people on whom they ultimately rely. ■

## Risk management

*Teams aimed at preventing violence on campus can offer a lifeline to those in crisis.*

How safe is your workplace? It is nearly four years since biologist Amy Bishop walked into a faculty meeting with a loaded pistol and shot six of her colleagues, killing three. Acts of violence involving multiple victims are extremely rare, especially on college campuses, which tend to be safer than the areas that surround them. But highly publicized events such as Bishop’s rampage and the shooting at Virginia Polytechnic Institute and State University in Blacksburg in 2007 — which had one of the highest death tolls of any attack on a college campus — have spurred rapid growth in what is known as threat assessment and management. Developed by behavioural psychologists

working with agencies such as the US Secret Service, threat assessment aims to identify concerning behaviour and situations, and to take pre-emptive action to stop them escalating into violence.

This can involve simply confronting an individual about inappropriate behaviour — aggression towards colleagues, for example — and working with them to correct it. Or it can include maintaining continual contact with an individual and putting them in touch with any help they might need, such as mental-health services.

It is a challenging goal. Universities are big, complex environments where many students, staff and members of the community interact, not always peacefully. But existing networks that organize and monitor housing, health, grades and social activities do offer ways for universities to identify aberrant or shifting behaviour, as well as a robust support structure to get people back on track.

A News Feature on page 150 explores the growth of such programmes and teams, particularly in the United States, where easy access to guns and several high-profile shootings have put the public on high alert. There seem to be some clear benefits, but the spread of these interdisciplinary teams, which often include law-enforcement officials and representatives of university mental-health services, also presents several risks.

One risk that team members often worry about is how to balance individuals' civil liberties with the need to protect others. In an age in which privacy is increasingly illusory, life within the boundaries of a college campus can be put under close scrutiny with little effort. And freedoms of speech and expression must be maintained if institutions of higher education are to continue to nurture ideas.

Another risk of the focus on threat assessment is more subtle, and relates to the all-too-easy assumption that people who commit unthinkable acts of violence are driven by mental illness. It is true that mental illness is implicated in many high-profile cases of targeted violence and that many behaviours that would initiate a call to a threat-assessment team are related to a deteriorating mental state. But the links between violence and mental illness are complex and hardly correlative. Most violence is perpetrated by people who are not mentally ill, and most

people with mental-health problems do not commit violent crimes.

The rhetoric of threat assessment therefore runs the risk of further ostracizing people who already face stigma. Many cases managed by a threat-assessment team — there are several hundred referrals per year at an institution such as Virginia Tech — are for students or staff going through a crisis in their personal or professional life. Practitioners are quick to point out that theirs is a support-focused process, more about putting individuals in touch with the help they need to weather that crisis than punishing them, banishing them or branding them as potential threats.

**“For students these services can be extraordinarily helpful, even life-saving.”**

Such nuances can be hard for an individual to remember when facing a threat-assessment investigation. And the leading part played by law-enforcement officials in proceedings adds an air of presupposed criminality.

All of this is not to devalue the efforts of these teams. They can be among the first to recognize and the most eager to serve those struggling with mental illness. And they often partner with other student-service organizations whose goals are not focused on averting the next mass shooting. If a case is not deemed particularly risky, threat-assessment teams may pass it over to these groups. For students, who are often facing unfamiliar challenges, these services can be extraordinarily helpful, even life-saving. Many referrals to threat-assessment teams are prompted by threats of suicide, for example.

The politics at play here are sadly familiar in the United States. A highly publicized mass shooting is followed by calls for stricter gun control, followed by pressure from gun supporters to maintain the status quo or even loosen restrictions on firearms. Somewhere along the line, fingers are pointed to the role mental illness had in the attack and attention shifts to the dismal state of mental health care in the country. Accusations are made, as are promises, but little is done. Threat assessment may not be a solution to violence, but if it means that more people get the help they need, irrespective of whether it staves off the next attack, then, to some people at least, it is a success. ■

## Conflict of interest

*How two world wars affected scientific research, and vice versa.*

This year marks the anniversary of two significant events from the last century, perhaps the most significant of any century: 100 years since the outbreak of the First World War and 75 years since the start of the Second World War. It is natural for specialist publications to search out a 'local' angle on major news events, and *Nature* is no different. When it comes to modern warfare, however, the task is easier than with most events, for science is not a tangential topic in armed conflict. It lies, for both good and evil, at its heart.

We live, said Martin Luther King, in an age of guided missiles and misguided men. Scientists can do little about the latter (although we must still try), whereas the former shows the contradictions of military research in all its shades of grey. If we are to kill people, then is it a good thing that we are able to target them more precisely? The death of one becomes more likely; the deaths of others less so.

In times of war, such ethical tongue-twisters tend to give way to the pragmatism of national politics. In 1943, James Collip, one of the 'Toronto group' of scientists that isolated insulin, observed that: "Today, with total war upon the world, there can be no doubt that more than ever before in history this war is a contest between the brains, imagination, inventiveness and teamwork of the scientists and production workers of one group of nations pitted against those of another

group." Whereas the first three of those attributes were always common in science, teamwork, as Collip pointed out, came less naturally.

There are two ways to address the topic of science and war. The first, and the most conventional route, is to assess the impact that research has on conflict. Science in the First World War marked a turning point in tactics; no longer was a speedy and resourceful attacker likely to win. With machine guns and barbed wire at the front line, and behind them railroads for resupply, a well-dug-in defender became the favourite. (The US Civil War had demonstrated this too, but European generals were slow learners.) Technology made warfare asymmetric, and it has remained that way — the dreadful stalemate of mutually assured destruction by nuclear weapons notwithstanding.

The second route is to look at the reverse of the equation: how has conflict influenced research? What lessons are there for peacetime science in the panicked scramble of work that aims not to understand how the world works and to improve quality of life, but to ensure that it remains at all?

*Nature* intends to address both topics in several articles this year. And we kick off this week with a good example of each. On page 156, Sharon Weinberger reviews two books that analyse the wartime role of physics and psychology. And on page 153, David Kaiser explores how practical ways of getting US physicists to work together during the Second World War had an enduring impact on the organization and funding of science. For one thing, Kaiser writes, it turned on a "fire hose" of federal funds for research, a model that continues. The teamwork continues too, and if the stakes for winning and losing are lower now than when the original collaborations were forged, that can only be a good thing. ■

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