

Now comes a shocking reality check, revealed this week in the *British Medical Journal* (*BMJ*). As we report on page 15, a London-based team has scrutinized reports of all the randomized trials of bone-marrow stem-cell treatments for heart disease they could find.

The authors searched for discrepancies that might undermine the results and found plenty — errors such as numbers not adding up, or individual patients reported variously as male and female, dead and alive. In fact, the researchers found a linear relationship between the number of discrepancies and the claimed effect size. The small number of trials that they identified as unflawed showed an effect size of zero. In other words, the scientists declare this stem-cell emperor to have no clothes.

The multitude of discrepancies may not necessarily invalidate the conclusions of an individual trial — the authors point out that all too often the clinical data are not available, leaving them unable to check whether the discrepancies are real errors or just the result of sloppy reporting.

But, at the very least, the *BMJ* report should raise the question of whether the data are really strong enough to support the big step of moving to a phase III trial, particularly given that in the case of adult stem cells the results of animal studies have been ambiguous. Initially, researchers suggested that these cells became specialized to the target organ and replaced damaged tissue, but this idea has since been rejected. Many clinicians now think that the cells instead act to heal the surrounding tissue, releasing molecules that cause inflammation and the growth of oxygen-bearing small blood vessels, processes important to repair.

The findings of the *BMJ* study raise another worrying question: why did the clinical journals concerned fail to notice the discrepancies, given that many of the errors seem, in hindsight at least, to be startlingly visible? If a table claims to describe n clinical events, for example, but in its columns refers to $n + 2$ events, is that really so hard to catch?

Agency for change

Japan's proposed reforms to science monitoring are welcome but long overdue.

Scientific misconduct is a universal problem. Policies to investigate and prevent it, however, are patchy. Japan is now taking welcome steps to address the issue.

Japan has certainly produced some of the more bizarre cases of scientific fraud identified in recent years. In 2000, an amateur archaeologist was caught on film burying stone tools that he later unearthed as evidence of human civilization — his 'discoveries' over two decades falsely pushed back Japanese history by 650,000 years and corrupted a generation of history textbooks (see *Nature* **408**, 280; 2000).

In 2009, a University of Tokyo professor, Serkan Anilir, was found to have lied about several of his career achievements, including his claim to be the first Turk in a NASA programme: an image of him wearing a spacesuit was uncovered as a fake. And in 2012, the 20-year career of an anaesthesiologist came under question amid the record retraction of more than 100 of his papers (see *Nature* **489**, 346–347; 2012).

There is more to these cases than embarrassing tales of individuals gone off the rails. They indicate a lack of oversight in research and the common cultural reluctance of colleagues to act on suspicions for fear of challenging their peers. They highlight how misconduct is not reported enough in Japan, partly because the country has lacked a high-level agency to deal with it.

Japan is now preparing to clean up its scientific act. At a 14 April meeting of the Council for Science and Technology Policy (CSTP),

This, in turn, raises more queries about the process. Who should take responsibility for fact-checking a paper for internal consistency? Is it the notoriously busy clinical experts who act as referees? Or the editors, many of whom also have a full schedule of clinical duties? Few of the journals that published the papers scrutinized in this case have professional editors or significant numbers of in-house editing staff. Pressure to review and publish quickly is high. The two sides of the equation don't balance, and the problems identified in the study suggest something of a crisis.

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To address this, the publishers of clinical journals must do more to ensure that someone takes responsibility for the fact-checking. That could involve asking authors to guarantee that they have checked figures, tables, text and abstracts for internal consistency. Publishers could require authors to make available suitably anonymized data on each patient as metadata to the study, so that readers can trace the source of any discrepancy that might creep through. Or the publishers could reach into their pockets and provide more in-house resources to perform the necessary checking. What is not acceptable is for the situation to continue as it is, with responsibilities undefined and inexact publishing distorting clinical messages.

The problem seems to run deeper than the heart and stem-cell studies checked in this case. For years, analyses have highlighted a bias towards publishing clinical trials that show a positive outcome. (A similar trend has also been found with scientific results.)

Translational medicine is one of the buzz-phrases of the twenty-first century. In a way, it should be a surprise that it has taken so long for the idea to catch on. What use is medicine that is stuck in the scientific laboratory? But as the curious case of adult stem cells demonstrates, the right checks and balances are not brakes on progress, but an essential foundation for that progress. Fools rush in. So do those who have not done their homework. ■

the nation's highest science-policy organization, an eight-person subcommittee called for the cultivation of research integrity in individual researchers, and for the setting up of fraud prevention and response measures at the institutional level to restore public faith in science.

The council's chair, Japanese Prime Minister Shinzo Abe, expressed concern that “the recent rash of cases involving scientific misconduct threatens to erode the foundation of our research.” He noted that an approach to misconduct based purely on the experience of individual cases is inadequate; instead, he has asked the CSTP to develop measures “from a broad perspective”.

In its call for action, the CSTP cited the ongoing case of Haruko Obokata of the RIKEN Center for Developmental Biology in Kobe. In January, she published research in this journal that suggested adult cells can be reprogrammed into stem cells through stress. Within weeks, allegations emerged that the work contained errors. On 1 April, RIKEN charged Obokata with misconduct. She is appealing the decision.

It is unclear how Japan will act on the CSTP call for action, but the country should take this opportunity to create an agency, akin to the US Office for Research Integrity, that can handle allegations of fraud and misconduct in a systematic way and encourage whistleblowers to come forward. The need for such an agency has been noted often, including in these pages (see *Nature* **437**, 595–596; 2005).

Researchers now deal with more data than ever before, and the evaluation of misconduct allegations often comes down to distinguishing sloppiness from deception in the presentation of data. For this reason, Japanese institutions should be given funding to educate their researchers in the responsibilities of data management. Whatever the outcome of the CSTP's proposals, the high level of attention given to the issue is long overdue. ■

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