

# THIS WEEK

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## Trial and error

*Italian officials should not go ahead with expensive clinical tests of an unproven stem-cell therapy that has no good scientific basis.*

**T**he Italian government is planning to oversee a clinical trial of a controversial stem-cell therapy. There are many reasons for the trial to be stopped — and no good reason for it to be carried out.

Last week, *Nature* revealed that the method used by Italian researcher Davide Vannoni, founder of the Stamina Foundation in Brescia, to treat scores of very sick patients is based on flawed data. The revelation struck a major nerve, and hit the front pages of the main newspapers in Italy, as well as featuring on television and radio talk shows. A highly emotional debate about whether Stamina therapy works, or could ever work, has been running long and hot for months. Vannoni denies any wrongdoing.

The reverberations of *Nature*'s exposé are still being felt. Negative coverage in Italian newspapers has featured patients who received the Stamina therapy on compassionate grounds. At the same time, pro-Vannoni demonstrations have been organized by families of patients who see him as their last hope. Now scientists — as well as some politicians — are questioning whether the ministry of health should continue with the €3-million (US\$3.9-million) clinical trial of the technique that it agreed to support in May. It should not.

In large part, the government-sponsored trial was intended as a pragmatic attempt to put the matter to rest: if the method failed, the Stamina Foundation would have no grounds for continuing to push it. To go on with the trial now, given the therapy's uncertain scientific basis, would be absurd.

Vannoni has provided no details of his clinical protocols, referring instead to the scanty methods in his 2010 US patent application. That describes a method for promoting the differentiation of bone-marrow-derived stem cells into other cell types for therapeutic use, and includes two micrographs purporting to document the successful creation of nerve cells. Both, *Nature* revealed, were lifted from papers published by Ukrainian and Russian scientists (see *Nature* <http://doi.org/m57>; 2013).

The very unlikelihood of the Stamina story should have made the Italian government extremely wary. Vannoni claims to be executing cures that he prefers to conduct without oversight by independent parties. He has provided no detailed protocol to the authorities even though his treatment is invasive — it involves drawing marrow from the bones of patients, manipulating the cells *in vitro* (ostensibly to condition them into becoming healing stem cells) and injecting them back into the patients' veins or spinal cord. He insists that his therapy can only be prepared by his own people, without using good manufacturing practice (GMP). His operation has moved from city to city as public prosecutors try to pin him down.

Vannoni is not a qualified doctor, but a teacher of general psychology at the University of Udine. His response to critics tends to be indirect — stating that they have vested interests, or that they want to stop him from helping those who would otherwise die. He dismisses the only real test so far of his therapy, by doctors in Trieste, saying that

the outcome was negative because they used GMP.

Movement of any therapy into a clinical trial requires much more transparency. It also needs a solid theoretical basis for why it should work, backed by scientific evidence, either published or presented confidentially to the appropriate authority, in this case the Italian Medicines Agency. Vannoni has not provided this. Indeed, there is no convincing evidence in the literature to suggest that the mesenchymal stem cells found in bone marrow, which can generate bone, fat and cartilage, can be coaxed into producing nerve or any other cell type that Vannoni has claimed is the basis of his cure.

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Although there are no scientific reasons to justify the trial, Italian officials have mooted a legal one. Various courts in Italy have ruled that individual patients demanding compassionate therapy from Stamina have the right to it, whereas others have ruled that they do

not. But that is not sufficient: human experimentation to settle legal differences of opinion is not ethically justified.

Stem cells have huge potential to treat currently incurable diseases and scientists are working systematically to this end. A trial that could bring stem cells into disrepute will hinder their efforts. As Irving Weissman, director of the Stanford Institute for Stem Cell Biology and Regenerative Medicine in California, says: “If the Italian government uses money that could have gone to research that will deliver real stem-cell therapies in the future, a whole cohort of people will die because these therapies had not yet been invented.” ■

## In the dark

*Germany's main funding agency must specify how it will deal with false charges of misconduct.*

**W**hen it comes to the thorny issue of scientific misconduct and how to police it, Germany is a role model for many. Its main research-funding agency, the DFG, published exemplary guidelines in 1998 to steer good scientific practice in universities.

The guidelines comprise 16 recommendations, and are effectively mandatory because universities that do not sign up to them are not eligible to receive DFG grants. Among the recommendations are mechanisms to drum the importance of honesty into trainee scientists, and a requirement for each university to appoint an independent mediator to whom young scientists can turn in confidence in cases where they suspect misconduct. The DFG also created a central ombudsman

system to handle disputes that cannot be resolved locally.

The DFG formed the recommendations after a landmark 1997 fraud case in Germany that shook the academic community to its roots. A pair of clinical researchers had been systematically fabricating research results for almost a decade; in the final count, more than 100 papers were implicated.

It was the digital revolution that allowed their faking to remain undetected for so long — they could cut and paste gel images and other data on their computers at a time when referees were not tuned into such tricks. And in Germany's rigidly hierarchical academic system, they were able to control any potential leaks from their labs. As star professors who had soared through the academic ranks on the back of their publication lists, they were easily able to intimidate any research student daring to query how papers were generated overnight when experiments seemed not to have been done. Any whistle-blower would lose all career prospects.

The digital revolution has continued, and so have the scandals. Plagiarism is the latest trend, and recent years have seen leading politicians exposed for cheating in their PhD theses. Remember Karl-Theodor zu Guttenberg? The aristocrat soared through the political ranks to become Germany's defence minister in 2009. But in early 2011, plagiarism hunters found that parts of his thesis had been copied, told the press and forced his rapid resignation. After zu Guttenberg came a series of similar exposures involving high-ranking politicians in Germany, where a PhD is an advantage in politics. The revelations devastated careers.

Anyone with a computer can now run plagiarism software. Some have wielded it for great good, such as the website Integru.org, which has exposed deep academic and political corruption in Romania. But in some cases, the software seems to have been used for smearing, or at least for the thrill of the chase. Many, for example, were unconvinced by accusations of plagiarism against Germany's education and research minister, Annette Schavan. But enough publicly thrown mud managed to stick, and she was forced to resign in February.

With the rise in digital scrutiny and increasing legions of self-styled fraud-busting bloggers, the DFG is rightly concerned about the need for due process. Is it right, for example, that the accused is named while their accuser hides behind Internet anonymity?

Last week, the DFG updated its scientific-practice guidelines to underline the benefits of its system, which, as far as possible, facilitates a confidential, fair and thorough investigation of charges. Its latest

***"The DFG has put the universities in a difficult position."***

recommendations now emphasize the value of a whistle-blower, and the importance of protecting him or her at all costs. It warns against breaking the confidentiality of an ongoing investigation by going public with names. It explicitly notes that all accusations

must be made 'in good faith', stating that 'bad-faith' accusations may also be considered a form of scientific misconduct, and that anonymous complaints may not be followed up.

All well and good — but this time the DFG has formulated its recommendations surprisingly poorly. The consequences of breaking confidentiality, or of being charged with accusing in bad faith, are left open, prompting conspiracy theorists to fill the blogosphere with wild charges that the DFG is gagging the scientific community.

That is far-fetched. But it is true that the threat of punishment for accusations that cannot be proved could make even the most confident whistle-blower nervous to move forward. And in announcing its updates, the DFG has not addressed a key issue that makes whistle-blowers go public in the first place — the justified fear that the procedure will drag out, while no one knows what is going on.

The DFG has put the universities in a difficult position. It is universities that investigate claims of misconduct against their own, and therefore the universities who will be asked to implicitly convict whistle-blowers if their information cannot be confirmed. The DFG should take care to explain how and when sanctions would be used, and what those sanctions are likely to be. ■

## Headline message

*Science communication is changing, but investigative reporting is still important.*

**M**idsummer in Helsinki is a blast. The nights are white and the pavement cafés crowded. Last month, an unusual ingredient joined the mix: more than 800 journalists, science communicators and scientists from 77 countries, there for the biennial World Conference of Science Journalists.

The Helsinki attendees and indeed all science journalists are caught between an idealized past and a volatile future. Until a decade ago, most newspapers employed a dedicated science reporter or three, and television networks had whole teams of science journalists. These days, specialist science correspondents are an endangered species.

Yet while mainstream science journalism fears for its future, the parallel field of science communication is booming. Blogs, Tumblr and Pinterest pages provide small to medium-sized audiences with compelling coverage of every topic imaginable. Funders such as the Wellcome Trust in London and the John Templeton Foundation in West Conshohocken, Pennsylvania, launch flashy, well-produced science publications on what seems like a weekly basis, supporting talented writers. Curation websites such as reddit.com can focus immense traffic on little-known sites. It has never been easier for science communicators to reach their audience.

Some of this output is by and for scientists — who else but a computational biologist would read a 2,000-word analysis of the shortcomings of algorithms for analysing RNA-sequencing data? Writing for the general

public tends to focus on explanatory celebrations of scientific discovery.

But the mass media, whatever that has become in 2013, remains the major conduit for scientific information when it really matters.

For example, blogs featured outstanding technical coverage of the 2011 Fukushima nuclear meltdown, but most of the world's public learned about the disaster and how it could affect them through conventional media. And the relationship between politicians and the mass media often drives public policy.

The UK Science Media Centre (SMC) in London, and its founding director, Fiona Fox — who is profiled in a News Feature on page 142 — know this. The centre focuses on getting scientific voices into big stories in newspapers and broadcast news. Some media observers bristle at the SMC's approach of cultivating relationships with science and health reporters and providing them with quotes and stories from scientists. Critics see it as an attack on the independent and investigative reporting that flourished during a supposed golden age of science journalism.

To be sure, there has been good journalism on scientific matters in the past. But most newspaper science pages — then as now — were filled with stories, albeit well-written ones, about press-released research papers. True investigation into scientific matters, such as journalist Brian Deer's dismantling of the claim that vaccines are linked to autism, or a report in the *Financial Times* this year about the mysterious death of a US scientist working for the Singaporean government on a technology with military applications, has often reached beyond the science desk.

Expensive, time-consuming and often unpopular with readers, this is the science journalism that is most in danger. It is the science journalism that needs to survive if the public is to be properly informed and the powerful to be held accountable. ■

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