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A signature trial?

Nayanah Siva

> "The experimentation must be done with the human body, for testing a drug on a lion or a horse might not prove anything about its effect on man."
>
> (Ibn Sina [Avicenna], 1025)

And so the clinical trial was born. Not only did the Persian philosopher lay down essential foundations for clinical research as we now know it, but he also contemplated ethical issues, such as patient consent, and proposed the use of written documents in medical practice. Nearly 1,000 years later, these issues are still proving problematic. Earlier this year, Dieter Bollmann, a 70-year-old man from Berlin, filed, and won, a lawsuit against the Medical University of Innsbruck, Austria. Bollmann was misled into signing a consent form to undergo stem cell treatment for urinary incontinence, which he thought was an established therapy when it was actually still in its experimental stages; he even paid for his experimental treatment. On 8 September this year, *The Lancet* retracted a paper from researchers at Innsbruck after reports of serious research misconduct.

Hannes Strasser and colleagues' procedure involved obtaining muscle tissue from a patient's arm, from which myoblasts and fibroblasts were isolated. These were cultured and injected back into the same patient's urinary sphincter to promote regeneration of the rhabdosphincter and urethral submucosa, thereby improving incontinence symptoms. However, a recent report by the Austrian government's Agency for Health and Food Safety found that there were serious errors in the group's study design: proper ethical approval was not requested, and patient consent documents were presented unsigned, undated or forged. Such high-profile misconduct casts doubt over the validity of hundreds of studies published by Strasser and colleagues.

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N Siva is Locum Editor of Nature Clinical Practice Urology.

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European guidelines on good clinical practice state that the investigators of a clinical trial are responsible for obtaining proper patient consent. But, as demonstrated by the Austrian scandal, 'signed' patient consent forms or approval from an ethics board might not guarantee an ethically sound trial. A signature on a consent form does not indicate whether a clinician has given patients accurate information about their disorder, treatment options and risks—if they have provided any at all. Informed consent depends on the all-important patient–doctor relationship and the investigator appropriately tailoring and judging what information each patient should be given. However, difficulties arise when researchers feel pressured to judge the exact risks and prognosis of a treatment that has not yet been tested in humans.

With the advent of implied and electronic consent in some areas of medicine, there is a danger that informed patient consent could lose significance. Signed patient consent has its limitations, and may not be an ideal formula, but its importance should not be underestimated or taken lightly. It is essential that investigators are up front with potential trial participants about their treatment risks, options and prognosis during clinical trials. Considered and appropriate informed patient consent does not only protect the safety and dignity of patients, but also offers a safeguard for researchers, and in turn supports the integrity of clinical trials and medical research. Without patients, high-quality clinical research cannot be performed, so it is essential that investigators do not violate the trust and relationship between doctor and patient. Signed, informed patient consent may sometimes be difficult to navigate, and it may not be the perfect model, but has anyone come up with a better method for ensuring ethical research during the past 1,000 years?