**Do Patient Always Know about the Medical Experiments They are In?**

**David Papineau**

Earlier this year the *New Statesman* ran [an article](https://www.newstatesman.com/politics/health/2019/02/surgical-stitch-meet-placebo-surgeon) about a medical study of a popular shoulder operation. In its own terms, the study was a great success. It showed that the operation does no real good. As a result, much unnecessary surgery will be avoided in future. The CSAW study (“Can Shoulder Arthroscopy Work?”) has been widely acclaimed as a model for future research.

At the same time, however, this study highlights some disturbing issues about the use of ordinary patients to further the cause of medical knowledge. The modern medical establishment is fully committed to the scientific assessment of traditional medical practice. As a rule this means conducting “randomised trials” in which the standard treatment is compared to various alternatives. But such trials raise ethical issues, and at times come dangerously close to performing experiments on noncompliant subjects.

Many people suffer chronic shoulder pain, especially as they age, and it is often treated by surgically removing bone spurs or other tissue. The CSAW trial run by Oxford University’s Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences set out to discover whether this “decompression treatment” is actually effective.

As Xan Rice explained in his article [“Surgical stitch-up: meet the placebo surgeon”](https://www.newstatesman.com/politics/health/2019/02/surgical-stitch-meet-placebo-surgeon), the study recruited 313 shoulder pain sufferers and divided them into three groups at random. The first group were given the standard surgical procedure involving a keyhole arthroscopy operation under general anaesthetic. The second were subject to exactly the same process, save only that, after the arthroscope had investigated the shoulder joint, no tissue was removed and the patients were simply sewn up again. The third group was monitored without treatment.

The results of the study showed that normal surgery led to slightly better outcomes than monitoring with no treatment, though scarcely enough to justify a major operation. Even more interestingly, those in the second group, who simply had the operation with no tissue removal, did just as well as those who were given real surgery. The positive effect of the operation, such as it was, turned out to be a “placebo” effect, nothing to do with the tissue removal, but all down to the patients’ belief that the doctors were doing something to make them better.

This striking result, [published in *The Lancet* last year](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)32457-1/fulltext), will lead to a marked decrease in the 30,000 decompression operations performed annually in the UK. What Xan Rice’s article did not explain, however, was how over 300 patients were persuaded to take part in the CSAW trial in the first place. After all, participation meant a 33% chance of a full-scale operation with no medical benefit, complete with general anaesthetic and an intrusive arthroscope being poked around inside your shoulder. Perhaps a ready supply of pubic-spirited patients were prepared to undergo this risk in the interests of medical science. But it does seem a bit surprising, especially as it was always open to them to opt out of the trial and simply have the normal decompression operation on the NHS.

In this connection, the “Patient Information Sheet” for the CSAW study makes interesting reading. Here is how it describes the two surgical options:

(1) **Shoulder Arthroscopy**

This is a key-hole operation performed under general anaesthetic. The inside of your shoulder is viewed using a special camera. The shoulder is assessed to see if there are any problems with your tendons or joint. Your shoulder joint will also be washed out.

(2) **Arthroscopic Sub-acromial Decompression**

This is also a key-hole operation performed under general anaesthetic. Apart from the shaving away of a small amount of bone that sits above the tendons, the operation is very similar to the shoulder arthroscopy (above).

To my mind, it’s worrying that these descriptions omit to say that the first option contains no active medical ingredient. Nor is the oversight remedied elsewhere. On the contrary, in the only passage where the information sheet does return to the three options, all it says is that, “Any one of the three treatments that we are comparing would be a good option for you, and until we’ve completed the study, we can’t be sure which one is best.”

Given the wording of the information sheet, it might occur to a casual reader, and no doubt did occur to some of the prospective subjects, that the “shoulder arthroscopy” option offered some therapeutic benefit, perhaps related to the joint being “washed out”. But that was no part of the study’s design. The *Lancet* report, written for medical professionals, was quite explicit on the point: “Athroscopy only was a placebo as the essential surgical element (bone and tissue removal) was omitted.”

Three of the investigators involved in the CSAW study wrote [an article](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5256399/) about the ethics of placebo surgery in the *Journal of Medical Ethics* in 2016. The main focus of the article was not patient information, but whether it could possibly be right for the patients who end up with the placebo operation to undergo the attendant risks without themselves deriving any medical advantage. The article made a convincing case that, if the surgical risks of the placebo operations are not too great, they can be justified by the future benefits of improved medical knowledge. When the article did turn to the issue of patient information, though, the authors were adamant that the patients should be clearly informed about what they were signing up to.

We should remember that patients who end up in NHS medical trials start off with ordinary ailments and go to their doctors because they trust them to provide advice about the best treatment. Sometimes the doctors will say, entirely reasonably, that they are not sure about the best treatment, and ask their patients to take part in a study designed to find this out. But in such cases the doctors must make sure the patients understand the request. In particular, with placebo-contolled surgical trials, they must make sure that the patients know they have a good chance of undergoing a fake treatment with no medical benefit, in the interests of advancing medical knowledge to help others. To obscure this would manifestly breach the trust the patients have placed in their doctors. As the the *Journal of Medical Ethics* article put it, “Patients must know, understand and consent to to the fact that they are participating in a placebo-contolled trial.”

It is hard to see how the CSAW information sheet respects these requirements. True, it doesn’t actually say anything false. But, given that it omits to mention that the “shoulder arthroscopy” leaves out the essential surgical element, no ordinary person reading it could be expected to figure out that they were being asked to take part in a placebo-controlled trial.

I have no reason to doubt that the doctors who enrolled patients in the CSAW study explained everything to them properly, and in particular made it clear that a placebo operation could be on the cards. But ordinary people do not always take in everything they are told in doctors’ surgeries, and the whole point of patient information sheets is to help them go through it again in their own time. (“Please feel free to take the information sheet home with you and discuss your participation with friends, family or your own GP” the CSAW sheet urged.) The system doesn’t really work, though, if the patient sheets itself fails to make things explicit.

All NHS medical research projects need to be approved by an ethics committee, and the CSAW study was no exception. One of the main jobs of these committees is to scrutinize the patient information sheets, precisely to protect the interests of patients against the research zeal of doctors. You might well wonder what the CSAW ethics committee made of this information sheet. Documents designed for ordinary readers can’t of course explain all the scientific details, but it wouldn’t have been hard simply to say that a third of the patients would undergo placebo surgery.

I had a chance to find out more about the thinking behind the CSAW project when the lead author of the study, Professor David Beard, gave a talk at King’s College London a couple of years ago about the work of the Oxford Surgical Intervention Trials Unit of which he is co-director. When pressed about the limited information given to the patients enrolled in the CSAW study, he allowed that some “sleight of hand” had been involved, but pointed to the many future operations that would be avoided. He said that the researchers viewed it as a utilitarian calculation, with the boon of greater medical knowledge justifying leaving patients somewhat in the dark. As he saw it, if patients couldn’t be induced to enroll in surgical studies, we would never escape from the dark ages of medical ignorance.

The contemporary commitment to “evidence-based medicine” has led to enormous resources being devoted to the rigorous assessment of all aspects of medical practice. Even so, patient deception is generally regarded as a red line that violates the trust that patients place in their doctors. One senior academic doctor of my acquaintance, second to none in his enthusiasm for medical trials, described the CSAW study to me as “brave”. He admired its ambition, but even he felt that it pushed the envelope of ethical constraints on medical research.

The CSAW study is only one case, but it illustrates a danger that is inherent in all randomized controlled trials. Trials of this kind, in which patients are assigned to different “treatment groups” at random, are regarded as an essential investigative tool by medical researchers. They don’t trust ordinary “pilot” studies that lack any comparison group or retrospective surveys that simply chart past treatment success. As they see it, randomization is the only way that to be sure that observed positive outcomes are really due to the relevant treatment itself, and not the result of some extraneous influence.

But by their nature randomized trials need selling to patients. The different treatments involved in a trial will not generally offer them the same expected benefits. This is most obvious with placebo treatments that lack any active medical ingredient. But even among non-placebo treatments, initial evidence will often favour one over the others. In any such set-up, it will be tempting for doctors to be less than fully open with their patients. After all, once prospective trial subjects understand that they could end up with an inferior treatment as a result of a coin-toss, they might understandably be disinclined to take part.

A number of studies have investigated how far patients in randomized trials understand what they have signed up to. The [findings](https://www.ncbi.nlm.nih.gov/pubmed/19716887) are not encouraging. By and large, only about half the patients know that different treatments are being assigned at random, or even that different treatments are being compared. No doubt plenty of factors play a role in hindering patients’ comprehension. People are not always at their most clear-headed when they enter a doctor’s surgey. Still, if the CSAW study is any guide, the readiness of doctors to be economical with the truth is likely to be part of the problem.

Randomized trials are an essential element in the armory of medical research. But their conduct needs to be more tightly regulated and any exploitation of uniformed patients eliminated. A commitment to evidence-based medicine is no excuse for cutting ethical corners. The first duty of doctors is to those who have come to them for help, and ethics committees should do more to ensure that they respect this duty. The end of inceased medical knowledge cannot justify the means of patient deception.

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