

Yes, there are risks but these tests are VITAL



by Michael Hanlon

DONATING one's body to medical science is something most of us think is only possible once we are dead. But it is live volunteers who have given medicine some of its biggest breakthroughs.

The simple fact is that for medicine to advance, clinical trials – sometimes risky clinical trials – must be performed.

It wasn't always like this of course.

In the days before proper evaluation, doctors prescribed medicines and surgical procedures not because of evidence that they worked, but on the basis of blind faith and tradition. Doctors dosed, prodded, poked and sometimes cut because that was what was done.

Now, though, before any new medicine is allowed anywhere near a human trial, drug companies must conduct extensive pre-clinical trials, on animals and 'in vitro' – effectively in the test tube. This will determine the medicine's basic efficacy and safety.

It is these tests that provoke outrage among the animal rights lobby. But if animal testing was banned, either drug companies would not risk producing new medicines at all, or human trials would have to begin without the benefit of prior animal testing – in which case we are going to see a lot more disasters like the one in North-West London.

Yet animal testing, while immensely valuable, cannot tell doctors everything they need to know. At some stage, the medicine

has to be tried out on humans. At the dawn of the age of modern medicine, these 'clinical trials' were often ad hoc and unregulated. It was common (it still is, in fact) for doctors to test a new theory, medicine or treatment on themselves.

In the 19th century, for example, there was a fierce debate over the role of micro-

organisms as the cause of infectious disease. By 1892, nearly everyone accepted that cholera was caused by a water-borne germ, but not German scientist Max von Pettenkofer, who still clung on to the old idea that the disease was caused by foul air, or miasma.

To prove his ideas, he swallowed a glass of festering water drawn from a well in Hamburg – a city then at the height of a particularly nasty epidemic. The result? He got

cholera. The point here is not that von Pettenkofer was a fool, but rather that he had a theory – that infection was not carried by water – that could be tested.

Another famous case of an ad-hoc 'trial' was the deeply unethical experiment in vaccination carried out by Edward Jenner in 1796. He deliberately infected a young boy with cowpox, knowing that people who had contracted this mild disease often had an immunity to the much more serious smallpox.

After waiting for the boy to recover, he then injected him with deadly smallpox pus. The boy remained well, and Jenner became a medical hero, acknowledged as the father of modern vaccination. He risked that boy's life. But his discovery probably saved several billion lives in the subsequent

centuries. Today of course, clinical trials are a lot more regulated. Typically, they involve three phases. The first phase is to test the basic safety of any new drug on healthy volunteers (the London trial which went wrong was a phase 1 trial).

Next, researchers test its efficacy on large groups of patients suffering from the condition the new drug has been designed to treat.

Finally, phase 3 trials are conducted. These are expensive, large-scale experiments using the 'randomised, double blind' protocol, where neither patient nor doctor knows



which treatment, or dummy treatment, they are being given.

These trials are fiercely regulated. Patients must give 'informed consent'. You certainly can't inject young boys with smallpox anymore.

Little in the modern doctor's armoury has not gone through these three-stage trials, although there are some curious exceptions.

Perhaps the most interesting one is aspirin. Aspirin is widely recognised as one of the most useful medicines in the world, not only as an effective painkiller but also as a preventative against heart disease.

Yet it also has several side effects - including possible damage to the stomach lining - that mean it would probably never be licensed today as a new drug.

Ironically, the main argument against the modern testing regime is not that it is too lax, but that it can be too stringent.

Some diseases are so nasty, and some cures needed so desperately, that it can be argued that expensive, time-consuming three and even four-stage trials delay effective medicines from reaching the market for so long that they lead to a great deal of unnecessary suffering and death.