

## Unaffordable for our patients

Having been involved in many clinical drug trials, both industry sponsored and investigator initiated, I want to share my concern regarding the future of investigator-initiated clinical trials and non-commercial drug research. My first trial was exactly 30 years ago when, as an undergraduate student, I studied the stress response of two systemic anaesthetics in Cambridge, UK. It was an observational trial with pure academic interest. Two experienced anaesthetists had made clinical observations and were interested in the physiological background. The protocol was one A4 sheet. I went to the wards the night before surgery to ask the patients for their consent. At home the blood bank had trained me in taking blood samples, and with this I was assumed to be fully qualified.

More recently I ran a double-blind comparison of two intrathecal local anaesthetics [1]. A highly practical question was at stake: which drug would act faster and provide faster recovery. There was no commercial interest. It was a patient interest-driven trial, fortunately initiated before EU Directive 2001/20/EC came into force. If we had to do the trial under the conditions of the EU Directive, the products and experimental conditions would have been the same, but it would have cost a fortune due to all the paperwork. At a recent meeting of the Science Research Council a colleague estimated that about 80% of the cost of a drug trial nowadays goes to meet regulatory requirements, which do not in themselves advance medical or scientific knowledge.

Who pays the bill? In the end, it will *always* be the patient. With the ongoing financial crisis, pressures are already being felt on the healthcare system. We cannot afford to let paperwork costs spiral up any longer. Patients get older, there are more chronic diseases, innovative drugs become more expensive, and on top of it comes this overkill of administrative costs for simple, safe studies [2]. That was not the intention of the legislators and hopefully they will find the way back to what really matters: care for patients. The 2001/20/EC Directive was intended to increase patient safety in the context of large-scale industrial trials. All of a sudden the rules became prohibitive for small-scale investigator-initiated non-industrial trials directly for patient benefit. Can patient advocates use their influence to right this situation?

The focus of this issue is clinical trials. We are grateful to Dr Ingrid Klingmann of the European Forum for Good Clinical Practice, who leads this series as our guest editor. Important contributions come from the University of Düsseldorf, Germany (Dr Wolfgang Kuchinke and Professor Christian Ohmann), the European Organisation for Research and Treatment of Cancer (EORTC), Professor Morris Brown (Cambridge, UK). Worrying stories will continue in the next issue. Europe has major expertise in this field and it is detrimental to patients to jeopardise independent clinical trials conducted with the aim of establishing the best treatment strategies without commercial aims (Professor Françoise Meunier). As Professor Brown writes: "Whenever offered participation in a research study, patients are effectively offered a choice between research and everyday medicine" [3]. However, the hoops you have to jump through make it feel as though you are defending something improper instead of an act of benevolence for patients.

What pharmacists seem to forget is that the Good Manufacturing Practice guidelines are not a set of dead rules but *recommendations* on how to balance safety and quality based on common industry standards. Things are not black and white: as a highly educated professional you have to justify your conclusion that it will be safe for the patient in this condition to take this medicine. There are several ways to do this, based on risk assessment, and the risks in small-scale well-controlled trials are different from those in large-scale commercial trials. Paperwork is fine, but quality of patient care comes first. With the current and coming financial constraints we as professionals have to take decisions. What comes first, patient well-being or rules?

I have made my decision. I am prepared to defend the quality of care for the patient, within the everyday constraints I have. The future looks far from bright and I hope you never lose sight of the patient's perspective. It is the only reason for taking all this trouble. It is the only *raison d'être* of our profession, and nothing, nothing else.

1. Dijkstra T, et al. Br J Anaesth. 2008;100(1):104-8.
2. Schnitzbauer AA, et al. BMJ. 2009;338:b1893. doi:10.1136/bmj.b1893.
3. Brown MJ. Eur J Pharm Prac. 2009;15(5):28-30 and also Brown MJ. Br J Clin Pharmacol. 2009;67(5):487-93.



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