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Guest Editorial

Forensic Pharmacovigilance

Law and medicine have in common that both disciplines are involved in making serious decisions with long term consequences on information that is heterogeneous and often incomplete.

Evidence used in court ranges over several kinds of scientific discipline that underpin observations made by both experts and members of the public. The evidence is then subject to cross examination and ultimate judgment by the presiding legal officer and (in the United States' jurisdictions) a jury. Usually a judgment can subject to appeal if the Judge has misunderstood the facts of the case or misapplied the law to it.

Evidence used in treating patients in the clinic similarly involves several scientific disciplines and the observations of the patient and possibly relatives or carers. The evidence is assessed usually by a medical practitioner, sometimes assisted by a team of other medical and health care practitioners. Often the decision on a diagnosis is reached in an iterative process where other information is sought before a therapy is instituted. Treatment follow up may result in changes.

From the above process descriptions both professions are dependant on fully understanding the strengths and weaknesses of the range of both subjective and objective evidence presented to them. In medicine, the scope is more limited and medical practitioners are expected to be familiar with the science and behaviours surrounding their day-to-day work. Medical processes are more circumscribed and not normally open to public scrutiny: medicine is more reliant on personal judgments by those in charge of a particular case. The law challenges the medical model, often in public, by questioning clinical processes and using its own assessments of evidence. Moreover, the legal process is supported by sanction; in the civil law by the award of damages, in the criminal law state sanctioned punishment.

The medical practitioner is therefore very likely to be challenged in court, whether as a defendant or as an expert witness because s/he is playing by another profession's rules. In particular public scrutiny and accountability of personal professional behavior and decisions on evidence can seem very threatening: experts may be asked to give evidence damaging to professional colleagues, and defendants may find themselves compared (favourably or unfavourably) to those recognized as most eminent in their Peer group. In most Courtrooms however, the Judge will hold the ring allowing a recognisable process of medical peer review to take place unless and until that peer review fails to come to a conclusion in the issue being tried, then the Court will look to intervene to break the deadlock. In the United States the Judge will pose the factual issue and the peer review process to the Jury – in most cases the Jury favours the medical/scientific status quo. Occasionally – just occasionally – it upsets that status quo. In a non jury Trial the Judge will make findings of fact against which the medical evidence will be interpreted; where there is a deadlock between experts the Court will use a variety of tools – in England and Wales the Bolam/Bolitho tests will assess the reasonableness of those experts' positions.

The biggest problem that confronts any judge is to assess what would have happened had there not been the complained of falling short of standard. This inevitably requires the parties to look at medical/scientific evidence of reported outcomes; those outcomes are reported using medical/scientific standards of proof. The problem is that lawyers employ a lower standard of proof than the experts whom they ask to report in a case.

Pharmacovigilance, as a medical discipline, is used in forensic cases in a variety of ways. The main themes are: could this drug (or chemical) have caused this harmful effect in this person (these people), and did it cause the effect either 'beyond all reasonable doubt?' (criminal case) or 'as a balance of probabilities?' (civil case).

Distilling all the evidence available to the pharmacovigilance expert in a clear, unbiased way to help the court is a major challenge. After this, the other hurdle for the pharmacovigilance expert is often to offer comment on various aspects of professionals' behavior on what was the state of knowledge, when and how should that knowledge have been used in the prevention and management of harm.

The pharmacovigilance expert must help the Court understand the different sorts of scientific evidence available and alert the Court to the relative weight that such evidence commands. At the same time the pharmacovigilance expert must have regard to the evidential test that the Court will apply and be prepared to help the Court relate the evidence in the case (with its different probative weight) to the test that the Court applies. This is the point at which most scientists and clinicians find themselves in difficulty – because the Court has to weigh evidence not in a vacuum but having regard not just to the evidence itself but also to the role it is fulfilling and the relative position of the litigating parties.

The articles included in this issue are a miscellany, intending to pursue some of the main themes both theoretically and by examples.

Perhaps most of all the pharmacovigilance experts' role is to remind the Court – and some of those that appear before it – that a lot of apparently 'objective' evidence has flaws and to assist in balancing the different parties reliance on that inevitably flawed body of evidence.

The Journal is interested in pursuing this general area, since the interface between medicine and law can be confusing because of apparently conflicting interpretations of evidence on the harm caused by medicines. Any such confusion affects the perceptions of health professionals and the public and their approach to using medicines in their daily lives.

Comments and further papers will be welcome.

Guest Editors
I. Ralph Edwards FRCP (Lond), FRACP, FRCP (Edin)
Senior Advisor and Emeritus Director
The Uppsala Monitoring Centre
Box 1051, S-751 40 Uppsala, Sweden
E-mail: Ralph.Edwards@who-umc.org

David Body
Partner and National Head
Medical Law & Patients' Rights
Irwin Mitchell Solicitors Sheffield
Riverside East, 2 Millsands
Sheffield, South Yorkshire S3 8DT, UK
E-mail: david.body@irwinmitchell.com