EDITORIAL

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What do Stakeholders Think about Pharmacovigilance?

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Sylvie Fainzang, a medical anthropologist, has written on ''Discourse on Safe Drug Use: Symbolic Logics and Ethical Aspects'' in this edition of *Drug Safety*. To many, this article will seem very different in structure, method and content compared with usual *Drug Safety* material.

The article is based on a presentation made at the 2009 International Society of Pharmacovigilance (ISoP) meeting and it caused controversy. In discussions with colleagues following the presentation, some found it interesting and thought provoking, others thought it was 'unscientific'. Although anthropology has used some of the broadly positivist thinking that we use in medical science, there is in social anthropology much use of ethnography. Ethnography uses techniques such as direct observation, individual and group interviews, and others that resemble focus group analysis conducted by interviewing, directly or by questionnaire, a number of selected people on a particular matter of interest. The result of this is a reasoned analysis of the interviewees' responses and the investigator's interpretation of them, and the validity of this approach is argued within Dr Fainzang's article. The aim is to develop a hypothesis about how humans behave, and how their beliefs shape their behaviour. Understanding the logic of these beliefs within their own social context can illuminate some behaviour that might otherwise be derided as noncompliant or irrational. In this instance, Fainzang looks at patient behaviours around drug use, and some factors that influence them; the interaction between doctors and patients in discussing drug risks; and the pharmaceutical industry's stance over self-medication and risks.

Fainzang opens by arguing that patients are an active part of the pharmacovigilance team, not only passive recipients, whether or not the professionals on the team accept them as such; they make choices based on their own perceptions of drug safety, which may result in them refusing to buy or to take drugs they regard as too risky. Fainzang argues that patients' views about safety are inextricably related to their background knowledge and beliefs. Their perceptions are real to them and influence how they behave and what they say, and in turn this influences clinical trials and case reports. The focus of Fainzang's patient study explores the influence of religious-cultural origins on attitudes to drug therapy and outcomes. Her study group is small and the assessments are qualitative, so this information in pharmacovigilance terms represents a fascinating signal that can open the door to further similar studies or to alternative approaches. To pick one example, she points out the prime importance of memory to Jewish individuals and the fear they expressed that psychotropic drugs might impair memory. This realization might result in comparative studies of drug use and individual case harm reports (ICHRs).

Fainzang's commentary on the discourse between doctors and patients and her reflections on aspects of the discourse between the industry and the public are based on information we may already know. Indeed, her assertion that some doctors adumbrate or prevaricate around adverse reactions to drugs is well recognized. More important are her comments around the effects of such practices. These demonstrate and perpetuate a mutual lack of trust between the two

parties; this in turn may contribute to patients withholding certain information from their physicians, such as their use of supplements or alternative therapies or their compliance (or lack of it) with 'doctor's orders'.

Her comments on the industry's discourse are even more interesting since, if industry promotes self medication, this has strong synergy with consumer empowerment views. Self-medication is supported by the availability of huge amounts of information and misinformation on the web, and certainly suggests a dramatically changed role for health professionals in society. This change is well underway.

Before journal readers dismiss the content of this article as 'subjective' or 'unscientific', they should consider that some of her conclusions, particularly those on the attitudes of patients to the safety of medicines and the possible reasons for them, could not reasonably have been investigated in any other way. So, the content and the methods used in anthropology should be of interest to any professional with an interest in the field of drug safety.

1. Other Stakeholders

The challenge of other stakeholders' views to our epidemiological and medical paradigms does not stop with anthropology (note that stakeholders are often referred to as 'actors' in anthropology). Apart from patients themselves, two other important players are lawyers and the media. We choose to comment on these because they are so often belittled, and it seems that the paradigms from which those professions operate are anathema to pharmacovigilance professionals. Nevertheless, one can take a totally positive view and try to understand the strengths and weaknesses of each and to reach a happier dialogue with them.

What appears in the following sections should be taken as an interested party's overview of the two disciplines with the aim of suggesting more fruitful cooperation between them and pharmacovigilance.

1.1 The Law

The law operates by written statutes and guidance that are modified on the basis of legal practice experience and government edicts. The interpretation of the wording of laws in a given case situation is critical, but each case must be judged on the basis of all evidence made available: a decision must be made. Evidence given in trials may come from very different sources: forensic science, lay observation and witness, professional (police) observation, expert witness, and many other records and variously corroborated information. This is not unlike the situation over a signal in pharmacovigilance, although the nature of the evidence is even more diverse than in pharmacovigilance. Different, though, is the public nature of the process of the trial, which is very strongly peer reviewed through the verbatim record of the proceedings and summary of the salient points leading to a judgement. There is a painstaking effort made to record performance in trials against the wording used in statutes and precedents to ensure conformity, and where any interpretation or deviations occur, to record the reasoning around them. This is different from the pharmacovigilance process where the evidence and judgmental logic around them are not disclosed. Another difference is the open, adversarial and formal way in which evidence is debated both inside the courtroom and outside.

There seem to be two key, general differences in legal premises compared with those in regulatory pharmacovigilance. One is that the 'burden of proof' is held to be based upon a reasonable opinion ('beyond reasonable doubt') that the totality of the assessed evidence points more in one direction than another. The use of a jury or a panel of judges is used to go some way to assure that the judgement is indeed 'reasonable'. The second is that all competing causal hypotheses are evaluated in order to apportion culpability. Many legal cases relating to pharmacovigilance are related to 'failure to warn'. Actions are brought because warnings about adverse reactions are regarded as missing, too imprecise, too delayed or inadequate. In these situations, it is the legal standards of what is reasonable that will decide the judgement at the time, and arguments that statistical proof is lacking, or indeed that prior case reports of adverse reactions are inadequate evidence, may well not be enough to conclude

that regulatory actions should not have been taken or warnings given.

Understanding the legal paradigm better is not only wise, but many basic aspects contain much to enrich pharmacovigilance in offering a different view of drug safety issues, and indeed a different professional practice.

1.2 The General Media

The general media operates within a working environment that is heavily time pressured and the information they promote must be topical, succinct and of widespread interest. Reporters cover many stories and they need to précis information to the essentials as well as present it interestingly to a large and varied readership. The media both represents and influences societies' views. Where there is debate, the usual approach is to give both sides of the argument for the readers to judge. This 'balanced reporting' is considered essential, although editorials and special articles give more evaluative commentary. It is also considered that human interest adds attraction and meaning to stories. For those of us who work in pharmacovigilance, this makes the media paradigm a difficult one to handle. Injury to people makes a story dramatic, and the fact that patients are ill and vulnerable excites greater sympathy. It is very hard to argue statistics in this setting (''How many people must die before you take action?'' was one journalist's response to being told that deaths were very rare due to Stevens-Johnson syndrome related to a particular drug).

Like the law, the general media hold huge power in society and, also similarly, they may either help or challenge what we do, according to their own paradigm of judging what will be in the public interest and of interest to the public. It is all too easy to say that the general media distorts issues and is superficial, although we doubt that there are many that do not follow media stories: it is the best we have for independent views of timely world occurrences. We should also remember that many readers' time is very limited, that the human attention span is short and that many are not very literate or scientifically knowledgeable. Although we all know this, or have at least read it, we still behave as though it was not true.

If we feel that society does not understand pharmacovigilance it is because we still ignore all this pedagogic knowledge (think of the number of conferences where one is forced to suffer lecture after lecture with the minimum relief of a curtailed coffee break because the lectures were over time and there was no time for discussion!). It may be due partly to our failure to use the media as an ally, and to understand the concerns of all people over issues that may affect their health. It is high time we stopped talking about educating the public and teamed up with the media for action. We will have to convince them that we have a story worth telling, but that is our responsibility. As Dr Fainzang's article demonstrates, people are indeed interested in the safety of the drugs they are expected to take.

2. Conclusions

In this editorial we argue for broadening our approach to drug risk and safety issues and to accept that other stakeholders, with very different backgrounds and attitudes, have something important to add, both to the science we use and to the way it is understood.

Notably, for the second two examples here we have used an approach akin to anthropology; we have described the essentials of two major discourses and given a simple analysis of their place in society and in our pharmacovigilance society. Our vision will only be more complete if we utilize these additional perspectives, although of course the truth of what we say can only be judged by critical evaluation.

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