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Drug safety and the media

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This article reviews the problems that may arise as a result of media coverage of drug safety issues. In order to promote more balanced coverage and avoid unnecessary scares, professionals working in the area of drug safety should rethink their strategies for dealing with the media.

Introduction

Scare stories are a fact of modern life. The possibility that almost anything could cause serious harm to somebody has become intrinsically newsworthy. It is therefore not surprising that, when it is suggested that something given for a beneficial purpose might itself threaten life or cause permanent damaging effects, this is enough to produce major media interest and public concern. Most people know that medicines may have 'side-effects' but, unless clearly told otherwise, they expect these to be minor and reversible, or to be so rare that it 'won't happen to them'. Medicines undergo extensive testing before being made widely available and people expect them to be 'safe' to use. These are generally reasonable expectations, but the science underpinning drug safety has some way to go before they can be met completely.

Perhaps the biggest problem faced by people working in this field is that it is relatively easy to raise a new safety concern (or 'signal') that may or may not turn out to be real but impossible to disprove conclusively one that is false. Add to this the debatable nature of much of the relevant evidence, experts with their own vested interests, television broadcasts and newspapers for whom scares tend to increase sales, and the result may be very confusing. The safety of medicines depends on influencing the behaviour of prescribers and consumers so that appropriate safeguards are followed. However, in this respect, the influence of drug regulatory bodies may be limited and the potential behavioural influence

of media is often far greater. There is no doubt that media coverage of safety issues with medicines has, in itself, the potential to contribute to harm caused to patients. In some situations, e.g. MMR vaccine [1], it has been possible to quantify this to some extent, but often the effects are unknown.

The benefits of media coverage must also be considered – well-informed patients are likely to use medicines more appropriately. It should be recognized that, in some cases, e.g. interactions between the herbal treatment St John's wort and various prescription medicines, lay media coverage has been very well-balanced and a vital element in the communication process.

This review is an attempt to stand back from recent high-profile issues such as the safety of MMR vaccine [2] and of paroxetine [3], and consider these general problems from a broad perspective.

The problem of uncertainty

'What do you mean you don't know?', a patient might reasonably ask. Admission of uncertainty may be uncomfortable in the context of potentially causing harm to patients, but to scientists or prescribers it should be preferable to making claims of safety (or harm) when the evidence available is simply insufficient. Uncertainty is inevitable given finite-sized studies, variability between individuals in their responses to medicines and imperfect methods for assessing cause and effect. Consequent to that often wide uncertainty, making decisions about the safety of medicines often calls for difficult judgements [4]. The precautionary principle [5, 6] or, put simply, erring on the side of caution when causation is unproven, is a reasonable approach in this context [6] but its application can also have disadvantages for patients if useful or life-saving treatments are delayed or never implemented [6].

Media coverage of drug safety issues rarely reflects uncertainty. The media, understandably, like simple messages. Not knowing is usually not news and experts who say that they are not sure will probably not appear on television or their contributions will be edited for effect. The outcome is that the public may take away a clear message that a medicine is harmful in a particular way when, in fact, the evidence for that is quite uncertain. Also, it is well recognized that use of relative rather than absolute risks may lead to perceptions that a medicine is much more likely to cause harm than is really the case.

More than 10 years ago television coverage of hypoglycaemia unawareness, supposedly caused by human insulin, led some patients to stop their insulin [7]. In recent times, many journalists and producers seem to have responded to concerns that their work might cause some patients inappropriately to stop taking their medicines. In a BBC *Panorama* programme in 2004 about paroxetine [3], viewers were reminded more than once that they should not stop taking it without first seeing their doctor. Thus patients were given two contrasting messages – the drug is highly problematic . . . but don't stop taking it. Doctors were left to pick up the pieces and trust in some practitioners may have been undermined.

Underlying drivers

Regulatory decisions about the safety of medicines are based on consideration of the balance of benefit and risk. Taking into account the alternatives, a view is taken as to whether or not the expected benefits exceed the harm associated with treatment in the overall population of users (which includes both existing and potential future users). Clinical decisions are based on balancing anticipated benefits and risks to individual patients in the context of their particular circumstances. The distinction is important here because the balance of benefit and risk could legitimately be considered to be different at the population and individual levels in either direction. One striking aspect of media coverage of almost any kind of harm is that tragic individual cases are presented, presumably to add immediacy and human interest. However, even if the medicine was indeed harmful in the individual case shown (and the methods for assessing causation from one case are intrinsically imperfect), any inferences drawn at a population level could be suspect. For a preventive medicine, only harm can be portrayed as no individual who has demonstrably benefited can be shown.

The world of pharmaceuticals is *de facto* a commercial one. Despite a high level of regulation, when things go wrong there are understandable suspicions that the system has failed and that commercial interests could have been put before those of patients. The balance of benefit and harm may be perceived as commercial benefit *vs.* harm to patients. In our experience, the vast majority of well-informed people would agree that this argument is not justified but proponents of such views are more vocal and their case more newsworthy. In this way, trust in the system is continuously undermined.

Another important driver, at least for pharmaceutical companies, is the threat of litigation. In this respect there are major international differences, but one could certainly question whether existing systems of litigation ultimately work in the interests of patients (see below).

Winners and losers

An inherent part of balancing benefits and risks is that it will lead to 'winners' and 'losers' in the population at

large. This point is probably not widely appreciated. The acceptance by governments, regulators and healthcare planners that some people will be harmed so that many more can benefit may shock some people. In terms of the media, 'losers' are more easily identifiable and forthcoming than 'winners'. How, for example, do you identify individuals whose myocardial infarction was prevented by aspirin, in contrast to the easy identification of someone with a peptic ulcer? In general terms, society does not compensate people who lose out and, understandably, they feel aggrieved. For all these reasons, the media will tend to focus on them.

What should be the aims?

We return to the underlying problem of media publication bias generated because balanced coverage is relatively unnewsworthy. The ideal would be balanced coverage that would help users to make informed choices about risks and benefits, acknowledging an inevitable degree of uncertainty, particularly for individuals.

Medical scientists are used to presenting their work in journals and at meetings, but most are complete amateurs in the world of the general media. Journalists and television presenters have total control over how they use material provided to them by medical experts. They may also use material that is considered newsworthy or controversial in preference to that which is more mundane but a fairer representation of the scientific evidence. The 'sound-bite' is often used to convey a simple message but this may be inappropriate for complex issues requiring balanced judgement. In the complicated and uncertain world of the safety of medicines, experts need to become much more professional in dealing with the media and to act as regular spokespersons in this area.

Some possible ways forward

There are already established principles of communication in this field [8] but most of the problems described above are not unique to the safety of medicines – they are applicable much more widely in healthcare [9, 10]. As far as we are aware, there are no specific guidelines for the medical profession relating to dealing with the media (other than in relation to protecting the confidentiality of individuals). Whilst it could be very difficult to persuade the media to buy into any guidelines, there is no reason why the professions should not address this and, in doing so, attempt to redress the balance. One could, for example, question whether it is professionally acceptable to give a television or radio interview without obtaining the right to see and approve the finished material. Ultimately, if possible, some means should be found of forcing the media to relinquish some of their total control over the end-product.

Even without the present imbalance in much of what is presented to the public about the safety of medicines, there would still be the question of how the public deal with it. Do lay people generally have an appropriate framework enabling them to respond logically to complex issues of benefit and risk? Do they realize that there are inherent statistical uncertainties involved? A public which is more knowledgeable about the general issues involved here is clearly desirable and, despite some recent initiatives [11], efforts still need to be made in this respect.

When things go wrong it is fashionable to blame somebody and change the system. In this case there also needs to be some acceptance that major drug safety problems will occur no matter how well things are done. System credibility is important but confidence in it is relatively easily undermined. The secrecy of the past is no longer acceptable or appropriate and everything possible needs to be done to maintain confidence in the principle that patients' interests are being put above commercial ones. Much has been made of the (declared) financial interests of experts involved in regulatory processes [12]. Whether or not this makes a practical difference could be debated endlessly and from various angles, but if this undermines public confidence, a better way needs to be found. In the past it has been argued that it would be impossible to obtain the necessary expertise if such interests were not allowed, but this seems to be changing and, in Europe, there is increasing acceptance that regulatory experts should not have relevant personal financial interests [13].

There are many difficulties for individual medicine takers when things go wrong. At present this is an issue for the courts, but the odds are stacked against the claimants. Few make it as far as a court and, in Europe at least, few are compensated. In some specific circumstances, 'no fault' financial compensation is provided (e.g. vaccine damage payments) but these are unusual. The prospect of compensating everyone who experienced a serious adverse drug reaction would be a logistic nightmare, but the current situation whereby such people may resort to forming campaign groups seeking media attention is unsatisfactory. Society needs to give some serious thought as to what help can be provided to people who are damaged by medicinal drugs. Japan, for example, perhaps because of their experience with the atom bomb, seems to be ahead in this respect [14].

In conclusion, to help promote more balanced coverage and avoid unnecessary scares, professionals work-

ing in the area of drug safety need to rethink their strategies for dealing with the media.

Conflict of interests

P.C.W. was an employee of the UK Medicines Control Agency (MCA) from 1990 to 2002 and currently holds a contract to consult for the Medicines and Healthcare Products Regulatory Agency (MHRA). S.J.W.E. was an employee of the UK MCA from 1995 to 1999 and 2000–2002 and currently consults for the MHRA. S.J.W.E. is a member of the Committee on Safety of Medicines (CSM) Working Groups on HRT and on COX-2 inhibitors, and has also been an advisor to the European Medicines Agency on various safety issues. K.B. is a member of the CSM Sub-Committee on Pharmacovigilance, and of the CSM Working Groups on Patient Information and on COX-2 inhibitors. The views expressed here are personal and do not reflect the views of the CSM or the MHRA.

References

1 Owens SR. Injection of confidence: the recent controversy in the UK has led to falling MMR vaccination rates. EMBO Reports 2002; 3: 406–9.

2 Anderson P. Another media scare about MMR vaccine hits Britain. BMJ 1999; 318: 1578.

3 Waller P. When TV damned the regulators (personal view). BMJ 2004; 329: 865.

4 Waller PC. Dealing with uncertainty in drug safety: lessons for the future from sertindole. Pharmacoepidemiol Drug Safety 2003; 12: 283–7.

5 Commission of the European Communities. Communication from the Commission on the Precautionary Principle, 2 February 2000, COM 2000(1). http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf (accessed 1 February 2005).

6 Alban S. The 'precautionary principle' as a guide to future drug development. Eur J Clin Invest 2005; 35 (Suppl. 1): 33–44.

7 Williams G, Patrick AW. Human insulin hypoglycaemia: burning issue or hot air? BMJ 1992; 305: 355–7.

8 The ERICE report. Effective Communications in Pharmacovigilance. The Uppsala Monitoring Centre 1998.

9 Schwitzer G. Ten troublesome trends in TV health news. BMJ 2004; 329: 1352.

10 Campion E. Medical research and the news media. N Engl J Med 2004; 351: 2436–7.

11 Committee on Safety of Medicines Working Group on Patient Information. Always Read the Label. Available at: http://medicines.mhra.gov.uk/inforesources/publications/Alwaysreadtheleaflet.pdf (accessed 4 August 2005.

12 Strom BL. Potential for conflict of interest in the evaluation of suspected adverse drug reactions: a counterpoint. JAMA 2004; 292: 2643–6.

13 Medicines and Healthcare Products Regulatory Agency consultation letter MLX 316. Review of the Code of Practice on Interests to Apply to the Chairmen and Members of the Advisory Bodies Laid Down in the Medicines Act 1968. http://medicines.mhra.gov.uk/inforesources/publications/mlx316.doc (accessed 1 February 2005).

14 Japanese Pharmaceuticals and Medical Devices Agency. Profile of Services 2004. http://www.pmda.go.jp/pdf/20040401pamphlet-e2.pdf (accessed 1 February 2005).