LEADING ARTICLE

Drug Safety 2005; 28 (5): 379-386
0114-5916/05/0005-0379/$34.95/0

The WHO World Alliance for Patient Safety

A New Challenge or an Old One Neglected?

I. Ralph Edwards

The Uppsala Monitoring Centre, Uppsala, Sweden

Abstract

The WHO World Alliance on Patient Safety is a new, all encompassing project to improve medical care. Individual patients are the focus and all countries are encouraged to develop systems in which medical error, therapeutic accidents and failures are minimised. The potential for adverse events is present at all levels of healthcare and in all disciplines. One working group in the Alliance is charged with promoting and developing a 'reporting and learning' culture for adverse events in all areas of medical care. Central to current thinking for this group is a no-fault approach and to report near misses. The aim is not to provide certainty over the individual events, but rather to draw attention to possible improvements in systems that may prevent future problems. Adverse events relating to drug therapy have been reported for decades to national pharmacovigilance authorities, but this is aimed at finding problems with the drugs themselves as early as possible. The Alliance approach in the area of drug safety, by contrast, has a greater focus on safety in the systems of drug provision (including prescription and dispensing) and other systematic issues relating to safe drug provision, such as fraudulent drugs. Thus, current pharmacovigilance can be seen as representing a part of the reporting and learning envisaged by the Alliance. The two approaches are also complementary, but there are practical and philosophical areas of overlap in which difficulties may occur, such as anonymised reporting in a no-fault system and consequent impossibility for follow-up. In pharmacovigilance follow-up for more information is regarded as essential. Whether pharmacovigilance broadens into the area of patient safety or the latter involves completely new systems to do its work will be a matter for each country to consider. One thing is certain, working together both systems will improve patient care, but without cooperation more bureaucracy will take valuable health professional time with a lesser result.

In September 2004 in Shanghai, the first meeting of the World Alliance on Patient Safety discussed its proposed work programme with the WHO regional heads and other closely associated parties. On 27 October 2004, the World Alliance for Patient Safety was formally launched, with its main purpose being

to coordinate international action and avoid duplication of effort in coping with the escalating problem of iatrogenic disease and healthcare misadventures of all kinds.

The WHO has been working towards the launch of such a venture since 2002, when the 55th World Health Assembly called upon all member states to take action in relation to patient safety.[1] The World Health Assembly passed a resolution that drew attention to the growing body of evidence regarding iatrogenic disease and the fact that the complexities of medical care everywhere in the world were such that error and technical failures were inevitable. Attention was drawn to the cost of this iatrogenic disease burden, apart from the human morbidity and mortality. It is also clear that such a cost might be disproportionately burdensome in countries with limited resources. Patient safety is a global imperative. It has extensive implications for all WHO member states, for all healthcare workers and for all of us when we become patients.

This paper will critically review how the Alliance intends to accomplish its mission to improve patient safety, taking Hippocrates dictum "First, do no harm". It will also refer to current pharmacovigilance practice and consider how medical care can be improved by a joint venture.

Note that I will use the term 'Alliance', not only in the context of the global, WHO-supported group, but also in the context of individual national governmental efforts that might be started as a result of the work of the Alliance or fall under its aims.

1. The Alliance and its Current Proposals

Approximately 10% of people who receive healthcare in industrialised countries will suffer because of preventable harm and adverse events.[2-6] The nature and scale of the problem in developing countries and countries in economic transition is not known at the moment. Early indications from a pilot study being carried out by the WHO suggest that the figure will be significantly higher than 10% of healthcare recipients. As an indication, recent WHO data suggest that developing countries account for approximately 77% of all reported cases of counterfeit or substandard drugs.[7] It is also reported that at least half of all medical equipment in many of these countries is unusable or only partly usable, resulting in an increased risk of harm to patients and healthcare workers.[8] Economic restrictions can mean that a lot of equipment is used to breaking point and the pressures on the limited numbers of healthcare workers are even greater than in developed countries.

Adverse events can occur in all settings where healthcare is provided. Most of the current evidence comes from hospitals because the risks associated with hospital treatment are higher, but many such events occur in other healthcare settings such as consulting rooms, nursing homes, pharmacies, community clinics and patients' homes. Private medical care statistics are sometimes difficult to obtain.

At every point in a process there is an inherent issue about safety. Wherever a choice is made, a wrong choice can be made; anything that is made can contain defects; anything that is used can wear out; rules may not cover every situation. Adverse events may, therefore, be the result of problems in practice, products, procedures or systems.

Current conceptual thinking on the safety of patients places the prime responsibility for adverse events on deficiencies in system design, organisation and operation rather than on individual practitioners or products. Checks and quality assurance should be built into the use system, rather than assuming that all will be well.[9] For those who work on systems, adverse events are shaped and provoked by 'upstream' systemic factors that differ in each organisation. These include strategy, culture, working practices, approach to quality management, risk prevention and capacity for learning from failures. Countermeasures based on changes in the system

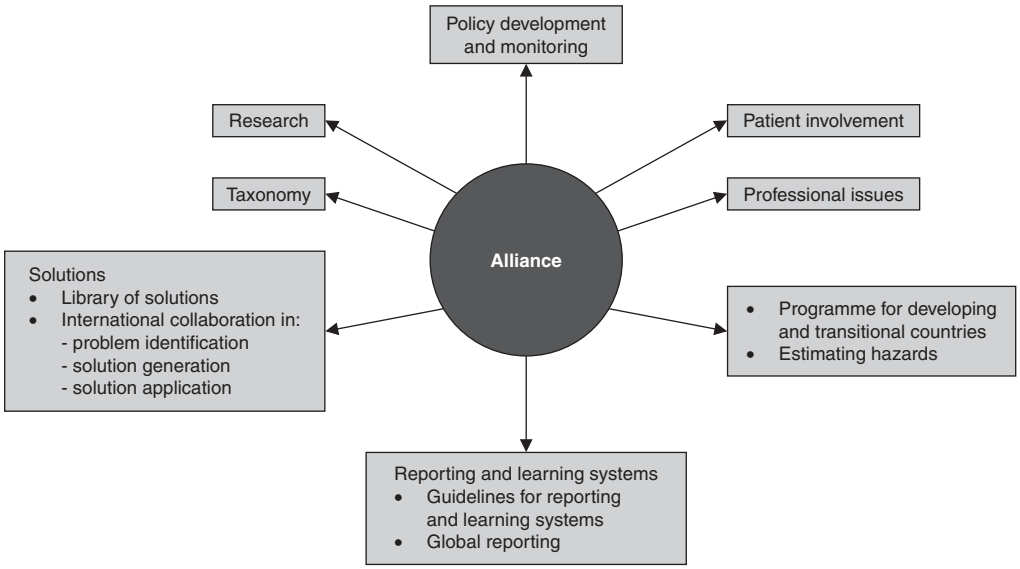

Fig. 1. Currently established working groups for the WHO World Alliance for Patient Safety.

are, therefore, more productive than those that target the behaviour of individuals and their propensity to commit error.

The WHO has established a number of working groups and programmes that tackle selected systemic issues such as taxonomy, estimating hazards, maintaining a library of solutions and the development of reporting and learning systems (see figure 1). The WHO also brought together its technical experts to deal with the safety of blood, injections, vaccines, drugs and medicines, pregnancy procedures and medical devices so that their individual expertise could be harnessed to find global solutions. Thus, the Alliance's action areas set out in its forward plan[10] will enable us to learn more about why adverse events occur and to find solutions that will prevent them in the future. Importantly, it will also strive to increase awareness and to mobilise and sustain political commitment.

So that the best practices can be established to provide decision makers with options when shaping national strategies, the Alliance will provide international leadership to ensure that answers to the following crucial questions are sought globally.

- What can policies and regulations that govern the healthcare system do to improve healthcare safety?
- How can we create leadership, undertake research and develop tools to enhance the knowledge base about safety?
- How can we identify and learn from adverse events through mandatory and voluntary reporting systems?
- What are the best mechanisms for raising standards and expectations for improvements in safety through the actions of oversight bodies, group purchasers and professional associations?
- How do we deal with questions concerning the cost of safety measures and possible variations in acceptable levels of risk, especially in resource-poor settings?

Every health system in the world has the opportunity to make care safer for the patients it treats. This is not just a primary humanitarian priority; there is also a large cost implication in inefficiencies and the additional care required for patients affected by medical errors.[11] The first step to improving patient

safety is to secure the commitment of political leaders, health policy makers and the main professional bodies in each country to the goal of safer care. With the addition of technical support, skilled leadership of health organisations and the input of patients and consumers there will be an unstoppable global movement for patient safety that will save many lives and prevent much serious harm.

2. A Critical Look at Some Possible Outcomes from the Work of the Alliance

2.1 General

It must be a main intention of the Alliance to find and promote systematic methods to optimise the safety and minimise the risks of medical practice at all levels. Quality assurance checks and balances in healthcare have been introduced over the years in all areas of medicine, but these vary from place to place. One consequence of the Alliance's work will be to evaluate procedures that are already used and to see if there is a recommendable 'gold standard' that can be used everywhere (or perhaps it is more likely to have a small selection of such standards?). This will provoke discussion amongst those involved in healthcare delivery and must be a major positive outcome for the evaluation of healthcare delivery.

2.1.1 A Common Language for Safety?

In order for the Alliance to achieve its goals, there will have to be a commonly understood language and definitions. The work of the Taxonomy Group will be of immense importance. There are too many groups who are currently involved in producing international medical terminologies and definitions. Only a few are quality assured and most are validated only for developed countries. The WHO has developed and maintained the International Classification of Diseases (ICD) for nearly 5 decades. Most countries have regarded this as the standard for epidemiology in health. This position is now challenged by several newcomers that have not sought the international buy-in that is the hallmark of the WHO. To extend the WHO family of terminologies to encompass the needs of patient safety will be a major step forward since, of necessity, this will need to include terms and definitions for devices, medical activities and many other things including all the adverse reaction terms. This work is not trivial since there are not only the lexical translations to be considered, but also the semantic meanings in different countries. The WHO has a structure for dealing with this challenge. Although the ICD is the main international disease terminology, there are others to be linked, mapped and developed. This overall task will be of great advantage to all who work in epidemiology and healthcare research and assessment.

2.1.2 Reporting and Learning

In order for there to be solutions, there must be defined problems! The 'reporting and learning' programme will need to bring together the national findings of patient safety problems, to analyse them and to propose solutions that can be adapted internationally. This is very similar to the WHO Programme for International Drug Monitoring. One major challenge is to convince people, particularly health professionals, to report their own errors and near misses or those of their colleagues. It is proposed that reporting will be confidential to avoid disciplinary action, litigation or other retribution against individuals. Indeed the whole idea is to promote a solution finding rather than a blame culture. There are potential difficulties with this confidentiality, including allowing the possibility of false, untraceable reporting, being unable to follow up for more information when necessary and generally having rather 'soft' data. Much will need to be debated on how best to use information of this type (see section 2.1.3).

The principle of reporting 'near misses' is welcome, since it will reinforce the 'no blame' aspect of reporting and also puts prevention to the forefront. Reporters who have such a proactive attitude are likely to be very positive in that they will have an outlet for their concerns and may also have suggestions on how to avoid the risk they are reporting. The challenge will be to fulfil their expectations that 'something will be done'.

2.1.3 A 'No Blame' Culture?

A 'no blame culture' is a curiously paradoxical entity in our society. One extreme view is that there are no errors in human fallibility, only system errors. Clearly humans can make errors because of all kinds of reasons, but the systems they work within should be capable of detecting and correcting them before they cause damage. On the other hand, there is a current societal demand for doctors to be made more individually and collectively responsible for their actions (for example, see the extensive debate over reforms to the General Medical Council in the UK[12-14]) with the threat of disciplinary actions for those who fail to maintain the standards of care that are demanded by the public (however those are measured). Should our systems be made to be so robust that even deliberate attempts to cause harm will be detected and prevented? Is that reasonable? Is detection and punishment of deliberate misdoing and negligence part of a safety system? How should instances of punishable errors be dealt with?

These are weighty issues, but they should be seen as a positive outcome of the aims of the Alliance, since I think these issues are badly dealt with in current society. In particular, doctors and other healthcare professionals are being put under increasing scrutiny for good performance and the provision of 'evidence' for such good performance without any clear debate on what is meant by 'good performance' and how it is measured. In the UK, the General Medical Council is grappling with these issues while also being under pressure to review and revise its own performance.[12-14] At the very least, the reporting of medical errors and near misses will provide some tangible information and the actions taken on such information will be even more informative.

2.1.4 Impact

The Alliance will need to help put into place some standards and procedures for the analysis of the impact of patient safety work. Pharmacovigilance has not been very active in assessing the impact of its efforts except in a crude way by counting the number of drugs withdrawn or changes made to drug product information. A few studies have been done on the impact of letters to healthcare professionals and have reported that 'Dear Doctor' letters result in very little change in prescribing habits. This is in contrast to the contained warnings that are usually of some considerable importance to medical practice.[15]

2.2 Relationship with Pharmacovigilance

2.2.1 The Background of Pharmacovigilance

Modern pharmacovigilance has been in existence since the 1960s. At that time, several countries and the WHO decided that the pooling of spontaneous reporting of clinical concerns about drugs by medical practitioners and, more recently, a broader health professional group and consumers (or patients), was a useful early warning tool to detect problems with drugs. The emphasis has been on finding new adverse drug reactions, particularly for new drug products. Reports of suspected adverse drug reactions are analysed, the early warning signals are derived and are sometimes subjected to further investigation. These activities may then lead to changes in the information that is enclosed with drug products, to changes in formularies, to scientific articles, to warning letters and to drug withdrawals.

Drug safety has been an unusual scientific discipline in that hypotheses have been generated from a structured review of the spontaneous reports and not

only from random, individual ideas as in other scientific endeavours. Hypotheses have been explored by epidemiological methods to measure public health impact and to give confirmation of the signal. Laboratory confirmation of signals has been less important. Over the years the science has grown and societies like the International Society of Pharmacovigilance and the International Society for Pharmacoepidemiology have fostered this growth.

2.2.2 Pharmacovigilance and Regulation

The collection of the adverse reaction reports has, in most countries, become an increasingly important part of drug regulatory affairs. The emphasis is more and more on the processes for getting the reports into confidential drug company and regulatory databases. This has led to pharmacovigilance being an esoteric practice. The cognoscenti involved, either on the regulatory side or within the industry, have operated in secrecy until recently. Even now there is a general view that only the select few should be involved in what is inappropriately often called 'signal generation' (as if signals are manufactured). The reasons given for this have been that early signals are not 'proved' and that public concern will be enhanced by making these uncertainties public. Moreover, there is a fear, and in some instances a reality, that litigation will ensue where there is even suspected damage from a drug and it is certainly true that the legal proof of injury is based on different premises to those assumed in pharmacovigilance.[16]

It seems in the industry and amongst regulators that the implied corollary to this fear of litigation and public panic over drug-induced injury is that the fewer people that have the knowledge of possible adverse effects of drugs, the better. This is to be contrasted with the relative non-involvement of regulators in initiating and supporting the essential, more focussed and often epidemiological work on the further elaboration of a signal. This work is often done by independent research groups in a largely unstructured way, which leads to delays in getting definitive answers to the hypotheses raised by the early signals.[17,18]

2.2.3 Secrecy or Communication?

The media and public are often concerned, and rightly so, about the culture of secrecy surrounding adverse event reporting evaluation and decision making and have a distrust of experts who are not perceived to be accountable or even trustworthy. Some would have all the information freely available, even when considerable doubt as to its veracity exists. However, the sensitivities of many people (often vulnerable patients), who prefer simply to trust and do not wish to deal with uncertainty, must be considered.

It seems to me that the science of patient safety, as envisaged by the Alliance, is the antithesis of secrecy. In the presentations made by the Alliance staff so far, much has been made of the need to openly admit error and blame. Certainly the current strong consumer involvement in the Alliance is totally committed to such an approach. There is, therefore, a risk that the general concerns that people have about medication errors and the safety of medicinal products would indeed be fuelled by more reports of problems that are made public. The Alliance will need to be aware that politicians, healthcare professionals and the pharmaceutical industry in different countries may be uncomfortable with this and that it will have to work hard with the media to make sure that the public have reliable and balanced information as is envisaged in the Erice Declaration.[19,20] They must also be seen to be active in investigating any safety issues and providing solutions.

The Alliance already has a precedent on its side in another area. The aviation industry has, for many years, used the process of open public enquiry about incidents. It also has a confidential reporting system for faults and near misses that do not lead to any incident, but are thoroughly investigated. This infor-

mation appears in the media and does not seem to lead to undue and inappropriate public reaction. On the contrary, the aviation industry seems to enjoy the image of responsible and safe performance. Clearly a major difference between aviation safety and patient or drug safety is the frequency with which major catastrophes are reported in the media and the general complexity of the healthcare business. On the other hand, it is not immediately clear why the various systems that support healthcare *seem* to work so much less efficiently than that of the international airline industry! Some investigation of the differences and similarities of the two industries would be interesting, but it seems that it is at least possible to have an open system on errors/near misses and open enquiries about disasters, without it leading to public mistrust.

The follow up of patient case reports is core to the use of spontaneous reports. Many case reports do not have key information for an objective, remote analysis of the case and particularly the causal role of drug(s). Over the years, the pharmacovigilance discipline has worked hard to improve data quality and completeness, but with a generic, continuous monitoring system there are likely to be significant questions about important reports that arise after independent review. The Alliance will need to readdress this very important issue and find methods that encourage and facilitate the best data capture, since follow-up will be impossible in a confidential reporting system. If there is confusion, or worse, conflict between drug safety reporting and general patient safety reporting, it will be to the detriment of overall public health.

2.2.4 Cooperation or Confusion?

Ideally, it seems to me that there should be common oversight of both systems, if not a single organisation to cover both tasks. The potential for overlap in reporting is too great and the ensuing confusion would possibly deter reporters. Guidance as to what should be reported where, already exists, but experience, for example in the UK over the 'black triangle' guidelines, suggests that most health professionals do not follow or know about them.[21] This does not bode well for separate reporting systems.

Another area where close cooperation between pharmacovigilance and patient safety is essential, is in proposed solutions over risks. The messages from health authority patient safety groups over how to minimise drug risks, must be compatible with regulatory information, particularly the summaries of product characteristics (SPC) or equivalent. The problem is more than just giving consistent information from government sources because the SPC has an important legal status, particularly vis-à-vis the pharmaceutical companies' duty to warn. If the results of patient safety activity are new recommendations, they will need to be discussed very quickly to ensure consistency of official information.

If the coordination over solutions works well, this may lead to more practical information being given to healthcare professionals on how to avoid or minimise some drug safety problems. It may also be that the confidential reporting will encourage reports on how healthcare workers respond to the information they receive.

3. Conclusions

The World Alliance on Patient Safety has the aim of introducing the principles of safer healthcare to all countries around the world. An open culture of admission of concerns/faults, investigation and improvement is advocated.

There are bound to be inter-relationships with pharmacovigilance efforts. Careful consideration of the actual or potential overlaps in visions and goals, methods of operation and communication practices are necessary. They should be harmonised and made complimentary. Much good and essential improvement in safe healthcare delivery and in drug safety can result from the imaginative and wise use of this new enterprise.

Acknowledgements

I acknowledge the very useful input and the helpful, critical views of two colleagues: Professor Sir Liam Donaldson, Chairman and Ms. Pauline Philip, Programme Lead, both of the World Alliance for Patient Safety, World Health Organization, Geneva, Switzerland. No sources of funding were used to assist in the preparation of this study. The author has no conflicts of interest that are directly relevant to the content of this study.

References

1. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. BMJ 2001; 322: 517-9
2. Resolution WHA55.18. Quality of care: patient safety. In: Fifty-fifth World Health Assembly, Geneva, 13–18 May 2002. Volume 1: Resolutions and decisions. Geneva: World Health Organization; 2002. WHO document WHA55/2002/REC/1
3. Schioler T, Lipesak H, Pedersen BL, et al. Danish Adverse Event Study. Incidence of adverse events in hospitals: a retrospective study of medical records. Ugeskr Laeger 2001; 163: 5370-8
4. Davis P, Lay-Yee R, Briant R, et al. Adverse events in New Zealand public hospitals. I: Occurrence and impact [abstract]. N Z Med J 2002; 115: U268
5. Davis P, Lay-Yee R, Briant R, et al. Adverse events in New Zealand public hospitals. II: Preventability and clinical context [abstract]. N Z Med J 2003; 116: U624
6. Baker GR, Norton PG, Flintolf V, et al. The Canadian Adverse Events Study. The incidence of adverse events among hospital patients in Canada. Can Med Assoc J 2004; 179: 1678-86
7. Progress in essential drugs and medicines policy 1998–1999. Geneva: World Health Organization, 2000. WHO document WHO/EDM/2000.2
8. Issakov A. Health care equipment: a WHO perspective. In: van Grutting CWG, editor. Medical devices: international perspectives on health and safety. Amsterdam: Elsevier, 1994
9. Berwick DM, Leape LL. Reducing errors in medicine. Qual Health Care 1999; 8 (3): 145-6
10. World Alliance for Patient Safety: forward programme. Geneva: World Health Organization, 2004
11. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients: results of the Harvard Medical Practice Study II. N Engl J Med 1991; 324 (6): 377-84
12. Smith R. The GMC: expediency before principle. BMJ 2005 Jan 1; 330 (7481): 1-2
13. Twisselmann B. The GMC: expediency before principle: summary of responses [letter]. BMJ 2005 Jan 29; 330 (7485): 254
14. Dyer C. GMC must protect patients says government minister [letter]. BMJ 2005 Feb 5; 330 (7486): 271
15. van Grootheest AC, Edwards IR. Labelling and 'Dear Doctor' letters: are they noncommittal? Drug Saf 2002; 25 (15): 1051-5
16. Dyer C. Judge dismisses test case on third generation pill [letter]. BMJ Aug 2002; 325: 237
17. Lindquist M, Edwards IR, Bate A, et al. From association to alert: a revised approach to international signal analysis. Pharmacoepidemiol Drug Saf 1999 Apr; 8 Suppl. 1: S15-25
18. Olsson S, Edwards IR. Tachycardia during cisapride treatment. BMJ 1992; 305 (6856): 748-9
19. Bowdler J. Effective communications in pharmacovigilance. Birmingham: W Lake Ltd, 1997
20. The Erice declaration: on communicating drug safety information [abstract]. Prescrire Int 1998 Dec; 7 (38): 191
21. Belton KJ, Lewis SC, Payne S, et al. Attitudinal survey of adverse drug reaction reporting by medical practitioners in the United Kingdom. Br J Clin Pharmacol 1995; 39 (3): 223-226

Correspondence and offprints: Professor *I. Ralph Edwards*, Uppsala Monitoring Centre, Stora Torget 3, S-75320 Uppsala, Sweden.
E-mail: ralph.edwards@who-umc.org