INTERNATIONAL MEDICATION SAFETY NETWORK POSITION PAPER ON PHARMACOVIGILANCE AND MEDICATION ERRORS

Adverse drug reactions and medication errors are two sides of the same coin: medication safety

Medication safety or, as expressed in other words, the reduction and/or prevention of adverse drug reactions and medication errors, relies on the reporting of both types of events by healthcare professionals, as well as on the analysis and evaluation of these events, that lead to the development and implementation of effective measures to reduce or prevent their recurrence.

Adverse drug reactions are monitored by well-established product safety organisations, such as the drug agencies, the regional and national pharmacovigilance centres, and the WHO Foundation Collaborating Centre for International Drug Monitoring.

In the last decade of the 20th century, medication error reporting systems (MERS) began to emerge following the initiative of safe medication practices centres (SMPC). Currently cooperating within the International Medication Safety Network, these systems serve to analyze and manage information about and prevention of medication errors. Medication errors are also being managed by patient safety incident reporting systems that gather information on all types of errors and unsafe conditions associated with health care services. These learning and reporting systems have resulted in undeniable public health benefits.

Frequent confusion and misunderstandings occur among healthcare professionals who have to report medication incidents, due to a lack of consistent terminology and an operative framework for medication incident reporting systems. This situation has become more complicated in the last few years due to the new regulations and legislative proposals that were developed in some countries. At the same time, risk identification, and, especially, the publication and implementation of measures for patient safety improvement by healthcare authorities, could be more beneficial and efficient if the medication error or patient safety incident reporting systems and the pharmacovigilance system were to join forces against preventable medication related risks.

Considering that the current situation at regional, national, and global levels leaves the management of patient safety at risk, the International Medication Safety Network urges to establish - in the best patients' interest - practical and complementary ways to support efficient collaboration between safe medication practices centres and pharmacovigilance centres.

Patient safety first!

No matter which medication safety organisations receive reports of an incident, each report is a treasure chest of information for public interest. It is a pity not to conduct an in-depth analysis of each adverse drug event since other patients will very likely be exposed to the same risks. Such deliberate unawareness of an adverse drug reaction or of the specific causes of medication errors puts other patients treated under the same conditions at risk a leads to a broader public health problem.

In order to avoid repetition of preventable adverse drug events, it is the duty of the organisations involved, be they public, independent, or non-profit safe medication practices centres, and of pharmacovigilance, to be as patient safety oriented as possible and to not only give feedback but to also share information and expertise in patients' best interest.

The time has come to build efficient working relationships between pharmacovigilance centres and safe medication practices centres, even if pharmacovigilance still must be strengthened (1,2). With such cooperation, information on medication safety will be better organised and managed in such a way as to be more efficiently utilized as a resource for learning how to develop medication use systems that are continually safer for patients.

Recognising complementary ways of reporting adverse drug events

Pharmacovigilance systems assess adverse pharmacological effects of drugs, as illustrated by algorithms developed to assist in identifying causative agents. However focusing on the product itself, rather than on drug use, does not permit problems to be identified all along the medication use system.

Medication error reporting systems scrutinize the risks of the medication use system, with particular attention to all associated practices. Special expertise is in place to facilitate root cause analysis of incidents. The centres receive reports of medication errors that have caused harm (preventable adverse drug events), and also of medication errors that did not cause harm, including potential adverse drug events, close calls and hazardous conditions. They receive, as well, information concerning the circumstances or events that may have led to errors. Causes of medication errors are multifactorial, involving both product and practice-related issues. Medication error reporting systems strive to develop prevention strategies aimed at the practice community, the organizations in which they work (e.g., hospitals, clinics, etc.) and they serve in an advisory capacity to regulatory authorities and the medical product industry. Mechanisms are available to rapidly communicate important information to the practice community.

Advancement and learning in pharmacovigilance and medication error prevention both depend on reporting. But this dependence on reporting does not imply that there should exist only one way of reporting both medication errors and suspected adverse drug reactions.

Although pharmacovigilance systems have been put in place to identify and manage adverse drug reactions, confidential, non-punitive and independent medication error reporting and learning systems are also being introduced and strengthened at all levels of the healthcare system, such as national independent centres for safe medication practices. They are being established in a collaborative, complementary, yet distinct way from pharmacovigilance systems (3).

Although adverse drug reactions are attributed to the properties of the medication itself rather than to the actions of professionals who use the medication (as with medication errors), the mindset of our culture tends to lay the blame, in many cases, on the healthcare professionals who use the medication. This is true even with errors ▶▶

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provoked by unclear labelling on a medicinal product. For all of these reasons, medication error reporting needs to be voluntary and the current legal framework must meet all requirements that guarantee anonymity and confidentiality. If these guarantees are not upheld, the likelihood of important errors not being reported to any system is only going to increase.

According to the World Health Organization (WHO) recommendations, successful patient safety incident reporting systems, encompassing medication error reporting systems, should be voluntary, non-punitive, confidential, independent, based on expert analysis, timely, system-oriented, and responsive (4). These principles were endorsed by the Recommendation Rec (2006)7 of the Council of Europe, which stipulates that such systems should: be non-punitive and fair in purpose; be independent of other regulatory or accrediting processes; offer enabling conditions for the healthcare providers and healthcare personnel to report safety incidents (such as voluntarism, anonymity, confidentiality, where applicable) (5).

Recognising complementary activities for medication risk management

An important problem when considering medication safety worldwide is that the different terms used for medication safety are not clearly defined and not used in the same way (6). A clear and consistent terminology should be established at an international level such that would permit accurate distinction between medication error and adverse drug reaction. This terminology should be provided to healthcare professionals and public health officers involved in pharmacovigilance as well as to those involved in patient safety, in order to properly report and manage each type of incident (7).

There is a need to establish a complementary design between the different medication error or patient safety incident reporting systems and the pharmacovigilance systems to avoid any confusion regarding what should be reported to each system. Otherwise, professionals who now are unclear as to what they need to report will continue to be in doubt as to where they should report patient harm related to medication, whether the harm be due to an adverse drug reaction or a medication error. For example, adverse drug events especially resulting from overdose may be the consequence of a medication error. Often, when these adverse effects are well known and caused by old medications, they are not reported to the pharmacovigilance systems since practitioners think that pharmacovigilance is only interested in unexpected or rare adverse drug reactions produced by newly registered medications. In fact, such serious adverse drug events resulting from medication errors should be submitted for specific analysis.

Establishing and strengthening co-operation between pharmacovigilance and safe medication practice centres

Co-operation between pharmacovigilance and medication error or patient safety incident reporting systems should be clearly described, particularly regarding the conditions and the nature of exchanges between these entities.

The International Medication Safety Network believes that medication error or patient safety incident reporting systems should be authorized to anonymously share with pharmacovigilance centres the reports involving preventable adverse drug events, in order to guarantee the confidentiality of healthcare staff. In this way, all suspected adverse drug events due to reported medication errors would be handled by the pharmacovigilance system along with adverse drug reaction reports. In these cases, the information available to the pharmacovigilance centres would be the same as that gathered by the medication error or patient safety incident reporting systems without obliging reporters to duplicate reporting or to face confidentiality breaches.

Medication error or patient safety incident reporting systems should especially inform the pharmacovigilance system and drug agencies of all serious adverse drug events observed as a consequence of reported medication errors, because these reports are fundamental to the necessary follow-up with marketing authorisations by regulatory authorities (drug agencies, healthcare authorities). In particular, serious adverse drug events resulting from errors related to naming, labelling and packaging of authorised drugs should stimulate regulatory authorities to reassess these particular risks.

Conversely, the medication error analytical expertise needed for avoiding recurrence of medication errors should lead national authorities to recognise established safe medication practice centres and to use the medication error analysts who work with them as key resources for patient safety improvement. Excellent models exist for such a relationship (8).

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The International Medication Safety Network (IMSN) is an international network involving the main programmes for safe medication practices, the aims of which are to prevent medication errors and contribute to safer healthcare.
Established by the "Salamanca Declaration to promote safe medication practices globally" in November 2006, this specific network aims at promoting and reinforcing cooperation between independent, multidisciplinary programmes for safe medication practices (http://www.intmedsafe.net/about.php).

1- International Society of Drug Bulletins EU "Berlin Declaration on Pharmacovigilance" January 2005 http://www.prescrire.com/docus/BerlinDeclaration.pdf
2- International Society of Drug Bulletins, Medicines in Europe Forum "Pharmacovigilance in Europe: the European Commission's proposals endanger the population" October 2009 http://www.prescrire.org/docus/En_PharmacovigBriefingNoteOct2009.pdf
3- International Network of Safe Medication Practice Centres (INSMPC) "Salamanca Declaration to promote safe medication practices globally" November 2006 http://www.intmedsafe.net/SalamancaDeclarationINSMPC.pdf
4- World Alliance for Patient Safety WHO Draft guidelines for adverse event reporting and learning systems: from information to action. World Health Organization 2005; 77 pages. http://www.who.int/entity/patientsafety/events/05/Reporting_Guidelines.pdf
5- Council of Europe "Recommendation Rec(2006)7 of the Committee of Ministers to member states on management of patient safety and prevention of adverse events in healthcare" 24 May 2006 https://wcd.coe.int/ViewDoc.jsp?id=1005439
6- Council of Europe Expert Group on Safe Medication Practices "Creation of a better medication safety culture in Europe: Building up safe medication practices" Preliminarily version available as from 19 March 2007: 257 pages. http://www.edqm.eu/medias/fichiers/Report_2006.pdf
7- Medication errors are linked to the safety of health care service, whereas adverse drug reactions are linked to product safety. This distinction between safety of practices and product safety was clearly assumed by the Resolution WAH55.18 "Quality of care: patient safety" adopted by WHO's 55th World Health Assembly on 18 May 2002 http://apps.who.int/gb/archive/pdf_files/WHA55/ewha5518.pdf and its associated report http://apps.who.int/gb/archive/pdf_files/WHA55/ea5513.pdf.
8- In the United States of America, all medication error reports received by the Institute for Safe Medication Practices (ISMP) are shared automatically with the US Food and Drug Administration and vice versa (any information regarding identity of reporters, their organizations, patient and practitioner names, etc. is redacted before sharing). In the Canada, Health Canada relies on the expertise of ISMP Canada for analysis of reports of some serious preventable adverse drug reactions. In England and Wales, the National Patient Safety Agency shares reports and learning with the Medicines and Healthcare products Regulatory Agency (MHRA).