3rd Annual Symposium on Pharmacovigilance

Challenges in Pharmacovigilance and Drug Safety

Programme Book

19 March 2012

Kai Chong Tong, Postgraduate Education Centre
Prince of Wales Hospital, HONG KONG

Organisers

Centre for Food and Drug Safety
Faculty of Medicine
The Chinese University of Hong Kong

Department of Health
The Government of the Hong Kong SAR

Co-organiser

Medication Safety Committee
Hospital Authority, Hong Kong

Supported by:

ISoP

Division of Clinical Pharmacology
Department of Medicine and Therapeutics

School of Pharmacy CUHK

Welcome message from the Permanent Secretary for Food and Health (Health)

On behalf of the Food and Health Bureau, I warmly welcome you all to the Third Annual Symposium on Pharmacovigilance. Building on the success of the symposia held in 2010 and 2011, this year's symposium with the theme "*Challenges in Pharmacovigilance and Drug Safety*" comes at a right time, allowing health care professionals, academics, researchers and government officials to share ideas with one another on matters relating to pharmacovigilance, risk management and effective drug safety monitory systems. I congratulate the Organising Committee for hosting this meaningful event.

Pharmacovigilance involves monitoring the safety of drugs and formulating effective strategy to reduce risks and increase benefits associated with their use. As the number of drugs and the complexity of therapeutics increase, pharmacovigilance plays an increasingly vital role for optimizing drug treatment and management of adverse drug effects. The Government has all along been committed to strengthening drug regulation in Hong Kong to ensure that only medicines that are safe, efficacious and of good quality are made available to patients. Close collaboration and continuous commitments among key players in the pharmaceutical industry are also important in maintaining the high standard of drug safety in Hong Kong. To this end, we continue to count on your support in pharmacovigilance to safeguard the well-being of patients.

The Third Symposium will provide an ideal platform for all participants to share new knowledge and vision for the future of pharmacovigilance and drug safety. Once again, I extend my heartiest appreciation to the Organising Committee for coming up with such a comprehensive programme and wish the Symposium great success.

Mr. Richard M.F. Yuen, JP
Permanent Secretary for Food and Health (Health)
The Government of the Hong Kong SAR

Welcome message from the President of ISoP

On behalf of the ISoP Executive Committee, it is a great pleasure to continue to collaborate in the Third Annual Symposium on Pharmacovigilance, 19 March 2012 in partnership with the Chinese University of Hong Kong, and Department of Health.

At ISoP, our interests have and continue to be the provision of training and the development of tools and strategies to ensure that medicines are safe and that patients and health professionals use these medicines safely and rationally. By encouraging research in pharmacovigilance, promoting regular exchange of information through symposia and workshops and by contributing to education on drug safety, ISoP provides significant scientific and professional leadership to all working the field of drug safety. The global nature of our membership and our frequent interactions with global normative and technical agencies ensures that ISoP maintains a broad global view of all issues on drug safety with significant inputs from both developed and developing countries. We are therefore pleased about the initiatives in Hong Kong and warmly congratulate the organizers.

We sincerely hope you will enjoy this informative programme and you will have a great opportunity to learn from the work of some of the best international experts in Pharmacovigilance and share experiences with friends and colleagues.

Prof. Alexander Dodoo
President
International Society of Pharmacovigilance

Welcome message from the Chairman of the Organising Committee

On behalf of the Organising Committee, we would like to extend our warmest welcome to all colleagues attending the Third Annual Symposium on Pharmacovigilance on 19 March 2012. This Annual Symposium has been held in Hong Kong since 2010 to emphasise the importance of pharmacovigilance in ensuring the safe use of medicines in everyday practice and to promote the safe, rational and more effective use of medicines. The Symposium is jointly organised by the Centre for Food and Drug Safety, Faculty of Medicine, the Chinese University of Hong Kong, the Department of Health and the Medication Safety Committee, Hospital Authority of Hong Kong, with full support from the International Society of Pharmacovigilance and the Division of Clinical Pharmacology, Department of Medicine and Therapeutics and the School of Pharmacy, the Chinese University of Hong Kong.

Drugs provide significant health benefits in the prevention and treatment of diseases and by improving the quality of life of patients. Drugs that reach the market should have favourable benefit-risk profiles, meaning that the benefits (when the drugs are used for the approved indications and dosages in the appropriate patients) outweigh the risks of adverse effects. In general, more information is needed about use in certain subject groups (e.g. the elderly) and their effectiveness and safety in real-life situations, especially when other drugs are also used and genetic factors are important. In order to maximise benefits and prevent harm to the patients, national systems, with full involvement of all stakeholders, to ensure the safe use of medicines are vital. Pharmacovigilance is the process and science of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicines. It is an important component of effective drug regulatory system, clinical practice and public health function.

This one-day Symposium will address the current challenges in pharmacovigilance and drug safety. We greatly appreciate the contributions from the renowned speakers, who agree to share their expertise with the participants. The Symposium will also provide the participants with the opportunity to share ideas how we can work together to meet the needs for safe and effective medicines and to optimise safe and effective use of medicines.

We wish to thank all the speakers, chair persons, participants and the supporting organisations for their contributions to the success of this Symposium.

Prof. Thomas Y.K. Chan, JP
Chairman, Organising Committee
Director, Centre for Food and Drug Safety, Faculty of Medicine, CUHK

Organisers, Co-organiser and Supporting Organisations

Organisers

Centre for Food and Drug Safety, Faculty of Medicine
The Chinese University of Hong Kong

Department of Health
The Government of the Hong Kong SAR

Co-organiser

Medication Safety Committee
Hospital Authority, Hong Kong

Supporting Organisations

International Society of Pharmacovigilance

Division of Clinical Pharmacology, Department of Medicine and Therapeutics
The Chinese University of Hong Kong

School of Pharmacy
The Chinese University of Hong Kong

Organising Committee and Secretariat

Organising Committee

Prof. Thomas Y.K. Chan, JP (Chairman)

Dr. Jones C.M. Chan
Ms. Anna Lee
Prof. Hervé Le Louet
Prof. Brian Tomlinson
Ms. Suet Li Yuen
Dr. Heston Kwong
Prof. Vincent H.L. Lee
Dr. Joseph Lui
Ms. Linda Woo
Dr. Raymond S.M. Wong (Secretary)

Secretariat

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Target Participants

Health care professionals involved in pharmacovigilance and drug safety, regulatory affairs, public health, risk management, quality assurance, drug safety research and clinical trials, DTC members, DSC members, academics and pharmaceutical associates

Faculty

Prof. Thomas Y.K. Chan

Director, Centre for Food and Drug Safety, Faculty of Medicine, and

Director, Prince of Wales Hospital Poison Treatment Centre, and

Professor, Division of Clinical Pharmacology

Department of Medicine and Therapeutics

The Chinese University of Hong Kong

Prof. Vivian W.Y. Lee

Associate Professor, School of Pharmacy

The Chinese University of Hong Kong

Prof. Hervé Le Louet

Head, Department of Pharmacovigilance

The University Paris-Est Créteil, France, and

Head, Pharmacovigilance and Risk Management Department

Henri Mondor University Hospital (AP-HP), France, and

Chairman of Education and Training Program

International Society of Pharmacovigilance (ISoP)

Dr. Wilson Y.S. Leung
Pharmacist, Pharmacy Department
Queen Elizabeth Hospital, Kowloon
Hong Kong

Dr. Sian C.S. Ng
President
The Hong Kong Association of the Pharmaceutical Industry

Dr. Joanna S.K. So
Senior Medical and Health Officer (Drug)
Department of Health
The Government of the Hong Kong SAR

Prof. Brian Tomlinson
Professor of Medicine and Therapeutics, and
Head, Division of Clinical Pharmacology
Department of Medicine and Therapeutics
The Chinese University of Hong Kong

Prof. Ian C.K. Wong
Head, Department of Pharmacology and Pharmacy
The University of Hong Kong

Dr. Raymond S.M. Wong
Consultant Physician
Prince of Wales Hospital Poison Treatment Centre, and
Division of Clinical Pharmacology
Department of Medicine and Therapeutics
The Chinese University of Hong Kong

Programme

8:30 – 9:00 REGISTRATION

9:00 – 9:05 Welcome Remarks

Prof. Thomas Y.K. Chan, JP
Chairman, Organising Committee, and
Director, Centre for Food and Drug Safety

9:05 – 9:15 Opening Address

Mr. Richard M.F. Yuen, JP
Permanent Secretary for Food and Health (Health)
The Government of the Hong Kong SAR

9:15 – 11:00 Keynote Lectures – Importance of Pharmacovigilance and Drug Safety

Chair Persons:
Prof. Bernard M.Y. Cheung
Dr. Joseph Lui

9:15 – 10:15 Importance of Pharmacovigilance and Risk Management

Prof. Hervé Le Louet

10:15 – 11:00 Promoting Drug Safety – Need for Training of Prescribers

Prof. Brian Tomlinson

11:00 – 11:15 TEA BREAK

11:15 – 13:00 Progress in Pharmacovigilance and Drug Safety

Chair Persons:

Dr. Heston Kwong

Dr. Raymond S.M. Wong

11:15 – 11:45 Systems to Monitor Drug Safety – Hong Kong Perspectives

Prof. Thomas Y.K. Chan

11:45 – 12:15 Pharmacovigilance in Hong Kong – Need for Change and Improvement

Dr. Joanna S.K. So

12:15 – 12:45 Pharmacovigilance in Europe – The New Deal

Prof. Hervé Le Louet

12:45 – 13:00 Questions and Answers

13:00 – 14:00 LUNCH

14:00 – 15:45 Improving Pharmacovigilance and Drug Safety

Chair Persons:

Prof. Brian Tomlinson

Prof. Ian C.K. Wong

14:00 – 14:30 Role of the Qualified Person Responsible for Pharmacovigilance

Dr. Sian C.S. Ng

14:30 – 15:00 Role of the Pharmacists in Pharmacovigilance and Drug Safety

Prof. Vivian W.Y. Lee

15:00 – 15:30 **Patients' Involvement in Drug Therapy and ADR Reporting**

Dr. Wilson Y.S. Leung

15:30 – 15:45 **Questions and Answers**

15:45 – 16:00 TEA BREAK

16:00 – 17:25 **Current Topics in Drug Safety**

Chair Persons:

Prof. Thomas Y.K. Chan

Prof. Vincent H.L. Lee

16:00 – 16:30 **Proactive Pharmacovigilance and Prevention of Adverse Drug Events Using Computerised Physician Order Entry**

Dr. Raymond S.M. Wong

16:30 – 17:10 **Worldwide Pharmacovigilance Using the WHO Global Individual Case Safety Report Database, VigiBase**

Prof. Ian C.K. Wong

17:10 – 17:25 **Questions and Answers**

17:25 – 17:30 **Closing Remarks**

Prof. Hervé Le Louet

Prof. Brian Tomlinson

Importance of Pharmacovigilance and Risk Management

Prof. Hervé Le Louet, The University Paris-Est Créteil, France

In the seventies use of thalidomide led to one of the most prominent disasters in the history of drug development. This catastrophe initiated a change of paradigm in the world with regard to drug safety. Quickly after, a global system called pharmacovigilance was implemented in different parts of the world. Pharmacovigilance concerns the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem (WHO 2002).

The pharmacovigilance system, based on signal detection, spontaneous reporting and methods for causality assessment of ADRs will be also presented.

Today, the aim of pharmacovigilance is an ongoing assessment of the benefit risk balance of medicinal product at any stage of the lifecycle and the use of spontaneous reporting, pharmacoepidemiological studies and clinical pharmacology.

The only use of spontaneous reporting may lead to extreme regulatory decisions with product withdrawal and delay or refusal of marketing.

There is no efficient drug on the whole population or risky for the whole population. Therefore, the concept of global drug risk management with implementation of Risk Management Plan appeared in the early 2000 and will be mandatory for all new drugs in July 2012. The goal is to define an early (pre-approval) and pro-active approach in order to ensure that the benefits always outweigh the risks during all the lifecycle of the drug and to better target the drug in sub-population with a high benefit risk balance.

Several approaches (EU, EMA and FDA) have been developed in the frame of ICH recommendations.

But can a global risk management plan be considered for all countries?

Promoting Drug Safety – Need for Training of Prescribers

Prof. Brian Tomlinson, The Chinese University of Hong Kong, Hong Kong

It is commonly believed that the modern medical curriculum will produce new doctors who are well trained in prescribing drugs in addition to all the other skills required to practice medicine. However, a recent study of newly qualified doctors in the United Kingdom which tested 8 areas of prescribing ability from the core curriculum found that in groups from some UK medical schools less than half of them could answer some of the questions correctly. It is likely the findings would be similar in Hong Kong and many other countries. Simple things like the importance of writing legibly and using the generic names for drugs are taught from an early stage but medical students are not tested for their handwriting ability and the use of brand names flourishes in the public hospitals and is the norm in the private sector in Hong Kong. Many of the prescribing problems can be overcome by the use of computerized prescribing systems, but these can never be perfect and must not be considered as a substitute for the proper training of prescribers. Sophisticated computer systems could help to determine the appropriate dosage for individual patients with conditions such as renal impairment or help to calculate paediatric dosages. They can also identify potential adverse drug interactions and warn the prescriber, assuming all the relevant data are in the system. Unfortunately, there is sometimes a delay in the accumulation of information about adverse drug interactions for regulatory authorities to make informed decisions and for this information to be officially entered into the computer system so informed prescribers could take preventative action at an earlier stage. Furthermore, computerized prescribing systems will not usually identify inappropriate selection of drugs unless there is a well known drug interaction or a requirement for a specific safety test, such as HLA-B*1502 screening before prescribing carbamazepine.

Prescribing errors still occur frequently and there are many issues which are considered as causes or contributing factors. Some of these are related to adequate knowledge and training but there are additional problems related to the work environment. Although it is well recognized that excessive workload and fatigue of junior doctors is likely to result in more medical errors, there is a common misapprehension that a good measure of efficiency of a medical doctor is how quickly they can deal with each patient and it sometimes becomes a race to find who can see the largest number of patients in the shortest time in the clinic. Such practices typically result in increasing polypharmacy and risks of adverse drug interactions, inappropriate drug usage and prescription errors.

Overall, it is essential to continue to improve the training of prescribers and to ensure that the working environment is conducive to preventing errors. It is important to have time to check and recheck at every stage of the prescribing and administration of drugs and the learning of safe and effective prescribing is one of the essential life-long learning skills that must be acquired by all medical graduates.

Systems to Monitor Drug Safety – Hong Kong Perspectives

Prof. Thomas Y.K. Chan, The Chinese University of Hong Kong, Hong Kong

Before a drug is marketed, information on its safety and efficacy is limited to its use in clinical trials. However, the conditions under which patients and drugs are studied in clinical trials do not necessarily reflect the way the drugs are used in real-life situations after they are marketed. At the time of its licensing, a drug has only been studied in a relatively small number of patients for a limited length of time. Drug safety information is also limited in certain subject groups (e.g. children, pregnant women, the elderly, subjects with renal/liver disease or polypharmacy). It is vital that the safety of all drugs is monitored throughout their use ("life cycle") in clinical practice. Post-marketing surveillance is important for providing additional safety information on drugs,

Since 1986, the drug safety research centre based at the Chinese University of Hong Kong has been evaluating the information sources used for pharmacovigilance and the systems to monitor drug safety in Hong Kong. These include spontaneous adverse drug reaction (ADR) reporting scheme, hospital and community-based studies, pharmacoepidemiological studies, morbidity and mortality databases, published medical literature, worldwide regulatory authorities and pharmaceutical companies. Spontaneous reporting remains the only feasible and inexpensive method to monitor drug safety. To improve ADR reporting, it is important to convince the health care professionals of its importance by publicity campaigns. It will be useful to study their attitude and knowledge on ADR reporting. Another key factor is having immediate and easy access to a means of reporting ADRs in hospitals and the community. Information from these sources may identify unexpected side effects. If necessary, the regulatory authority may take action to ensure that the drug is used in a way which minimises risks and maximises benefits to the patient.

Since 2005, health care professionals are encouraged to report ADRs to the Department of Health. In late 2009, one of the key initiatives recommended by the Review Committee on Regulation of Pharmaceutical Products was to enhance pharmacovigilance among health care professionals and the pharmaceutical industry. In 2011, the Pharmaceutical Service in the Department of Health was expanded and reorganised into the Drug Office to strengthen the organisational capacity in drug regulation and pharmacovigilance. These developments will help strengthen the systems to monitor drug safety in Hong Kong.

Pharmacovigilance in Hong Kong – Need for Change and Improvement

Dr. Joanna S.K. So, Department of Health, The Government of the Hong Kong SAR

Pharmacovigilance is the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. In Hong Kong, the regulation of pharmaceutical products is essentially governed by the Pharmacy and Poisons Ordinance (Cap 138) (PPO) and implemented through a two-tier monitoring at pre-market and post-market levels.

For pre-market control, it is stipulated in the PPO that all pharmaceutical products in Hong Kong must be registered with the Pharmacy and Poisons Board, the statuary body under the PPO, before they can be sold in Hong Kong. Only products with proven safety, quality and efficacy will be registered and these data are mainly collected from clinical trials. However, as clinical trials usually test medicines for their short-term safety on limited number of selected subjects, they cannot detect all Adverse Drug Reactions (ADRs) of pharmaceutical products.

Post-market pharmacovigilance activities aim to safeguard the health of public by early detection and prevention of hazards related to use of medicines after the product has been released into market. Similar to other countries, spontaneous reporting of ADR is an essential component of the pharmacovigilance in Hong Kong. In the 80's, some clinicians began to collect and analyse ADRs in a teaching hospital which later has extended to cover the whole territory. In 2005, the Department of Health (DH) established an ADR Monitoring System to collect ADRs from healthcare professionals including doctors, Chinese medicine practitioners, dentists and pharmacists. The reports are assessed by professional staff for appropriate follow-up actions. Despite the promotion by health professionals and the DH, the ADR reporting rate is low compared with those of the developed countries. It is difficult to generate significant signals from this data for further follow-up actions.

Drug safety problems are not limited to ADR. Reports on cases of suspected health damage due to consumption of products adulterated with Western medicines are received. With the popularity of Internet, problematic products are sometimes found to be sold on the Internet. Furthermore, drug safety issues identified in other places of the world may also affect the risk management of locally available pharmaceutical products.

In response to the recommendations from the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong, the Government took the initiatives to reorganise the Pharmaceutical Service of DH into the Drug Office to enhance the organisation capacity in

drug regulation in September 2011. The Pharmacovigilance and Risk Management Division has been established under the Drug Office to strengthen the pharmacovigilance activities to meet the local needs. DH adopts a multidisciplinary approach to maintain its pharmacovigilance work, conduct risk analysis on ADR reports received and formulate risk management plans.

Pharmaceutical companies are required to provide Risk Management Plans (RMP) or Risk Evaluation and Mitigation Strategy (REMS) imposed on the drug by other drug regulatory authorities and indicate whether these plans will be adopted in Hong Kong during registration of pharmaceutical products containing a new chemical entity.

On post-marketing, Drug Office has enhanced the ADR collection by making reporting available on-line. Pharmaceutical companies are requested to report any serious and unexpected ADRs related to registered products received and submit relevant safety reports to the DH. Besides, DH will continue to promote pharmacovigilance and ADR reporting among healthcare professionals and pharmaceutical industry.

To cope with the local needs, the scope of pharmacovigilance has been broadened to cover various products such as health products with undeclared western medicines and substandard medicines, as well as issues like poisoning. Announcements from overseas drug regulatory authorities are closely monitored to keep abreast of the global drug safety information. Upon identification of important drug safety information, DH will communicate with the healthcare professionals and the public as appropriate. These information will be summarised in a monthly bulletin, *the Drug News*, as a reference for relevant stakeholders.

DH will continue to closely liaise with local stakeholders and overseas health authorities to face the challenges and to improve the pharmacovigilance activities in Hong Kong. Dedication and continuous support by relevant stakeholders will be essential to achieve the ultimate success in pharmacovigilance in Hong Kong.

Pharmacovigilance in Europe – The New Deal

Prof. Hervé Le Louet, The University Paris-Est Créteil, France

A new European legislative framework on pharmacovigilance with a directive (2010/84/EU) and a regulation (1235/2010) came into force in December 2011 and shall be applied in July 2012.

The overall aim of the legislative framework is to improve the postmarketing safety of medicinal products in the European Union (EU). Therefore, responsibilities and obligations for the different stakeholders (EMA, Marketing Authorisation Holder and Member States) are clearly defined and all of them have to include patient in the decision making process.

The EMA will have to set up the PRAC (Pharmacovigilance Risk assessment Committee) for procedures and mandates, coordinate the assessment of PSUR and Post Authorization Safety Study (PASS), maintain a web portal and restructure its databases.

MAH will have to keep a pharmacovigilance master file (PSMF), to assess the benefit-risk balance in its PSURs instead of providing line listing and to provide the possibility of conducting PASS as well as Post Authorisation Efficacy Study (PAES).

The decision-making process will be modified because patient is more involved in the pharmacovigilance system with the direct patient reporting of suspected adverse drug reactions and with the conducting of public hearings. Transparency and communication are improved with a setting up of an EU and national web portals to better inform the public on drug safety. These web portals are publically available and show the list of intensively monitored products and drugs safety announcements.

The new proposed pharmacovigilance system should have a major impact on the pharmaceutical industries and on the EU regulators.

The EU will have a comprehensive set of tools to ensure greater safety for patients.

Role of the Qualified Person Responsible for Pharmacovigilance

Dr. Sian C.S. Ng, The Hong Kong Association of the Pharmaceutical Industry, Hong Kong

The aims of pharmacovigilance within the pharmaceutical industry are essentially the same as regulatory bodies; that is to protect patients from unnecessary harm by identifying previously unrecognized drug hazards, clarifying pre-disposing factors, identifying safety signals and quantifying risk in relation to benefit. Although the perspectives of companies and the regulatory agencies may be different, pharmaceutical companies are now working more and more closely with regulatory bodies in this area. Major pharmaceutical companies invest heavily in pharmacovigilance because patient safety is the most important concern of the industry.

Pharmaceutical companies continuously develop, improve, and search for new ways of detecting, evaluating, understanding, and preventing adverse drug reactions. From the views of pharmaceutical companies, pharmacovigilance also covers a number of disciplines such as self-medication, counterfeit drugs, contamination and production error, and resistance development.

Thus the role of pharmacovigilance team is pivotal in pharmaceutical company. They will need to ensure the highest standards of public safety for medicinal products. Typically, the team involves in receiving, processing and reporting of adverse event reports; following up with reporters to obtain further details; providing information service to healthcare professionals and patients on product safety, and providing safety expertise to internal cross-functional colleagues.

Nevertheless, a satisfactory pharmacovigilance system is more than documentation, coding, assessment and signal detection. It requires an understanding of how all the pieces fit together. A qualified pharmacovigilance expert should therefore be a specialist that goes beyond the tasks and systems to focus on people. After all, pharmacovigilance is about the people and patients that the industry serves.

Role of the Pharmacists in Pharmacovigilance and Drug Safety

Prof. Vivian W.Y. Lee, The Chinese University of Hong Kong, Hong Kong

Drug safety is important to all drug users. The delivery of the proper medications to our patients is vital to maximize clinical efficacy and minimize adverse events as well as toxicity. Inter-individual responses to medications are expected in certain medications. How can we ensure we will deliver the most appropriate medication to our patients? Pharmacists can be part of the answer. We are currently still facing a lot of challenges and issues for drug safety.

The rapidly aging population demands a system that promotes better healthcare by decreasing morbidity and mortality in our community. Over 50% of our elder subjects had multiple chronic diseases including hypertension, diabetes and hypercholesterolemia that required both pharmacological interventions and lifestyle modifications. In our previous pharmacy outreach project, more than half of subjects had polypharmacy. Over 80% of them had drug-related problems including those stemming from non-compliance, adverse drug reactions (ADRs), sub-optimal drug storage, and/or drug-drug/drug-traditional Chinese medicine interactions; there were also cases of ineffective drug regimens. Elder subjects or their caregivers may not know how to correct or seek help when facing those drug-related problems. There are many drug-related problems faced by our patients. How can we as pharmacists to help?

In this presentation, the following topics will be discussed:

1. The current issues of drug safety;
2. Roles of pharmacists in pharmacovigilance drug safety;
3. The challenges of faced by pharmacists to ensure medication safety.
4. The possible solutions to address the needs of drug safety.

Patients' Involvement in Drug Therapy and ADR Reporting

Dr. Wilson Y.S. Leung, Queen Elizabeth Hospital, Hong Kong

Patients play an increasingly important role in their drug therapy. The term "compliance", which indicates "the extent to which the patient follows the health professionals' advice and takes the treatment", has well illustrated the traditional approach where patients are expected to be passive and obedient. In recent years, the terms "adherence" and subsequently "concordance" have been advocated to replace the term "compliance". Such changes have highlighted the growing emphasis on the patients' involvement in drug therapy including an informed, shared decision-making process.

The patients' and health professionals' awareness of adverse drug reactions (ADR) is of vital importance in clinical practice. An increased awareness of and enhanced communication on ADR not only may improve patient's drug adherence, but also promote rational prescription practices, thereby decreasing the burden of drug side effects.

As far as the detection of ADR is concerned, spontaneous reporting system has been one of the most widely used methods. In many countries, ADR reporting is restricted to health professionals, primarily including doctors and, in some, also pharmacists and nurses. Nevertheless, it is recognized that there is substantial under-reporting of ADR by healthcare professionals. In recent years, patient reporting of ADR has become an important topic of debate. Patient reporting has been incorporated into the pharmacovigilance systems in an increasing number of countries, including the USA, Canada, Australia, New Zealand, UK, Denmark, Sweden and the Netherlands. For instance, in the UK, patients have been allowed to directly report suspected ADR to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card Scheme since 2005.

Direct reporting of ADR by patients may offer several benefits from the perspective of pharmacovigilance. For example, it has the potential to offset the problem of under-reporting, thereby increasing the statistical power for signal detection. It also enables a better understanding of the patients' experience of ADR without filtering or interpretation by health professionals. There are though some practical concerns such as the possible duplication of reports of the same ADR, creation of background "noise" that could distract the signal detection, the burden of data interpretation, and potential system misuse, etc. Overall, the experiences with patient reporting from different countries seem to be favourable so far, although the reporting methodology has to be further optimized. Reference could be drawn to these overseas experiences with the local situation taken into account in the long-term enhancement of the pharmacovigilance system in Hong Kong.

Proactive Pharmacovigilance and Prevention of Adverse Drug Events Using Computerised Physician Order Entry

Dr. Raymond S.M. Wong, Prince of Wales Hospital Poison Treatment Centre, Hong Kong

In a world of greater and growing medication complexity it is important to ensure safe and effective use of medications. This requires effective monitoring to identify patients that may be at risk for adverse drug events, or to identify those patients who have experienced adverse events from their medications.

Computerised Physician Order Entry (CPOE) can help to prevent medication errors at the time of order entry by the clinician. CPOE with Clinical Decision Support System (CDSS) has been proven to improve patient safety. Most of the benefits of the CPOE system result from integrated clinical decision support tools for drug overdoses, interactions, allergies, etc. These tools can provide real time alerting and warning to prescribers.

With the widespread use of electronic medical records (EMR), a large number of data, including details such as smoking, symptoms and signs, and laboratory data can be collected. Such large number and detail of the variables can be combined to generate new diagnoses or adverse events. Quantitative techniques are being developed to facilitate the signal detection process to enable a more detailed analysis of patient characteristics, drugs and the ADRs involved, thus enhancing the quality and widening the scope of pharmacovigilance.

Worldwide Pharmacovigilance Using the WHO Global Individual Case Safety Report Database, VigiBase

Prof. Ian C.K. Wong, The University of Hong Kong, Hong Kong

VigiBase™ is the name of the World Health Organization (WHO) global Individual Case Safety Report (ICSR) database; it consists of reports of adverse reactions received from member countries since 1968. VigiBase is updated with incoming ICSRs on a continuous basis. The VigiBase data resource is the largest and most comprehensive in the world, and it is developed and maintained by the Uppsala Monitoring Centre (UMC) on behalf of the WHO. VigiBase is a computerised pharmacovigilance system, in which information is recorded in a structured, hierarchical form to allow for easy and flexible retrieval and analysis of the data. The case reports in the WHO database do not identify the patient or reporter. Its purpose is to provide the evidence from which potential medicine safety hazards may be detected [1]. I will share my experience in working with the UMC in using the Vigibase for a paediatric pharmacovigilance study.

[1] VigiBase. http://who-umc2010.phosdev.se/DynPage.aspx?id=98082&mn1=7347&mn2=7252&mn3=7322&mn4=7326 (Access on 28/02/2012)