2011 Joint Conference of Drug Safety Research Centres • 2011 藥物安全研究中心聯合會議

Strategies to Ensure Medicine Safety and Quality

15 November 2011

Shaw Auditorium, Postgraduate Education Centre
Prince of Wales Hospital, Shatin, Hong Kong

PROGRAMME BOOK

Organisers

- **Centre for Food and Drug Safety**
  Faculty of Medicine, The Chinese University of Hong Kong
- **Department of Pharmacovigilance**
  The University of Créteil Paris XII
  Henri Mondor Hospital, Créteil, France
- **School of Pharmacy**
  The Chinese University of Hong Kong
- **The Nethersole School of Nursing**
  The Chinese University of Hong Kong
- **Department of Health**
  The Government of the Hong Kong SAR
- **Medication Safety Committee**
  Hospital Authority, Hong Kong
- **Prince of Wales Hospital Poison Treatment Centre**
  Hong Kong

Welcome message from the Director of Health

It gives me great pleasure to extend a warm invitation to you to attend the 2011 Joint Conference of Drug Safety Research Centres. This annual conference provides a platform for health care professionals and the Drug Safety Research Centres in Hong Kong, Europe and other regions to exchange knowledge and discuss the strategies to ensure the safety and quality of medicines in the market and the effective and safe use of medicines.

It is the responsibility of the Government to ensure the availability of good quality, safe and effective medicines and promote their rational use in various clinical settings. As repeatedly emphasised by the World Health Organization, the most important system to ensure medicine safety, quality and effectiveness is to establish a strong, nationwide regulatory authority and pharmacovigilance programmes for the monitoring and reporting adverse drug reactions. To strengthen the organisational capacity in drug regulation and pharmacovigilance in Hong Kong, the Pharmaceutical Service in the Department of Health was expanded and reorganised into the Drug Office on 1 September 2011.

The immense tasks of ensuring medicine safety and quality and rational drug use require the close and effective collaboration between the Government, health care professionals, hospitals, professional organisations, pharmaceutical industry, patients and drug information centres. As for the safe, effective use of medicines, all health care professionals should also have a good understanding of allergic reactions to commonly used drugs and the importance of pharmacogenetics and evidence-based pharmacotherapy. The topics covered in this Joint Conference are of great importance to their daily practice.

Given the importance of medicine safety and quality and rational use of medicines, I would encourage all health care professionals to attend this annual Joint Conference. I wish to thank the participating Drug Safety Research Centres for their continuing efforts in promoting medicine safety through research, education and training. I wish to express my heartiest congratulation to the Organising Committee for coming up with such a comprehensive and coherent programme and I also wish the Joint Conference every success.

Dr. P.Y. Lam, JP
Director of Health
The Government of the Hong Kong SAR

Welcome message from the Chairman of the Organising Committee

On behalf of the Organising Committee and the Drug Safety Research Centres in Hong Kong and France, I am pleased to welcome everyone attending the 2011 Joint Conference of Drug Safety Research Centres. This Joint Conference becomes an important annual event in Hong Kong after a successful meeting in November 2010. This Joint Conference will bring together the experts from the region and Europe to present and discuss the latest advances in drug safety and the strategies to promote rational use of medicines. The participants will learn from the speakers how to ensure that the medicines available to the public are safe to use and are used safely, effectively and efficiently.

In keeping with the main theme of the 2011 Joint Conference "Strategies to Ensure Medicine Safety and Quality", there is a special session on the present and future systems approach to ensuring medicine safety and quality in the hospital and out-patient clinic settings. The roles of clinical decision support, targeted health care provider education, monitoring and reporting systems as well as capability and multidisciplinary team building will be discussed. Another focus of the Conference is the mechanisms, management and prevention of common allergic drug reactions. In addition, there will be discussion on the applications of pharmacogenetics in clinical practice in relation to drug safety and efficacy. This Joint Conference will address the advances and challenges in drug safety and therapeutics that all health care professionals should know about.

We greatly appreciate the contributions from the renowned speakers, who agree to share their expertise with the participants. The Conference will also provide the participants with the opportunity to share ideas how we can work together to promote drug safety and rational use of medicines.

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

Prof. Thomas Y.K. Chan, JP
Chairman, Organising Committee, and
Director, Centre for Food and Drug Safety
Faculty of Medicine, The Chinese University of Hong Kong

Organisers and Organising Committee

Organisers

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

Department of Pharmacovigilance
The University of Créteil Paris XII
Henri Mondor Hospital, Créteil, France

School of Pharmacy
The Chinese University of Hong Kong

The Nethersole School of Nursing
The Chinese University of Hong Kong

Department of Health
The Government of the Hong Kong SAR

Medication Safety Committee
Hospital Authority, Hong Kong

Prince of Wales Hospital Poison Treatment Centre

Organising Committee

Prof. Thomas Y.K. Chan (Chairman)
Dr. Jones C.M. Chan
Prof. Diana T.F. Lee
Prof. Hervé Le Louet
Prof. Brian Tomlinson
Dr. Raymond S.M. Wong (Secretary)
Ms. Anna Lee
Prof. Vincent H.L. Lee
Dr. Joseph Lui
Ms. Linda Woo

Secretariat

Ms. Maggie Lee, Centre for Food and Drug Safety, Faculty of Medicine, CUHK
Ms. Caran Chan, Prince of Wales Hospital Poison Treatment Centre
Tel: 2632 3907, Fax: 2646 8756, E-mail: maggielee@cuhk.edu.hk
Website: http://www.med.cuhk.edu.hk/cfds/whatsNew.html

Faculty

Ms. S.C. Chiang
Senior Pharmacist, Chief Pharmacist's Office
Hospital Authority, Hong Kong

Prof. Nelson L.S. Lee
Associate Professor, Division of Infectious Diseases
Department of Medicine and Therapeutics
The Chinese University of Hong Kong

Prof. Hervé Le Louet
Head, Department of Pharmacovigilance
The University of Créteil Paris XII, France

Mr. Bill C.W. Leung
Senior Pharmacist, Drug Quality Assurance
Chief Pharmacist's Office
Hospital Authority, Hong Kong

Prof. L.S. Tam
Professor, Division of Rheumatology
Department of Medicine and Therapeutics
The Chinese University of Hong Kong

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

Dr. Bonnie C.K. Wong
Resident Specialist, Division of Infectious Diseases
Department of Medicine and Therapeutics
Prince of Wales Hospital

Dr. Raymond S.M. Wong
Consultant, Division of Clinical Pharmacology
Department of Medicine and Therapeutics
Prince of Wales Hospital

Prof. Vincent W.S. Wong
Associate Professor, Division of Gastroenterology and Hepatology
Department of Medicine and Therapeutics
The Chinese University of Hong Kong

Prof. Joyce H.S. You
Associate Professor, School of Pharmacy, and
Convener, Centre for Pharmacoeconomics Research
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, and
Director, Prince of Wales Hospital Poison Treatment Centre

9:05 – 9:15 OPENING ADDRESS

Dr. P.Y. Lam, JP
Director of Health
The Government of Hong Kong SAR

9:15 – 11:00 WHAT YOU NEED TO KNOW ABOUT ALLERGIC DRUG REACTIONS

Chair Persons:
Dr. Heston K.W. Kwong
Dr. N.M. Luk

9:15 – 10:05 Epidemiology, Risk Factors and Mechanisms Allergic Drug Reactions

Prof. Hervé Le Louet

10:05 – 10:45 Management Approach to Patients with Drug Allergies

Dr. Raymond S.M. Wong

10:45 – 11:00 Questions and Answers

11:00 – 11:15 Tea Break

11:15 – 13:00 Allergic Reactions to Commonly Used Drugs

Chair Persons:

Prof. Bernard M.Y. Cheung

Dr. Joseph Lui

11:15 – 11:45 Penicillins and Other β-lactam Antibiotics

Dr. Bonnie C.K. Wong and Prof. Nelson L.S. Lee

11:45 – 12:15 Non-Aspirin NSAIDs

Prof. L.S. Tam

12:15 – 12:45 Drugs Causing Liver Diseases

Prof. Vincent W.S. Wong

12:45 – 13:00 Questions and Answers

13:00 – 14:00 Lunch

14:00 – 15:45 Applications of Pharmacogenetics in Clinical Practice

Chair Persons:

Prof. Hervé Le Louet

Dr. Raymond S.M. Wong

14:00 – 14:50 Pharmacogenetics of Adverse Drug Reactions

Prof. Brian Tomlinson

14:50 – 15:30 Warfarin Dosing Algorithms and Care Models for Chinese Patients

Prof. Joyce H.S. You

15:30 – 15:45 Questions and Answers

15:45 – 16:00 Tea Break

16:00 – 17:50 Systems to Ensure Medicine Safety and Quality

Chair Persons:

Dr. C.B. Law

Mr. Benjamin Kwong

16:00 – 16:30 The Challenges and Gains of Using Clinical Decision Support to Improve Patient and Medication Safety

Ms. S.C. Chiang

16:30 – 17:00 Systems to Monitor Medicine Safety and Quality in French Hospitals

Prof. Hervé Le Louet

17:00 – 17:30 Strategies to Ensure Medicine Safety and Quality in Hospital Authority

Mr. Bill C.W. Leung

17:30 – 17:50 Questions and Answers

17:50 – 18:00 Closing Remarks

Prof. Hervé Le Louet

Prof. Brian Tomlinson

Epidemiology, Risk Factors and Mechanisms Allergic Drug Reactions

Prof. Hervé Le Louet, The University of Créteil Paris XII, France

The World Allergy Organization defined 'drug allergy' as an immunologically mediated drug hypersensitivity reaction and the mechanism of drug allergy may be either IgE or non-IgE mediated, with T-cell mediated reactions largely represented in the latter.

The concept of trivial pseudoallergic reactions, drug idiosyncrasy and intolerance will be clearly defined as well as their differences with allergy hypersensitivity.

Adverse drug reactions (ADRs) occurred for 3 to 6% of all hospital admissions and in 10% to 15% of hospitalized patients. While the main epidemiological studies on ADRs do not differentiate immunologically and non-immunologically mediated drug hypersensitivity, few data on cutaneous drug allergy are available. It is clearly shown that overestimation of drug allergy rate leading to inappropriate drug prescription.

There is an accepted conceptual and very practical framework for understanding immune reactions called Gell and Coombs classification. However some reactions are not easily classified and the same drug can induce different types of allergic reactions like penicillins. The example of amoxicillin molecule is very interesting because it can induce reaction belonging to the 4 major mechanisms described by Gell and Coombs and the most frequent reactions are type I, which are IgE mediated, and type IV, which are non immediate and T-cell dependent. Another example is the case of allopurinol in patients with a common HLA genotype inducing severe cutaneaous adverse reactions (SCARs) like Stevens Johnson syndrome (SJS) and Drug Reaction with Eosinophilia and Systemic Symptoms.

This presentation will also describe the drugs allergic side effects in the main system organ class: Drugs induce agranulocytosis, auto-immune like hepatitis, hypersensitivity-type lung disease and interstitial or glomerular nephritis.

A "special highlight" will be given to SCARs like SJS.

References:

1: Gomes ER, et al. Curr Opin Allergy Clin Immunol 2005; 5:309-16
2: Thong BY, Tan TC. Epidemiology and risk factors for drug allergy. Br J Clin Pharmacol. 2011 May; 71(5):684-700

Management Approach to Patients with Drug Allergies

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

Drug allergy encompasses a spectrum of hypersensitivity reactions with heterogeneous mechanisms and clinical presentations. Allergic drug reactions can affect numerous organ systems and manifest in a variety of reactions, including various drug-induced allergic syndromes, and many drug allergies can have more than one mechanistic pathway. Cutaneous manifestations are the most common physical manifestation of drug allergies; however, many other organ systems can be involved, including hematologic abnormalities, hepatitis, pneumonitis, lymphadenopathy, or arthralgias. Each clinical presentation is not unique or specific to drug allergies, and therefore other conditions might need to be considered based on the presentation.

Determining whether a particular drug is involved can be accomplished with a careful history and physical examination, knowledge of the common and idiosyncratic reactions of the drugs in question, and selective skin testing. A thorough history is the primary tool in trying to discern a drug reaction and in distinguishing allergic reactions from other adverse reactions. The history helps guide the clinician in the choice of diagnostic tests and whether it might be safe to reintroduce the medication.

Laboratory testing has a very limited role in the management of drug allergy. Routine laboratory evaluation appropriate to the clinical setting (based on the history and physical examination findings) might be useful for the evaluation of a patient with a suspected drug reaction. Although eosinophilia is often suggestive of an allergic drug reaction, absence of eosinophilia clearly does not exclude the condition. Autoantibodies might be helpful in the evaluation of drug-induced vasculitis and drug-induced lupus erythematosus. A diagnosis of anaphylaxis might be made by detecting an increase in serum total tryptase levels. For immediate hypersensitivity reactions mediated by IgE antibodies, demonstration of the presence of drug-specific IgE is usually taken as sufficient evidence that the patients is at significant risk of having a type I reaction if the drug is administered. Drug patch testing might be useful for certain types of cutaneous drug reactions, including maculopapular exanthems, acute generalized exanthematous pustulosis, and fixed drug eruptions, but generally is not helpful for Steven-Johnson syndrome or urticarial eruptions.

If a drug allergy is suspected, appropriate alternative agents should be used. There may be situations in which there is a definite medical need for a particular agent, absence of suitable alternative agent, and testing with high negative predictive value does not exist. Induction of drug tolerance (desensitization) can be performed to induce temporary drug tolerance to allow the patient to take the drug safely. In contrast, a test dose or graded challenge can be administered to determine whether the patient is currently allergic to that drug.

Penicillins and Other β-lactam Antibiotics

Dr. Bonnie C.K. Wong, Prince of Wales Hospital, Hong Kong
Prof. Nelson L.S. Lee, The Chinese University of Hong Kong, Hong Kong

Although allergic reactions to antibiotics account for only a small proportion of reported adverse drug reactions, we do often encounter them in our daily practices. It is important to differentiate between true drug allergy, pseudo-allergy and non-allergic adverse effects by means of history taking and relevant investigations. True allergic reactions should be further categorized according to their severity. Being mislabeled as having antibiotic allergy may adversely affect patient care and result in substantial morbidity and mortality and increased health care costs. A practical approach to antibiotic allergy and the different strategies employed in our hospital to ensure safe use in antibiotics will be discussed in this talk.

Allergic Reactions to Commonly Used Drugs - Non-Aspirin NSAIDs (NSAIDs)

Prof. L.S. Tam, The Chinese University of Hong Kong, Hong Kong

NSAIDs are the most important group of drugs involved in hypersensitivity drug reactions, and include heterogeneous compounds with very different chemical structures. These reactions can be IgE dependent (immediate reactions), T cell-mediated (non-immediate), or induced by a non-specific immunological mechanism related with the blocking of the COX-1 enzyme and the shunting to the lipooxygenase pathway (cross-intolerant reactions). Cutaneous symptoms are the most frequent, with ibuprofen, naproxen and diclofenac being common culprit drugs worldwide, although others can be involved because patterns of consumption and exposure rates vary between countries. A very important proportion of immunological reactions are immediate, with urticaria and anaphylaxis being the typical clinical manifestations. Non-immediate reactions comprise a number of heterogeneous entities ranging from mild exanthema to severe TEN or DRESS syndrome, as well as organ-specific reactions such as hepatitis or pneumonitis. Cross-intolerant reactions appear to non-chemically related drugs, and involve respiratory airways, skin or both. This talk summarizes up-to-date information on clinical manifestations, pathogenesis, diagnostic tools and management algorithms of hypersensitivity reactions to NSAIDs. Diagnosis of hypersensitivity to a NSAID includes understanding of the underlying mechanism and is necessary for prevention and management. A stepwise approach to the diagnosis of hypersensitivity to NSAIDs will be discussed including clinical history, or alternative drug depending on the type of the reaction. The diagnostic process should result in providing the patient with written information both on forbidden and on alternative drugs.

Drugs Causing Liver Diseases

Prof. Vincent W.S. Wong, The Chinese University of Hong Kong, Hong Kong

Drug hepatotoxicity, more commonly referred to as drug-induced liver injury (DILI) nowadays, occurs in 1 in 10 000 to 1 in 100 000 people exposed to pharmacological agents. Its annual incidence in the general population is estimated to be around 13.9 per 100 000 people. It also happens in around 1.4% of hospitalized patients. Although DILI is a rare event among people on drug treatment, it remains one of the leading causes of acute liver failure. It is also the most common cause of post-marketing withdrawal of new drugs.

Depending on the liver test results, DILI may be classified as hepatocellular pattern (predominant elevation of aminotransferases), cholestatic pattern (predominant elevation of alkaline phosphatase) and mixed pattern. Chronic forms of DILI and progression to cirrhosis have also been reported. Overall, around 10% of patients with DILI die from liver failure or require liver transplantation.

The diagnosis of DILI is based on careful history taking and judicious exclusion of other liver diseases. The timing and duration of drug exposure in relation to symptom onset and resolution must be documented carefully. Blood tests and imaging studies should be performed based on the original clinical picture and local epidemiology. The liver histology of DILI is seldom pathognomonic, but these patients more commonly have prominent eosinophils, granulomatous hepatitis and central hepatocyte dropout. Since liver biopsy is associated with some complications such as bleeding, it is usually reserved for patients whose liver tests do not improve despite cessation of the offending drug.

Patients who die from DILI or require liver transplantation are more likely to have jaundice and high liver enzymes at presentation. They also have higher aspartate aminotransferase-to-alanine aminotransferase ratio, indicating severe hepatocyte injury. Patients with encephalopathy or other features of fulminant liver failure (e.g. severe coagulopathy, very high bilirubin) have poor prognosis and should be considered for liver transplantation.

The current management of DILI is largely supportive. The offending drug must be stopped. Close monitoring of the liver function and nutritional status is important. N-acetylcysteine, traditionally used as an antidote for paracetamol poisoning, has recently been shown to improve the transplantation-free survival in other types of acute liver failure as well, particularly when the drug is started before severe encephalopathy sets in.

Pharmacogenetics of Adverse Drug Reactions

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

Many adverse drug reactions (ADRs) are detected during the process of drug development and many drugs are abandoned at this early stage because of these problems. However, some serious ADRs may not detected until after drug approval, partly because the number of patients exposed to the drug is limited during clinical development and the randomized clinical trials are not large enough to identify rare ADRs against a background rate in the population receiving a placebo or active control. Furthermore, clinical trials might deliberately exclude subjects who may be at greater risk of some adverse event, such as subjects with baseline abnormality of the QT interval, who may be at increased risk of developing QT interval prolongation. The effect of a new drug on this parameter may be missed if it only occurs in susceptible individuals. Understanding the underlying genetic predisposition to ADRs should help to identify the subjects in whom particular drugs should be avoided and will help in the development of safer novel therapies.

Adverse drug reactions can be classified in various ways and one useful approach is to classify them as ‘avoidable’ and ‘unavoidable’ ADRs. Avoidable ADRs are often due to excessive exposure to the drug and this may result from differences in the pharmacokinetics which is typically related to genetic variations in drug-metabolizing enzymes (DMEs) or drug-transporter proteins (DTPs). Knowledge of these will in turn facilitate prediction of potential drug interactions with concomitant medications or perhaps with dietary supplements. It has been reported that ADRs due to pharmacokinetic effects resulting from genetic variations or drug interactions represent a substantial proportion of all ADRs with figures between 59% and 90% quoted in different publications. In some circumstances off-target binding of the drug could lead to ADRs and this may not involve the same level of exposure that is responsible for on-target efficacy. A recent example of the off-target effects of a drug was with the novel cholesteryl ester transfer protein (CETP) inhibitor torcetrapib where the adverse affects of increased levels of aldosterone and increased blood pressure were not fully appreciated until it became obvious in the cardiovascular outcome trial that these were offsetting the potential benefits from the impressive increase in HDL cholesterol. These off-target mechanisms are still the subject of detailed investigations.

An area of considerable interest is to establish the risk factors associated with the ADR so that individuals at risk can be identified and this can potentially change an unavoidable to an avoidable ADR. This has been particularly useful with the severe cutaneous adverse reactions (SCAR) of Stevens–Johnson syndrome and toxic epidermal necrosis which occur relatively frequently with certain drugs. With the abacavir hypersensitivity reaction an association with

HLA-B*5701 was identified and similarly with carbamazepine SCAR that was a strong association with HLA-B*1502 in Asian populations but different associations have been found in western countries. One of the drugs most frequently causing SCAR is allopurinol and this reaction has been associated with several HLA genes and in particular HLA-B*5801. Better understanding of these genetic predispositions to ADRs will result in the safer use of many important drug therapies.

Warfarin Dosing Algorithms and Care Models for Chinese Patients

Prof. Joyce H.S. You, The Chinese University of Hong Kong, Hong Kong

Warfarin was shown to effectively reduce risk of ischemic stroke in patients with atrial fibrillation (AF). The anticoagulation effect of warfarin, measured by the international normalized ratio (INR), is subject to wide inter- and intra-individual variability that possibly leads to hemorrhagic events despite careful dosage titration. The target INR range was examined for Chinese patients and the results showed that a narrow INR window (1.8-2.4) is required to optimize the risk of bleeding and thromboembolism for moderate-intensity anticoagulation.

Genotyping *VKORC1* and *CYP2C9* in Hong Kong Chinese patients showed that, while the frequency of *CYP2C9* *3 was low, *VKORC1* haplotypes H1 (group A) and H7 (group B) were most common, accounting for 86% and 13% of all haplotypic variation in the study cohort. Patients carrying at least one copy of a *VKORC1* group B haplotype required a significantly higher stable warfarin dose than patients that were homozygous for group A haplotypes. Patients who were in *VKORC1* A/A group and were heterozygous for *CYP2C9*3* had a significantly lower dose requirement than patients that exhibited the *CYP2C9 *1/*1* genotype. A warfarin dosing algorithm using patient clinical characteristics and genetic test results of *CYP2C9* and *VKORC1* for Chinese patients was developed and validated. Five factors were identified in a stepwise regression model: *CYP2C9* and *VKORC1* genotype, age, weight and vitamin K intake (in the past 7 days). This dosing model explained 68% of the variation of warfarin dose in the study cohort. Despite promising findings of improvement in dosing accuracy were reported in validation studies, the clinical benefits of genotype-guided dosing have not been clearly demonstrated in clinical trials.

Outcome research comparing costs and clinical benefits of different care models (routine medical care, physician-managed anticoagulation care and pharmacist-managed anticoagulation care) has demonstrated that pharmacist-managed anticoagulation care is the least costly and most effective approach in Hong Kong. Nevertheless, the time-in-therapeutic range (TTR) achieved was only 64%, less the target TTR (>75%) which associated with lower bleeding and thromboembolic event rates. The present seminar will discuss the different strategies to optimize the outcomes of oral anticoagulation therapy.

The Challenges and Gains of Using Clinical Decision Support to Improve Patient and Medication Safety

Ms. S.C. Chiang, Hospital Authority, Hong Kong

Clinical Decision Support features such as drug allergy checking, adverse drug reactions checking serves to prevent prescribing errors due to known patient allergy and other adverse drug events. Such features which have been introduced in the Computerized Medication Order Entry system is an auto-suggestive alert, which physicians may or may not choose to accept. Since these features were introduced, they are seen as practical and effective solutions to improve medication safety. However, these alerts if they are designed and fine tuned can lead to excessive and constant alerts which could lead to alert fatigue.

A 3 year retrospective observational study was conducted in the public hospitals to determine the clinicians' behaviour towards the alerts and their acceptance of various alert features. The data analyzed alert patterns from prescriptions within local outpatient clinics between 1 April 2007 to 31 March 2010. Data collected included medication prescribed, clinician's response to the alert (i.e. override or accept), reasons for overriding the alerts, and level of certainty of allergic response.

The experience in the process of developing and introducing the various clinical alerts into the medication order entry system and some of the findings from the observational study would be shared in this talk to cover how useful were the alerts, what were the clinicians behaviour, what alerts were being accepted and why and what alerts were being rejected and why, etc.. What are the challenges and what are the gains and what are the future directions in this path of technology support to further enhance patient and medication safety.

Systems to Monitor Medicine Safety and Quality in French Hospitals

Prof. Hervé Le Louet, The University of Créteil Paris XII, France

Several adverse drug reaction monitoring systems contribute to the safety in French hospitals.

The Pharmacovigilance system with an European, a national and a local level is the key system to monitor the adverse drug reactions (ADRs) in France. In hospitals, ADRs can be collected by the pharmacovigilance referent by phone, fax, email, department visits or through network systems. The first one is the adverse events network system, allowing recording all adverse events occurring in hospital, including ADRs. The second network system is the medicalization program information system. This system was elaborate to control health care cost but allows also detecting ADR through encoded events of the hospitalised patient.

Concerning medication errors monitoring system, two levels exist: a national level with a direct phone line and a local system in several hospitals. This local monitoring system conducted in respect of a confidential charter and with a non-punitive environment was set up with a local assistant management medication error team. These two systems, national and local, allow taking respectively general and local corrective actions which are additional and synergic. The pharmaceutical prescription validation contributes also to the safety of the medical prescriptions.

The system to monitor medicine quality in French hospitals relies on one national agency: the French national authority for health. Procedures to publication of guidelines to accreditation of healthcare organisations were set up. Each 4 years, health professionals mandated by the French national authority for health achieve certification visits on the basis of a manual.

Strategies to Ensure Medicine Safety and Quality in Hospital Authority

Mr. Bill C.W. Leung, Hospital Authority, Hong Kong

There is growing demand and expectation for quality pharmaceutical drugs from an aging and better informed society. The roles of regulatory & health authorities are forever changing to ensure the drug available for sale on the market is of good quality, efficacious and safe to consume.

To meet the demands of public expectation and to ensure the public safety can be ascertained, the Hospital Authority (HA) has developed and established strategies from the pre-procurement selection, chemical/microbial testing and acceptance of drugs to the post procurement surveillance Quality Assurance program to assure the quality of the product meets HA's specifications and requirement. Following the 2009 medication blunders, HA have strengthened monitoring of the drugs in use in key areas: from receipt of goods, critical selection of high risk products for testing right through to investigative follow ups of any quality defects received.

To achieve these objectives there have been closer collaboration with the suppliers and manufacturers, local universities, independent third party laboratories and the HK Department of Health to ensure a more rapid response to any adverse findings that may compromise the safety to the public.