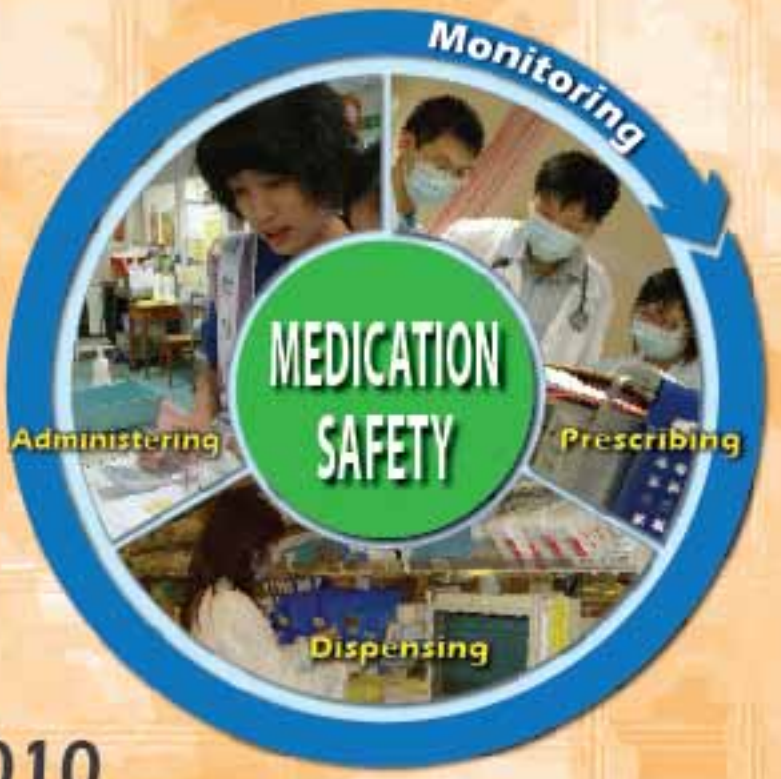
2010 Joint Conference of Drug Safety Research Centres • 2010 藥物安全研究中心聯合會議

Strategies for Preventing Medication Errors



28 November 2010

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

PROGRAMME BOOK

Organisers

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Faculty of Medicine, The Chinese University of Hong Kong

Centre for Paediatric Pharmacy Research
School of Pharmacy, The University of London, UK

Department of Pharmacology
The University of Bordeaux, 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 Co-Chairman of the Organising Committee

On behalf of the Organising Committee, it gives us great pleasure to welcome you to the 2010 Joint Conference of Drug Safety Research Centres. This Conference is jointly organised by the Drug Safety Research Centres of the Chinese University of Hong Kong, the University of London, the University of Bordeaux, the Department of Health, the Hospital Authority and the Prince of Wales Hospital Poison Treatment Centre. The focus of this Conference is on the strategies for preventing medication errors.

The requirement for safe medication use is to prescribe, dispense and administer the right drug, with the right dose and route, at the right time to the right patient. An error can occur at any stage of the medication use process, which may lead to patient harm. To prevent medication errors, there should be continuing efforts and structured programmes to teach and train health care professionals, to monitor for these adverse drug events, to oversee the implementation of improvement plans and to conduct research.

As can be seen in the programme, this Conference covers the important aspects of medication safety, including the root causes and management of medication errors, the high risk situations and the multidisciplinary approach and systems approach to prevention of medication errors.

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 medication safety.

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
Co-Chairman , Organising Committee
Director, Centre for Food and Drug Safety
Faculty of Medicine, CUHK

Prof. Ian C.K. Wong
Co-Chairman, Organising Committee
Centre for Paediatric Pharmacy Research
School of Pharmacy, The University of London

Organisers and Organising Committee

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Organising Committee

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Dr. Jones C.M. Chan
Ms. Anna Lee
Prof. Vincent H.L. Lee
Prof. Nicholas Moore
Ms. Linda Woo

Prof. Ian C.K. Wong (Co-Chairman)
Dr. Michael C.H. Chan
Prof. Diana T.F. Lee
Dr. Joseph Lui
Prof. Brian Tomlinson
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Programme

8:30 – 9:00 Registration

9:00 – 9:05 WELCOME REMARKS

Prof. Thomas Y.K. Chan, JP
Co-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. Gloria Tam, JP
Deputy Director of Health
The Government of the Hong Kong SAR

Prof. Ian C.K. Wong
Professor of Paediatric Medicines Research, and
Director, Centre for Paediatric Pharmacy Research
School of Pharmacy
The University of London, UK

9:15 – 11:00 UNDERSTANDING THE ROOT CAUSES AND MANAGEMENT OF MEDICATION ERRORS

Chair Persons:
Prof. Vincent H.L. Lee
Dr. Joseph Lui

9:15 – 9:45 International Perspective
Prof. Brian Tomlinson

9:45 – 10:15 Hong Kong Experience
Dr. C.B. Law

10:15 – 10:45 Actions to be Taken Following the Discovery of Medication Errors
Prof. Nicholas Moore

10:45 – 11:00 Questions and Answers

11:00 – 11:15 Tea Break

11:15 – 13:00 FOCUSING ON HIGH RISK SITUATIONS

Chair Persons:
Dr. C.K. Li
Prof. Timothy C.Y. Kwok

11:15 – 11:45 Medication Incidents in Children
Prof. Ian C.K. Wong

11:45 – 12:15 Managing Anticoagulant Therapy
Dr. Raymond S.M. Wong

12:15 – 12:45 Elderly Patients with Recurrent Admissions and Polypharmacy
Miss Ritchie C.C. Kwok

12:45 – 13:00 Questions and Answers

13:00 – 14:00 Lunch (Sandwiches and drinks will be served in the Foyer)

14:00 – 15:45 PREVENTING MEDICATION ERRORS – A MULTIDISCIPLINARY APPROACH

Chair Persons:
Prof. Brian Tomlinson
Prof. Diana T.F. Lee

14:00 – 14:30 Educating and Training Doctors in Prescribing
Prof. Nicholas Moore

14:30 – 15:00 Strategies to Improve Medication Safety on the Wards

Prof. S.Y. Chair

15:00 – 15:30 Working Hand in Hand with Health Care Professionals to Improve Medication Safety

Mr. Michael H.M. Ling

15:30 – 15:45 Questions and Answers

15:45 – 16:00 Tea Break

16:00 – 17:50 Preventing Medication Errors – The Systems Approach

Chair Persons:

Prof. Bernard M.Y. Cheung

Dr. S.F. Lui

16:00 – 16:30 Enhancing Manufacturing of Medicines to Improve Patients Safety

Prof. Vincent H.L. Lee

16:30 – 17:00 Evaluation of Electronic Prescribing System in Clinical Practice

Prof. Ian C.K. Wong

17:00 – 17:30 Building up Safe Medication Prescribing Practices

Prof. Thomas Y.K. Chan

17:30 – 17:50 Questions and Answers

17:50 – 18:00 Closing Remarks

Prof. Nicolas Moore

Prof. Ian C.K. Wong

Prof. Thomas Y.K. Chan

Understanding the Root Causes and Management of Medication Errors: International Perspective

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

Medication errors occur in all countries throughout the world. The incidence rates reported vary considerably, partly because of the differences in definitions of medication errors and the different study methods used in trying to identify them. For instance, there is disagreement about whether cases of error that do not cause harm should be included in calculations of medication error rates. Furthermore, when harm does occur in relation to some medication incident it may not be clear whether the problem could have been prevented and therefore whether the incident should be regarded as an error. Similarly, it may be difficult to define the denominator for calculation of rates of error and this has not always been done consistently. It is thus important to consider these problems when interpreting reported incidence rates.

It has been estimated that the rate of medication errors varies between 2% and 14% of patients admitted to hospital in the United States and 1-2% of patients suffer harm as a result. Medication errors have been reported to result in mortality in 7000 patients per year and to account for nearly 1 in 20 hospital admissions in the United States. The rates are likely to be similar in the United Kingdom and other European countries. Many of the errors are due to poor prescribing and often involve relatively inexperienced medical staff, who are responsible for the majority of prescribing in hospitals. These represent one of the most preventable causes of patient injury. Insulin is one of the most important medications to consider in medication errors, partly because it is commonly used and also because errors are more likely to result in serious harm or death. A recent audit of inpatients with diabetes in England and Wales reported prescribing errors in an alarming 20% of cases. Two common preventable errors relating to insulin dosage were using abbreviations in the prescription or failing to use insulin syringes for the administration, illustrating that medication errors can occur at any stage of the medication use cycle from prescribing, through dispensing, to administration. Electronic prescribing should help to reduce the risk of prescribing errors from illegible handwriting, although electronic systems can in turn lead to other problems such as incorrect drug selection and their effects on patient outcomes have not been fully studied. It is important to develop a multidisciplinary approach to help to solve the problem of medication errors and to adopt an attitude of ‘no blame’ to help facilitate accurate detecting and reporting.

Understanding the Root Causes and Management of Medication Errors: Hong Kong Experience

Dr. C.B. Law, Princess Margaret Hospital, Hong Kong

Medication error is a popular hospital "blunders" that captured media's attention. In the past several years, high profile cases such as a young woman given intra-thecal vincristine, allopurinol contaminated with fungus and bolus injection of concentrated KCL have painted a stark picture of medication safety in public hospitals.

Medication error is one of the most commonly reported adverse incidents. In 2009, HA hospitals reported 1,415 incidents of medication error through AIRS (HA's incident reporting system). Most of them were minor – 99% cases were of severity index 3 or less. There were only 8 incidents with severity index 4. There was no death attributed directly to medication error. Although we believe there was under-reporting especially for incidents with severity index 0, given the volume of prescription in HA hospitals, the figure represent a remarkable achievement in medication safety. Of course, this must not be a reason for complacent.

Medication error is inherently difficult to manage. The volume of drugs is huge, there are over 1,200 items in the formulary of a typical acute hospital with a daily transaction of over 5,000 prescription line. The problem will only grow with advances in science. Supply of drugs comes from multiple sources with little standardization in labeling and packaging. Price rather than safety is the primary factor in purchasing. Use of medication entails prescribing, dispensing and administering. The process is highly variable contingent to operational needs and clinical requirement and it involves multiple disciplines. Errors can occur in any of the process or at the interface. Ward stock, verbal order, drug allergy, poor hand writing, non-standard abbreviation, lack of knowledge of drugs, patient identification and look alike, sound alike medications (LASA) are common source of mistakes. Drug-drug interaction will be increasingly problematic with the need of poly-pharmacy in elderly.

Addressing medication error required systematic collection of incidents to identify gaps and prioritize effort. Concerted efforts in the past several years from physicians, nurses, pharmacy and management has bought about greatly improved medication safety. The strategies used including: standardization of prescribing e.g. standard dilution table, standard abbreviation; limiting high risk medication with different strength to only critical clinical area, removal of concentrated electrolytes, read-back policy of verbal order and special requirement for intra-thecal injection. The more serious medication incidents in recent year related to allergy for in-patient prescription especially for drugs with multiple ingredients. The use of electronic prescribing has greatly reduced medication error. It is fully used in out-patient and HA is developing the in-patient system which will surely improve medication safety further.

Actions to be Taken Following the Discovery of Medication Errors

Prof. Nicholas Moore, University of Bordeaux, France

The discovery of a medication error should result in a series of actions that would normally have been decided upon beforehand, while setting up the institutional drug safety system. Errors can arise at any point from prescription to dispensation and drug administration, and can involve the prescriber, the pharmacy staff, nurses administering the drugs (mostly in hospital) or patients.
The first point is the analysis of the root cause of the medication error:
- Wrong prescription (wrong drug, wrong dose, wrong duration or timing, potential interaction). Prescription analysis with the prescriber will identify the reasons for this wrong prescription, and hopefully avoid repetition of the error. Wrong prescription may occur through lack of knowledge or prescription error (for instance choice of the next drug on the list in computerized systems).
- Wrong dispensation (drug, dose): in this case there is a discrepancy between what was the intended prescription, and the final resulting administration to a patient. The error can concern the product or the dose. Errors can arise at all steps between prescription and dispensation or administration. The prescription might have been misread because of illegible writing, or because of confusion by the pharmacist between similar drugs (by name or presentation, (e.g. adrenaline/atropine ampoules)), or by erroneous storage, or any number of other reasons.
The analysis of the cause of the error should lead to corrective action: increased training of prescriber in pharmacotherapy, especially if new drugs are concerned, change in prescribing interface, improved drug selection software for dose adjustment, including therapeutic drug monitoring or interaction detection software. Medication errors when the are caused by drug confusion (name, aspect) should lead to better information, and possibly to changes in the labelling, name or presentation of the drug, which would imply interaction with regulators and pharmaceutical industry. Errors arising from defective pharmacy circuits should lead to changes in the way drugs are identified/stored or prepared.
- Wrong utilisation by patients (patient-related errors) are in fact the most common medication errors, and may be related to name confusions, miscompliance, selective patient choice of medications, etc.
Special care must be set on the identification of near-misses, errors that were avoided (using whatever methods may be available, such as pharmacist review of prescriptions, drug markers, patient surveillance, etc.), that can indicate defects in the drug circuit that could be fixed or improved before an accident happens. This may mean a complete change of culture from error and punishment to no-guilt reporting to improve systems quality, but is the only sure way to move from regrets to prevention. Careful planning of the drug circulation is the first step, that should involve prescribers, pharmacologists and pharmacists, logistics engineers and quality assurance experts, and patients.

Medication Incidents in Children

Prof. Ian C.K. Wong, The University of London, United Kingdom

Medical errors are a major problem in the healthcare system. Apart from the direct expense to the healthcare system, there are great personal costs to patients, their families and staff and public confidence is undermined. Therefore, policy initiatives have been implemented to reduce such mistakes[1]. Medication errors are thought to be the most common type of medical error. Recent evidence highlights the fact that medication error is a significant problem in the paediatric population.

Children are at a higher risk of medication errors because[1]:

- Drug doses are usually calculated based on a patient's age, weight or body surface area.
- Weight changes over time & recalculation of drug doses is required, particularly in neonates.
- Inadequate availability of appropriate dosage forms and concentrations of many drugs.
- Fewer internal reserves to buffer any medication errors which may occur.

A systematic literature review concluded medication errors in children are common. Although the actual size of the problem depends on the settings and methodology used[2], the error rate is no less than in adults. A recently published study involving five London hospitals has shown that an overall prescribing error rate is 13.2% of medication orders (95% CI 12.0 to 14.5). There was great variation in prescribing error rates between wards. The overall incidence of 19.1% administration errors is (95% CI 17.5% to 20.7%) [3].

Studies revealed that a 10-fold overdose is not uncommon and many cases of fatal overdose in children, particularly in neonates, have been reported[2]. This presentation will briefly introduce the epidemiology and risk factors associated with medication errors in children.

This presentation will also present a real morphine overdose case of 100 times the correct dosage in a neonate[4]. The case will be analysed in a step-by-step approach using the Accident Causation Model. This case will demonstrate some important factors which contributed to the error. These factors include the inappropriate formulation availability, poor communication within the healthcare team, the poor mathematical skills of the prescriber, protocol violation of healthcare professionals and poor reflective practice within the unit. By identifying these factors and understanding their contribution to the errors, the audiences will be able to reflect on their own practice and improve the safety of medication use in children.

1. Wong IC, Wong LY, Cranswick NE. Minimising medication errors in children. *Arch Dis Child* 2009;94(2):161-4.

2. Ghaleb MA, Dean Franklin B, Barber N, Khaki Z, Yeung Y, Wong ICK. A Systematic Review of Medication Errors in Pediatric Patients. *Annals of Pharmacotherapy* 2006 40(10):1766-76.

3. Ghaleb M, Barber N, Franklin B, Wong ICK. The incidence and nature of prescribing and medication administration errors in paediatric inpatients *Arch Dis Child* 2010;95(2):113-8.

4. Wong ICK. Medication Errors in Paediatric Patients. Paediatric Drug Handling Editors: Florence AT, Moffat T. Pharmaceutical Press 2007.

Managing Anticoagulant Therapy

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

Warfarin is the most common oral anticoagulants in clinical use. It has been shown to be effective in the management of patients with a wide range of clinical conditions, such as stroke prophylaxis in atrial fibrillation, venous thromboembolism, prosthetic heart valves and anti-phospholipid syndrome. Environmental factors such as drugs, diet, and various disease states can alter the pharmacokinetics of warfarin. Using the correct intensity of warfarin and maintaining the patient in the therapeutic range are two important determinants of its therapeutic effectiveness and safety. The main risks of anticoagulation, namely bleeding, can be minimized by maintaining anticoagulation control within the optimal international normalized ratio (INR) range. Management strategies that improve the time in the therapeutic target range include centralized care in anticoagulation clinics and computer-assisted dosing algorithms. In addition, self-testing of the international normalized ratio and self-dosing of vitamin K antagonists has been introduced over the past 20 years and has been shown to be an effective and safe treatment modality. The use of algorithms for dosing that incorporate pharmacogenenomic information perform better than those using clinical data alone. These strategies may improve the quality of anticoagulation and facilitate the management of these patients and thereby further facilitate optimal anticoagulation management.

Elderly Patients with Recurrent Admissions and Polypharmacy

Miss Ritchie C.C. Kwok, Queen Mary Hospital, Hong Kong

Introduction

Hospital readmission can be caused by various reasons. It could be due to social problems, medical problems or medication related problems. A previous study showed that patients with more than four discharge medications and patients prescribed with diuretics were at higher risk of hospital readmission[1]. Polypharmacy is certainly one of the important causes of recurrent admission. Minimizing medication use in elderly patients is not always feasible as our geriatric patients often suffer from different kinds of diseases and complicated treatment is sometimes needed. However, unintentional use of medications can be prevented by clinical medication review and patient education.

Service in place

Medication reconciliation service was pilot in Queen Mary Hospital in 2008 and it is now provided to all medical and surgical admission wards. Clinical pharmacists would reconcile medications by patient interview upon admission and compare medication history with admission orders. If there is any drug use problem found within the process, clinical pharmacist would discuss with the prescribing doctor find a possible solution for the problem. Clinical medication review would also be provided by clinical pharmacists to review the indication, side effects and drug interaction of the treatment regimen. It aims at rationalize drug use and avoid preventable drug related problems.

Discharge medications would also be reviewed by clinical pharmacists to ensure the accuracy of discharge medications. Patient drug education would also be provided to patients or their care-givers at discharge to make sure that the patient know clearly about their medications. If the patient would be discharged to another hospital or old age home, a medication reconciliation record would be provided to the next point of care to maintain continuity of drug treatment. Effective communication on medications at transit of care would definitely prevent readmission caused by unintentional use of drugs.

Evaluation of service

Data from Oct 2009 to Sep 2010 was retrieved. Within 14258 admissions in the reviewed period, 11834 (83% of all admission) of all admission orders were reviewed. 746 (6% of reviewed orders) contain unintentional prescribing discrepancies. 5790 discharge prescriptions were reviewed and 1216 (21%) of them contain unintentional prescribing discrepancies. All these discrepancies can potentially cause unplanned readmissions if left unattended.

Conclusion

Unplanned readmission can be prevented by clear communication of medications and patient education especially when complicated regimen was prescribed. More case examples would be provided in the oral presentation to better illustrate the current situation.

[1] E.F. Ruth Morrissey, James C. McElnay, Michael Scott and Brian J. McConnell. Factors Regarding Hospital Readmission of Elderly Patients. Clin Drug Invest. 2003;23(2)

Educating and Training Doctors in Prescribing

Prof. Nicholas Moore, University of Bordeaux, France

Prescribing is the single most common therapeutic activity of physicians, and yet in most countries it is taught for only a few dozen hours in medical schools, often a much shorter course than nurses or physiotherapists receive. Some countries also provide hands-on training during internships and residencies using role-playing strategies, but most often physicians are sent off into the world with only scanty knowledge of the powerful drugs they are allowed to prescribe the day they get their diploma. Most young physicians feel undertrained in clinical pharmacology. The effects of this can be seen in the adverse reactions resulting in patient hospitalizations: most of these adverse reactions are well known reactions to old drugs (anticoagulants, non-steroidal anti-inflammatory agents, antiepileptics, antibiotics), most are related to the drugs' pharmacological properties, and most might perhaps have been avoided. They are related to a poor choice of drugs, to inappropriate dosage or duration, to lack of proper monitoring, or to concomitant prescription of other drugs. Prescribing powerful drugs is a skill that requires careful training, as for any other hazardous occupation. In addition, these tools change regularly, and a few years after graduation, most of the therapeutic arsenal will not have been taught in medical school. Prescribers will therefore need to be trained in the proper choice of medication for optimal patient treatment, which also implies mastering evolving diagnostic methods, and new physiopathological and pharmacological concepts. Training by Evidence based medicine and its proper application will need to be understood and applied, as well as the assessment of patient-related risks in relation with the drugs that are being envisioned. In polypathological patients, decision analysis processes will be needed to understand tradeoffs between medical needs and the exponentially increasing risks of polyprescriptions. All these points are in the EACPT and BPS definitions for core curriculums, or the IUPHAR document on the teaching of clinical pharmacology.

Local teachers in clinical pharmacology and rational drug use need to assess their programs' and their student's proficiency and propose ways to improve the prescribing skills of the younger doctors, and maintain them over the prescriber working lifetime. This also implies the understanding by the prescribers that drugs are powerful and therefore dangerous instruments of medical practice and need to be treated with the respect they merit, despite their apparent ease of prescription, and repeated claims of safety by regulators and industry alike. Probably training patients in proper use of medicines might also reduce drug-related harms. Both prescribers and users of drugs need to be impressed with the fact that all drugs are dangerous, and some are also useful. Any operators of dangerous machinery, and surgeons need regular reaccreditation in most countries. Do prescribers?

Strategies to Improve Medication Safety on the Wards

Prof. S.Y. Chair, The Chinese University of Hong Kong, Hong Kong

Medication therapy has been a mainstay of medical intervention in the current health care system. With the increasing reliance on medication therapy, patients are inevitably exposed to potential harm as well as benefits. Failure to take the right drug at the right time and in the right way often results in serious medical and/or legal consequences. When administering medications (AOM), safety rules such as 'The Six Rights' should be carried out. The Six Rights refer to right medication, right client, right time, right route, right dose and right documentation. However, considering the fundamental causes of medication errors are complex and usually interrelated, more proactive AOM safety strategies, on top of 'the Six Rights', should be developed.

Medication-related error has been identified as a significant cause of morbidity and mortality. Moreover, medication error is one of the most common errors in health care settings, and it has been a major concern for health care management. Errors may possibly occur at any point in the process, and nurses have been served a vital role in detecting and preventing medication errors throughout the process of prescribing, transcribing, dispensing and administrating stages. Comparing medication errors committed in different stages, administration errors account for a significant portion of all errors. With increasing complexity in patient conditions together with multiple prescriptions, it is anticipated that medication error is an immense problem and strategies for medication safety are in urgent need.

Though causes of medication error are multifactorial; system, process and human factors are identified as the major contributors to medication errors. System factors such as excessive workloads, staff inadequacies, high patient turnover rate and unfavorable working conditions; process factors such as difficult or illegible handwriting in prescriptions, flawed dispensing system and problems with the labeling of drugs; and human factors such as fatigue, inadequate cognitive ability, unfamiliar with the medication and inexperience are all factors contributing to medication errors. To promote medication safety; studies had suggested that adequate staffing, administrating bar-coded medication, effective supervision in delegating administration and developing a culture of safety are important strategies to improve the system to safeguard human error. In addition, reducing or eliminating interruptions and distractions during medication preparation and administration, adopting computerized physician order entry (CPOE), reading back verbal orders, posting signage to avoid distraction during administration and standardizing labeling of medication are the suggested strategies to reduce process factors which may contribute to medication-related errors.

Regarding human factors, adequate rest to maintain the alertness at work, using interactive web-based educational program, introducing mandatory medication error prevention seminars and implementing medication administration policies are useful strategies to improve medication safety.

Working Hand in Hand with Health Care Professionals to Improve Medication Safety

Mr. Michael H.M. Ling Kwong Wah Hospital, Hong Kong

Potent medications, if improperly handled, will not only delay disease management, but also cause harm to the patient. Medication management today is a highly complex matter. A chain of personnel are usually involved in a simple prescription, and a series of steps are gone through before the patient finally takes the medication. During the process, human errors could be made, and if not checked and stopped would result in harm.

Medication error reporting has begun in Hong Kong since the early 1990's. A lot has been learned which were subsequently made used of to design systems improvement. Mr Ling will discuss medication safety initiatives that have been made by various healthcare professionals and institutions over the years.

Medication safety is a business for every body. The drug manufacturers have a responsibility to improve the labeling and packaging of their products. Doctors should choose and prescribe drugs properly and clearly. Pharmacists should ensure the storage and dispensing of medications to be accurate. They could also help doctors and nurses in the distribution and clinical management of medications. Nurses would follow proper procedures in drug administration. Even patients also have a responsibility to work with the healthcare professionals by taking the medications properly. Examples will be used to illustrate how multidisciplinary collaboration could make our workplace safer for the patient.

Enhancing Manufacturing of Medicines to Improve Patient Safety

Prof. Vincent H.L. Lee, The Chinese University of Hong Kong, Hong Kong

This presentation will discuss how patient safety is ultimately linked to an in-depth understanding of the drug product manufacturing process, including knowledge of the critical product attributes (CPAs) to target in vivo product performance. This is a long-overdue paradigm shift to phase out the empirical, inefficient and costly approach commonly used in drug product manufacture. At the core of this revolution in the manufacture of drug products is a shared commitment by both industry and regulatory agencies to the tenet of quality-by-design (QbD). The main task is to determine how clinically relevant critical quality attributes (CQAs) could be directly or indirectly linked to critical process parameters (CPPs), which in turn can be monitored by real-time testing or process analytical technology (PAT). Acceptance criteria based on the multi-dimensional relationship between CPPs and CQAs would ensure maintaining the operational criteria within the design space. Thus, QbD is intended to anticipate and preempt problems during the manufacture cycle, to quickly pinpoint the source of the problem when it occurred, and to stimulate continuous innovation in the product once it is launched.

Pharmaceutical scientists from academia, industry and regulatory agency must utilize evolving science and technology to drive continuous improvement to ensure higher-quality products. This calls for the development of a repertoire of high throughput and preferably in line analytical methods highly discriminant of quality defects. It also spurs a renewed interest in refining dissolution methods, including the selection of biorelevant media composition based on the conditions desired to simulate. It is as important in early development to assess active pharmaceutical ingredient (API) characteristics that may control dissolution and to identify critical excipients and/or controls needed to enhance in vivo (pre-clinical and clinical) performance. In addition, *in silico* modeling and greater understanding of formulation sensitivities are needed to streamline development programs. The regulatory objectives are to ensure that the marketed batches have the same safety and efficacy profiles as the ones tested in clinical trials and the risk to patient is minimized by decreasing variability.

Evaluation of Electronic Prescribing System in Clinical Practice

Prof. Ian C.K. Wong, The University of London, United Kingdom

Children are a particularly challenging group of patients when trying to ensure the safe use of medicines. The increased need for calculations, dilutions and manipulations of paediatric medicines, together with the need to dose on an individual patient basis using age, gestational age, weight and surface area, means that they are more prone to medication errors at each stage of the medicines management process. A UK Department of Health-commissioned report[1], [2] has shown that the main intervention to reduce medication errors is an electronic prescribing system. Most electronic prescribing studies showed some degree of reduction in medication errors, with some claiming that no errors occurred after implementation of the intervention. However, one study showed a significant increase in mortality after the implementation of an electronic prescribing system. Most interventions identified were US based, and since medicine management processes are currently different in different countries, there is a need to interpret the information carefully when considering implementing electronic prescribing systems elsewhere.

Today's talk aims to share the experience of Great Ormond Street Hospital for Children (GOSH) in implementing and evaluating an electronic prescribing system. In turn, GOSH's experiences could assist other hospitals in planning the implementation and evaluation of their own electronic prescribing systems.

GOSH used a stepwise approach in order to implement and evaluate an electronic prescribing system. Firstly, the team evaluated the literature and the needs of the electronic prescribing system. The team then established baseline prescribing medication errors prior to implementing the system in the first ward (renal ward).

The error rate was then measured again after the implementation of the system. By comparing the error rates, the team were able to evaluate the effectiveness of the system in terms of error reduction[3,4]. More importantly, the team were able to identify problems which needed to be dealt with swiftly.

Finally, the team also used qualitative methods to evaluate the "Users' Perspective" and "Organisation Perspective". This information was very important as it ensured the success of the wider implementation of the electronic system in other wards.

1. Wong ICK. Report on Co-operative Of Safety of Medicines In Children (COSMIC): Scoping study to analyse interventions used to reduce errors in calculation of paediatric drug doses. Department of Health in England, National Patient Safety Research Programme 2007. Available from: http://www.haps.bham.ac.uk/publichealth/psrp/documents/PS026_COSMIC_Final_Report.pdf

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Building Up Safety Medication Prescribing Practices

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Prescribed medication is the most frequent treatment given to patients. The five rights of safe and effective medication management are clearly defined as the right medication being given to the right patient at the right time, in the right form and at the right dose. All health care professionals involved in medication management are governed by a professional and legal accountability to follow best practice when prescribing and administering medications to the patients.

The three key components of rational prescribing are efficacy, safety and cost-effectiveness. Safe prescribing requires knowledge and skills in prescribing, accurate information about the medications and practical advice on their use. Important challenges to the prescribers include special patients (children, elderly and pregnant), drug interactions and co-morbid conditions, such as impaired renal and liver function. Continuing training in prescribing and therapeutics for doctors should enhance their knowledge and skills. Provision of up-to-date and accurate prescribing guidance to prescribers should also help improve safety. In Hong Kong, little information exists on the prescribing guidance sources, key information they should contain and the utility of such guides by the prescribers.

To optimise treatment outcome, transforming the medication use *process* into a medication use *system* is the first step. There are many opportunities to enhance safety in all stages in the medication use system. The addition of a feedback loop between the first stage (developing the therapeutic plan) and last stage (consuming the medication) in the medication use process allows for ongoing monitoring of patient care and progress.

Given the high proportion of errors that occur during the ordering of medications, much work has focused on the development of prevention strategies at this stage in the medication use process. In general, prescribing is more likely to be appropriate if there is a clear therapeutic plan with objectives that are understood by the prescribers, the patients and other health care professionals. One of the frequently recommended approaches is the computerised physician order entry, which is designed to reduce dosage errors by only offering the appropriate doses. The programme can be linked to guidelines on drug use and can provide prompts to check on drug allergies, potential drug-drug interactions, etc. This technology eliminates the need for transcription. The cost of implementation and introduction of new opportunities for errors are the limitations. Training should be provided to the junior doctors. The users should try to improve the system by evaluating its application in different practice settings and impact on patient outcomes. Clinical decision support systems are the most effective when integrated with the computerised physician order entry systems and clinician work-flow.

Many factors can possibly contribute to medication errors. Policies and procedures must be followed to ensure medication safety. The systems approach identifies places in the policies and procedures that can be modified to prevent medication errors. This approach seeks to identify and correct the errors to prevent as many as possible before they occur. When using the systems process, the basic question to ask is: "What improvements in the medication use system are required so that errors do not happen again?"

Forthcoming Meetings on Pharmacovigilance and Drug Safety

- **Second Annual Symposium on Pharmacovigilance**

  Pharmacovigilance Strategy to Maximise Drug Safety

  4 March 2011, Hong Kong

  Venue: Postgraduate Education Centre
  Prince of Wales Hospital
  Shatin, New Territories

  Main Themes: Pharmacovigilance to Ensure Drug Safety
  Pharmacovigilance in Drug Regulation
  Regulatory Aspects of Pharmacovigilance
  Building Capacity and Improving Pharmacovigilance Process

- **Asia-Pacific Conference on Pharmacovigilance and Drug Safety**

  2012, Hong Kong

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