PHARMACY DEPARTMENT, HOSPITAL SEGAMAT

Pharmacy Bulletin

Issue 001/2016

Medication Error Reporting (MER)

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Introduction

One of the important missions of the healthcare providers is to help patients make the best use of medications and to ensure patient safety. Medication safety is one of the major components in patient safety; unfortunately medication errors do occur and often go undetected. Some medication errors may result in serious patient morbidity and mortality.

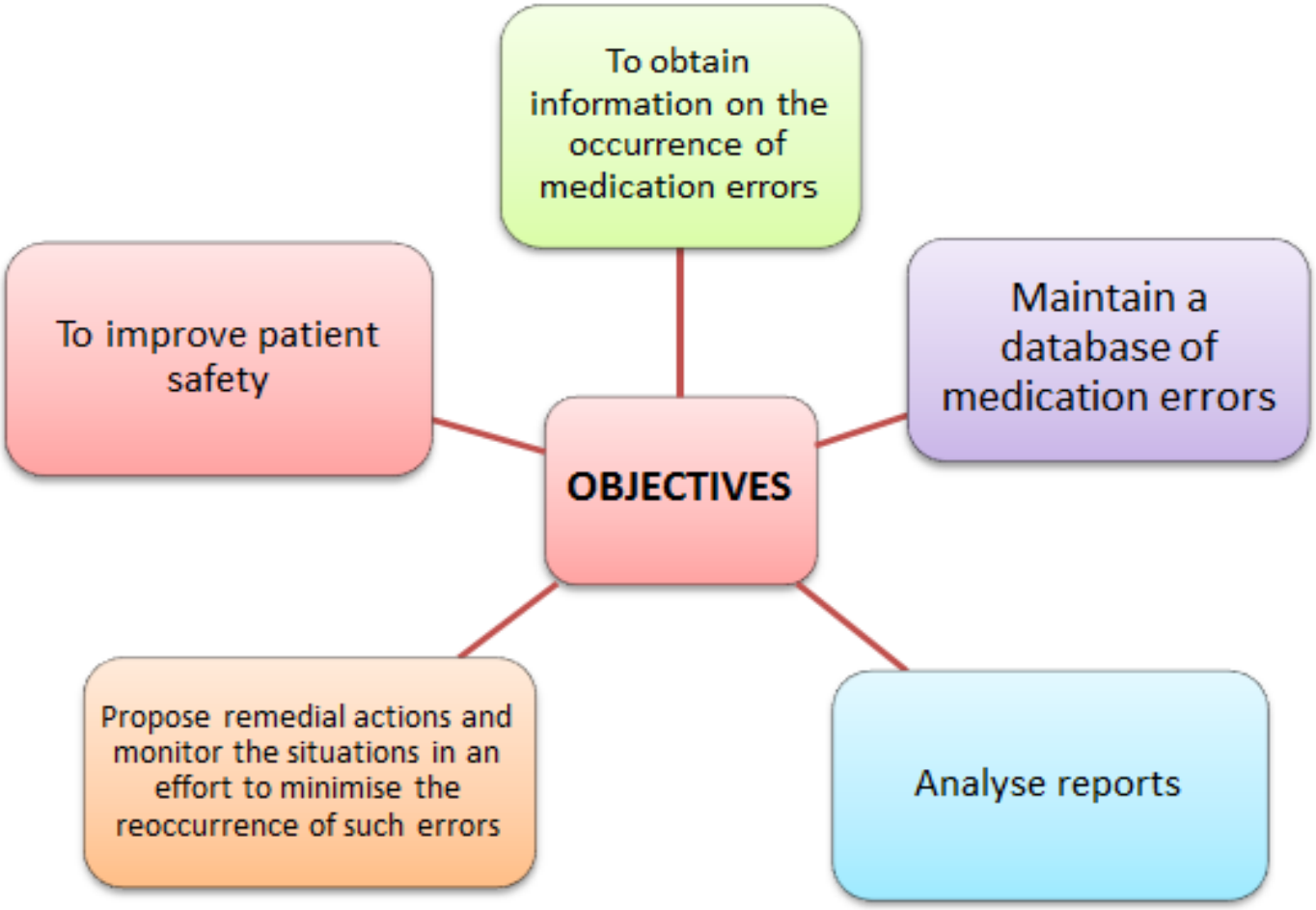
The current system need to be further strengthened with a mechanism to monitor and make recommendations for remedial actions when errors occur and are reported. The proposed mechanism is a 'Medication Error Reporting System' through which medication errors will be monitored and preventive measures can be defined. This system requires a collective effort from various parties and a change in the way we manage medication errors. We need to be able to discuss errors openly, encourage reporting of errors and maintain a culture that is non-punitive and blamelessness. This can help healthcare providers to learn from the errors.

A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer. Such an event may be related to professional practices, healthcare products, procedures and systems including prescribing, order communication, product labelling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.

Medication errors may be committed by both inexperienced and experienced personnel like doctors, pharmacists, dentists and other healthcare providers, patients, manufacturers, caregivers and others.

Reference: Guidelines on Medication Error Reporting, Ministry of Health Malaysia,2009

Objectives and Impact of Medication Error Reporting



Types of Medication Error

- **Presribing error**
- **Omission error** (Failure to administer an ordered dose)
- **Wrong time error**
- **Unauthorised drug error** (Dispensing or administration of medication not authorised by a legitimate prescriber)
- **Dose error**
- **Dosage form error**
- **Drug preparation error**
- **Other medication error**
- **Route administration error**
- **Deteriorated drug error** (Dispensing or administration of a drug that has expired)
- **Monitoring error** (Failure to review a prescribed regimen for appropriateness and detection of problems)
- **Administration technique error**
- **Compliance error**

Procedures for Reporting Medication Error

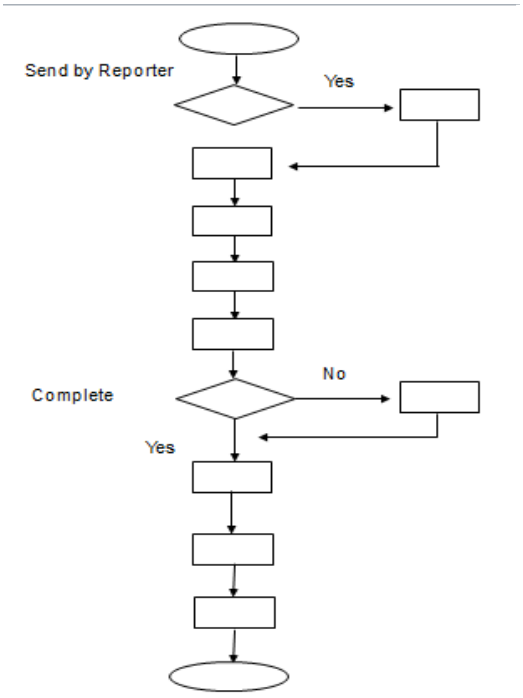
General

- All Medication Error Reports should be submitted via http://mers.moh.gov.my
- OR send to Medication Safety Centre, Pharmaceutical Services Division, Ministry of Health MalaysiaP.O. Box 924, Jalan Sultan, 46790 Petaling Jaya, Selangor
- OR Fax to 03-79682268 or call 03-78413200 for enquiries

Reporting Format

- Medication Error should be reported using the prescribed format which is available from the Pharmaceutical Services Division website (www.pharmacy.gov.my.)

Procedures for Reporting Medication Error in Hospital



Reporter recognize the medication error

Reporter send a printed copy to Drug Information Service (DIS) pharmacy or Pharmacist In – Charge ME.

Reporter obtain Medication Error (ME) form from (DIS) pharmacy or Pharmacist In – Charge ME.

Reporter fill the report form with details

Reporter send form to DIS pharmacy or pharmacist In – Charge ME

DIS pharmacy or pharmacist In – Charge ME check the received form

DIS pharmacy or pharmacist In – Charge ME contact reporter to get details

DIS pharmacy or pharmacist In – Charge ME submit the ME reports via online through http://mers.moh.gov.my

DIS pharmacy or pharmacist In – Charge ME send a copy of the completed ME forms for cases in category C to I to Head Of Department/Unit

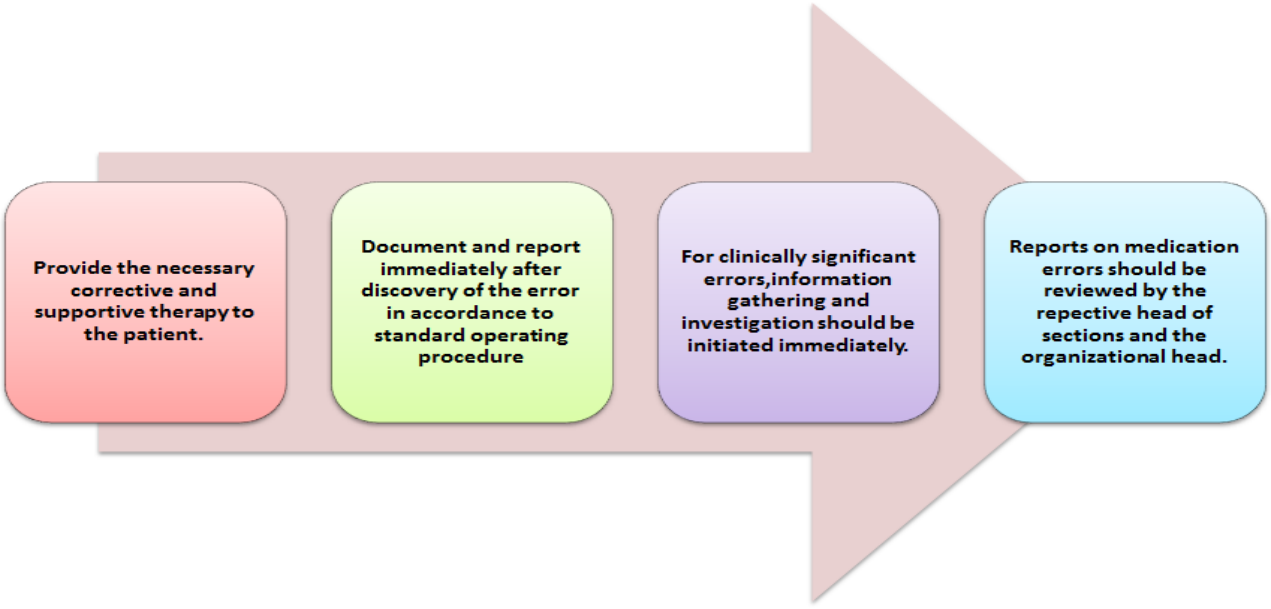
DIS pharmacy or pharmacist In – Charge ME file the completed ME forms

Related healthcare professional propose and take actions to prevent future re-occurrence

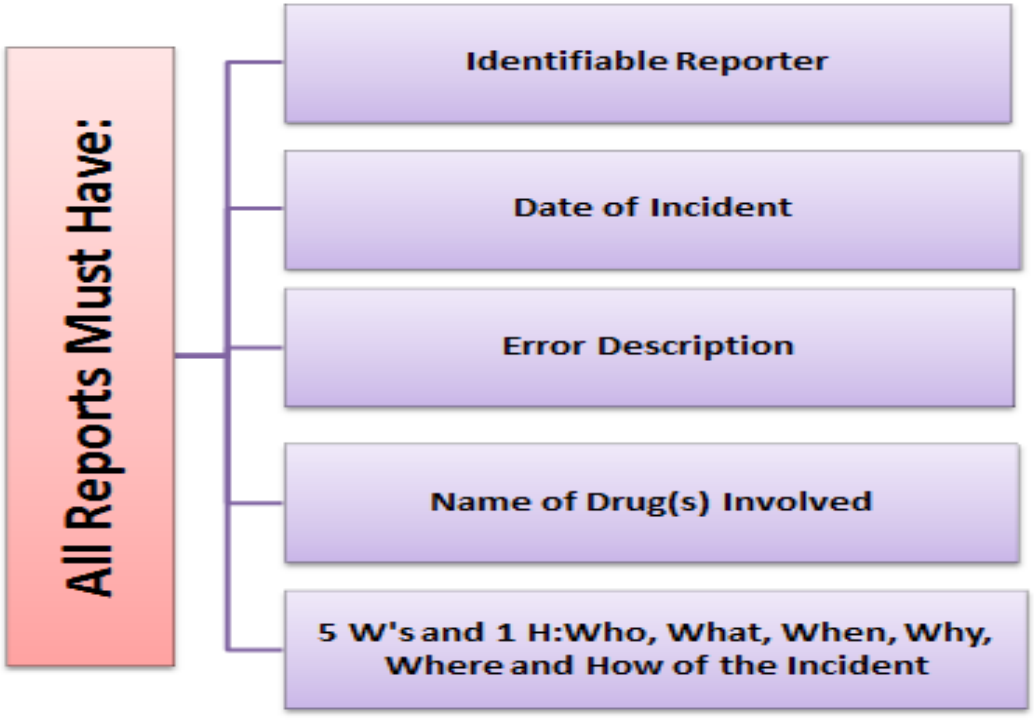
Classification of Medication Error Severity

A - Potential Error	NO ERROR
B - Actual error did not reach Patient	ERROR, NO HARM
C - Actual error caused no harm	
D - Required additional Monitoring	
E - Treatment / Intervention	
F - Initial / Prolonged Hospitalization	ERROR, HARM
G - Caused permanent harm	
H - Near death event	
I - Death	ERROR, DEATH

What to Do When There is Medication Error?



Basic Principles of Efficient Reporting



MADRAC
Malaysian Adverse Drug Reactions Newsletter
National Pharmaceutical Control Bureau, Ministry of Health Malaysia
This newsletter is also available on our website: http://www.bpfk.gov.my
ACTIVITIES OF MALAYSIAN ADVERSE DRUG REACTIONS ADVISORY COMMITTEE (MADRAC)

Malaysian Adverse Drug Reactions Newsletter August 2015

ROTAVIRUS VACCINE: RISK OF INTUSSUSCEPTION

Rotavirus is the leading cause of severe dehydrating diarrhoea in children aged under 5 years. The World Health Organisation (WHO) estimated that it caused 453,000 rotavirus gastroenteritis-associated child deaths worldwide. In Malaysia, rotavirus accounts for 30.3% of childhood acute gastroenteritis .

Background of Safety Issue

Intussusception, an invagination of the intestines, is a serious and potentially fatal condition that commonly occurs in children aged between 4 months to 2 years. The first marketed rotavirus vaccine, Rotashield®, was withdrawn by the United States Food and Drug Administration (US FDA) in June 1999, just nine months after it became available, when researchers observed an increased risk by one or two cases of intussusception per 10,000 infants vaccinated with Rotashield.

Currently, there are two oral rotavirus vaccines available internationally, namely Rotarix® and Rotateq®. Large clinical trials for these two vaccines involving 60,000 to 70,000 infants have been carried out to study the risk of intussusception, as previously observed with Rotashield®. Although the results showed no increased risk when compared to placebo market surveillance has detected cases of intussusception with risk varying in different populations, as described below.

Research Findings

In a study conducted by Patel et al. (published in June 2011), the potential risk of intussusception with Rotarix® was investigated after routine immunisation of infants in Brazil and Mexico . The study revealed an increased risk of intussusception in Mexican infants at 1 – 7 days after first dose of Rotarix®, but no significant risk observed in Brazilian infants after the first dose. However, there was a small increased rate of intussusception 1 – 7 days following second dose of vaccine in Brazilian infants. The study attributed an annual excess of approximately 96 cases of intussusception to the vaccine, in Mexico and Brazil combined.

Another study on intussusception following rotavirus vaccination in Australia, where both Rotarix® and Rotateq® are commercially available, allowed estimation of product-specific risk. Findings were similar for both vaccines, showing an increased risk of intussusception 1 – 21 days after first dose and 1 – 7 days after the second dose. It was estimated that the risk of intussusception with rotavirus vaccination was 14 excess cases per year.

In February 2014, the WHO Global Advisory Committee on Vaccine Safety acknowledged the risk of intussusception following administration of Rotarix® and Rotateq®, particularly during the first seven (7) days following first dose .

Conclusion

Overall, the risk of intussusception remains small compared to the benefits of preventing severe rotavirus gastroenteritis. In order to facilitate better risk assessment, healthcare professionals are encouraged to report suspected cases of intussusception related to rotavirus vaccination to the NPCB Drug Safety Monitoring Centre. Healthcare professionals should also counsel parents on the risk of intussusception, and advise them to seek immediate medical attention if the child shows signs and symptoms of the said condition.

Reaksi
DRUG SAFETY NEWS

Reaksi Drug Safety News November 2015,No. 26

IVABRADINE: RISK OF CARDIOVASCULAR ADVERSE EVENTS

Overview

Ivabradine is approved in Malaysia for:

- treatment of chronic heart failure;
- symptomatic treatment of chronic stable angina in adults who are unable to take beta blockers, or in combination therapy for patients inadequately controlled with an optimal beta-blocker dose.

It lowers the heart rate by selective and specific inhibition of the cardiac pacemaker If current, which controls the spontaneous diastolic depolarisation in the sinus node. The cardiac effects are specific to the sinus node, slowing the heart rate without affecting cardiac contractility or ventricular repolarisation. The molecular subunits of the If channel are the hyperpolarisation-activated cyclic-nucleotide gated (HCN) channels. Some genetic alterations of this channel gene may be associated with the increased risk of bradycardia, arrhythmia and atrial fibrillation (AF).

Background of Safety Issue

A review into the safety of ivabradine was triggered by the preliminary results of the SIGNIFY clinical trial. The results of this trial showed a small but significant increase (3.4% vs 2.9% yearly incidence rates) in the combined **risk of cardiovascular death** or **non-fatal heart attack** with ivabradine compared with placebo, in patients with symptomatic angina. The study also revealed an increased risk of **bradycardia** (17.9% vs 2.1%) and **AF** (5.3% vs 3.8%) in participants taking ivabradine compared with placebo.

Local Scenario

There are currently two (2) products containing ivabradine registered in Malaysia since 2008 under the brand name Coralan® . Following this review, the product PIs have been updated with safety information to reduce the risk of cardiovascular adverse events. Ivabradine is listed in the Ministry of Health Drug Formulary (FUKKM) under category A* (to be initiated by consultants for specific indications only).

ADR Reports

Since ivabradine was first registered in Malaysia, the NPCB has received **six (6) ADR reports** related to these products with 15 adverse events. **Two cases** reported patients suffering adverse cardiovascular events about one hour after taking ivabradine for angina. One patient suffered marked bradycardia (37 beats per minute- bpm), blurred vision and dizziness, while the second patient experienced palpitations with associated joint pain and tingling sensation. Both patients were taking concomitant medication which may have contributed to the adverse events, therefore the cases were assigned causality C3 (possibly-related to the drug).

Among the other adverse events reported for ivabradine were dyspepsia, nausea, shortness of breath, vomiting, and yellowish vision.

Hospital Segamat Diary

Farewell

December 2015 was the last month for our dearest Pn Fazenon, Pn Mazni and Pn Yusnira working in Hospital Segamat.

Good Luck, new FRPs!

Best wishes to Miss Halen Law and Mrs Nur Amaliya Wafiya

CNY !

Chinese New Year Feast for all staff of Hospital Segamat at Dewan Perdana On 18th February 2016.