

**Pharmacy  
Department,  
Hospital  
Segamat**

# Antimicrobial stewardship program

**Bulletin  
Pharmacy**

**04/2015**

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## Antimicrobial Resistance (AMR)

In the last 40 years, the prevalence of multidrug resistant microorganisms (e.g. extended spectrum Beta-lactamase inhibitor *enterobacteriaceae*) have risen alarmingly. Antimicrobial resistance (AMR) occurs when microorganisms change in ways that render the medications used to cure the infections they cause ineffective. Antimicrobial resistance correlate with the use of antimicrobials.

The emergence of AMR can cause the resistance to first-line medicines and leads to the use of second or third-line drugs which is less effective, more toxic and more costly. Therefore, AMR could give a negative impact on patient outcomes, poses a major threat for patient safety, increases health expenditure and results in loss of treatment options for common infections.

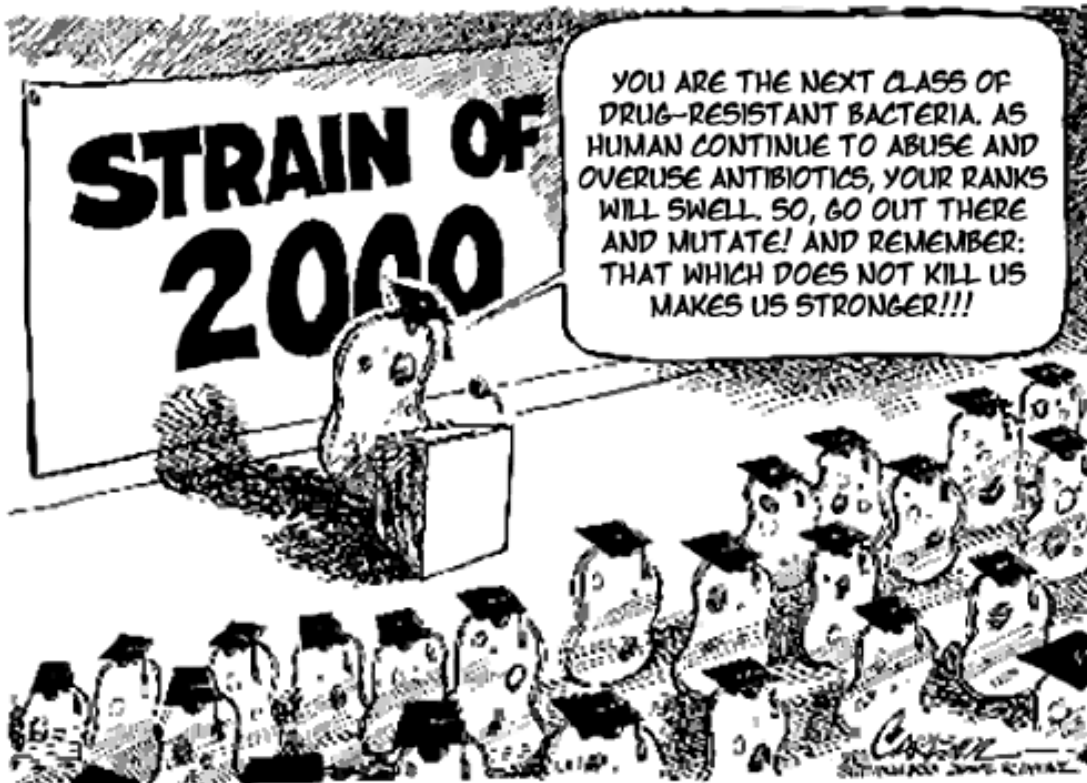
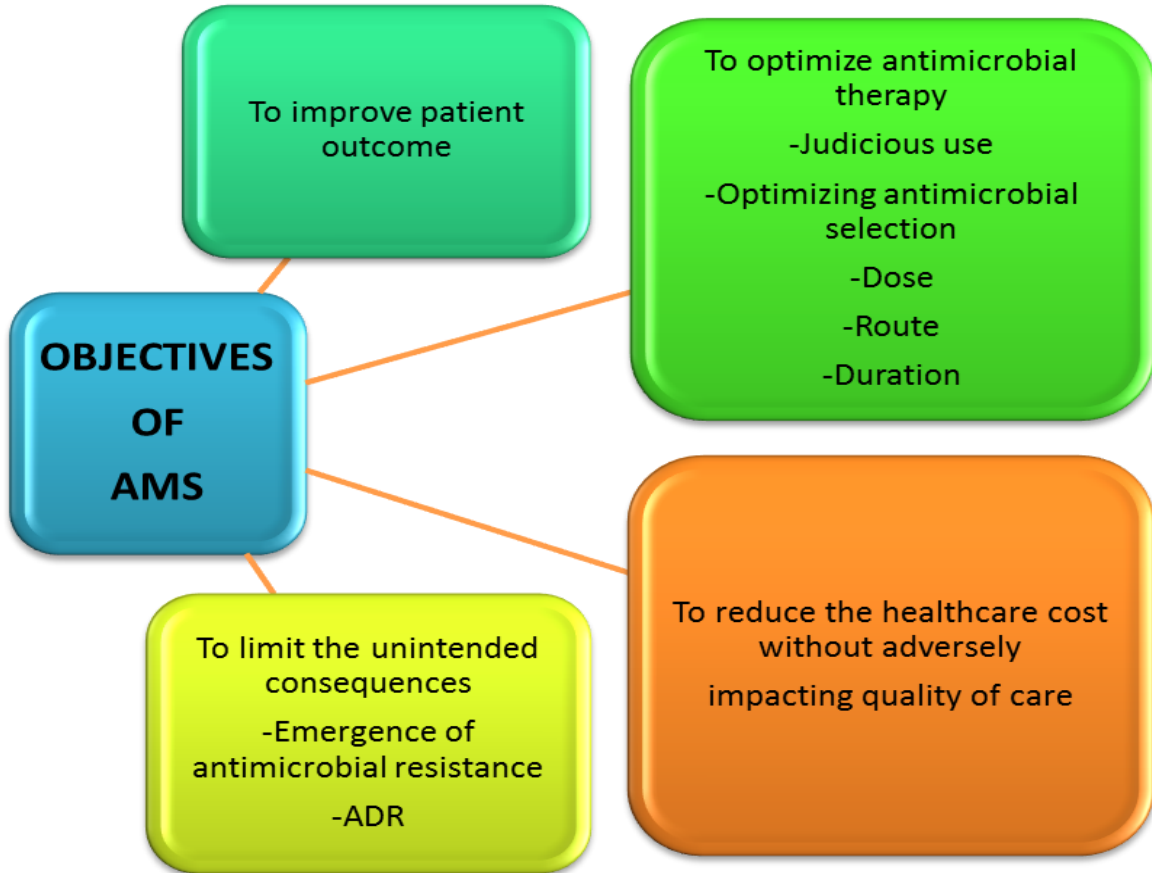
## What is Antimicrobial Stewardship Program (AMS)?

To respond on the issues of AMR, Antimicrobial management or stewardship program have been developed. Antimicrobial Stewardship (AMS) is thus a coordinated systematic approach to improve the appropriate use of antimicrobials by promoting the selection of the optimal antimicrobial drug regimen; right choice of antimicrobial, right route of administration, right dose, right time, right duration and minimize harm to the patient and future patients.



A campaign by advocated by World Health Organization (WHO)

# Objectives of AMS



# Antimicrobial Stewardship Program in Hospitals

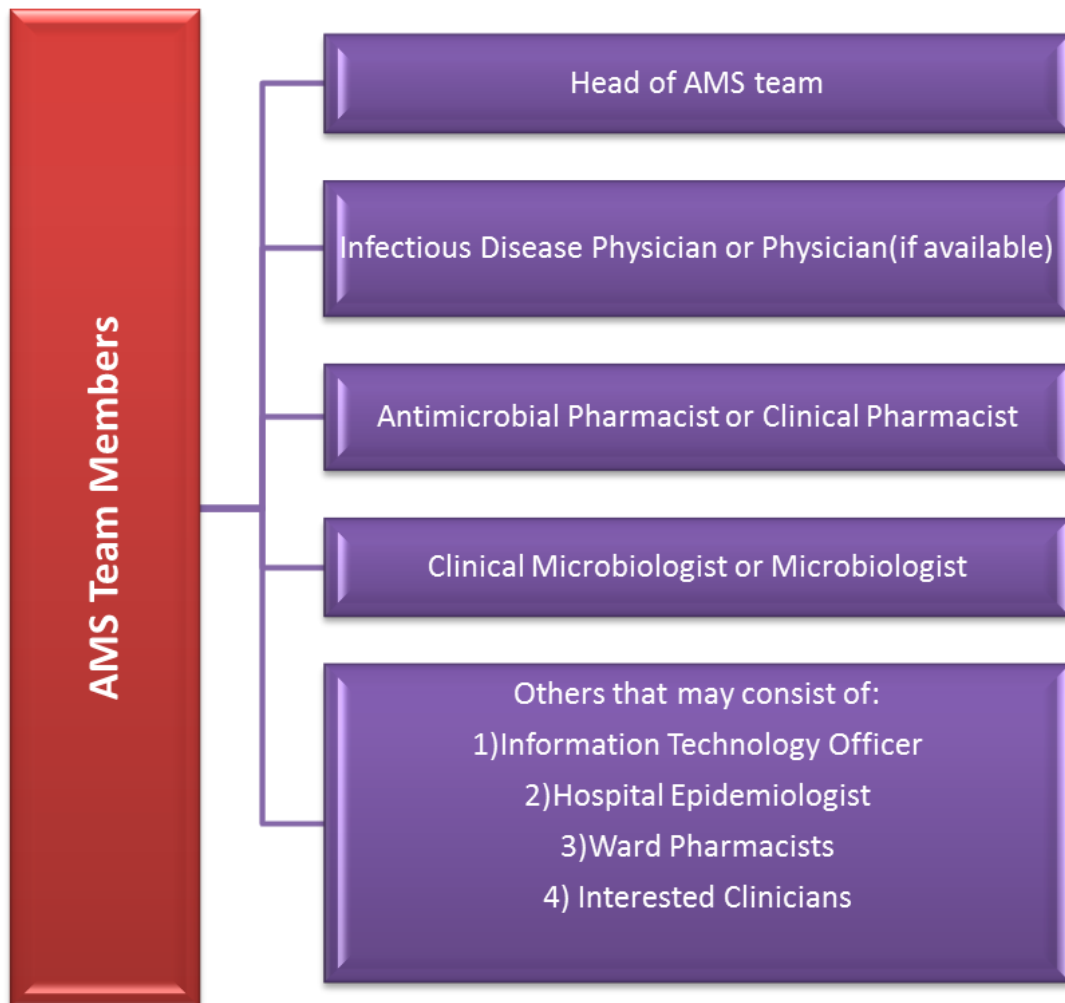
## Antimicrobial Stewardship Team

### Governance

The AMS Program in hospitals is under purview of the Hospital Infection Control and Antibiotic Committee and is supported by the :

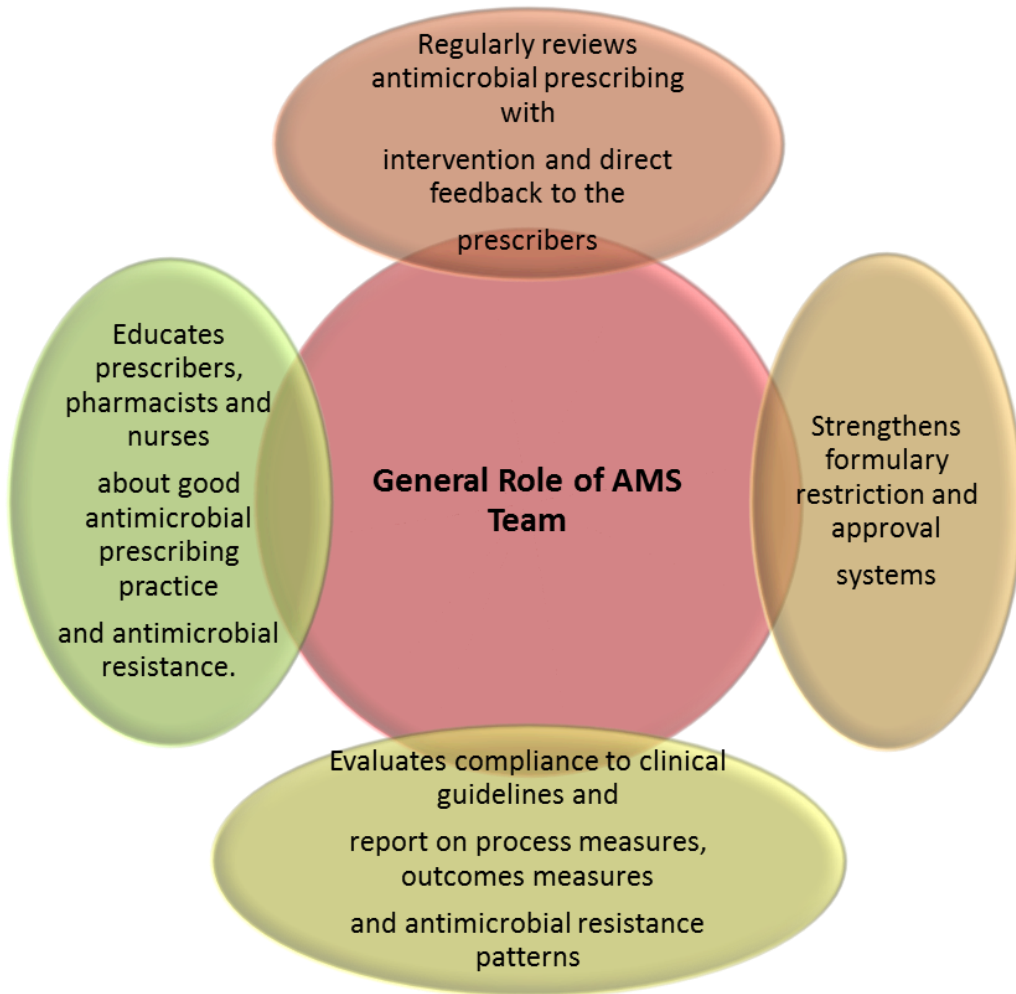
- a. Hospital Director
- b. Head of various clinical departments
- c. Head of Pharmacy Department
- d. Head of Medical Biology

AMS team should be appointed by the Hospital Director.



# Antimicrobial Stewardship Program in Hospitals

## Antimicrobial Stewardship Team



## Accelerating Antimicrobial



## STEWARDSHIP PROGRAMS

# Antimicrobial Stewardship Program in Hospitals

## What are the Antimicrobial Stewardship Activities?

### 1. Encourage Formulation of Local Guidelines & Clinical

Local antibiotics guidelines & clinical pathways should be formulated based on the national antibiotic guideline, evidence in the literature and local microbiology and resistance patterns.

Clinical pathways such as common infections can be produced to bring about uniformity in Prescribers approaches in local setting.

### 2. Surveillance and Feedback

Monitoring antimicrobial prescription and consumption behavior provides insights and tools needed to inform therapy decisions, to assess the public health consequences of antimicrobial misuse, and to evaluate the impact resistance containment interventions.

### 3. Prospective Audit and Feedback

A prospective audit and feedback system involves a multidisciplinary team who regularly reviews patients. However occasionally there may be further directive from national or state level if local usage is not in keeping with national or state usage trend.

### 4. Formulary Restriction and Pre-authorization

A list of restricted antimicrobials would need to be included in the antimicrobial policy which will be reviewed on regular basis.

Restriction can be implemented through a number of ways:

- pre-approval (can only be started after getting a specific approval)
- temporary approval (can be started but would need approval for continued usage)

### 5. Antimicrobial Order Tools

An antimicrobial order tools may improve the quality of prescriptions by increasing the awareness of clinicians of desired antimicrobial spectrum. By filling in the antimicrobial order tools, the prescribers also provide themselves the data for drug utilisation surveillance.

### 6. Antimicrobial Streamlining

The De-escalation strategy

1. Target broad spectrum antimicrobials that are used empirically.
2. Review at :
  - 72 hours after antimicrobial initiation or;
  - Once a week review of a specific ward, unit, hospital
3. Identify de-escalation opportunities

### 7. Antimicrobial Selection and Dose Optimization

- extended or continuous infusion of beta-lactams
- once-daily dosing of aminoglycosides
- appropriate dosing of antimicrobials (e.g.; vancomycin, polymyxins, cefepime)
- weight-based dosing of certain antimicrobials
- dose adjustments for patients

### 8. Intravenous (IV) to Oral (PO) Antibiotics Conversion

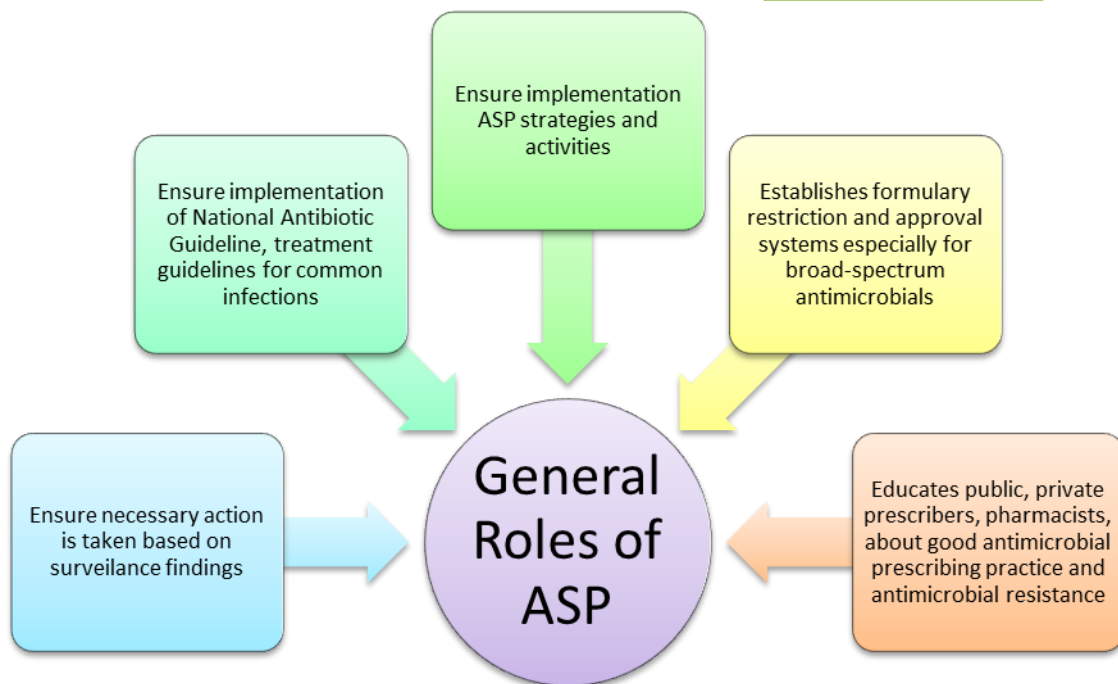
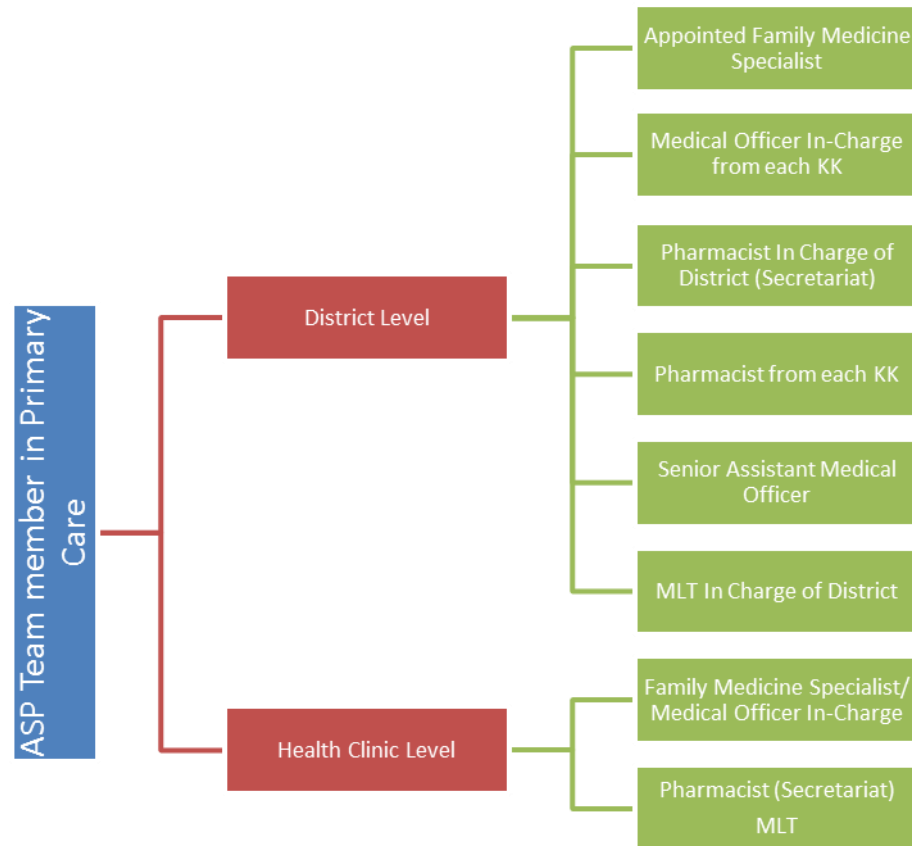
This describes the practice of converting intravenous antimicrobials therapy to an effective alternative oral formulation. Cost savings are achieved through lowering direct acquisition costs, eliminating the need for ancillary supplies, reducing pharmacy and nursing time, and shortening the length of hospital stay.

### 9. Education

Antimicrobial Stewardship team would prepare a program of ongoing education for pharmacists, doctors and nurses to influence prescribing behavior and to provide knowledge that will enhance and increase the acceptance of Antimicrobial Stewardship strategies.

# Antimicrobial Stewardship Program in Primary Care

## Antimicrobial Stewardship Team





# Antimicrobial Stewardship Program in Primary Care

## What are the Antimicrobial Stewardship Activities?

### 1) Implementation of Treatment Guidelines and Clinical

ASP team should ensure the implementation of treatment guidelines and clinical pathways when they are available.

Clinical pathways should be developed for these two common conditions such as in the areas of upper respiratory infections and diarrhea in the primary care setting inappropriate antimicrobial use.

If successful, it can make a significant impact on decreasing antimicrobial use in primary care.

### 2. Surveillance and Feedback

Should be conducted continuously in clinics with IT system. Where else, for Advanced Clinics without IT system, antimicrobial point prevalence survey should be conducted yearly.

Surveillance of antimicrobial use can show us how and why antimicrobials are being used and misused by patients and healthcare providers.

### 3. Audit and Feedback

The scope of clinical audit is to include appropriateness of antimicrobial prescription. Annual report of the clinical audit should be presented in ASP District Meeting.

### 4. Formulary Restriction

Is one of the pillars of AMS Program. MOH formulary already has restrictions based on category of prescribers, however these restrictions may not be adequate to guide the local prescribers about judicious use of antibiotic.

### 5. Antibiotic Selection and Dose Optimization

Should be tailored to the patient's characteristics, causative organism, site of infection, and pharmacokinetic and pharmacodynamic characteristics of the antimicrobial agent.

Strategies that may be considered include:  
weight-based dosing of certain antimicrobials for paediatric. dose adjustments for patients with renal dysfunction

### 6. Education

Should prepare a program of continuous education for doctors, pharmacists and paramedics to influence prescribing behavior and to provide knowledge that will enhance and increase the acceptance of Antimicrobial Stewardship strategies.

This program should be included in the induction training for all newly reporting medical, paramedic and pharmacy staff.

Educational Key Points must be highlighted during these session to instill appropriate use of antimicrobial.



## Malaysian Adverse Drug Reactions Newsletter August 2015

### Early Detection of Serious Skin Reactions: Auxiliary Warning Label

**I**n 2014, NPCB received reports on 322 patients who suffered serious adverse cutaneous drug reactions, of which eight (8) resulted in deaths suspected to be due to the reactions. The reactions also prolong hospitalisation and carry high cost implications.

Malaysian ADR data (2000-2014) indicates that the drugs most commonly associated with causing serious skin reactions are allopurinol, antiepileptics, antibiotics, and non-steroidal anti-inflammatory agents (NSAIDs).

MADRAC proposed that an auxiliary warning label related to serious skin reactions be added during the dispensing process of these drugs. This is to ensure patients are able to recognise the first signs of skin reactions and seek immediate medical advice to help prevent serious reactions.

Six (6) drugs were chosen for the first phase of this auxiliary warning label implementation, namely allopurinol, co-trimoxazole, diclofenac, mefenamic acid, carbamazepine and phenytoin. Since August 2014, all government and private healthcare facilities have been advised to implement the use of these warning labels (in Malay Language or English), as follow:

For drugs which can be stopped immediately:

**Allopurinol, Co-trimoxazole, Diclofenac, Mefenamic acid**

If you have side effects such as a rash, fever, sore throat, or eye irritation, stop using this medication IMMEDIATELY and consult your doctor/ pharmacist.

**For anti-epileptics which should NOT be stopped suddenly without medical advice:**

**Phenytoin, Carbamazepine**

If you have side effects such as a rash, fever, sore throat, or eye irritation, seek medical advice from your doctor/ pharmacist IMMEDIATELY.

#### Local Scenario

From year 2000 to Feb 2015, NPCB has received 1,018 ADR reports related to paracetamol, with 1,972 adverse events. A total of 790 reports (78%) involved at least one skin reaction, with the most commonly reported ADRs being pruritus, rash, urticaria, and angioedema. There were also a total of 30 reports involving serious skin reactions, namely SJS (18 reports), erythema multiforme (5), TEN (4), SJS-TEN overlap (2), and AGEP (1). The time to onset of reaction for these cases ranged from 24 hours (recurrence on second exposure) to several days.

On 3 June 2015, the DCA issued a directive [Bil. (29) dlm. BPFK/PPP/07/25] requiring all product registration holders of paracetamol-containing products to update their local product information (including labels, package inserts, and consumer medication information leaflets – RiMUPs) with a warning on the risk of serious skin reactions.





## Reaksi Drug Safety News September 2015, No. 25

### Hydroxyzine: Risk of Effects on Heart Rhythm

#### Overview

Hydroxyzine, one of the first generation antihistamines, has been known to cause QT interval prolongation and *torsades de pointes*. Apart from its common use in acute management of anxiety and treating generalised pruritus, hydroxyzine also has the potential to block the human Ether-à-go-go-Related Gene (hERG) channels as well as other cardiac channels. This may result in abnormal heart rhythms, and possibly even cardiac arrest in patients with underlying heart disease and cardiac arrhythmia.

#### Background of Safety Issue

In March 2015, the National Pharmaceutical Control Bureau (NPCB) initiated a review into this safety issue following an alert from the European Medicines Agency (EMA) regarding the risk of effects on heart rhythm with medicines containing hydroxyzine. After reviewing clinical and post-marketing data, EMA restricted the use of hydroxyzine in patients at high risk of arrhythmias, limiting the usage to the lowest therapeutic dose for the shortest duration possible. The maximum recommended dose for adults should not be more than 100 mg/day, and for children weighing below 40 kg, a maximum of 2 mg/kg. EMA also recommended that hydroxyzine should be avoided in patients with cardiovascular disease, as well as in geriatric patients due to reduced elimination of hydroxyzine and greater vulnerability to anticholinergic effects or other adverse reactions.

#### Local Scenario

In Malaysia, there are currently three (3) registered products containing hydroxyzine, under the brand name Atarax®. All three products share the following indication but at different suggested dosage and frequency:

- ⇒ In adults, for symptomatic relief of anxiety and tension associated with psychoneurosis and as an adjunct in organic disease states in which anxiety is manifested.
- ⇒ As a sedative used as premedication and following general anaesthesia.
- ⇒ As symptomatic treatment in atopic pruritus.

The product insert of Atarax® has been updated with the new dosing recommendations and warnings on use in patients who have risk factors for heart rhythm disturbances or who are taking certain other medicines.

#### ADR Reports

To date, NPCB has received **20 ADR reports** related to hydroxyzine use. A total of 37 adverse events have been reported, **none** of which are related to heart rate or rhythm disorders. The majority of the ADRs reported involved skin reactions, namely pruritus (6), rash (5), dry skin (2) and urticaria (2).

#### Advice to healthcare providers

- ⇒ Hydroxyzine should be used at the **lowest effective dose** for the **shortest possible duration**.
- ⇒ Use is **contraindicated** in patients with known acquired or congenital QT interval prolongation, or with a known risk for QT interval prolongation such as cardiovascular disease, significant electrolyte imbalance (hypokalemia, hypomagnesaemia), family history of sudden cardiac death, significant bradycardia, or concomitant use of drugs known to prolong the QT interval and/or induce *torsades de pointes*.
- ⇒ Use is **not recommended** in elderly patients.
- ⇒ Use with caution in patients with bradycardia, or on hypokalaemia-inducing drugs.
- ⇒ **Please report** any hydroxyzine-related ADR to the NPCB for safety monitoring of this drug, allowing prospective data collection and utilisation in the future.

## DID YOU KNOW?

A standardized Antimicrobial Order Form has been introduced in conjunction with the Antimicrobial Stewardship (AMS) Program. Soft copy of this form can also be downloaded from Jabatan Kesihatan Negeri Johor's official website(<http://jknjohor.moh.gov.my>).

## Antimicrobials That Require An Order Form

Carbapenems
Inj. Imipenem
Inj. Meropenem
Inj. Ertapenem
Inj. Doripenem

Cephalosporins
Inj. Ceftriaxone
Inj. Cefotaxime
Inj. Ceftazidime
Inj. Cefoperazone
Inj. Cefepime

Lincosamides
Inj. Clindamycin

Glycopeptides
Inj. Vancomycin

Glycylcycline
Inj. Tigecycline

Oxazolidinones
Inj. Linezolid

Polypeptides
Inj. Polymyxin B
Inj. Colistimethate Sodium (Polymyxin E)

$\beta$ -lactam/ $\beta$ -lactamase Inhibitor
Inj. Piperacillin/Tazobactam
Inj. Cefoperazone /Sulbactam

Quinolones
Inj. Ciprofloxacin
Inj. Moxifloxacin

Antifungal
Inj. Amphotericin B
Inj. Fluconazole
Inj. Caspofungin
Inj. Anidulafungin

\*Antimicrobial availability subject to respective hospital formularies

### ANTIMICROBIAL ORDER FORM

pharmacy copy

**72 hours Antimicrobial Review Form**

(Please make sure that this form is COMPLETELY filled to ensure continuous drug supply)

Patient's name :		Age :	
RN :		BW : _____ kg	
Ward :		SCr : _____ µmol/L	
Specialty :			
Diagnosis :			
Drug, dose & frequency :			
Date started :		Duration planned :	
Positive culture from :			
<input type="checkbox"/> Blood	<input type="checkbox"/> Urine	<input type="checkbox"/> Tissue	
<input type="checkbox"/> Sputum/ ETT/ BAL	<input type="checkbox"/> Pus	<input type="checkbox"/> Others (specify): _____	
Organism :		Sensitivity :	
1. _____		1. _____	
2. _____		2. _____	
Serology result (if applicable) : _____			
Justification for continuation If culture negative :			
Specialist signature & stamp		After office hours : Signature & stamp (MO/ Specialist)	
		Spoken to : _____ (Specialist)*	
		*If continued by MO	

**Antimicrobial Initiation Form** (Please make sure this form is COMPLETELY filled before sending to pharmacy)

Patient's name :		Age :	
RN :		BW : _____ kg	
Ward :		SCr : _____ µmol/L	
Specialty :			
Diagnosis :			
Drug, dose & frequency :		Remarks :	
Date started :			
Indication :		Cultures sent prior to the initiation of antimicrobial(s) :	
<input type="checkbox"/> Prophylaxis	<input type="checkbox"/> Blood	<input type="checkbox"/> Tissue	
<input type="checkbox"/> Empirical	<input type="checkbox"/> Sputum/ ETT/ BAL	<input type="checkbox"/> Pus	
<input type="checkbox"/> Treatment for known pathogen	<input type="checkbox"/> Urine	<input type="checkbox"/> Others (specify): _____	
Previous antimicrobial(s) :		Organism (if available) :	
<input type="checkbox"/> Not on any antimicrobials previously			
<input type="checkbox"/> Switch from _____			
		Sensitivity :	
Specialist signature & stamp		After office hours : Signature & stamp (MO/ Specialist)	
		Spoken to : _____ (Specialist)*	
		*If started by MO	



**Hospital Segamat**

**Bulletin Pharmacy  
04/2015**

**PHARMACY  
DEPARTMENT**

## **Our Final Moment with Them**



## **Goodbye and Thank You for Everything!**



Wishing all the best to :

- 1) Pn. Nor Azlina binti Mohd Tahir
- 2) Mdm. Teh Siew Gyn
- 3) Miss Lim Xin Ru
- 1) Miss Goh Siow Chin
- 2) Mr. Lawrence Lim
- 3) Miss Tan Wan Xian