

In this issue:

- ◇ Chief Pharmacist's Update
- ◇ Medication Safety Updates
- ◇ IRA update
- ◇ New 4th edition of Fiji Essential Medicines List
- ◇ Medication in Focus—DICLOFENAC
- ◇ New Cardiovascular Therapeutic Guidelines

Pharmanews *Bulletin*

AN INFORMATIVE & EDUCATIONAL PHARMACEUTICAL PUBLICATION FOR ALL HEALTH CARE WORKERS

Free Medicines Initiative – Promoting Equity of Access to Medicines

Medicines are essential commodities and are considered a vital component of all health systems. However, the out of pocket expenses to purchase medicines can often place a large financial burden on Fijian patients and their families.

In Fiji, medicines are available free of charge in public health facilities, however, patients who choose to access private health services are required to purchase their medicines from private (retail) pharmacies.

The new **Fiji Free Medicines Program** allows all eligible Fijians to access 72 medicines, that have been prescribed by a licensed medical practitioner, free of charge from any Government pharmacy or selected private pharmacies. Whilst medicines provided *free of charge* target **equal** access to all, the free medicines initiative additionally improves **equity** of access by addressing affordability determined by income.

One of the main policy objectives of the Fiji National Medicinal Products Policy (NMPP) is *to ensure the ready and reliable availability of good quality, acceptably safe and proven effective medicines at a price the individual and the community can afford.* The Program reflects the NMPP objectives as it will increase acces-

~ Chief Pharmacist's Update ~

sibility to medicines for all patients who earn less than \$20,000 a year.

The initiative has increased **equity** by creating accessibility to much needed essential medicines by removing out of pocket expenses for patients in the private sector. This means, financial burden due to medication costs is reduced even if patients opt to obtain treatment privately.

Furthermore, patients who obtained prescriptions from private General Practitioners (GP's) are able to go to either Government health facilities or private pharmacies to get their eligible medicines dispensed free of charge. Thus, increasing patient's options of accessibility to medicines, and therefore further improving accessibility and affordability of medicines for Fijian patients.

This initiative transfers medicine costs, which had previously been paid by patients and their families, to the public health system, thus reducing financial burdens which can be a barrier to patients accessing health services.

Fiji is moving towards the goal of universal health coverage and this

Program aims to provide equitable and affordable access to medicines which will directly benefit all Fijian patients.

The FPBS team has been busily procuring the 72 medicines for the implementation and maintenance of the **Fiji Free Medicines Program**. In addition, public awareness leaflets and posters detailing the 72 medicines available, list of private pharmacies participating in this Program and frequently asked questions are being produced and will be disseminated to the public in the near future.

Wishing you all a happy, healthy and productive 2015.

*Apolosi Vosanibola, Chief Pharmacist
Fiji Pharmaceutical &
Biomedical Services*

L to R: Jeremaia Mataika, Ilisabeta Pesamino, Amele Lalibuli, Apolosi Vosanibola, Vijayeta Prasad, Muniamma Gounder and Waisea Kelo at the Senior Pharmacist Meeting held in February.



Bula Vinaka from the Editor

Bula vinaka and welcome to the first issue of Pharmanews for 2015. We hope you all had an enjoyable festive break and enjoy this issue to get you back into the swing of the new year.

If you have any questions, comments or suggestions for future articles or would like to contribute an article or be included in our electronic distribution, please contact:

The Essential Medicines Authority (EMA): jeremaia.mataika01@govnet.gov.fj

We are looking forward to bringing you more issues in 2015! ***Vinaka Vakalevu!***





*Informative
articles
highlighting
medication
safety issues*

Co-trimoxazole and sudden death in patients receiving inhibitors of renin-angiotensin system

An article published in late September 2014, has concluded that; **in older patients receiving angiotensin converting enzyme inhibitors or angiotensin receptor blockers, co-trimoxazole is associated with increased risk of sudden death.** Unrecognised severe hyperkalemia may underlie this finding. When appropriate, alternative antibiotics should be considered in such patients.

Abstract Objective

To determine whether the prescription of co-trimoxazole with an angiotensin converting enzyme inhibitor or angiotensin receptor blocker is associated with sudden death.

Design Population based nested case-control study.

Setting Ontario, Canada, from 1 April 1994 to 1 January 2012.

Participants

Ontario residents aged 66 years or older treated with an angiotensin converting enzyme inhibitor or angiotensin receptor blocker. Cases were those who died suddenly shortly after receiving an outpatient prescription for one of co-trimoxazole, amoxicillin, ciprofloxacin, norfloxacin, or nitrofurantoin. Each case was matched with up to four controls on age, sex, chronic kidney disease, and diabetes.

Results

Of 39 879 sudden deaths, 1027 occurred within seven days of exposure to an antibiotic and were matched to 3733 controls. Relative to amoxicillin, co-trimoxazole was associated with an increased risk of sudden death. The risk was marginally higher at 14 days. This corresponds to approximately three sudden deaths within 14 days per 1000 co-trimoxazole prescriptions. Ciprofloxacin (a known cause of QT interval prolongation) was also associated with an increased risk of sudden death (adjusted odds ratio 1.29, 1.03 to 1.62), but no such risk was observed with nitrofurantoin or norfloxacin.

Fralick M et al, 2014, 'Co-trimoxazole and sudden death in patients receiving inhibitors of renin-angiotensin system: population based study,' *BMJ* 2014;349:g6196. Available from <http://www.bmj.com/content/349/bmj.g6196>



Enalapril is the only angiotensin converting enzyme inhibitor listed on the Fijian EML

High Rates of Paracetamol Medication errors contributing to acute liver failure

An article published in September 2014 has concluded that **paracetamol overdose secondary to medication errors is the leading cause of paediatric acute liver failure** in Australia & New Zealand (NZ). The authors recommended a review of regional safety practices surrounding paracetamol use in children.

Paracetamol-associated acute liver failure in Australian and New Zealand children: high rate of medication errors

Abstract

Background

In children, paracetamol overdose due to deliberate self-poisoning, accidental exposure or medication errors can lead to paediatric acute liver failure and death. In Australia and NZ, the nature of ingestion and outcomes of paracetamol-associated paediatric acute liver failure have not been described.

Design

Retrospective analysis of paracetamol-associated paediatric acute liver failure cases presenting 2002 – 2012.

Setting

NZ and Queensland Paediatric Liver Transplant Services.

Results

Fourteen of 54 cases of paediatric acute liver failure were attributed to paracetamol, the majority were secondary to medication errors. Twelve of the 14 children were under the age of 5 years. Seven children received doses in excess of 120 mg/kg/day. Many of the other children received either a double dose, too frequent administration, co-administration of other medicines containing paracetamol or regular paracetamol for up to 24 days. Three children underwent transplant, one of these and one other child died.

Rajanayagam J et al, 2014, 'Paracetamol-associated acute liver failure in Australian and New Zealand children: high rate of medication errors,' Archives of Disease in Childhood, Arch Dis Child doi:10.1136/archdischild-2013-304902. Available from: <http://adc.bmj.com/content/early/2014/09/16/archdischild-2013-304902.abstract?sid=9c602016-3874-4793-8a24-765dec30a3b9>

YOU DON'T NEED TO BE CERTAIN, JUST SUSPICIOUS!

As part of the Pharmacovigilance program FPBS encourages the

REPORTING OF ALL SUSPECTED ADVERSE REACTIONS

to medicines, including vaccines, over-the-counter medicines, herbal, traditional or alternative remedies.

Adverse Drug Reporting forms can be obtained from all hospital pharmacy departments.

Please submit forms to the hospital Pharmacy Departments which are to be submitted to the Drug and Therapeutic Committees.

CARDIOVASCULAR THERAPEUTIC GUIDELINES

The Fiji Medical CSN has revised the 2006 (second edition) of the cardiovascular therapeutic guideline. This 3rd edition includes a holistic approach to the management of cardiovascular disease (CVD) by incorporating pharmacological and non-pharmacological aspects of treatment compared to previous editions which only focused on pharmacological therapies. The new edition will be published and distributed in the first half of 2015.

Some of the new edition's features include:

- ◆ The cardiovascular risk assessment using the WHO risk assessment chart and adapting the WHO PEN protocols
- ◆ Behavioural risk factor modification by addressing: smoking, nutrition, alcohol, physical activity and stress (SNAPS).
- ◆ Most of the medications stated are available on the Fiji Essential Medicines List and for those not listed, this is clearly stated.
- ◆ Section on Acute Rheumatic Fever and Rheumatic Heart Disease
- ◆ ECG pictures of tachy- and bradyarrhythmias for easy reference and recognition
- ◆ Management of DVT, arterial and venous thromboembolism and anticoagulation
- ◆ Perioperative and peri-procedural management of patients with CVD in non-cardiac surgery
- ◆ Advice on when to refer the patient to the next level of care.

We hope that this guideline will reduce the mortality and morbidity associated with CVD in Fiji. We would also like the users of this guideline to provide feedback, in order for us to improve the next therapeutic guideline. Please forward your comments to Dr Shrish Acharya at shrish.acharya@health.gov.fj.

Meropenem Drug Use Evaluation

A drug use evaluation was performed investigating the usage of meropenem at the Colonial War Memorial Hospital between October 2013 and October 2014.

Data from the *Restricted Antimicrobial Request Form*, pharmacy dispensing program PatisPlus[®] and microbiology laboratory records were used to analyse the prescribing of meropenem compared to the *Indications for Meropenem use at Divisional Hospitals Policy* and treatment guidelines.

It was found that meropenem use can be optimised in several areas including; appropriate dosing, use of sensitivity data, infection control and prevention and stock management.

A few of the critical interventions recommended include; the updating of the *Indications for Meropenem use at Divisional Hospitals Policy*, development of the *Meropenem Treatment Guideline*, microbiology results be made available on PatisPlus[®], recommending all cases of multi-resistant organisms be treated as an outbreak to ensure infection control measures are activated and development of stock management SOPs.

The DUE report was presented to the Medical Superintendent of CWMH, Dr Jemesa Tudravu on 24 March 2015.

FIJI ESSENTIAL MEDICINES LIST

The Essential Medicines Authority has been busily preparing the fourth edition of the Fiji Essential Medicines List which is due to be published later this year.

The new edition of the Fiji EML will reflect the *National Medicinal Products Policy 2013* concept of rational use of medicines and focuses strongly on the Standard Treatment Guidelines and Clinical Practice Guidelines driving medicines use in Fiji.

By using this concept, the aim is to ensure medicines are rationally prescribed adhering to the relevant STGs and CPGs; thereby resulting in accurately predicting medicine usage which will ensure medicine availability at all times in adequate amounts, with assured quality, safety and efficacy and at a price the Fijian community and the Government can afford.

Left to right: Jessica Dayment (Monash University, Melbourne), Moreen Devi (CWMH Inpatient Pharmacist) and Frances Cameron (FPBS IRA department).



Inspectorate & Regulatory Affairs (IRA) update

Registration for pharmacists, pharmacy premises, wholesalers, manufacturers and retail outlets with medicine license including hotels is now due. Please forward your payments as soon as possible to the IRA.

As of February, the following have been registered for 2015:

- 123 pharmacists
- 50 pharmacies
- 17 wholesalers
- 19 medicine license holders
- ◆ **The Fiji Medicinal Products Board 1st meeting is scheduled for 10 April 2015.**
- ◆ **The Fiji Pharmacy Profession Board 1st meeting is scheduled for 25 March 2015.**

The recruitment for a junior staff member to join the IRA unit is underway, with the successful applicant to start next month. In addition, new software is currently being designed to assist with the introduction on the medicinal products registration for Fiji.



Left to right: Ilisabeta Pesamino, Frances Cameron & Muniamma Gounder of the IRA department

Diclofenac tablets linked to serious cardiac side effects

On the 14 January 2015, the Medicines and Healthcare Products Regulatory Agency, of the National Health Service in the United Kingdom announced the decision to make diclofenac tablets a prescription only medicine in the UK. People will no longer be able to purchase diclofenac tablets, used to treat pain and inflammation, from pharmacies without a prescription from their doctor due to the small risk of heart problems. Topical products such as gels will remain available for purchase from pharmacies.

Dr Sarah Branch, MHRA Vigilance and Risk Management of Medicines Deputy Director said:

“Diclofenac is associated with a small but increased risk of serious cardiac side effects in some patients, particularly if used at high doses and for long-term treatment. Because of this the Commission on Human Medicines (CHM) has advised that patients need to have a medical review before taking oral diclofenac to make sure it is suitable for them.

“If patients have recently bought diclofenac tablets from their pharmacy and continue to need pain relief they should talk to their pharmacist about suitable alternative treatments. However there is no problem if they wish to stop taking diclofenac in the meantime.

“People who have been prescribed diclofenac from their doctor should continue to take their medicine as instructed as their medical history and any tests will already have been assessed. If you have any questions about your treatment you should discuss this with your doctor at the next visit.

In August 2013, MHRA consulted on the continued availability of oral diclofenac as a pharmacy medicine in the UK following a European review that found there was a small but significant increased risk of cardiovascular side effects associated with diclofenac. The product information for diclofenac was updated to reflect this new information. However this evidence has been looked at by the Commission on Human Medicines (CHM), which concluded that these side effects cannot be ruled out even when the medicine is taken for a short time or at a lower dose. Therefore in the interests of patient safety the product is being reclassified to prescription-only medicine (POM). Oral diclofenac will now only be available as a POM with effect from 15 January 2015. For further information refer to: www.gov.uk/government/news/diclofenac-tablets-now-only-available-as-a-prescription-medicine

Diclofenac is not listed on the Fiji Essential Medicines List, however, is widely available in the private pharmacies of Fiji

MEDICATION IN FOCUS

DICLOFENAC

Class: Non-steroidal anti-inflammatory drugs (NSAIDs)

Mode of Action: Diclofenac has analgesic and anti-inflammatory actions. It inhibits the synthesis of prostaglandins by non-selectively inhibiting both cyclo-oxygenase enzymes (COX-1 & COX-2).

Indications:

- ◆ Arthritis pains
- ◆ Inflammation such as back pain, muscle strains, sprains and tendonitis
- ◆ Menstrual cramps
- ◆ Pain relief post operations

Precautions:

- ◆ Asthma—bronchospasm may worsen
- ◆ Avoid use in history of gastrointestinal bleeding or use with extreme caution
- ◆ Increased cardiovascular risk—increases risk of thrombotic events e.g. myocardial infarction and stroke

PHARMANEWS FIND-A-WORD

Fill in the blank words found throughout this edition of *Pharmanews* & find them in the Grid, the left over letters will spell the name of a new Therapeutic Guideline to be published this year.

- ◆ Paracetamol overdose secondary to ____ errors is the leading cause of paediatric acute ____ failure in Australia & New Zealand.
- ◆ In the UK, ____ will no longer be able to be purchased over-the-counter without a prescription due to small but increased ____ of serious ____ side effects
- ◆ The new ____ edition of the Fiji Essential Medicines ____ also known as the (____) is to be published this year.

A	N	G	I	O	T	E	N	S	I	N
L	I	S	T	L	H	T	R	U	O	F
C	E	M	L	D	A	R	K	S	I	R
D	I	O	V	E	A	S	F	R	E	E
C	A	I	D	R	A	C	C	U	L	V
C	A	N	E	F	O	L	C	I	D	I
S	U	S	P	E	C	T	E	D	A	L
R	N	O	I	T	A	C	I	D	E	M

◆ There is an increased risk of sudden death in ____ patients receiving angiotensin converting enzyme inhibitors or ____ receptor blockers and co-trimoxazole.

◆ The Fiji ____ Medicines Program was initiated in January.

◆ Report all ____ adverse reactions