THE NAMIBIA
MEDICINES WATCH

Updates for healthcare providers and consumers

Republic of Namibia
MINISTRY OF HEALTH AND SOCIAL SERVICES

Publisher: The Namibia Medicines Watch is a quarterly publication of the Therapeutics Information & Pharmacovigilance Center (TIPC)
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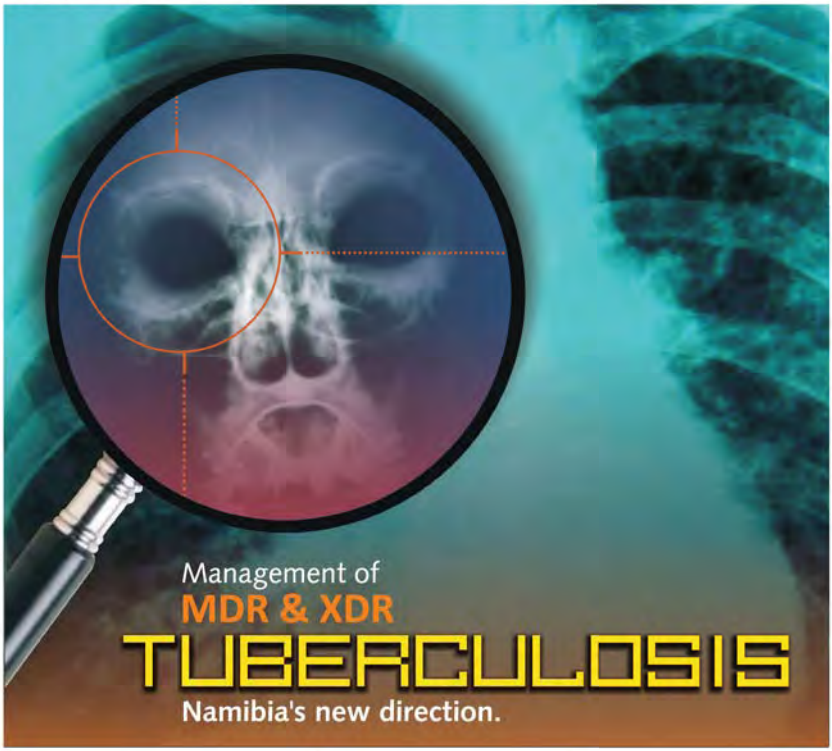

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WITH SUPPORT FROM

EDITORIAL

Welcome to this third issue of the ***Nambia Medicines Watch;*** a quarterly publication of the Therapeutics Information and Pharmacovigilance Center (TIPC).

Day by day, TIPC is putting in place a strong safety monitoring and therapeutics information system. So far, it has laid the basic pharmacovigilance system in place and applied for membership to the WHO international drug monitoring program. As it has fulfilled the basic criteria for this membership, we are anticipating our centre's membership acceptance soon.

The centre has started entering its adverse reaction data into the web based data base Vigiflow® since the end of October 2008, and has so far recorded nearly 50 adverse reaction reports. Even as this number is on the increase, we certainly know that we are far behind what is regarded as good adverse reaction reporting, which is an average of 200 reports adverse event per million inhabitants.

Based on the experiences of other more established national pharmacovigilance centers, it takes a new centre, such as ours, some time to overcome the issue of under-reporting. Thus, there is a need to strengthen our reporting of adverse reaction while making use of whatever available information obtained from our database, to ensure the safe use of medicines in our market.

Aside from our regular columns on **Regulatory Issues, Global Literature Scan of Safety Alerts, Comparative Effectiveness Review, Rational Medicines Use, Substances Abuse, Medicines News, and Regulatory Notices,** this third issue of the ***Nambia Medicines Watch*** also includes interesting clinical case studies on **Possible Medication Errors**. We believe this column will serve as a forum where our readers can bring common medication errors observed in their day to day clinical practice to the attention of fellow practitioners, so as to prevent a re-occurrence.

This third issue gives particular emphasis to the problems pertaining MDR and XDR tuberculosis, which has increasingly become public health concern in Namibia, and indeed the world.

We would like to thank all the health professionals from across the regions, who have contributed to the realization of this third ***Namibia Medicines Watch***. Your contribution is vital for sustaining the regular quarterly publication of the ***Namibia Medicines Watch.***

This bulletin will also be made available on the upcoming NMRC website: **www.nmrc.com.na**

Thank you and enjoy reading the ***Namibia Medicines Watch***, and I wish you a merry X-Mass and a prosperous 2009.

The Namibia Medicines Watch

Editorial Policy

The *Namibia Medicines Watch* is a specialized publication of the TIPC that provides comparative information on medicines and communicates all local and international efforts that contribute to the ready availability of information to improve medicines safety and promote rational use.

All articles published in the *Namibia Medicines Watch* must have relevance to the public and private health sectors of Namibia. *The Namibia Medicines Watch* shall be independent of any form of sponsorship from both local and international pharmaceutical industries.

The bulletin's primary focus shall be to provide information that will contribute to improvement in the clinical management and safety of patients. The editorial team and other key contributors to the publication shall be required to proffer full disclosure of conflict of interests.

Aim

The *Namibia Medicines Watch* aims at improving the safe and rational use of medicines through the dissemination of information that improves regulation, prescribing, dispensing and use of medicines.

In Namibia, The bulletin provides therapeutics information to guide treatment decisions, and conduct comparative effectiveness reviews to support essential medicines management system. It also provides safety information to guide regulatory and guidelines development.

Target Audience

The target audience of the *Namibia Medicines Watch* includes all health care workers particularly doctors, nurses, pharmacists, community health care workers, other health care workers, and health consumers in Namibia.

The publication will work closely with local opinion leaders and local associations like the Namibia Medical Association, the Pharmaceutical Society of Namibia, Namibia Nurses Association, the Health Profession Councils of Namibia, and other professional associations to improve the circulation and impact of the bulletin.

Editor and Human Resources

The TIPC Coordinator or Advisor shall serve as the editor of the *Namibia Medicines Watch*. The editor shall be supported by a three-member editorial team to be made up of interested persons working on voluntary basis. The editor shall identify writers, reviewers and others who may be supporting the publication of the bulletin. It is proposed that there shall also be a three-member editorial advisory team to review every issue before it goes to press.

Every one nominated to work for the bulletin as members of the editorial team, the editorial advisory team, and contributors of articles, shall be acknowledged in each publication of the bulletin. They shall provide their support for the publication of the *Namibia Medicines Watch* purely on a voluntary basis.

Publication Cycle

The *Namibia Medicines Watch* shall be published every quarter with the first issue debuting mid May, 2008. The following production schedule shall be strictly adhered to.

ID	Task Name
1	Identify themes and commission writers
2	Collect first drafts from authors
3	Edit drafts
4	Circulate to editorial team
5	Collect editorial team's comments and revise articles accordingly
6	Circulate final draft to editorial team
7	Proofread and quality control
8	Circulate finalized bulletin to MoHSS for approval
9	Publish and distribute bulletin

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KEN JOU MEDISYNE

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TJIUA OMITI VIOJE

DIVA NOMUTJI DOGE

MU ZIBE MILYANI YA MINA

THERAPEUTICS INFORMATION & PHARMACOVIGILANCE CENTRE

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Announcement

The editorial team of the ***Namibia Medicines Watch*** would like you to join us in congratulating Ms. Jennie Lates on her appointment as Deputy Director: Pharmaceutical Services, effective 1st October 2008. We wish Ms. Lates a fruitful tenure in her new position.

Assegid Mengistu / Evans Sagwa

Basic Research Methods Training Workshop for CHS Staff (26th-29th August 2008)

The Catholic Health Service (CHS) in collaboration with Management Sciences for Health / Strengthening Pharmaceutical Systems (MSH /SPS) and Therapeutics Information and Pharmacovigilance Centre (TIPC) conducted a training workshop on basic research methods at Greiters Lodge, Windhoek.

A total of 22 health care providers participated in the training workshop. The participants included Medical Officers, Pharmaceutical personnel, Nurses, Social Workers, M & E officer and Health Program Managers from CHS health facilities, the CHS head office, Intrahealth/ Capacity project and Lutheran Health Services.

The overall objective of the training was to equip the trainees with skills in order to conduct basic operational research using routinely collected health data to obtain information that contributes to the provision of better quality of healthcare services, improved patient safety and better treatment outcome.

The need for conducting basic problem solving research was brought to the attention of the CHS program managers during a CHS's review meeting in February 2008, where many questions related to treatment of health conditions of major public health and clinical importance were raised, with no readily available answers.

These questions touched on issues such as:

a. The substantial mortality rate of patients on ART in Andara.
b. The recorded high defaulter rate amongst patients on ART in Rehoboth and Andara.
c. The low VCT uptake and low male involvement in VCT sites.
d. The low follow up on HIV/AIDS pediatric patients.
e. The comparative effectiveness of the new PMTCT regimen.
f. The failure of ART in some settings.

At the end of the training, participants applied the acquired knowledge and skills to develop draft research protocols on the priority problems in their respective health facilities, which will involve use of routinely collected clinical, pharmacy and administrative data.

TIPC will closely collaborate with CHS to refine and implement the research projects aimed at improving patient safety and treatment outcomes.

Basic Research Methods Training Workshop for CHS Staff 26-29 August 2008.

Efforts to Establish INRUD

Namibia Gains Momentum

L-R: Dr. L. Haoses-Gorases, Mr Evans Sagwa, Prof. Jacob Mufunda and Prof Paul Waako during the INRUD out-briefing session.

Professor Paul Waako, Coordinator of **International Network for Rational Use of Drugs (INRUD) Uganda** *and Head, Department of Pharmacology and Therapeutics at Makerere University* was in Windhoek from the 8th-11th September, 2008 for a four day working visit.

The aim of his visit was to share experiences gathered, while setting up the Uganda INRUD Chapter, and to also assist in the setting up of the Namibia INRUD Chapter.

According to Professor Waako, INRUD is a network of different stake holders putting their effort together to act synergistically in addressing problems that arise from the use of medicines. He stressed that INRUD works through collaboration, and not by competition.

Professor Waako visited and held discussions with delegates from the Faculty of Medical and Health Sciences of the University of Namibia, the Pharmaceutical Services of the Ministry of Health and Social Services, Department of Special Programmes (DSP), Catholic Health Services (CHS), Namibia Institute of Pathology (NIP), and Myhealth. His presentations to these potential members for INRUD Namibia highlighted what INRUD is, it's possible structure, advantages, possible sources of funds and the INRUD experience of Uganda.

So far, all the contacted persons and organizations expressed their interest to be active members of the INRUD Namibia chapter. The Faculty of Medical and Health Sciences of the University of Namibia expressed interest in establishing the chapter and playing the challenging role of bringing together all identified stakeholders.

It was agreed that the proposed INRUD Namibia chapter will have a secretariat which will be located at the premises of the University.

Together with Professor Paul Waako, staff members of the Faculty of Medical and Health Sciences of the University of Namibia, developed a work plan for the group.

This plan will be implemented by all stakeholders in the coming few months to realise INRUD-Namibia.

Increasing Capacity for Pharmaceutical Training in Namibia

Assegid Mengistu / Evans Sagwa

The Minister of Heath and Social Services of Namibia Hon. Dr. Richard Nchabi Kamwi and the US Ambassador to Namibia, Dennis Mathieu witness a practical demonstration during the inauguration ceremony of the Pharmacist Assistants Training Unit at the NHTC (August 4, 2008).

Namibia faces an acute shortage of pharmaceutical personnel. The increased burden that HIV/AIDS has placed on the health system has made this shortage even more severe. More pharmacists and pharmacist's assistants are required to continue decentralizing antiretroviral treatment (ART) services and making ART available to patients in rural settings.

In response to this challenge, the Ministry of Health and Social Services requested USAID/Namibia to expand the capacity of the National Health Training Centre (NHTC) to train more pharmacist's assistants. Management Sciences for Health/Strengthening Pharmaceutical Systems Program, Namibia (MSH/SPS), refurbished lecture rooms, developed a simulation laboratory and provided tutors with U.S. President's Emergency Plan for AIDS Relief funding.

As a result of this successful intervention, NHTC increased pharmacists' assistants (PAs) training threefold from a previous annual average of 6 to 10 students per year to 20 to 25 students per year. This increased number of pharmacist's assistants graduating from the centre will ensure greater capacity to deliver critically needed pharmaceutical care to the Namibian people. In 2009, the intake is expected to surpass 25 students.

In addition, NHTC, with suport from MSH/SPS is currently updating the PA training curriculum and have the course registered on the National Qualifications Framework (NQF), accredited by the Namibia Qualifications Authority (NQA) and supported by the Namibia Training Authority (NTA). In this process, various stakeholders including the Ministry of Health and Social Services (MoHSS), Ministry of Education, the Health Professsions Council, Pharmacy Council, Pharmaceutical Society of Namibia, the Private Sector, pharmacists and practising Pas.

All Training materials used at the NHTC has to be approved by the Pharmacy Council of Namibia.

TIPC Participates at the MAN Congress Exhibition

The 30th Annual Congress of the Medical Association of Namibia (MAN) presented yet another opportunity for the TIPC to spread the message of its framework, services, objectives, mission and vision to members of the Medical Association of Namibia, especially those in private practice, who had until now, been hard to reach due to their schedule.

The 30th Annual Congress of the MAN, titled *Emergencies in Medicine*, was a four day programme, consisting of plenary sessions, workshops, parallel sessions, symposiums, seminars, a two day exhibition, cocktail and gala evening.

It presented a forum for discussions and presentations on topics such as; Factors affecting Treatment- Outcome in Conflict & Catastrophe Environments by Dr. Jonathan Kapian, HIV Drugs Resistance in Namibia by Dr. Andreas Shiningavanwe, Use of Blood and Blood Products in Medical Emergencies by Dr Robert Crookes, and on many other thought provoking subjects.

The two day exhibition, which opeaed on the morning of the first day of the congress showcased key parties from local and international based medical service and pharmaceutical companies including the Namibia Institute of Pathology (NIP), MEDI-CLINIC Private Hospital Group, Renaissance Health Medical Aid Fund, Blood Transfuson Service of Namibia, Geka Pharma, Johnson and Johnson, Roche, Perry Hill International, Pfizer and of course the Therapeutics Information and Pharmacovigilance Centre (TIPC).

Mr Pascal Rite was on hand to explain the details pertaining the new Medicines and Related Substances Control Act

Visitors at the TIPC booth during the MAN exhibition.

Dr. Mengistu, TIPC Advisor, explaining the services available at the TIPC

TIPC PARTCIPATION

2nd Edusector Health Day, Arandis - Erongo region

The Ministry of Education in collaboration with the Ministry of Health and Social Services and other stakeholders conducted the second Education Sector Health Day activity on the 12th of September 2008 at the Namibia Institute of Mining and Technology (NIMT), Arandis in Erongo region.

The aim of the Edusector Health day is to motivate all members of the education sector to take the lead, know their health status and become actively involved in curtailing the spread of HIV /AIDS and other illnesses.

TIPC took this opportunity to reach out to teachers, other employees of the Ministry of Education and members of their families to raise awareness on the existence of, and objectives of the Therapeutic Information and Pharmacovigilance Centre in Namibia.

The three-man TIPC Team from Windhoek were supported by Mr. Mike Nzuzi, a Pharmacist, and Mr. Goamub Hendrik, a Senior Pharmacists Assistant, both from the Erongo Region. The team was also supported by Dr. Shidengi Shivolo, a Medical Officer from the Katutura Hospital in Windhoek, who also provides part time therapeutics consultation services at the TIPC.

Members of the TIPC team were involved with the awareness creation activity and participated in the provision of therapeutics information to visitors attending the TIPC booth.

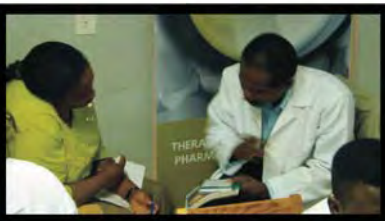
Out of the 600 plus hundred teachers and their families who attended the event, 202 visited the TIPC booth, and received general and specific therapeutics information for free.

Along with the TIPC, the 2nd Edusector Health Day in Arandis was supported by other health care providers, who also made their services available to all visitors.

Activities for the ESHD Erongo kicked off with a march

TIPC NEWS

Representatives of the Ministry of Education & Health carying the banner during the march past at the Erongo ESHD



One-on-one consultations at the TIPC Booth

TIPC BOOTH

Dr Shidenge Shivolo addressing the media during the ESHD activity

Know YOUR medicines

The TIPC is truly well equipped with standard, current, and state of the art resources to support any enquiry you may have related to therapeutics information and medicines safety

Therapeutics Information & Pharmacovigilance Center (TIPC)

ADVERSE EVENT REPORT

Catholic Health Services ART Clinics Adverse Events Reports, June–October 2008

Site	Number of events	Description of event	Causes	Action taken
Andara	2	Severe skin rashes—1 case	nevirapine	Switched to efavirenz
		Severe anemia—1 case	zidovudine	Changed to stavudine and transfused
Nyangana	6	Anemia—1 case	zidovudine	Switched to stavudine
		Peripheral neuropathy—1 case	stavudine	Switched to zidovudine
		Parasthesia of lower limbs—1 case	stavudine	Switched to tenofovir
		Myelotoxicity—2 cases	zidovudine	Switched to stavudine
		Hepatotoxicity—1 case	nevirapine	Switched to efavirenz
Oshikuku	31	Anemia—7 cases	zidovudine	Switched to tenofovir
		Anemia—6 cases	zidovudine	Switched to stavudine
		Gynecomastia—6 cases	efavirenz	Switched to nevirapine
		Gynecomastia—1 case	efavirenz	Switched to lopinavir and ritonavir
		Severe skin rashes—4 cases	nevirapine	Switched to efavirenz
		General body itching with urticaric eruption—1 case	nevirapine	Switched to efavirenz
		Abnormal sensations—1 case	stavudine	Switched to zidovudine
		Reduced white blood count—1 case	zidovudine	Switched to tenofovir
		Peripheral neuropathy—2 cases	stavudine	Switched to zidovudine
		Elevated alanine transaminase—2 cases	nevirapine	Switched to efavirenz
Rehoboth	6	Anemia—4 cases	zidovudine	Switched to stavudine
		Skin rashes—1 case	nevirapine	Switched to efavirenz
		Lactic acidosis (recurrent)—1 case	Suspected treatment failure	ART suspended

Victor Muthiani, Greatjoy Mazibuko, Job Muriuki and Benjamin Khumalo

PHARMACY WEEK '08

Ms. Dinah Tjipura addressing guests during the launch of the Pharmacy Week.

The need for a National Pharmacy Week was identified due to the fact that many Namibians are not familiar with the important role that pharmacy plays within health care provision. In addition, the pharmaceutical sector in Namibia also recognised the necessity of providing members of the public with health education about medicines, because if medicines are not used appropriately, the maximum benefit will not be gained and patients could potentially suffer from unwanted adverse effects of medicines.

Thus Pharmacy Week was decided as an ideal venture to raise the public's awareness of the Pharmacy profession, and to promote the appropriate use of medicines.

Pharmacy Week is jointly organised by the Pharmaceutical Society of Namibia and the Division: Pharmaceutical Services of the Ministry of Health and Social Services. It was first celebrated in Namibia in 2001.

This year, the Pharmacy week was commemorated in the 1st week of September, under the theme "Know Your Medicines". This theme was a continuation of the theme adopted for the Therapeutics Information and Pharmacovigilance Centre (TIPC) that was launched in May 2008 in Windhoek.

The Management Sciences for Health (MSH)/ Strengthening Pharmaceutical Systems (SPS) program provided financial assistance for the printing and distribution of materials as well as for conducting the official launch.

Several activities were carried out across the country during the Pharmacy Week:

National Level

- The official launch of Pharmacy Week was conducted at the Kalahari Sands hotel on Wednesday 03-Sep-2008. The ceremony was officiated by Dr. T. Ithindi-Shipanga, Regional Director of Khomas representing the Permanent Secretary MoHSS.
- The official launch was attended by about 50 people, including several top officials of the MoHSS, representatives of development partners, practising pharmacists from both the public and private sectors and some representative from the media.
- At the launch the Pharmaceutical Society of Namibia handed over to the Ministry of Health and Social Services British National Formularies (BNFs) for use as reference materials by pharmacy personnel and other healthcare workers in hospitals around Namibia
- Mr. Johannes Gaeseb- Chief Pharmacist: Pharmaceutical Control and Inspection, Mr. Job Muriuki, ARV Logistics Pharmacist at Division Pharmaceutical Services and Mr. Benjamin Khumalo, Pharmacist in the private sector, were hosted on talk shows on NBC TV, Radio Energy and National Radio Service. During these talk shows, they were able to explain to the public the purpose of the pharmacy week, services offered at the TIPC and the role of a pharmacist in healthcare provision among other topics.

Dr. Mabirizi delivers speech to guests during the Launch of the Pharmacy Week.

Dr. T. Ithindi-Shipanga, Regional Director of the Khomas Region officially opens the Pharmacy Week on behalf of the Permanent Secretary of MoHSS.

- T-shirts, medicine counting trays, copies of the TIPC bulletin (The Namibia Medicines Watch) and medicines information materials were distributed to healthcare workers and members of the public both at the MoHSS headquarters and at Windhoek Central Hospital, Katutura Referral Hospital and Khomas Regional headquarters.

Regions

Different regions had different activities for the pharmacy week. Two regions' activities are described here.

1. **Ohangwena Region**

- The PMO, PHC Supervisor, Clinic supervisors, matron, some doctors, Pharmacy staff and patients received the TIPC-branded T-shirts and a copy of the TIPC quarterly bulletin.

- Pharmacy staff at the district hospitals educated patients about their prescriptions using a guide developed by the regional pharmacist. Patients were reportedly happy with the move made by the Pharmacy staff to give them more information about their prescribed medicines. They participated fully in the sessions and T-shirts were given to them as a motivation.

2. **Otjozondjupa Region**

- The pharmacy and nursing staff held a joint meeting to discuss and promote rational prescribing by nurses. The nurses were also informed about the existence of and services offered by the TIPC.

- A meeting was held with doctors who were urged to take leadership in promotion of appropriate medicine use. Services offered at the TIPC were also explained at the meeting and doctors were encouraged to make use of these services as well as report Adverse Drug Reactions (ADRs) to this center.

- A team of health care workers visited two secondary schools to provide career guidance to Grade 12 learners. At least 15 learners from the 2 schools expressed an interest in pursuing pharmacy as a career.

The Division: Pharmaceutical Services, would like to thank all those who were involved in making the Pharmacy Week a success; both in the private sector And public sector.

What reports can I make to the *TIPC* ?

Know YOUR medicines

- Report all suspected unwanted effects (adverse reactions) on all medicines including prescription medicines, herbal medicines and other health care products.
- Report any adverse drug reaction experienced by a patient even if you are not certain that the product caused the adverse reaction and even if you do not have all the details.
- Report all quality problems relating to medical products including change of colour, or composition (in tablets, capsules or syrups) before completion of dosage.

NOTICES

University of Washington I-TECH
HIV/AIDS Clinical Seminar Series

Upcoming Sessions

Date	Event	Presenter
6 Nov 2008	HIV Dermatology: Virtual Office Hours: Cases from Jamaica, Trinidad & other Caribbean countries	Roy Colven, M.D.
20 Nov 2008	Immune Reconstitution Inflammatory Syndrome (IRIS)	Gurusamy Manoharan, M.D.
4 Dec 2008	Operations Research	Mark Micek MD
11 Dec 2008	HIV Game of Knowledge	Michael Chung M.D.
18 Dec 2008	Opportunistic Infections	Robert Harrington, M.D.
8 Jan 2009	Pediatric HIV	Lisa Frenkel, MD
22 Jan 2009	HIV Dermatology: Virtual Office Hours: Cases from India	Roy Colven, M.D.
5 Feb 2009	HIV and STIs	Hunter Handsfield MD
19 Feb 2009	TBA	Presenter TBA
12 Mar 2009	HIV and Cancer	Casper Corey, MD
26 Mar 2009	HIV and HSV	Jairam Lingappa MD

Distance Learning Course: "Clinical Management of HIV and STIs" January- March 2009

International Training & Education Centre on HIV I-TECH will be offering a free course entitled "Clinical Management of HIV and STIs" between January and March 2009 through the University of Washington, Seattle, USA.

This course targets those who are or will be clinical leaders in HIV and STI management with the objective of increasing skills and knowledge related to providing HIV and STI health care in developing and developed world settings. Course lectures will be delivered by the University of Washington faculty through a weekly seminar broadcast from Seattle, U.S.A to the International Training and Education Centre on HIV (I-TECH) - Namibia office in Windhoek.

Doctors or nurses who meet the prerequisites and wish to enrol in this course for a certificate must apply by submitting a CV and a letter describing your interest in taking the course as well as stating your commitment to attend at least 80% of lectures and complete assignments and quizzes.

Please send applications through e-mail to Nancy Scholtz, nancy@itechnamibia.org by no later than **Thursday 4th December 2008 at 17H00.**
Course days: January 13th and March 10, 2009.
Venue: I-TECH training room, 25 Kallie Roodt Street, Northern Industrial, Windhoek.

Lecture Topics

1. Diagnosing HIV/counselling and the initial evaluation
2. Opportunistic infections and prophylaxis
3. Antiretroviral medications
4. Antiretroviral toxicity, drug resistance, and drug Interactions
5. Paediatric HIV care and treatment
6. Vertical transmission and pregnancy
7. Management of STIs in HIV infected patients
8. Dermatology and Malignancies
9. Post-exposure Prophylaxis and Prevention
10. Operational aspects of providing HIV care in resource Limited settings

Prerequisites

1. Degree as a medical doctor or a nurse
2. Easy access to the internet to complete significant weekly online homework and quizzes
3. Ability to attend at least 80% of the computer Lecture presentations

Product Recall

Mr. Brown Instant Coffee and Milk Products:

On the 26th of September, 2008, the US Department of Health and Human Services, Food and Drug Administration, issued a letter of alert to the Embassy of the Republic of Namibia in the US. The letter listed seven (7) Mr. Brown Coffee and Milk Products, being recalled by a Taiwanese company, King Car Food Industrial Co. Ltd, due to possible contamination with melanine.

King Car Food Industrial Co. Ltd used non-dairy creamer manufactured by Shandong Duqing Inc. China which was found to be contaminated with Melamine.

Lists of products are:

- Mr. Brown Mandheling Blend Instant Coffee (3-in-1)
- Mr. Brown Arabica Instant Coffee(3-in-1)
- Mr. Brown Blue Mountain Blend Instant Coffee(3-in-1)
- Mr. Brown Caramel Macchiato Instant Coffee(3-in-1)
- Mr. Brown French Vanilla Instant Coffee (3-in-1)
- Mr. Brown Mandheling Blend Instant Coffee(2-in-1)
- Mr. Brown Milk Tea (3-in-1)

White Rabbit Creamy Candies

Similarly, the New Zealand Food Safety authority reported that white rabbit creamy candies has shown melamine contamination at a higher level. In light of the widespread contamination of milk and milk based product in china, FDA recommends consumers not to eat white rabbit creamy candies and retailers are also to remove these products from sale or service.
For more information Visit FDA web site at: ***http://www.Fda.gov/bbs/topics/NEWS/2008/NEW01891.html***

Recall Update

Adco- Nevirapine and Adco- Zidovudine tablets were recalled after investigation revealed that some blisters of Adco- Nevirapine were packed in Adco-Zidovudine tablet and some of the affected batch were distributed in Namibia.

All stock of affected products from **Adcock Ingram** has been returned to Nampharm (pty) Ltd and Geka (pty) Ltd.

Nampharm and Geka, who are wholesalers of Adcock Ingram products in Namibia, provided destruction certificates to Adcock Ingram.

REGULATORY ISSUES

Paul K. Tanui

The Case for Strengthening Pharmaceutical Regulatory Systems in Resource-constrained Countries

Introduction

There has been much debate in the recent past in pharmaceutical regulatory circles with regard to relying on stringent medicines regulatory authorities by resource-constrained countries in the middle-income and low-income categories for regulatory decisions.

The lack of resources and capacity limitations experienced by these countries is acknowledged as a major contributor to weak health systems and poses a serious threat to public health. Some arguments advanced have revolved around conservation of resources for more 'urgent' uses; avoidance of duplication of efforts by many medicines regulatory authorities and lack of capacity to carry out effective regulatory functions, amongst other reasons.

Several medicines regulatory authorities that have been identified as stringent include the US Federal Drug Administration (FDA), and other regulatory authorities in the International Conference on Harmonization of technical requirements for registration of pharmaceuticals for human use (ICH) regions amongst others. However this debate should bring salient issues into their proper perspective.

Post Marketing Surveillance

Medicine regulation though not the only component of medicines policy plays an important and synergistic role in the pharmaceutical sector and the overall health system of any country. The existence of a medicines regulatory authority in any country to ensure medicines quality, safety, and efficacy is the best guarantee that the public is getting the medicines it deserves.[1]

It is important to appreciate the role of medicines regulatory authorities in the context of medicines development and marketing process particularly in post marketing quality surveillance. Once a competent regulatory authority grants marketing authorization to an applicant, phase 4 stage of the Clinical Trial begins.[2]

Phase 4 normally encompasses post-licensing studies in the target population, with widening of entry criteria to broaden experience of using the medicine in clinical practice.[3] Study objectives for this phase are typically surveillance for safety (pharmacovigilance) or further comparison with other therapies.

It will be appreciated that this critical phase of medicines development needs close monitoring by an effective medicines regulatory authority which can deploy tools at its disposal to effect a medicine recall if that is the desired action; an effective pharmacovigilance system is useful for early detection of adverse medicines reactions particularly in monitoring adverse reactions of new medicines and formulations used in such diseases as HIV/AIDS. In most cases clinical practice experience in their use is limited.

A pharmacovigilance system embedded in the framework of an effective medicines regulatory authority will realize optimum results due to the ease with which pharmacovigilance decisions can be effected.

Quality Assurance (QA)

Further more one of the principle responsibilities of a medicines regulatory authority is the quality assurance of the medicines in the pharmaceutical system under its oversight. Quality assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.[4]

Quality Assurance (QA) therefore incorporates such practices as product design and development, quality control, current Good Manufacturing Practices (cGMP), and quality properties of the product in the marketing distribution channels. Therefore QA entails the sustenance of product quality attributes through the procurement and distribution channels until the product reaches the end-user who is invariably the patient. It is apparent that before the medicine reaches the patient it will have involved many parties and will have passed through many hands: health workers, salespeople and other intermediaries, and manufacturers.

The field of pharmaceutical manufacturing, procurement, distribution and use is fraught with important risks: people can die from a lack of medicines, but also from medicines that are impure, wrongly prescribed or irrationally used.[1] Thus it is easy to see why effective regulation is needed.

Medicines Stability

There is a gamut of stability concerns as a medicine moves through the pharmaceutical distribution channels. Different environmental conditions that a product is exposed to can predispose the to medicines degradative processes.

There is a variety of mechanisms by which drug products may degrade under different environmental conditions and thus a wide range of adverse effects that can occur.[5] These range from loss of active ingredient in the formulation, increase in concentration of active ingredient, alteration in bioavailability, loss of content uniformity, formation of toxic degradation products amongst other possible derivative end-product adverse effects.

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REGULATORY ISSUES

Bioavailability of a pharmaceutical product to the biologic system is paramount for its efficacy.[8] Since product stability can affect the bioavailability of a medicine, its handling in the distribution channels is critical. Due to the variation in environmental conditions (e.g. temperature and relative humidity) at the point of use and through the entire distribution chain, stability status of products has gained increased concern. In addition there are pharmaceutical products such as vaccines and biological sera that loose their efficacy if transported outside recommended cold chain conditions throughout the distribution chain including the patient.

It is clearly critical that policy makers ensure that resources are available to cater for such unique storage and transport requirements and that capacity is made available for much more stringent quality monitoring at the product's destination.

Counterfeit Medicines

Where regulatory controls are weak one will find increased influx of counterfeit and substandard products which are normally peddled by quacks or unaware and/or unculpable professionals. The emergence and proliferation of counterfeits and substandard medicines strictly adhere to market economic dynamics.

The returns of this illicit trade is handsome and the incentives are enormous as to make the trade self propagating. As the pharmaceutical market grows so does the counterfeit share of the market slice. The US based Centre for Medicines in Public Interest predicts that counterfeit medicines sales will reach US$ 75 billion globally in 2010; an increase of more than 90% from 2005.[6]

The urgency of strengthening pharmaceutical regulatory systems now rather than later therefore cannot be overemphasized Counterfeit medicines represent an enormous public health challenge.

In 2002, Nigerian health officials estimated that 70% of medicines in circulation in that country are either fake or adulterated.

In 2004 in Angola, according to the National Department of Intellectual Copyright Crime of the Economic Police, approximately 70% of medicines used by the Angolan population were forgeries.[7]

The absence of deterrent legislation and effective medicines regulatory system in many resource constrained countries encourages counterfeiters, since there is no fear of being apprehended and prosecuted.

Antimicrobial Resistance (AMR)

An effective medicines regulatory system has a critical role to play in containing emergence and spread of antimicrobial resistance (AMR). It is widely acknowledged that counterfeit and substandard medicines will certainly contribute to rapid emergence and spread of antimicrobial resistance.

Antimicrobial resistance costs money, livelihoods, lives and threatens to undermine the effectiveness of health delivery programmes. Resistance to first-line drugs in most pathogens causing a host of diseases such as AIDS, Malaria, Measles, Diarrheal disease, Tuberculosis etc ranges from zero to almost 100%. In some instances resistance to second-line and third-line agents is seriously threatening treatment outcomes.[9]

The introduction of widespread use of extended-spectrum agents and advances in medical techniques has resulted in a huge selective pressure that favour multiplication of resistant species.[10]

However antimicrobial use remains key driver of resistance, selective pressure arising from its overuse particularly for minor infections or underuse.[9] Counterfeits and substandard medicines will fuel the menace of antimicrobial resistance.

Way Forward

It is therefore important for each country to establish an effective medicines regulatory system with elaborate legislation and regulations. The necessary technical and operational infrastructure including quality assurance protocols and procedures should be grounded on a sound legislative framework.

Structures should be in place to ensure that all medicines on the market are safe, of acceptable quality and are efficacious and that they adhere to international standards. The regulatory authority should also develop indicators to monitor the quality assurance of medicines under its jurisdiction.

Since the strengthening of pharmaceutical regulatory systems is a long-term goal which requires substantial investments in terms of financial resources and human capital, it will not be possible to realize apparent immediate gains from these efforts.

However in the long run, these efforts will yield substantial benefits in terms of delivery of quality, safe and efficacious medicines in the public health interest. While it is clearly plausible to make use of regulatory decisions of stringent regulatory authorities in the short term, substantial effort should be expended in developing an effective in-country regulatory system.

While it is clearly unnecessary for regulatory authorities to duplicate efforts, there remain critical key responsibilities that an effective medicines regulation will play in a country. While efforts of strengthening the pharmaceutical regulatory system are given the necessary priority, a combination of strategies should be employed to ensure availability of quality, efficacious and safe medicines to the citizens.

These strategies include selective and judicious utilization of decisions of other regulatory authorities, use of the WHO Prequalification programme for medicines procurement needs amongst other strategies, but the ultimate responsibility for ensuring the medicines used in the country are efficacious, of acceptable quality and are safe lies with the in-country medicines regulatory authority.

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MEDICINES SAFETY UPDATES

Jude Nwokike.

Abridged from FDA drug safety newsletter. Volume 1 Issue 4 (SUMMER 2008)

Mefloquine associated pneumonitis or eosinophilic pneumonia

Postmarket safety review has identified cases of pneumonitis or eosinophilic pneumonia associated with the use of antimalaria mefloquine. From May 1989 (the date of original approval) to January 2008, FDA has received 13 reports (U.S.-3, non-U.S.-10) of pneumonitis associated with mefloquine therapy. Seventy-seven percent of patients (10/13) fully recovered when mefloquine was discontinued. Thirty-eight percent of patients (5/13) improved with systemic corticosteroid therapy. One patient was rechallenged with mefloquine and developed severe pneumonitis and a four-year-old female died after developing pneumonitis. These 2 case studies are listed below as copied from the FDA drug safety newsletter Volume 1 Issue 4 (SUMMER 2008)

Case 1

Three weeks prior to traveling to Kenya, a 60-year-old woman began prophylactic treatment for malaria with mefloquine (250 mg weekly). On the day following the first dose of mefloquine, she developed a high fever and chills. Empiric antibiotic treatment was started. Four days after her symptoms appeared, she was admitted to the hospital with a fever (101 °F), shortness of breath, cyanosis, myalgia, a nonproductive cough, and headaches. A work-up for the etiology of the infection, including tests for tuberculosis and HIV, was negative. Laboratory blood tests showed a leukocytosis [white blood cell count: 19.9 x103/mm3 (normal 4.3-10 x103/mm3) with 71% neutrophils, 18% lymphocytes and no eosinophils], an elevated C-reactive protein [CRP: 194 mg/dl (normal <3mg/dl)] and an elevated lactate dehydrogenase. A chest X-ray showed bilateral interstitial infiltrates.

The patient improved slowly without additional treatment and was discharged after a few weeks with a diagnosis of diffuse interstitial pneumonia of unknown etiology. Four months later, the woman self-started mefloquine prophylaxis (250 mg weekly) ahead of another scheduled trip to Kenya. On the day following the first dose, she once again became severely ill with high fever, and respiratory distress (positive rechallenge). The symptoms were so severe that she was admitted to intensive care unit. Laboratory tests showed results similar to those obtained during her previous hospitalization (leukocytosis, a raised CRP, and elevated LDH). Specifically, there was severe hypoxemia (PaO2: 45mm Hg, pCO2: 32 mm Hg, pH: 7.44) as evidenced by an arterial blood gas analysis. High resolution computed tomography (HRCT) indicated diffuse pulmonary infiltration with ground-glass attenuation. Evaluations for an infectious etiology remained negative. The patient responded well clinically and radiologically to treatment with corticosteroids. Concomitant medications included aspirin (for atherosclerosis), bisoprolol fumarate (for hypertension), and ciprofibratum (for hyperlipidemia). She had no history of smoking, allergies or pulmonary disease. There was no exposure to animals.

Case 2

4-year-old female patient died from pulmonary fibrosis and interstitial pneumonitis after prophylactic treatment with mefloquine. In 2006, prior to traveling, she was started on mefloquine 75 mg per week, an age appropriate dose for the prevention of malaria. The patient had previously taken mefloquine (unknown date). Before the trip, the child was tired and had weight loss. During the trip, she experienced rash and fever (102.2 °F) at night, but was afebrile during the day. She was given

Continued on next page

UPDATES

Changes to the Namibia Essential Medicines List (Nemlist) - April 2008

The Nemlist specifies which medicines are considered essential for the country and are to be made available for prescription and use at the various levels of the public health system. Procurement of medicines for supply to public health facilities by the Central Medical Stores (CMS) is based on the Nemlist.

The Essential Medicines List Committee (EMLC) is responsible for reviewing and updating the Nemlist. The committee met on 3rd April 2008, for the first time since October 2002, to evaluate recommendations for changes to the Nemlist from healthcare workers all over Namibia. The meeting was also attended by co-opted specialists from Windhoek Central Hospital and programme officers from the IMAI and DSP who were invited to support requests made by their respective departments or programmes.

Various changes were made to the Nemlist, a few of which are highlighted below:

- **Addition of a new category to the Nemlist- IMAI-R:**

  Medicines under this category will be available for use at the health centres and clinics designated as IMAI sites but unlike general clinic/health centre ABC items, they should only be prescribed for IMAI-registered patients.

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an antibiotic for a suspected infection, although subsequent tests revealed no evidence of an infection.

Tests revealed no evidence of an infection. On her return, she was hospitalized with suspected inflammatory disease, but no specific diagnosis was given. She was continued on the mefloquine and received corticosteroids which led to her improvement. After 45 days, however, her general state of health worsened. She started to cough and developed interstitial pneumonitis. Mefloquine was discontinued.

A chest radiograph showed bilateral infiltration confluent in the lung. Compared to a previous film, the degree of infiltration had progressed. She was intubated and ventilated due to her rapidly progressive lung failure. A pulmonary biopsy showed autoimmune interstitial alveolitis. She was treated with high dose corticosteroids, plasmaphoresis, and immunoglobulins. After five weeks of extracorporeal membrane oxygenation (ECMO) treatment, the patient died suddenly. An autopsy revealed alveolitis and pulmonary fibrosis.

This review was prompted by the manufacturer's request to revise the Adverse Reactions-***Postmarketing*** section of the label to include pneumonitis of possible allergic etiology. The product labeling has been updated to reflect this new safety information.

Mefloquine is used for the management of mild to moderate malaria and for prophylaxis of P. Falciparium malaria the predominant specie in Namibia. Mefloquine 250mg is in the NEMLIST with level of use AB. Mefloquine is also registered in Namibia is available in Pharmacies and private hospitals and clinics. Healthcare workers are therefore advised to monitor the safety of Mefloquine use in the treatment and prophylaxis of malaria. Healthcare workers and consumers should report all suspected adverse drug reactions to the TIPC.

Interaction between amiodarone and simvastatin: amiodarone potentiates the risk for simvastatin-associated rhabdomyolysis

FDA continues to receive reports of rhabdomyolysis in patients given amiodarone in combination with higher doses of simvastatin. The adverse event reporting system has 52 cases of rhabdomyolysis involved patients ranging in age from 50 to 88 years. Thirty-seven patients (71%) were male and 10 were female (19%).

In half of the reported rhabdomyolysis cases (26/52), amiodarone was being taken in combination with 80 mg simvastatin. Thirteen patients (25%) were taking amiodarone in combination with 40 mg simvastatin, while four patients (8%) were taking amiodarone with 20 mg simvastatin. One patient (2%) developed rhabdomyolysis when taking amiodarone with 5 mg simvastatin. Eight patients (15%) were taking an unknown dose of simvastatin in combination with amiodarone.

The postulated mechanism for the amiodarone-simvastatin interaction includes amiodarone inhibition of the enzyme CYP3A4, limiting simvastatin metabolism. By limiting the metabolism of simvastatin, there is an increase in levels of circulating simvastatin in the blood. High circulating simvastatin levels may result in myotoxicity in the skeletal muscles (rhabdomyolysis).

The rapid breakdown of muscle protein produces excessive levels of myoglobin in the blood, myoglobin reaches the kidneys where it can obstruct renal tubules and lead to acute renal failure. Amiodarone's direct inhibition of CYP3A4 has been characterized as weak, suggesting that other factors may also contribute to how these two drugs interact.

The mean time interval between the initiation of amiodarone therapy in conjunction with simvastatin (or simvastatin therapy in conjunction with amiodarone) and the onset of rhabdomyolysis was five months (median-2 months). Specifically, 42% of the cases (22) indicated that symptoms of rhabdomyolysis emerged within 2 months of the initiation of concurrent amiodarone-simvastatin Twenty-eight percent of the reported cases (15) were considered life-threatening. Ten percent of patients (5) who developed rhabdomyolysis were noted to have become disabled. One death was reported (2%).

The concomitant use of amiodarone with simvastatin reduces the dose threshold for simvastatin-associated rhabdomyolysis. The cessation of symptoms (and lowering of laboratory values indicative of rhabdomyolysis) after discontinuation of one or both of these drugs indicates that muscle breakdown can be halted and reversed if identified early. Amiodarone is an antiarrhythmic drug indicated to treat certain types of recurrent ventricular arrhythmias and Simvastatin is a HMG-CoA reductase inhibitor.

The FDA is also investigating a report from the SEAS trial (Simvastatin and Ezetimibe in Aortic Stenosis) of a possible association between the use of a combination product of simvastatin plus ezetimibe and a potentially increased incidence of cancer. Interim data from two large ongoing cardiovascular trials of combination product of Simvastatin and Ezetimibe the Study of Heart and Renal Protection (SHARP) and the Improved Reduction in High-Risk Subjects Presenting with Acute Coronary Syndrome (IMPROVE-IT) show no increased risk of cancer with the combination of simvastatin plus ezetimibe. FDA approved Ezetimibe in 2002; it lowers cholesterol by inhibiting its absorption in the intestine.

Amiodarone and Simvastatin are both registered in Namibia. Ezetimibe is also registered in Namibia. Physicians and Pharmacists should note that amiodarone may potentiate the risk for simvastatin-associated rhabdomyolysis. Simvastatin doses greater than 20 mg day daily should be avoided in patients taking or initiating amiodarone therapy. Healthcare workers and consumers should report all suspected adverse drug reactions to the TIPC.

Patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death

FDA is notifying healthcare professionals that both conventional and atypical antipsychotics are associated with an increased risk of mortality in elderly patients treated for dementia-related psychosis. Antipsychotics are not indicated for the treatment of dementia-related psychosis.

The following conventional antipsychotics are in the NEMLIST; Chlorpromazine, Haloperidol, Thioridazine, Fluphenazine, Flupenthixol, Lithium Carbonate, Prochlorperazine, Droperidol, Hydroxyzine, Pimozide, Sulpiride. The atypical antipsychotic Clozapine is also in the NEMLIST. The Namibia medicine register also contains atypical antipsychotics like Clozapine, risperidone, and olanzapine. Healthcare workers should monitor all patients on antipsychotic therapy and report all adverse events. Patients should also report all adverse events to their health worker or directly to TIPC.

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Increased risk of developing tendinitis and tendon rupture in patients taking fluoroquinolones

FDA has notified sponsors of fluoroquinolone antimicrobial drugs for systemic use of the need to add a boxed warning to the prescribing information about the increased risk of developing tendinitis and tendon rupture in patients taking fluoroquinolones and to develop a Medication Guide for patients. The addition of a boxed warning and a Medication Guide would strengthen the existing warning information already included in the prescribing information for fluoroquinolone drugs. Fluoroquinolones are associated with an increased risk of tendinitis and tendon rupture.

This risk is further increased in those over age 60, in kidney, heart, and lung transplant recipients, and with use of concomitant steroid therapy. Physicians should advise patients, at the first sign of tendon pain, swelling, or inflammation, to stop taking the fluoroquinolone, to avoid exercise and use of the affected area, and to promptly contact their doctor about changing to a non-fluoroquinolone antimicrobial drug. Selection of a fluoroquinolone for the treatment or prevention of an infection should be limited to those conditions that are proven or strongly suspected to be caused by bacteria.

The following Fluoroquinolones are available in Namibia; ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin, and ofloxacin. Healthcare workers and patients are advised to report all suspected adverse events to the TIPC.

Potential increased risk of atrial fibrillation in patients treated with a bisphosphonates

FDA issued an update about the Agency's review of safety data regarding the potential increased risk of atrial fibrillation in patients treated with a bisphosphonate drug. Bisphosphonates are a class of drugs used primarily to increase bone mass and reduce the risk for fracture in patients with osteoporosis, slow bone turnover in patients with Paget's disease of the bone, and to treat bone metastases and lower elevated levels of blood calcium in patients with cancer.

FDA reviewed data on 19,687 bisphosphonate-treated patients and 18,358 placebo-treated patients who were followed for 6 months to 3 years. The occurrence of atrial fibrillation was rare within each study, with most studies containing 2 or fewer events.

Across all studies, no clear association between overall bisphosphonate exposure and the rate of serious or non-serious atrial fibrillation was observed. Additionally, increasing dose or duration of bisphosphonate therapy was not associated with an increase rate of atrial fibrillation. Healthcare professionals should not alter their prescribing patterns for bisphosphonates and patients should not stop taking their
bisphosphonate medication.

The following Bisphosphonates are available in Namibia; Pamidronate, Alendronate, Risedronate. Healthcare workers and patients are advised to report all suspected adverse events to the TIPC.

Abridged from the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Commission on Human Medicines

Ergot-derived dopamine agonists: risk of fibrotic reactions in chronic endocrine uses

The European Medicines Agency has recommended new warnings and contraindications for ergot-derived dopamine agonists as a result of the risk of fibrosis, particularly cardiac fibrosis, associated with chronic use.

The risk of cardiac fibrosis is higher with cabergoline and pergolide than with the other ergot-derived dopamine agonists. Chronic use of ergot-derived dopamine agonists is associated with a risk of fibrosis, particularly cardiac fibrosis. Cardiac valvulopathy should be excluded by echocardiography before treatment with cabergoline or bromocriptine. Patients should be monitored during treatment.

Bromocriptine is the only dopamine agonist in the NEMLIST and Namibia medicine register. Bromocriptine is used for the treatment of Parkinson's disease. Healthcare workers are adviced to exclude cardiac valvulopathy as determined by echocardiography before using Bromocriptine or other dopamine agonist. Healthcare workers should monitor patients for signs or symptoms of pleuropulmonary disease and report all suspected adverse events.

Effects of erythromycin and co-amoxiclav in premature labor

A 7-year follow-up of a large randomised, placebo controlled trial to investigate the effects of erythromycin and co-amoxiclav in premature labor called ORACLE Children Study stated that parents reported small increases in the number of children with mild functional impairment or cerebral palsy born to mothers whose membranes were intact and who had received antibiotics.

This finding requires further study. The MHRA advices that antibiotics save lives, and pregnant women with possible or obvious infections must be considered for treatment with antibiotics. MHRA states that this research was conducted in a very specific group of women and so the results do not mean that antibiotics are generally unsafe for use in pregnancy.

Untreated infections can be dangerous and potentially life threatening for pregnant women and their unborn babies, and antibiotics should continue to be prescribed in line with current guidance and the product licence. MHRA also advices that the study confirms existing practice that antibiotics should not be given routinely to women who are in premature labor with intact membranes and who have no obvious infection.

Healthcare workers and patients are advised to report all suspected adverse events to the TIPC.

Abridged from the WHO Drug Information Vol 22, No. 3, 2008

Moxifloxacin: adverse hepatic reactions

The European Medicines Agency (EMEA) has concluded that moxifloxacin-containing medicines for oral use should only be prescribed in the treatment of acute bacterial sinusitis, acute exacerbation of chronic bronchitis and community acquired pneumonia when other antibiotics cannot be used or have failed. The Agency also recommended strengthening the warnings for oral moxifloxacin medicines. Moxifloxacin is a fluoroquinolone antibiotic for the treatment of acute exacerbation of chronic bronchitis, community acquired pneumonia, acute bacterial sinusitis and, in some Member States, for mild to moderate pelvic inflammatory disease. Oral

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moxifloxacin medicines safety concerns is mainly related to an increased risk of adverse hepatic reactions

Moxifloxacin is registered in Namibia. Healthcare workers and patients are advised to report all suspected adverse events to the TIPC.

Norfloxacin-containing medicines not for use in urinary infections

The European Medicines Agency (EMEA) has recommended restricting the use of oral norfloxacin- containing medicines in urinary infections. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the marketing authorizations for oral norfloxacin containing medicines, when used in the treatment of acute or chronic complicated pyelonephritis (kidney infection), should be withdrawn because the benefits of these medicines do not outweigh their risks in this indication. This is based on the fact that the efficacy has not been adequately demonstrated for this type of infection. Norfloxacin is a fluoroquinolone antibiotic.

Norfloxacin is registered in Namibia. Healthcare workers and patients are advised to report all suspected adverse events to the TIPC.

Abridged from the WHO Pharmaceutical Newsletter

Nitrofurantoin: reports of hepatotoxicity

Following two reports of submassive hepatic necrosis associated with nitrofurantoin to the Adverse Drug Reactions Advisory Committee (ADRAC), a review of hepatic adverse events with this drug was conducted. According to ADRAC, the Australian Therapeutic Goods Administration (TGA) has received 637 reports of adverse events associated with nitrofurantoin up to April 2008, which included 17 reports of death. Of the 637 reports received, 119 were reports of hepatobiliary reactions, including 32 serious cases; seven cases were fatal. Other reports included jaundice (4), hepatitis (13) or hepatic failure (2). In seventeen of the serious cases, nitrofurantoin was the only suspected drug.

The majority of reports involved women aged more than 50 years, who were taking nitrofurantoin 50-200 mg/day for acute urinary tract infections (UTIs; 11), recurrent UTIs (11), or as prophylaxis (10). (Nitrofurantoin is used to treat urinary tract infections.)

Nitrofurantoin is in the NEMLIST and registered in Namibia report all cases of adverse events to the TIPC.

Risperidone, pipamperone reports of epistaxis

As at 30 August 2007, the Netherlands Pharmacovigilance Centre (Lareb) had received 12 and 11 reports of epistaxis (nosebleeds) associated with the use of the antipsychotic drugs risperidone and pipamperone, respectively. The majority of reports involved children aged 5-14 years. Epistaxis is not listed in the Dutch Summary of Product Characteristics for either risperidone or pipamperone. However, the adverse reaction is listed in the American SPC for risperidone (incidence 0.1%-1%).

Risperidone is registered in Namibia. Healthcare workers and patients are advised to report all suspected adverse events to the TIPC.

Salbutamol dental caries associated with use in children

The Netherlands Pharmacovigilance Centre (Lareb) has received five reports of dental caries associated with the use of salbutamol (Albuterol) up to 5 September 2007. The five cases involved four boys and one girl aged 5-9 years who developed dental caries while receiving salbutamol, which is a beta-2 agonist used to treat asthma. While well-described in the literature, dental caries are not listed in the SPC for the antiasthmatic drug sodium cromoglicate nasal spray.

Salbutamol is registered in Namibia. Healthcare workers and patients are advised to report all suspected adverse events to the TIPC.

Summary of safety update

Product	Namibia Market authorization Holder	Comments
Etanercept	Wyeth South Africa	Etanercept *(Recombinant human tumor receptor : FC Fusion protein)*25,0mg + Diluent
Moxifloxacin Hcl	Bayer	
Norfloxacin	Cipla-Medpro	
Rotavirus *(Human, Human-Bovine; oral and lyophilized powder)*	MSD, GSK	
BCG vaccine	Biovacs SA	Each 1ml contains Mycobacterium Bovis 0.75 mg *(Danish 1331)*
Fluorescein		Minims Lidocaine and Fluorescein
Fluticasone	GSK	Fluticasone Propionate Metered Dose I nhaler 250µg per actuation, Salmeterol Xinafoate, Fluticasone Propionate
Nitrofuratoin	GSK	Nitrofuratoin
Pioglitazone	Eli Lilly	
Risperidone	Jansen	Many conventional and atypical antispychotics are registered in Namibia
Salbutamol *(and dental caries)*	iNova Pharmaceuticals (Pty) Limited, Glaxo Wellcome SA (Pty) Ltd, Pharmacare Ltd, etc.	
Statins	Pharma Dynamics (Pty) Ltd Myositis/rhabdomyolysis in situations where treatment with HMG-CoA reductase inhibitors. Simvastatin is registered in Namibia.	
Strontium	Egis Pharmaceuticals South Africa	
TNF inhibitors	Schering-Plough (Infliximab)	Infliximab *(Remicade)*, etanercept *(Enbrel)*
Bisphosphonates	Novartis South Africa (Pty) Ltd, MSD pty ltd, Aventis Pharma pty ltd	Bisphosphonates registered in Namibia include Pamidronate, Alendronate, Risedronate.

FOCUS

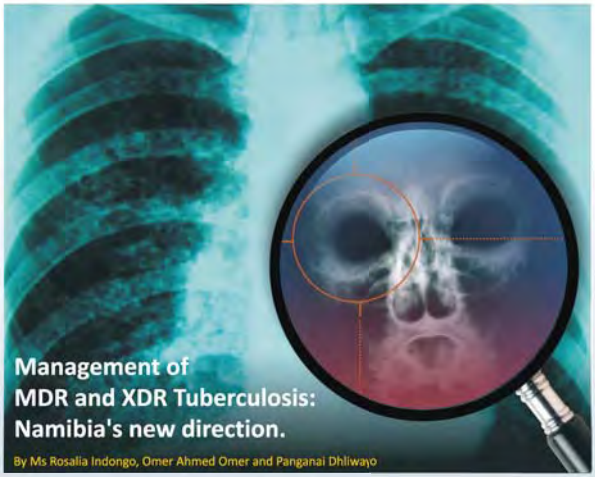
Other safety news

Proton Pump Inhibitors Increase Risk of Major Cardiovascular Event

Proton Pump Inhibitors increase risk of major cardiovascular event by more than 50 percent for patients taking Plavix(R) (clopidogrel). Medco Health Solutions, Inc. presented a study on November 11, 2008 at the 2008 Scientific Sessions of the American Heart Association that showed an increased risk for major cardiovascular events in patients taking clopidogrel (the active ingredient in Plavix) and proton pump inhibitors (PPIs) together. The study stated that PPIs inhibit the effectiveness of clopidogrel thus increasing the risk of a major cardiac event, such as heart attacks and strokes by 50 percent.

Crestor Demonstrates Dramatic CV Risk Reduction in a Large Statin Outcomes Study

New data from the JUPITER study demonstrated that CRESTOR® (rosuvastatin calcium) 20 mg significantly reduced major cardiovascular (CV) events (defined in this study as the combined risk of myocardial infarction, stroke, arterial revascularization, hospitalization for unstable angina, or death from CV causes) by a dramatic 44% compared to placebo (p<0.001) among men and women with elevated hsCRP but low to normal cholesterol levels. Results also showed that for patients in the trial taking rosuvastatin: the combined risk of heart attack, stroke or CV death was reduced by nearly half (47%, p<0.001), the risk of heart attack was cut by more than half (54%, p<0.001), the risk of stroke was cut by nearly half (48%, p=0.002), and total mortality was significantly reduced by 20% (p=0.02).



Management of MDR and XDR Tuberculosis: Namibia's new direction.

By Ms Rosalia Indongo, Omer Ahmed Omer and Panganai Dhliwayo

Namibia is facing the threat posed by drug resistant tuberculosis head on. After playing host to a number of consultancies on MDR tuberculosis; the Ministry of Health and Social Service MOHSS went on to implement the recommendations made by the various consultants who came to Namibia. The Permanent Secretary of the MOHSS has also issued a circular to provide guidance in the management of drug resistant tuberculosis (DR-TB).

One of the major shifts in the clinical management of DR-TB is the introduction of standardized regimens for all poly and multi-drug resistant tuberculosis. This is as opposed to the previous guideline where treatment was adjusted according to patients' anti-TB medicine susceptibility pattern, resulting in individualized regimens that result in difficulties in forecasting the drug requirements of the country.

Another important control measure is the designation of eight hospitals to serve as DR-TB management centres with the aim of centralizing and streamlining the initiation of second line anti-TB treatment in the country in line with international best practices.

Ideally; Namibia would use only one centre; but given the vastness of the country it is necessary to have eight hospitals namely Katutura, Walvis Bay, Oshakati, Onandjokwe, Keetmanshoop, Rundu, Katima Mulilo and Otjiwarongo.
Hospitals that manage drug resistant Tuberculosis will have to take infecion control seriously to avoid the spread of resistant TB strains within the institutions and in the community. To this end the MOHSS has embarked on a renovation exercise to ensure isolation of all infectious TB cases with special considerations for admission of patients with drug resistant TB.

Namibia has replaced some second line anti-TB medicines previously used for the treatment of drug resistant TB with new more potent second line medicines in line with the international best practices. In this regard; ciprofloxacin has been replaced by the more potent levofloxacin. Cycloserine, Capreomycin and Para Amino Salicylic Acid (PAS) have been added to the arsenal. Kanamycin replaces Amikacin on the basis of cost and evidence of less toxicity.

Realising that putting patients on second line anti-TB medicines is probably the last chance they have to be cured, the decision to initiate second line treatment is not to be taken lightly and never by one individual. To ensure a multi disciplinary team approach to the management of multi drug resistant TB the National TB Control Programme (NTCP) has propose the establishment of a Central Clinical Review Council (CCRC) at national level with similar regional structures.

A strong surveillance system is under development to ensure that all patients with drug resistant TB are reported to enable the NTCP to monitor trends and assess the magnitude of this particular form of Tuberculosis nationally.

For more detailed information contact the NTCP manager Ms Rosalia Indongo on indongor@nacop.net.

Jude Nwokike.

Review of Guidelines and Comparative Effectiveness of antidepressants

Introduction

Depression refers to a wide range of mental health problems characterized by the absence of a positive affect (a loss of interest and enjoyment in ordinary things and experiences), low mood and a range of associated emotional, cognitive, physical and behavioral symptoms.

Everyone can have low moods at any point in life, but it is the severity and persistence of the low mood and the interference with normal functioning that make for a clinically significant condition.

According to the American Psychiatric Association, major depressive disorder is a persistent and unreactive low mood and loss of all interest and pleasure accompanied by a range of symptoms including appetite loss, insomnia, fatigue, loss of energy, poor concentration, psychomotor symptoms, inappropriate guilt and morbid thoughts of death.

The incidence of depressive illness may be on the rise. The increased burden of HIV/AIDS in Sub-Sahara Africa may have led to more persons suffering from depressive illnesses, however it is not certain if all cases of depression are recognized, diagnosed, and treated in resource-constrained settings.

There are increasing concerns that many HIV/AIDS patients who present with depression are not treated. Untreated depressive illness can worsen HIV/AIDS and may lead to poor adherence and treatment outcome. Evidence-based clinical practice guidelines have developed recommendations for the management of mild, moderate and severe depressive illnesses.

There seem to be consensus that antidepressants are not very useful in the initial management of mild depression because of their poor risk-benefit ratio. Antidepressants are however useful in the management of established depressive illness.

Which Antidepressants Are Available?

Antidepressants can be grouped into the classes: Tricyclics (TCAs), monoamine oxidase inhibitors (MAOIs), selective serotonin reuptake inhibitors (SSRIs), and serotonin-noradrenaline reuptake inhibitors.

In Namibia all the above classes are registered. The TCAs; amitriptyline, trimipramine, and imipramine are available in the Namibia Essential Medicine List (NEMLIST). Other antidepressants including bupropion, citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, mirtazapine, nefazodone, paroxetine, sertraline, trazodone, and venlafaxine are available in the national medicine register. Data on the extent of use of these products in the public and private sectors are not readily available.

Why Comparative Effectiveness

During clinical trials medicines are studied under ideal conditions. These randomized controlled trails are useful for understanding the efficacy of medicines in ideal conditions and may provide some information on the disease process. Once the medicine is registered the conditions of use in the real-life are often not entirely the same with clinical trial conditions.

Effectiveness is concerned with the determination of how the medicine has lived up to expectation in real-life. Comparative effectiveness is therefore the comparison in real-life of one treatment to one or more other treatments for the same indication. The US Agency for Healthcare Research and Quality, AHRQ defines **comparative effectiveness review** (CER) as a unique type of systematic review that depicts how the relative benefits and harms of a range of clinical options compare in the context of real-world healthcare decisions.

CER answer more than the narrow question of whether a single therapy is safe and effective and compares tradeoffs of multiple alternatives each of which may vary with the underlying population and setting. Many resources like clinical practice guidelines and systematic reviews including the Cochrane library either conduct comparative effectiveness reviews or provide grades of evidence to guide their recommendations on choice of interventions.

Current Thinking On Effectiveness of Antidepressants

Interest has recently increased in efforts to obtain real-life data on the comparative effectiveness of antidepressants in the management of depression. The table below provides abridged data on the recommendations from internationally recognized clinical practice guidelines and other related resources on guidelines for the use of antidepressants in the management of depression:

Comparative Effectiveness of Antidepressants

	Reviewed Guideline	Key Conclusions
1	NICE: National Collaborative Center for Mental Health (**Depression: Management of depression in primary and secondary care.** The British Psychological Society & The Royal College of Psychiatrists, 2004)	• Antidepressants are not recommended for the initial treatment of mild depression, because the risk-benefit ratio is poor. • The use of antidepressants should be considered for patients with mild depression that is persisting after other interventions, and those whose depression is associated with psychosocial and medical problems. • The use of antidepressants should be considered when patients with a past history of moderate or severe depression present with mild depression. • When an antidepressant is to be prescribed in routine care, it should be a selective serotonin reuptake inhibitor (SSRI), because SSRIs are as effective as tricyclic antidepressants and are less likely to be discontinued because of side effects.
2	APA: American Psychiatric Association practice guideline for the Treatment of Patients With Major Depressive Disorder (2nd Ed) April 2000.	• The effectiveness of antidepressant medications is generally comparable between classes and within classes of medications. Therefore, the initial selection of an antidepressant medication will largely be based on the anticipated side effects, the safety or tolerability of these side effects for individual patients, patient preference, quantity and quality of clinical trial data regarding the medication, and its cost • In general, monoamine oxidase inhibitors (MAOIs) should be restricted to patients who do not respond to other treatments because of their potential for serious side effects and the necessity of dietary restrictions.
3	Systematic reviews and meta-analysis (Cochrane Library Review and others)	• This systematic review indicates that amitriptyline is at least as efficacious as other tricyclics or newer compounds. However, the burden of side-effects in patients receiving it was greater. In comparison with SSRIs, amitriptyline was less well tolerated, and although counterbalanced by a higher proportion of responders, the difference was not statistically significant. • Our findings suggest that SSRIs and TCAs are of the same efficacy. However, we have found some evidence suggesting that TCA related antidepressants and classical TCAs have different side effect profiles and are associated with differing withdrawal rates when compared with SSRIs. • There are statistically significant differences in terms of efficacy and tolerability between fluoxetine and certain antidepressants, but the clinical meaning of these differences is uncertain, and no definitive implications for clinical practice can be drawn. From a clinical point of view the analysis of antidepressants' safety profile remains of crucial importance. Treatment decisions should be based on considerations of clinical history, drug toxicity, patient acceptability, and cost. • It is unclear what the effect of SSRIs is on suicide completion. While untreated depression is associated with the risk of completed suicide and impacts on functioning, it is unclear whether SSRIs would modify this risk in a clinically meaningful way. • Adverse event profiles are similar among 2nd generation antidepressants. However, different frequencies of specific adverse events might be clinically relevant and influence the choice of treatment.

Comparative Effectiveness of Antidepressants

	Reviewed Guideline	Key Conclusions
4	AHRQ: Comparative Effectiveness of Second-Generation Antidepressants in the Pharmacologic Treatment of Adult Depression. Jan 2007.	• Evidence of moderate strength supports some differences among individual drugs with respect to onset of action and some measures (e.g., sexual functioning) that could affect health-related quality of life. These are statistically significant but of modest magnitude; potential benefits might be offset by specific adverse events. Nonetheless, some of these differences may influence the choice of a medication for specific patients • In major depressive disorders direct evidence from 1 good and 2 fair effectiveness studies and indirect evidence from efficacy trials indicate that no substantial differences in effectiveness exist among second-generation antidepressants.
5	Drug Information Bulletins	• Despite many trials in hundreds of patients in total, it remains to be demonstrated that Fluoxetine is any more effective than placebo in depressed children and adolescents. Any benefit would at best be limited. Many questions remain unresolved as to the risk of serious adverse effects.

Safety of Antidepressants

There is evidence that second generation antidepressants, example SSRIs are as effective as the TCAs. The safety profile and risk-benefit ratio of antidepressants are however not well established. The recent concerns about suicidality have even highlighted the need to have such data available.

Recently the FDA and other stringent regulatory authorities has provided boxed warnings and other regulatory alerts to warn that antidepressants compared to placebo increased the risk of suicidality in children, adolescents, and young adults in short-term studies of major depressive disorder and other psychiatric disorders.

The risk of suicide did not seem to increase with adults however regulatory authorities warn that patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior.

Conclusion

Antidepressants may not offer many benefits for the initial treatment of mild depression. Their roles are many times compromised by safety concerns. Selective serotonin reuptake inhibitors and other second-generation antidepressants are as effective as tricyclic antidepressants and are less likely to be discontinued due of side effects. The choice of antidepressants should not be guided solely by efficacy but by serious consideration of comparative effectiveness and cost.

TIPC Review of Guidelines and Comparative Effectiveness Search Strategy

Our key goal is to utilize information from notable guidelines and evidence-based publications and abridgea and adapt their recommendations to local relevance in Namibia. We routinely search the following databases:

1. Clinical practice guidelines and consensus statements
   - Notable international guidelines databases; Guideline International Network(GIN), National Guidelines Clearinghouse (NGC)
   Search on key individual guidelines databases like NICE, SIGN,
2. Systematic reviews and meta-analysis Cochrane Library of systematic reviews
   Other large systemic reviews of randomized controlled studies and observational studies not included in the Cochrane library
3. Comparative effectiveness/Health technology assessment reviews
   Comparative effectiveness review conducted by Agency for Healthcare Research and Quality (AHRQ), Canadian Coordinating Office for Health Technology Assessment
4. Drug information bulletins
   WHO Drug Information, member bulletins of the International Society of Drug Bulletin (ISDB) including Prescrire International, Regulatory information newsletters including FDA drug safety newsletter, MHRA Drug safety update, and WHO Pharmaceutical newsletter.

We report summaries of conclusions and recommendations from these databases in ways that will be helpful to health managers, clinicians, healthcare workers in decision making.

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[8] Gartlehner, G. et al. Comparative risk for harms of second-generation antidepressants. Drug Safety 2008; 31 (10): 851-865

[9] Rev Prescrire. Fluoxetine Depression in Children: Too many uncertainties 2008; 28 (294) : 410-411.

CASES FROM THE TIPC.

Preliminary survey on the observation of Nevirapine and prolonged labour

Dr. A. Mengistu / Dr. P. Tshiteta

BACKGROUND:

Self-administered single dose Nevirapine at the onset of labour is used for PMTCT in the HIV positive pregnant woman who is not already on ARV therapy. There has been a general perception held by some health care workers in the Erongo region of Namibia that women who take Nevirapine to prevent mother to child transmission of HIV have longer duration of labour than those who do not. However such concerns have no scientific basis and have not been validated or described in the reviewed medical literature.

OBJECTIVES

To assess the experience of health care professionals regarding duration of labour amongst women enrolled for the PMTCT program who took Nevirapine at the onset of labour

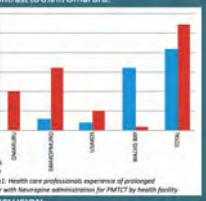
METHODOLOGY:

Cross sectional survey conducted in four hospitals of the Erongo region. 57 out of the 60 health care providers in the maternity service responded to the self administered questionnaire making the response rate to be 95%.

RESULTS:

All 57 responded satisfactorily to the use of Nevirapine in pregnancy and knew its precise indication.

As to whether Nevirapine has an effect on duration of labour, there was a vast difference in patterns of responses between health facilities, with 88,9% of those in Walvis Bay saying it does in contrast to 0% in Omaruru.



Graph1: Health care professionals experience of prolonged labour with Nevirapine administration for PMTCT by health facility

CONCLUSION:

The number of healthcare workers who believe that Nevirapine can prolong labour is uncomfortably high, particularly in Walvis Bay.

Of note is the fact that no scientific proof to support this view has been quoted. This may have a bearing on the reliability of information being disseminated at informal fora and in-service training at the different health facilities, as can be inferred from the vast differences between results from the different facilities that participated in the survey.

We, therefore, propose a rigorous scientific investigation to elucidate the relationship between Nevirapine and duration of labour which can help to clarify concerns that health workers and patients may have.

Joseph Rushubiza

MEDICATION ERRORS: A THREAT TO SAFETY OF PATIENTS (PART TWO)

In the previous edition of the *Namibia Medicines Watch*, the first part of "Medication Errors: A Threat to Safety of Patients" was discussed, covering definitions, modes of occurrence, effects and types of medication errors in dispensing and administration. The second part of the article continues:

Causes of Medication Errors

Medication errors are caused by weaknesses in the medication use systems, such as lack of policies regarding medicine prescribing, lack of communication among healthcare providers, lack of current medicines information, bad working environment and conditions, and also human factors such as deficiency in knowledge and performance skills.

Minimisation of Medication Error Occurrences

Institutions should develop policies and procedures that address every phase of medicines use by:

- Ensuring availability of up-to-date reference materials, appropriate equipment, and essential medicines.
- Providing appropriate number of staff to reduce fatigue.
- Providing appropriate working environment like well-lit places with minimal level of distractions.
- Designing and implementing medication errors reporting system. Therapeutics committees can play a key role in analysing errors, carrying out in-depth study to find out causes and designing interventional strategies to prevent medication errors.

Prescribers could minimise prescribing errors by:

- Ensuring adequate knowledge of a medicine before prescribing.
- Taking thorough patient history.
- Writing a prescription legibly and completely to include legal requirements and instructions on how the medicine should be taken.
- Avoiding using abbreviations.
- Always using a zero before a decimal point e.g. 0.5mg or avoiding using decimal points where possible, e.g. 500mcg instead of 0.5mg.
- Avoiding using a terminal zero (e.g. 5.0mg) after a whole number.

Dispensers could minimise dispensing errors by:

- Having safe dispensing procedures in place including rechecking every critical step.
- Concentrating on the task at hand and avoiding distractions.
- Physically separating medicines containers that look alike.
- Paying special attention to high risk medicines e.g. digoxin, warfarin.

Nurses could minimise drug administration errors by:

- Following the "Five Right" procedure right medicine, Right dose, Right patient, Right route, at Right time.
- Having current knowledge of prescribed medicines.
- Minimising interruptions during medication administration.

Patients and caregivers could minimise medication errors by:

- Informing healthcare providers about all known allergies and medications being taken.
- Knowing medicines being taken.
- Questioning the healthcare provider when there is something out of the norm.
- Taking effort to adhere to therapeutic plan.

Conclusion:

Medication errors have both economic and health importance to patients. There are many contributing factors to occurrences of medication errors. Every health practitioner should report medication errors to the TIPC. This will assist health institutions and the nation in identifying specific contributing factors and also in finding out ways to strengthen the medication use system.

MYHEALTH CASE STUDIES

Compiled by Dr. Abigail Feris

The cases outlined in this script are true cases picked up by MyHealth. None of the cases below are made up and the cases are from Pharmacies and General Practitioners in Windhoek and other regions in Namibia.

CASE STUDY 1

Patient X was prescribed the following by his doctor:

Kaletra 3 caps twice a day (180)
Tenofovir 300mg daily (30)
Aspen Lamivudine 150mg twice a day (60)
Centrum 1 tab daily (30)
Repeat x 12

The patient went home with the following:

Kaletra, Truvada, Lamivudine, Centrum

He received the same medication for the next 6 months.

This patient was receiving FTC & 3TC at the same time. FTC (Emtricitabine) and 3TC (Lamivudine) are equivalent. FTC is a component of Truvada (a fixed dose combination of FTC and Tenofovir disoproxil fumarate). Due to similarities between FTC and 3TC, 3TC should not be co-administered with Truvada or Atripla (a fixed dose combination of Efavarinz, FTC, Tenofovir).

Also, FTC should not be co-administered with drugs containing 3TC e.g. Combivir, Epivir, Epzicom, Trizivir.

FTC & 3TC together can be seen as "double dose" of 3TC. This can lead to renal impairment, lactic acidosis and severe hepatomegaly with steatosis.

Therefore it is important to know the generic names of the drugs. Brand names for fixed dose drug combinations can lead to confusion as seen with the above case. It is very important to know the contents of FDC drugs. Due to different brand names for a specific drug it is easier to stick to generics.

CASE STUDY 2

Mrs. H went to her doctor and received a script:

Zerit 30mg twice a day (60)
3TC 150mg twice a day (60)
Nevirapine 200mg twice a day (60)

She went home with the following:

Combivir 1 tab twice a day
Zerit 30mg twice a day
Nevirapine 200mg twice a day

MyHealth made a call to the Pharmacists to enquire why he had issued the medicines the way he did. He said that since Combivir contains 3TC he thought it is okay to issue Combivir with Zerit.

There is however a huge problem and dangerous because the patient received AZT and D4T together from the same class and they have an antagonistic effect on each other. They can potentiate each other's toxicities as both can cause mitochondrial dysfunction and lead to possible lactic acidosis, severe anaemia and peripheral neuropathy.

Once again it is emphasized that all contents of FDC drugs are known.

Here is a list of all unapproved drug combinations /regimens:

- Regimens containing AZT after D4T failure - Cross-resistance
- Regimens containing EFV after NVP failure - Cross-resistance
- Regimens containing both AZT & D4T - Antagonism
- Regimens containing both NVP & EFV - Antagonism
- Regimens containing both ddI & TDF interactions - Poor CD4 responses
- Regimens containing both ddI & D4T - Increased toxicities.

Abbreviations:

AZT- zidovudine
D4T- stavudine
EFV- efavarinz
NVP- nevirapine
ddI- didanosine
TDF- tenofovir

UPDATES *(contd)*

Changes to the Namibia Essential Medicines List (Nemlist) - April 2008 *(contd)*

- **Deletions from the Nemlist:**

  Several medicines were removed from the Nemlist and replaced with more efficacious or more readily available alternatives. Cimetidine tablets were replaced with Ranitidine tabs, Chloroquine tablets were replaced with Artemether/Lumefantrine tablets and Thiopental injection was removed to be replaced by Propofol- a medicine that was already in the Nemlist but only at referral hospitals.

- **Additions to the Nemlist:**

  More than 46 medicines were added to the Nemlist including antiretroviral medicines, medicines for multi drug resistant (MDR) TB and Mycobacteria Other Than Tuberculosis (MOTT), anti-cancer medicines and anaesthesia agents.

- **Re-classification:**

  13 medicines were reclassified to either a lower level or higher level of availability. These

Know your medicines

What range of products should be considered when reporting or making enquiries?

All pharmaceutical products including:

- Prescription medicines (including antiretrovirals, TB and other medicines for long illnesses)
- Over The Counter medicines (like cough syrups, pain killers or vitamins / supplements)
- Complimentary medicines (health/vitality boosting medicines)
- Herbal and traditional medicines
- Laboratory, X-ray and other diagnostic agents
- Vaccines(immunization events)

SUBSTANCE ABUSE

Alcohol use and misuse and its impact on the society (part 2)

Mrs. René A. Adams

In the first part of "Alcohol Use and Misuse and Its Impact on the Society", the global and national magnitude of alcohol misuse and associated social and health consequences were highlighted. In this second part, "Effects of Alcohol Abuse and Interventions to Control alcohol abuse" will be discussed.

Alcohol Abuse: Effects and Interventions Control.

The social cost of alcohol abuse is enormous. Excessive drinking leading to an exposure to risky sexual encounters is worrisome for Namibia. Abuse of alcohol leads to unprotected sex and increases the risk of HIV infection.

Alcohol abuse also decreases adherence to antiretroviral treatment in those who are already on treatment, thus leading to a treatment failure. People with an excessive alcohol drinking habit often spend money meant for other more important things to nurse their habit.

These alcohol related problems can happen to anyone who drinks until he gets drunk on any single occasion, like a Saturday night party.
With regard to the supply of alcohol, the abundance of shebeens, bars and cuca shops make alcohol easily accessible and available.

The Liquor Act 6 of 1998 clearly stipulates that alcohol beverages should not be sold to children under the age 18 and should not be sold on credit. However, at most drinking places, age restrictions are not enforced and alcoholic beverages are often sold on credit by the owners to such an extent that the consumer is unable to repay accrued debts.

Although it is against the law to sell alcohol to persons under the age of 18 years, a survey conducted by Ministry of Health and Social Services in collaboration with University of Namibia in 1999 titled: "Substance Use Among the Youth in Namibia" reported that 50% of the youth start experimenting with alcohol from a very young age (13years).

Heavy alcohol use takes a particular toll on the young, and has been linked to high rates of juvenile criminal behavior, injury and impaired ability to achieve educational qualifications. Premature involvement in alcohol use can also have a range of other developmental effects like coping strategies, social relationships and attitudes towards other forms of illegal substance misuse.

To address the problem of alcohol abuse, sustained and coordinated interventions are needed from all spheres and sectors, such as health, trade, legislation, law enforcement, education, research and the community.

One of such preventive approaches is the Coalition on Responsible Drinking, a programme of the Directorate of Social Welfare Services, of the Ministry of Health and Social Services. The coalition believes that this pattern of problematic drinking in the Namibian society needs to change.

We therefore aim at achieving a long-term change in attitudes to irresponsible drinking behavior by ensuring greater awareness of alcohol misuse issues among our citizens. This will include among others:

- Making the "responsible drinking" message easier to understand and apply.
- Creating awareness campaigns targeted at those most at risk particularly binge drinkers and chronic drinkers.
- Ensuring the availability of information at point of sale on the possible harm from the use of alcohol products.
- Creating awareness education and attitudes/behavior change programmes on alcohol use and misuse.
- Ensuring the media (radio, newspaper and TV) advertising does not glamorize irresponsible behavior or do not target the youth.

ACHIEVEMENTS OF THE TIPC

TIPC Participation -The 31st Annual National Centres Meeting: Uppsala, Sweden

Mr Evans Sagwa, one of the Namibian delegates, making a presentation.

The 31st Annual Centres Meeting, involving all representatives of National Centres participating in the WHO Programme for International Drug Monitoring was conducted in Uppsala, Sweden from the 20th to the 23rd of October 2008.

Over 150 representatives from more than 50 countries, 13 of which were African countries, attended and participated fully in this year's annual Meeting.

Activities for this year's meeting included discussions on ranges of safety problems, which are of current interest among member countries. Practical demonstrations on how to benefit maximally from the web based data base Vigiflow, Vigibase, Vigi-search, the WHO Drug Dictionary and other available tools at the UMC, were also given.

Representatives from centres across African countries briefly brainstormed on issues pertaining pharmacovigilance, and it's strengthening in the region. As a result, an e-mail discussion group was formed, with the objective of highlighting issues specific to Africa.

As it was the first time for the TIPC team at the 31st Annual National Centres meeting, the delegates from Namibia were hosted to a pre-meeting tutorial for new delegates. This pre-meeting tutorial served as a breaking-in session for all new delegates to the Annual National Centre's meeting.

At the end of the National Centres Meeting, the TIPC team also participated in a one day training seminar/workshop on adverse drug reaction signal detection.

The next Annual National Centres meeting has been scheduled to take place in Morocco.

Namibian delegates to the National Centres Meeting

Report on the National Training Course on Therapeutics Committees

Charles Ouma

The national training course on therapeutics committees (TCs) was held from 4th -9th August 2008 at the Windhoek Country Club and Resort. The course was organized jointly by the Ministry of Health and Social Services (MoHSS), MSH/SPS and the World Health Organization (WHO).

Thirty-nine key healthcare professionals drawn from all the 13 regions of the country and comprising of principal medical officer (PMOs), medical officers, pharmacists, nurses and pharmacist's assistants attended this intensive 6-cay course.

This course was organized to equip the participants with skills and knowledge to enable them to effectively conduct and implement TC activities in their respective facilities. The course was tailored to address specific knowledge and skills gaps, challenges and weaknesses that were identified from a national TC situational analysis and training needs assessment that was jointly carried out by MoHSS and MSH/SPS.

Course facilitators included two experts on TCs from the MSH/SPS Arlington office, technical staff from MSH/SPS, Namibia and officers from MoHSS national level and the regions. The WHO country office provided a number of training materials including manuals, circulars, guides and CDs which were utilized during the training course and subsequently distributed to the participants to take back to their facilities.

The individual training sessions were well received and made all the more informative from input by the participants. Field visits to a number of local health facilities enabled the participants to practice and apply some of the skills acquired during the course for identifying and resolving medicine use problems.

In order to ensure that TCs in the country are supported adequately after this course, a follow-up support plan and regional work plans were developed. MoHSS and MSH/SPS will provide the follow-up technical assistance to ensure that those TCs that require additional support will have it available when need.

In addition, a draft monitoring and evaluation (M&E) plan for monitoring the functionality of TCs in the country was drawn-up and will be implemented after incorporating input from all stakeholders and approval by MoHSS.

The successful implementation of this key training course and the planned subsequent follow-up support are expected to reinvigorate TCs in the country and subsequent rational medicine use activities.

Mr P.K. Ndaitwa, Under Secretary: Policy Development & Resource Management, giving the opening address on behalf of the Permanent Secretary, MoHSS during the official opening of the National TC Course

Participants and facilitators of the National Training Course on Therapeutics Committees, August 2008

Please detach form

Republic of Namibia

Ministry of Health and Social Services

Safety Yellow Form

For reporting ADRs(Adverse Drug Reactions) and medicine use /product problems

TIPC Pilot Form

A. Patient Information			
Patient identifier(initials/code)		*Sex*	*M*_____ *F*_____
Age at the time of event		*Weight in kgs*	

B. Adverse Event/Product problem/Error (*tick where appropriate*)

1. Event/Reaction		**2.Type of Event/Reaction**	
Event/Reaction to ARV/TB/ACT/New medicines/Product		*Adverse Event*	
		Product problem (e.g. defects/malfunctions)	
Serious events with other medicines/Products		*Product use error (e.g. medication error)*	

3. Outcomes attributed to adverse event (tick where appropriate)

Death (Date:____/____/____)		*Disability or Permanent damage*	
Life-threatening		*Congenital anomaly/ Birth defect*	
Hospitalization/prolonged hospital stay		*Other serious (important medical events)*	
Required intervention to prevent permanent impairment/damage e.g. use of devices		***4. Date of the Event***	
		5. Date of this report	

6. Describe the Event, Product problem or Product use error and Actions taken

7. Relevant tests/Laboratory investigations done (include dates)

8. Other relevant history, including pre-existing medical conditions (allergies, pregnancy, smoking, alcohol use, liver, kidney problems, race etc)

C. Suspect Product (obtain as much information as possible from product label/packaging)

Name		*Dose/amount*	
Strength		*Frequency*	
Manufacturer		*Route*	
Date of use (From/to or best estimate of duration):			
Event stopped after stopping use? (Yes/No)		*Event stopped after dose was reduced?(Yes/No)*	
Event reappeared after reintroduction (Yes/No)			
Lot number	*Expiry date*		

D. Other products taken by the patient within the last 3 months prior to the reaction

Product name 1		*Product name 3*	
Dosage and dates		*Dosage and dates*	
Product name 2		*Product name 4*	
Dosage and dates		*Dosage and dates*	

E. Information about the reporter

Names		*Profession*	
Telephone		*Fax*	
Region		Email	
Health Facility			

Send / Fax to the Therapeutics Information and Pharmacovigilance Centre: Room 21, Basement Area, Windhoek Central Hospital; Tel: 061 203 2312. Fax: 061 22 66 31

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