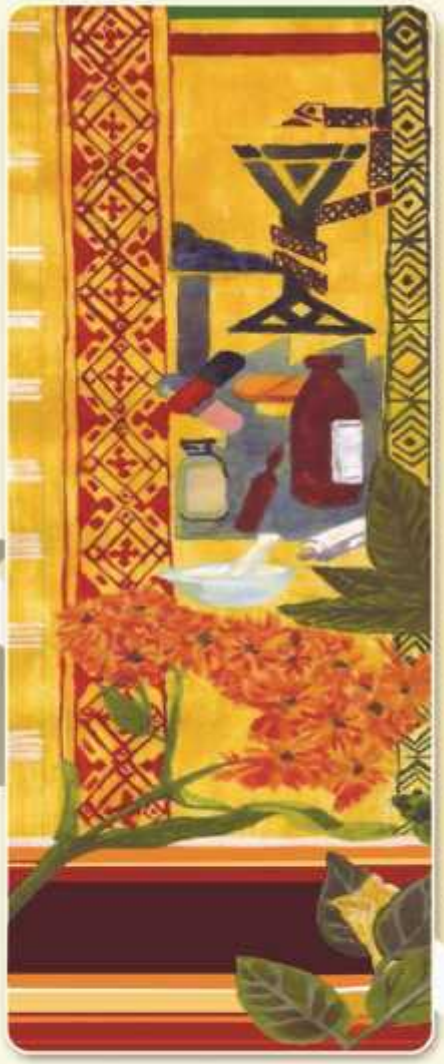
Pharma Forum

June 2013 | Volume 16 | Number 1

An Independent review of
Pharmaceutical News and Issues

Published biannually by the
Ethiopian Pharmaceutical Association (EPA)



In this Issue

Message from Editors

Pharma Forum has been one of the communication media between the association and its members. The Editorial committee is dedicated to give pharmacy related information through publications like pharma news and pharma forum bulletin. The committee was planed to publish pharma news every three month and pharma forum bulletin every six month.

Regarding distribution of publication EPA office distribute the hard copies to the members and the editorial committee forwarded the soft copies via E-mail addresses of members.

The editorial committee would like to use this opportunity to thank those members who made contribution in this publication. We would also like to invite others to make their effort in the future in the form of articles, suggestions on the issues and to give their comments.

We hope to hear from you.

Pharma Forum Editorial Committee

E-Mail **epapharmaforum@gmail.com**

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1. News

1. Antimicrobial Resistance Day

From EPA office

The Ethiopian Pharmaceutical Association (EPA) and the Ethiopian Pharmaceutical Students' Association (IPSA) in collaboration with the Federal Ministry of Health (FMOH), Food Medicine and Healthcare Administration and Control Authority of Ethiopia (FMHACA), Pharmaceutical Fund and Supply Agency (PFSA), USAID/SIAPS and WHO marked the AMR Day on June 15/2014.

This year's antimicrobial resistance day was marked at Ethiopia hotel with a theme of ***"AMR: a Major Public Health and Global Health Security Threat of the 21st Century!"*** for the second time in the country. The event started with Dr Ariaya Hymete's (EPA president) opening speech. It was then followed by two consecutive presentations, the first one being on ***Health Impacts of Antimicrobial Resistance*** by Mr Tenaw Andualem and the second one on ***Multidisciplinary Approach to Contain Antimicrobial Resistance*** by Professor Eyasu Makonnen.

Participants of the antimicrobial day at the end of the event

2. Training to model community pharmacy initiative enrolled 16 community pharmacies

The association in collaboration with FMHACA and PFSA conducted a five days training to community pharmacies enrolled in the EPA model community pharmacy

initiative. The training was conducted from April 29 to May 03/2014 at the new EPA office.

3. The Ethiopian Pharmaceutical Association is to start Continuous Professional Development

The Ethiopian Pharmaceutical Association is making all the necessary preparations to start continuing professional development as of January 2015. Accordingly, the association is closely working with the Ministry of Health and FMHACA. To this effect our association has got two training one of which is "Health Project Management" and the second one on "Instructional Course Design"

4. New Programmes introduction

By Ayenew Ashenef, School of Pharmacy, AAU.

Addis Ababa University, School of Pharmacy, College of Health Sciences is working on introduction of two new programmes at MSc and certificate levels of training in the subjects:

1. Health Supply chain Management
2. Pharmaceutical regulatory affairs.

For the Health Supply chain management, Ministry of Health and other partners are supporting the inception and are also willing to support its launching. Action plan, justification and curriculum were prepared for the programme. Besides a

School of Pharmacy, AAU and FMoH in collaboration with partners have held consultative workshop on strengthening human resources (HR) capacity in pharmaceutical supply chain management (SCM) at Aphrodite International Hotel in Addis Ababa from April 29 to 30, 2014. The aims workshop were to identify gaps and interventions in pre-service, in-service and postgraduate trainings of the pharmaceutical SCM in Ethiopia, to document the need for health SCM training programs, to discuss the roles and responsibility of stakeholders, and to reach on consensus with the proposed structure, option and method of delivery for health SCM program by the School of Pharmacy (SoP), Addis Ababa University (AAU).

The workshop was attended by 48 participants from FMoH, Schools of Pharmacy, Federal referral hospitals, health centers, regional health bureaus, PFSA (central

and regional hubs), Food, Medicine and Healthcare Administration Authority (FMHACA) and partners involved in health SCM. All the workshop participants agreed that pharmaceutical SCM in Ethiopia lacks adequately trained professionals. As a result, gaps in leadership, knowledge and skills are frequently observed at different levels of the health care system. While inadequate course coverage and lack of practical attachment were identified as major problems in pre-service trainings, fragmented, not need based, unsustainable and costly trainings were the major challenges in-service.

The Pharmaceutical regulatory affairs programme is also supported for its inception by Minsitry of Health, WHO and other partners. Both programmes will be multidisciplinary and inter departmental in the management and offering. Besides the traditional in class training distance based options are also in the process of consideration for the delivery of the trainings in the above two programmes.

5. Second round Capacity Building Training for Traditional Healers has been held in Dembia District

From the email system send to pharmaforum:

Abyot Endale[1*],Zewdu Birhanu[1], Mohammedberhan A/Wahib[2], Mulugeta Fente[3]
[1]Department of Pharmacognosy, School of Pharmacy, College of Medicine and Health Sciences, University of Gondar; [2]Department of Pharmacology, School of Pharmacy, College of Medicine and Health Sciences, University of Gondar; [3]Department of Pharmaceutics, School of Pharmacy, College of Medicine and Health Sciences, University of Gondar

*PI; mail: abyot.endale@gmail.com

Background: Traditional medicine has a crucial role in building the health system in developing country. The World Health Organization also recognized traditional medicine as a vital health-care resource in developing countries and has encouraged governments to adopt policies to officially acknowledge and regulate the practice of traditional medicine. Moreover, many of the pharmaceutical products used in modern medicine, have directly or indirectly derived from the knowledge of traditional medicine. However, in many countries, including Ethiopia, there is a critical lack of cooperation between conventional and traditional medicine practitioners. To strengthen this sector, University of Gondar, School of Pharmacy has conducted a capacity building training for traditional healers entitled "Capacity Building Training for Traditional Healers as Primary Health Care Workers in Gondar Town" for the first time in May, 2013. Significant improvement in quality of traditional medicine practice in Gondar town was obtained.. All trained healers are now using mortar and pestle for preparation of potions. Increased positive attitude towards ethical principle and patient handling were also obtained. Moreover, effort is ongoing to cultivate medicinal plant in common. Upon the feedback and implementation of the first round, the second round was held in Dembia district. The third will come soon in Chilga district.

Objective: This project was aimed to enhance the capacity of traditional health practitioners' as primary health workers in the aforementioned town.

Implementation: Prior to actual training, half day sensitization meeting was held with respective stake holders to design the appropriate training delivery and optimal training time. The training was therefore carried out based on the feedback and discussion with stake holders.. A total of 20 traditional health practitioners', were trained for five consecutive days, from March 31 to April 04, 2014 in Kolla Diba towe, Dembia district capital.

The THPs received training over the course of five consecutive days in the following areas:

- Overview on global situation of Traditional Medicine
- Method of standardization, processing and packaging of herbal medicine
- Conservation and sustainable use of the medicinal plant

- Increasing access to prevention and control of some priority diseases (HIV/AIDS,TB, Cancer and Malaria)
- Traditional Medicine and its regulation (In case of Ethiopian health policy)

Proclamation of Ethiopian health policy particularly on traditional medicine chapter was discussed. Especial emphasis was given to

- The current proclamation (Proclamation No.661/2009) by Food, Medicine and Health Care Administration and Control Authority (FMHACA) of Ethiopia.
- Ethics in traditional medicine
- Acquisition of traditional medicine knowledge

On top of this, mortar and pestle and measuring cylinder is on procurement process and will be disrupted for each trained healers.

Conclusion: In general, the practitioners' are eager to adopt standard methods and willing to collaborate with modern medicine. Therefore, we recommended extending such type of training throughout the region/country for better health care of our community.

Active engagement of participants

6. Metoclopramide: Changes to Use

Contributed by Mamo

In our national standards metclopramide is indicated for treatment of nausea and vomiting in gastrointestinal disorders and treatment with cytotoxics or radiotherapy, gastrointestinal osophagial reflux aid to gastrointestinal incubation and nausea and vomiting in maigrane for all sort of ages but witnessing the European Medicines Agency's Committee on Medicinal Products for Human Use (CHMP) WHO on its drug information vol.27 no3 2013 has recommended changes to the use of metoclopramide-containing medicines, including restricting the dose and duration of use to minimize the known risks of potentially serious neurological side effects.

WHO on this edition stated; metoclopramide-containing medicines have been authorized separately in individual Member States with differing licensed indications such as nausea and vomiting or gastrointestinal motility disorders. The review by European Medicines Agency's Committee on Medicinal Products for Human Use (CHMP) confirmed the known risks of neurological effects such as short term extrapyramidal disorders. The risk of acute neurological effects is higher in children, although tardive dyskinesia is reported more often in the elderly, and the risk is increased at high doses or

with long-term treatment. The evidence indicated that these risks outweighed the benefits of metoclopramide in conditions requiring long-term treatment. There have also been very rare cases of serious effects on the heart or circulation, particularly after injection.

The Committee recommended that metoclopramide should only be prescribed for use up to five days, **that it should not be used in children below one year of age and that in children over one year of age**, it should only be used as a second-choice treatment for the prevention of delayed nausea and vomiting after chemotherapy and for the treatment of post-operative nausea and vomiting.

In adults, it may be used for the prevention and treatment of nausea and vomiting such as that associated with chemotherapy, radiotherapy, surgery and in the management of migraine. In addition, the maximum recommended doses in adults and children should be restricted, and higher strength formulations removed from the market.

Reference: WHO Drug Information Vol. 27, No. 3, 2013

2. Current Issues

All information under this topic Contributed by Mamo

The Ethiopian Government ratified the WHO frame work convention on tobacco control (FTCTC)

The WHO Framework Convention on Tobacco Control Adopted at Geneva on the 21st day of May, 2003. The FCTC, one of the most quickly ratified treaties in United Nations history. The treaty is legally binding in most ratifying countries.

Ethiopia signed the convention in March 04, 2004.The House of Peoples Representative of the Federal Democratic Republic of Ethiopia has ratified the Convention at its session held on January 21, 2014.

The Foods, Medicines and Healthcare Administration and Control Authority of Ethiopia is empowered to undertake all acts necessary for the implementation of the convention.

The objective of the convention is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by enacting a set of universal standards stating the dangers of tobacco and limiting its use in all forms worldwide. To this end, the treaty's provisions include rules that govern hazard, demand and supply reduction of tobacco use.

In this regard, the role of pharmacists in smoking cessation and public health protection is immense. Pharmacists can provide public and individual health education and tobacco replacement therapies.

Minimum Working Standards for Retail Pharmacies to be Set

Prior to Food, Medicine and Healthcare Proclamation 661/2009, in Ethiopia there were three levels of retail pharmacies; the Rural Drug Vendors (Yegeter Medihanit Bet), Drug Stores (Medhanit Medebir) and Pharmacies. Rural Drug Vendors were/are run by one year trained pharmacy technicians, registered nursed and health assistants. They were allowed to be opened in remote rural areas where there were no health centers and other infrastructures such as roads, telecommunication and electricity. On the other hand, Drug Stores were run by five years experienced diploma graduate

pharmacists in any locations being limited with the number and type of the medicines they handle. The third label, the pharmacy, was run by B. pharm graduate pharmacists with minimum of five years of experience.

After Food, Medicine and Healthcare Proclamation 661/2009 some of the requirements for opening retail pharmacies have amended. For example, registered nurses and health assistants can't have license to open new Rural Drug Vendors and totally some regions of the country do not allow opening of new Rural Drug Vendors. The requirements for experience of professionals have also amended depending on the type of retail pharmacy to be opened.

The labeling and naming of retail pharmacies, **rural drug vendors, drug stores and pharmacies**, in Ethiopia is somewhat unique to it. This came from the historical perspective of our past healthcare coverage and system. Decade ago, our health coverage was very low and essential medicines were supplied through government owned clinics, latter innovated to health centers, and Rural Drug Vendors which are thought to be located in rural and remote areas where there were no health centers and other infrastructures such as roads ,telecommunication and electricity. Now some of these made history and there is no Woreda town having not these basic infrastructures.

The other historic reason for giving this kind labeling and system was available trained human resource in pharmacy disciplines. Again, a decade back the numbers of the trained pharmacy personnel were very few and even the existing ones prefer to work in larger cities and to overcome this, trained nurses and health assistants were allowed to open Rural Drug Vendors. Now all these made history and the pharmacy workforce is almost available in the market to work in remote areas though the turnover may be still high.

The public is confused with retail pharmacies system and some made beneficiaries from this and others get discouraged with it. For example, the owners of Rural Drug Vendors say we are named 'rural' irrationally being we are currently in towns and the fact is history. On the other hand, the name Drug Store in Amharic means 'medebir', meaning where anyone can get any sort of items he/she wants. The fact is that the reverse is true i.e one can get every sort of medicines he/she wants from Pharmacies not from Drug stores.

Above all; we did not teach the public the differences among the Rural Drug Vendors, Drug Stores and Pharmacies and our retail pharmacy system.

The introduction of pharmaceutical care with trained clinical pharmacist also necessitated the setting of minimum standard for retail pharmacies. We have started the clinical pharmacy programs and some of the graduate pharmacists are working in hospitals and health centers. In the future they shall get room to practice the pharmaceutical care at the retail pharmacies. In our old retail pharmacy facility set up there was no office to practice the pharmaceutical care.

Due to all the aforementioned and other reasons, FMHACA is setting minimum standards for retail pharmacies. The stakeholder's discussion on the draft minimum standards was carried out on October 17-18, 2013 at Siyonat Hotel, Addis Ababa. The minimum standards are expected to bring fundamental changes on rational use of medicines. The expected changes to the existing retail pharmacies will be naming and labeling, set up of the facility (total area and height), professional requirements and pharmacy service in general.

In the meanwhile developing minimum standards, FMHACA introduced Model Directive for running retail pharmacy. Accordingly many of the regions of the country adapted the model directive and applied considering their own regional situation.

Accordingly, the naming of retail pharmacies has changed from **Rural Drug Vendors, Drug Stores and Pharmacies** to small, medium and higher pharmacy. The requirements for personnel and premises are also revised.

The Need for Adverse Event Following Immunization (AEFI) Surveillance

Immunization is one of the cost effective child survival interventions in the world. It is more than 30 years since immunization programs started in Ethiopia. Immunization is not 100% safe and one of the issues that should be addressed in the immunization programs is to establish the Adverse Event Following Immunization Surveillance system that can detect rare case of AEFI that may degrade public trust in vaccine safety. The issue of public

trust on vaccine safety on national vaccination program is very concerning issue. Though vaccines used in national immunization programs (NIPs) are considered safe and effective; there may be rare cases of AEFI that will be the reason for the collapse of the whole vaccination program in the country as most parents of vaccine receiving child's parents are illiterate. If these rare AEFI cases happen at certain community; parents will communicate each other and no one will vaccinate his/her child afterwards. Thus public trust in vaccine safety is a key to success of national vaccination programs.

This has necessitated more than any time to have a stronger system for AEFI with well trained and capable experts at the different levels. For this reason, regional task force on AEFI monitoring and causality assessment (detection, monitoring and conducting proper investigation of AEFI) was established and trained on October, 2013. AEFI surveillance system is run in collaboration with World Health Organization, Country office.

3. Pharmacy practice

Ethiopian Hospital Reform Implementation Guidelines (EHRIG)

Contributed by Bethelehem Gulelat

There have been many standards and guidelines provided by many organizations internationally as well as nationally in order to improve pharmacy service. For instance in Ethiopia there were three successive HSDPs to improve the quality of the health sector of the country, the former DACA now FMHACA had developed different guidelines, directives and standard operating procedures (SOPs).

FMOH has developed Ethiopian Hospital Reform Implementation Guidelines (EHRIG) in 2010. The Ethiopian hospital reform is one of the important documents which established standardized, more patient oriented pharmaceutical service in hospitals along with tools to monitor the performance of each hospital in implementing the standards. This guideline (EHRIG) contains thirteen chapters as follows.

Chapter 1 Hospital Leadership Management

Chapter 2 Patient Flow

Chapter 3 Medical Record Management

Chapter 4 Pharmacy Services

Chapter 5 Laboratory Services

Chapter 6 Nursing Care StandardsChapter

Chapter 7 Infection Prevention

Chapter 8 Facilities Management

Chapter 9 Medical Equipment Management

Chapter 10 Financial and Asset Management

Chapter 11 Human Resource Management

Chapter 12 Quality Management

Chapter 13 Monitoring and Reporting

The standards and guidance set in chapter four of EHRIG are designed to align with and support hospital pharmaceutical services to meet the demands of different national programs. These national programs include Business Process Re-engineering (BPR); Pharmaceuticals Logistics Master Plan and Financial Reforms.

And this pharmacy chapter contains twelve operational standards which are listed below in the table in addition with the checklist and indicators.

List of standards for hospital pharmaceutical services for Ethiopia copied from EHRIG

Sr no.	Pharmaceutical standard
1	The hospital has a Drug and Therapeutics Committee (DTC) which implements measures to promote the rational and cost-effective use of medicines.
2	The hospital has a Medicines Formulary listing all pharmaceuticals that can be used in the facility. The Formulary is reviewed and updated annually.
3	The hospital has outpatient, inpatient, emergency pharmacies and a central medical store each directed by a registered pharmacist.
4	The hospital ensures that all types of drug transactions and patient-medication related information are properly recorded and documented.
5	The hospital has Standard Operating Procedures (SOPs) for all compounding procedures carried out.
6	The hospital provides access to drug information to both health care providers and patients in order to optimize drug use.
7	The hospital has policies and procedures for identifying and managing drug use problems, including: monitoring adverse drug reactions, prescription monitoring and drug utilization monitoring.
8	The hospital has a drug procurement policy approved by the DTC that describes methods of quantification, prioritization, drug selection, supplier selection and ordering of pharmaceutical supplies and is in line with national guidance.
9	The hospital has a paper-based or computer-based inventory management system to reduce the frequency of stock-outs, wastage, over supply and drug expiry.
10	The hospital conducts a physical inventory of all pharmaceuticals in the store and each dispensing unit at a minimum once a year.
11	The hospital ensures proper and safe disposal of pharmaceutical wastes and expired drugs.
12	The hospital has adequate personnel, equipment, premises and facilities required to store pharmaceutical supplies and carry out compounding, dispensing, and counselling services.

Since EHRIG contains minimum standards for hospitals, FMOH expects those government hospitals to implement it. Now adays government hospitals work to implement those standards in all aspect.

Principles of Practice for Pharmaceutical Care:

From http://www.pharmacist.com/principles-practice-pharmaceutical-care

Preamble

Pharmaceutical Care is a patient-centered, outcomes oriented pharmacy practice that requires the pharmacist to work in concert with the patient and the patient's other healthcare providers to promote health, to prevent disease, and to assess, monitor, initiate, and modify medication use to assure that drug therapy regimens are safe and effective. The goal of Pharmaceutical Care is to optimize the patient's health-related quality of life, and achieve positive clinical outcomes, within realistic economic expenditures. To achieve this goal, the following must be accomplished:

A. A professional relationship must be established and maintained.

Interaction between the pharmacist and the patient must occur to assure that a relationship based upon caring, trust, open communication, cooperation, and mutual decision making is established and maintained. In this relationship, the pharmacist holds the patient's welfare paramount, maintains an appropriate attitude of caring for the patient's welfare, and uses all his/her professional knowledge and skills on the patient's behalf. In exchange, the patient agrees to supply personal information and preferences, and participate in the therapeutic plan. The pharmacist develops mechanisms to assure the patient has access to pharmaceutical care at all times.

B. Patient-specific medical information must be collected, organized, recorded, and maintained.

Pharmacists must collect and/or generate subjective and objective information regarding the patient's general health and activity status, past medical history, medication history, social history, diet and exercise history, history of present illness, and economic situation (financial and insured status). Sources of

information may include, but are not limited to, the patient, medical charts and reports, pharmacist-conducted health/physical assessment, the patient's family or caregiver, insurer, and other healthcare providers including physicians, nurses, mid-level practitioners and other pharmacists. Since this information will form the basis for decisions regarding the development and subsequent modification of the drug therapy plan, it must be timely, accurate, and complete, and it must be organized and recorded to assure that it is readily retrievable and updated as necessary and appropriate. Patient information must be maintained in a confidential manner.

C. Patient-specific medical information must be evaluated and a drug therapy plan developed mutually with the patient.

Based upon a thorough understanding of the patient and his/her condition or disease and its treatment, the pharmacist must, with the patient and with the patient's other healthcare providers as necessary, develop an outcomes-oriented drug therapy plan. The plan may have various components which address each of the patient's diseases or conditions. In designing the plan, the pharmacist must carefully consider the psycho-social aspects of the disease as well as the potential relationship between the cost and/or complexity of therapy and patient adherence. As one of the patient's advocates, the pharmacist assures the coordination of drug therapy with the patient's other healthcare providers and the patient. In addition, the patient must be apprised of (1) various pros and cons (i.e., cost, side effects, different monitoring aspects, etc.) of the options relative to drug therapy and (2) instances where one option may be more beneficial based on the pharmacist's professional judgment. The essential elements of the plan, including the patient's responsibilities, must be carefully and completely explained to the patient. Information should be provided to the patient at a level the patient will understand. The drug therapy plan must be documented in the patient's pharmacy record and communicated to the patient's other healthcare providers as necessary.

D. The pharmacist assures that the patient has all supplies, information and knowledge necessary to carry out the drug therapy plan.

The pharmacist providing Pharmaceutical Care must assume ultimate responsibility for assuring that his/her patient has been able to obtain, and is appropriately using, any drugs and related products or equipment called for in the drug therapy plan. The pharmacist must also assure that the patient has a thorough understanding of the disease and the therapy/medications prescribed in the plan.

E. The pharmacist reviews, monitors, and modifies the therapeutic plan as necessary and appropriate, in concert with the patient and healthcare team.

The pharmacist is responsible for monitoring the patient's progress in achieving the specific outcomes according to strategy developed in the drug therapy plan. The pharmacist coordinates changes in the plan with the patient and the patient's other healthcare providers as necessary and appropriate in order to maintain or enhance the safety and/or effectiveness of drug therapy and to help minimize overall healthcare costs. Patient progress is accurately documented in the pharmacy record and communicated to the patient and to the patient's other healthcare providers as appropriate. The pharmacist shares information with other healthcare providers as the setting for care changes thus helping assure continuity of care as the patient moves between the community setting, the institutional setting, and the long-term care setting.

Practice Principles

1. Data Collection

1.1 The pharmacist conducts an initial interview with the patient for the purposes of establishing a professional working relationship and initiating the patient's pharmacy record. In some situations (e.g. pediatrics, geriatrics, critical care, language barriers) the opportunity to develop a professional relationship with and

collect information directly from the patient may not exist. Under these circumstances, the pharmacist should work directly with the patient's parent, guardian, and/or principal caregiver.

1.2 The interview is organized, professional, and meets the patient's need for confidentiality and privacy. Adequate time is devoted to assure that questions and answers can be fully developed without either party feeling uncomfortable or hurried. The interview is used to systematically collect patient-specific subjective information and to initiate a pharmacy record which includes information and data regarding the patient's general health and activity status, past medical history, medication history, social history (including economic situation), family history, and history of present illness. The record should also include information regarding the patient's thoughts or feelings and perceptions of his/her condition or disease.

1.3 The pharmacist uses health/physical assessment techniques (blood-pressure monitoring, etc.) appropriately and as necessary to acquire necessary patient-specific objective information.

1.4 The pharmacist uses appropriate secondary sources to supplement the information obtained through the initial patient interview and health/physical assessment. Sources may include, but are not limited to, the patient's medical record or medical reports, the patient's family, and the patient's other healthcare providers.

1.5 The pharmacist creates a pharmacy record for the patient and accurately records the information collected. The pharmacist assures that the patient's record is appropriately organized, kept current, and accurately reflects all pharmacist-patient encounters. The confidentiality of the information in the record is carefully guarded and appropriate systems are in place to assure security. Patient-identifiable information contained in the record is provided to others only upon the authorization of the patient or as required by law.

2. Information Evaluation

2.1 The pharmacist evaluates the subjective and objective information collected from the patient and other sources then forms conclusions regarding: (1) opportunities to improve and/or assure the safety, effectiveness, and/or economy of current or planned drug therapy; (2) opportunities to minimize current or potential future drug or health-related problems; and (3) the timing of any necessary future pharmacist consultation.

2.2 The pharmacist records the conclusions of the evaluation in the medical and/or pharmacy record.

2.3 The pharmacist discusses the conclusions with the patient, as necessary and appropriate, and assures an appropriate understanding of the nature of the condition or illness and what might be expected with respect to its management.

3. Formulating a Plan

3.1 The pharmacist, in concert with other healthcare providers, identifies, evaluates and then chooses the most appropriate action(s) to: (1) improve and/or assure the safety, effectiveness, and/or cost-effectiveness of current or planned drug therapy; and/or, (2) minimize current or potential future health-related problems.

3.2 The pharmacist formulates plans to effect the desired outcome. The plans may include, but are not limited to, work with the patient as well as with other health providers to develop a patient-specific drug therapy protocol or to modify prescribed drug therapy, develop and/or implement drug therapy monitoring mechanisms, recommend nutritional or dietary modifications, add non-prescription medications or non-drug treatments, refer the patient to an appropriate source of care, or institute an existing drug therapy protocol.

3.3 For each problem identified, the pharmacist actively considers the patient's needs and determines the desirable and mutually agreed upon outcome and

incorporates these into the plan. The plan may include specific disease state and drug therapy endpoints and monitoring endpoints.

3.4 The pharmacist reviews the plan and desirable outcomes with the patient and with the patient's other healthcare provider(s) as appropriate.

3.5 The pharmacist documents the plan and desirable outcomes in the patient's medical and/or pharmacy record.

4. Implementing the Plan

4.1 The pharmacist and the patient take the steps necessary to implement the plan. These steps may include, but are not limited to, contacting other health providers to clarify or modify prescriptions, initiating drug therapy, educating the patient and/or caregiver(s), coordinating the acquisition of medications and/or related supplies,

which might include helping the patient overcome financial barriers or lifestyle barriers that might otherwise interfere with the therapy plan, or coordinating appointments with other healthcare providers to whom the patient is being referred.

4.2 The pharmacist works with the patient to maximize patient understanding and involvement in the therapy plan, assures that arrangements for drug therapy monitoring (e.g. laboratory evaluation, blood pressure monitoring, home blood glucose testing, etc.) are made and understood by the patient, and that the patient receives and knows how to properly use all necessary medications and related equipment. Explanations are tailored to the patient's level of comprehension and teaching and adherence aids are employed as indicated.

4.3 The pharmacist assures that appropriate mechanisms are in place to ensure that the proper medications, equipment, and supplies are received by the patient in a timely fashion.

4.4 The pharmacist documents in the medical and/or pharmacy record the steps taken to implement the plan including the appropriate baseline monitoring parameters, and any barriers which will need to be overcome.

4.5 The pharmacist communicates the elements of the plan to the patient and/or the patient's other healthcare provider(s). The pharmacist shares information with other healthcare providers as the setting for care changes, in order to help maintain continuity of care as the patient moves between the ambulatory, inpatient or long-term care environment.

5. Monitoring and Modifying the Plan/Assuring Positive Outcomes

5.1 The pharmacist regularly reviews subjective and objective monitoring parameters in order to determine if satisfactory progress is being made toward achieving desired outcomes as outlined in the drug therapy plan.

5.2 The pharmacist and patient determine if the original plan should continue to be followed or if modifications are needed. If changes are necessary, the pharmacist works with the patient/caregiver and his/her other healthcare providers to modify and implement the revised plan as described in "Formulating the Plan" and "Implementing the Plans" above.

5.3 The pharmacist reviews ongoing progress in achieving desired outcomes with the patient and provides a report to the patient's other healthcare providers as appropriate. As progress towards outcomes is achieved, the pharmacist should provide positive reinforcement.

5.4 A mechanism is established for follow-up with patients. The pharmacist uses appropriate professional judgement in determining the need to notify the patient's other healthcare providers of the patient's level of adherence with the plan.

5.5 The pharmacist updates the patient's medical and/or pharmacy record with information concerning patient progress, noting the subjective and objective information which has been considered, his/her assessment of the patient's current

progress, the patient's assessment of his/her current progress, and any modifications that are being made to the plan. Communications with other healthcare providers should also be noted.

Prepared by the APHA Pharmaceutical Care Guidelines Advisory Committee, approved by the APHA Board of Trustees, August 1995.

Notes:

Pharmaceutical care is a process of drug therapy management that requires a change in the orientation of traditional professional attitudes and re-engineering of the traditional pharmacy environment. Certain elements of structure must be in place to provide quality pharmaceutical care. Some of these elements are: (1) knowledge, skill, and function of personnel, (2) systems for data collection, documentation, and transfer of information, (3) efficient work flow processes, (4) references, resources and equipment, (5) communication skills, and (6) commitment to quality improvement and assessment procedures.

Knowledge, skill, and function of personnel

The implementation of pharmaceutical care is supported by knowledge and skills in the area of patient assessment, clinical information, communication, adult teaching and learning principles and psychosocial aspects of care. To use these skills, responsibilities must be reassessed, and assigned to appropriate personnel, including pharmacists, technicians, automation, and technology. A mechanism of certifying and credentialling will support the implementation of pharmaceutical care.

Systems for data collection and documentation

The implementation of pharmaceutical care is supported by data collection and documentation systems that accommodate patient care communications (e.g. patient contact notes, medical/medication history), interprofessional communications (e.g. physician communication, pharmacist to pharmacist

communication), quality assurance (e.g. patient outcomes assessment, patient care protocols), and research (e.g. data for pharmacoepidemiology, etc.). Documentation systems are vital for reimbursement considerations.

Efficient work flow processes

The implementation of pharmaceutical care is supported by incorporating patient care into the activities of the pharmacist and other personnel.

References, resources, and equipment

The implementation of pharmaceutical care is supported by tools which facilitate patient care, including equipment to assess medication therapy adherence and effectiveness, clinical resource materials, and patient education materials. Tools may include computer software support, drug utilization evaluation (DUE) programs, disease management protocols, etc.

Communication Skills

The implementation of pharmaceutical care is supported by patient-centered communication. Within this communication, the patient plays a key role in the overall management of the therapy plan.

Quality Assessment/Improvement Programs

The implementation and practice of pharmaceutical care is supported and improved by measuring, assessing, and improving pharmaceutical care activities utilizing the conceptual framework of continuous quality improvement.

This document will not cover each and every situation; that was not the intent of the Advisory Committee. This is a dynamic document and is intended to be revised as the profession adapts to its new role. It is hoped that pharmacists will use these principles, adapting them to their own situation and environments, to establish and implement pharmaceutical care.

(1)Although "drug therapy" typically refers to intended, beneficial effects of pharmacologic drugs, in this document, "drug therapy" refers to the intended, beneficial use of drugs -- whether diagnostic or therapeutic -- and thus includes diagnostic radiopharmaceuticals, X-ray contrast media, etc. in addition to pharmacologic drugs. Similarly, "drug therapy plan" includes the outcomes oriented plan for diagnostic drug use in addition to pharmacologic drug use.

4. Continuing Education

Pharmacotherapy of Cryptococcal Meningitis associated with AIDS

Contributed by Minychel wale, from ALERT center email Minychelwale77 @ gmail.com

Cryptococcal Meningitis

A note on definitions:

Meningitis is an infection and inflammation of the meninges. Meninges are the membranes that cover the spinal cord and brain. Meningitis can be caused by many different germs, including bacteria, fungi, and viruses. Most cases of meningitis are caused by viruses. Cryptococcal meningitis (CM) is one of the exceptions. It is caused by two types of fungus: *Cryptococcus neoformans* and *Cryptococcus gattii*. This disease is rare in normally healthy people. It is more common in people who have compromised immune systems, such as AIDS patients.

Cryptococcal meningitis (CM) refers to Meningoencephalitis resulting from infection; disseminated cryptococcosis refers to infection of multiple body sites; and cryptococcosis (CC) refers to infection of anybody site, with an organism from the genus Cryptococcus, including Cryptococcus neoformans and C. gattii (formerly C. neoformans var. gattii). Where the term 'cryptococcosis' (CC) is used in this document, it refers to either Cryptococcal meningitis or disseminated cryptococcosis.

CM has emerged as leading causes of infectious morbidity and mortality in patient with AIDS. Among HIV seroposetive subjects CM is the second most common causes opportunistic neuron – infection.CM occurs in non HIV patient who are immounodeficient due to Diabetic, cancer, solid organ transplantation, chemotherapeutic drugs, hematological malignancy etc and rarely in healthy individuals with no obvious predisposing factors. Cryptococcosis is the most common cause of life threatening meningitis in AIDS. Approximately 5-8% of

patients with AIDS develop Cryptococcal infection. Meningoencephalitis is the most frequent manifestation of cryptococcosis in HIV-infected individuals.

The clinical features of Cryptococcal Meningitis are as follows:- insidious onset with non specific symptoms mean duration of 2wks , Headache 97% ,Fever 61% , Altered consciousness 58%, Neck stiffness 74%, Seizures 13%

Etiology of CM

CM is the most common form of fungal meningitis and is caused by Cryptococcus neoformans. Cryptococcus neoformans is an encapsulated heterobasidiomycetous fungus. Traditionally Cryptococcus neoformans is classified in to two varieties and five serotypes (A, B, C, D, and AD) based on its capsule structures. C. neoformans Var. neoformans include strains with serotypes A, D and AD, while C. neoformans Var.gattii includes serotypes B and C. Resent analyses of the URA5 gene DNA Fingerprinting patterns have shown that the serotypes A and D have significant differences .Hence C. neoformans Var. neoformans serotype A was recognized as a new Varity and named C . neoformans Var grubii. Serotype A and D and AD hybrid are globally responsible for 98 % of all Cryptococcal infection in patients with AIDS. Serotype B and C predominately affect immunocompitent individuals but have also been recently reported in patients with AIDS. Cryptococcus infection is commonly encountered in immunocompromised patients with impaired cell mediated immunity.

In those with HIV infection Cryptococcal infection occurs in the advanced stages of the disease when the CD4+ count is usually less than 50 – 200 cells/ml. infection can also occur in patients on long term steroid therapy, diabetic, cancer, renal failure, immunologic disease, immunosuppressive treatment, solid organ transplantation, those suffering from Lymphoma sarcoidosis and in some patients with idiopathic CD4+ Lymphocytopenia.

Epidemiology of CM

Incidences of Cryptococcal Meningitis in ETHIOPIA during 1998-2000 were 7%. Approximately One million people with AIDS develop Cryptococcal Meningitis (CM) annually.

- Estimated 12 week mortality rates range from 9% in North America and Western Europe to 70% in sub-Saharan Africa
- 625,000 deaths annually are due to CM, 80% of them occur in sub-Saharan Africa
- Deaths associated with CM are higher than those associated with Tuberculosis

Causes Cryptococcal Meningitis

Most cases of CM are caused by a fungus called *Cryptococcus neoformans.* This fungus is found in soil all over the world. It is usually found in soil that contains bird droppings. *Cryptococcus gattii*, the other fungus that causes CM, is not found in bird droppings. Instead, it is associated with trees, most commonly eucalyptus trees. It grows in the debris around the trees' bases. Cryptococcal meningitis usually occurs in people who have a compromised immune system. It rarely occurs in someone who has a normal immune system. Of the two fungi that can cause the condition, *gattii* is the one more likely to infect someone with a normal immune system. Cryptococcosis is a defining opportunistic infection for AIDS, and is the second-most-common AIDS-defining illness in Africa. Other conditions that pose an increased risk include certain lymphomas (e.g., Hodgkin's lymphoma), sarcoidosis, liver cirrhosis, and patients on long-term corticosteroid therapy.

Symptoms of Cryptococcal Meningitis

Symptoms of CM usually come on slowly. Within a few days to a few weeks of contact, an infected person may develop the following symptoms:

- headache
- nausea

- vomiting
- mental changes such as: confusion, hallucinations, and/or personality changes
- lethargy
- sensitivity to light
- In some cases, the infected person may experience a stiff neck and fever.

If left untreated, Cryptococcal meningitis may lead to more serious symptoms like:

- brain damage
- coma
- hearing loss
- hydrocephalus ("water on the brain")

Cryptococcal Meningitis Diagnosed

CryptococcalAntigen *Cryptococcal antigen in the serum is indicative of systemic disease. Cryptococcal antigen has greater than 95% sensitivity and specificity in the diagnosis of true invasive Cryptococcal infection. Serum Cryptococcal antigens are 99%positive in Cryptococcal meningitis. A negative serum Cryptococcal antigen result suggests that the patient is unlikely to have CNS disease. With management of Cryptococcal meningitis, CSF Cryptococcal antigen titers should decrease after 2 or more weeks of therapy.*

Detection of Cryptococcal antigen (capsular material) by culture of CSF, sputum and urine provides definitive diagnosis. Blood cultures may be positive in heavy infections. India ink of the CSF is a traditional microscopic method of diagnosis, although the sensitivity is poor in early infection, and may miss 15-20% of patients with culture-positive Cryptococcal meningitis. Unusual morphological forms are rarely seen. Cryptococcal antigen from cerebrospinal fluid is the best test for diagnosis of Cryptococcal meningitis in terms of sensitivity. Apart from

conventional methods of detection like direct microscopy and culture, rapid diagnostic methods to detect Cryptococcal antigen by latex agglutination test, lateral flow Immuno chromatographic assay (LFA), or enzyme immunoassay (EIA). A new Cryptococcal antigen LFA was FDA approved in July 2011.Polymerase chain reaction (PCR) has been used on tissue specimens.

A simple new test for Cryptococcus

A new "dipstick" test for detecting Cryptococcal antigen is simple to use on a small sample of serum (a component of blood). The test accurately detects both early and advanced Cryptococcal infections more than 95% of the time. In addition, the test is inexpensive, and the results are ready in just 10 minutes.

Pharmacology management of Cryptococcal Meningitis

The nature and duration of treatment for Cryptococcal infection is based on the immunity of the host and anatomic site of involvement. For immunocompitent individuals with Cryptococcal meningitis, the standard therapy consists of Amphotericin B 0.7 – 1.0 mg/kg /day along with 5 –Flucytosine 100 mg /kg/day for 6 -10 weeks. An alternative to this regimen is Amphotericin B 0.7 – 1.0 mg/kg /day with 5 –Flucytosine 100 mg /kg/day for 2 weeks, followed by Fluconazole 400 mg /day for a minimum of 10 weeks. Fluconazole consolidation therapy may be continued for as long as 6 – 12 months depending on the clinical statues of the patients. For a patient with HIV infection and CM induction therapy with Amphotericin B 0.7 – 1.0 mg/kg /day plus 5 –Flucytosine 100 mg /kg/day is given for 2 weeks, followed by Fluconazole 400 mg /day for a minimum of 10 weeks. After ten weeks therapy the Fluconazole dosage may be reduced to 200 mg /day depending on the clinical statues of the patients. Fluconazole should be continued for life or at least up to the time the CD4+ count reaches 350/cmm

(WHO Guidelines 2011)

Induction phase	2 weeks	Amphotericin B + Flucytosine OR AmphotericinB+Fluconazole 800mg/d
Consolidation phase	8 weeks	Fluconazole 400-800mg/d
Maintenances phase (secondary prophylaxis)	Until CD4>200 on ART FOR 6 Months	Fluconazole 200mg/d

1. Treatment: Drugs

- Amphotericin B
    - Amphotericin B deoxycholate (0.7 mg/kg/day)
    - Nephrotoxic
    - A cute infusion rxn (F/C, N/V, SOB)
    - Liposomal Amphotericin B (3-6 mg/kg/day)
    - Amphotericin B lipid complex (3-6 mg/kg/day)
- Flucytosine (100 mg/kg/day) (FC)
    - MIC ≥128 mg/ml associated with treatment failure
    - Drug resistance as Monotherapy
    - Monitor for cytopenias
    - 2hr post-dose level 30-80 mg/ml 3-5 days after initiation of treatment
- Fluconazole (200-1200 mg/day
    - MIC ≥16 g/ml associated with treatment failure
    - Resistance emerging problem when used as Monotherapy (Africa)

2. Treatment: HIV

- Induction phase
    - Amphotericin B + FC x 2 weeks
    - Continue up to 6 weeks if pt sx (AMS), persistent increased ICP, CSF culture remains positive
- Consolidation phase
    - Fluconazole 400 mg Qday (6 mg/kg) x 8 weeks
- Suppressive phase
    - Fluconazole 200 mg Qday

- Initiate HAART 2-10 weeks after commencement of initial antifungal treatment
- Stop if CD4+> 100 cells/ l, VL ND x ≥3 months, CrAG negative, minimum 12 months of antifungal therapy
- Reinstitute maintenance therapy if CD4+< 100 cells/ml or CA i Cr Ag increase
- Primary antifungal prophylaxis not recommended

3. Treatment: Organ Transplant

- Induction phase
  - Amphotericin B + FC x 2 weeks
- Consolidation phase
  - Fluconazole 400 mg – 800 mg Qday (6 mg/kg) x 8 weeks
- Suppressive phase
  - Fluconazole 200 mg - 400 mg Qday 6 – 12 months
- Reduce immunosuppressant
  - Lower prednisone to < 20 mg/day

4. Treatment: Norma

- Induction phase
  - Amphotericin B + FC x 4 weeks
  - No-neurological complications
  - CSF culture results negative after 2 weeks of treatment
  - Extend treatment to 6 weeks if neurological complications
  - If low-risk for therapeutic failure can shorten treatment to 2 weeks
- Consolidation phase
  - Fluconazole 400 mg Qday (6 mg/kg) x 8 weeks
- Suppressive phase
  - Fluconazole 200 mg Qday x 6 – 12 months

Problems with treatment

Amphotericin B side effects

- Phlebitis
- Renal impairment
- Hypokalaemia & hypomagnesaemia
- Anemia
- Febrile reactions

Amphotericin B and Flucytosine unavailable in many African countries

Alternatives

- High dose Fluconazole (1200mg/d) + Flucytosine
- High dose Fluconazole (1200mg/d)

Acetazolamide 250mg qid and for if evidences of raised Intracranial pressure raised and can be Manage the raised intracranial pressure (>20 cm CSF) by Alleviate pressure initially by draining not more than 20 - 30 ml of CSF (to decrease opening pressure by 20 - 50%) at initial LP. Thereafter the need for pressure relief should be dictated by recurrence of symptoms of raised intracranial pressure. Patients may require daily LPs.

Pain and symptom management

Reduction of intracranial pressure alleviates headache and confusion. Residual pain may be managed with paracetamol and mild opiates (WHO level 1 and 2 analgesics). Non-steroidal anti-inflammatory drugs should be avoided in patients receiving Amphotericin B because concomitant administration may increase potential for nephrotoxicity

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Update on Management of Helicobacter Pylori Infection

Contributed by Bethelehem Gulelat from the Hong Kong Medical Bulletin VOL.15 NO.12

Introduction

The discovery of Helicobacter pylori led to the award of the Nobel Prize to two scientists Dr Robin Warren and Dr Barry Marshall in 2005. Although there has been intense research on this bacterium which affects half of the world's population, there are still areas of controversy and the ideal simple regime of treatment is yet to come. This article summarizes some of the important issues related to indication, diagnosis and treatment of H. pylori.

Indications

Three indications for treatment are supported by definite evidence with clinical benefits (Table 1). Most physicians are aware of these conditions. Patients with active or past history of gastric or duodenal ulcers with or without ulcer complications (bleeding, perforation, gastric outlet obstruction) should be tested for H pylori, and if positive, be treated. The treatment not only heals the ulcer but will prevent relapse of the ulcer in the long run. Patients with gastric MALT lymphoma and those with early gastric cancer after endoscopic or surgical resection should also be tested and treated if positive.

Table 1. Indications for treatment

Definite evidence of clinical benefits	
1	Active or past history of gastric and/or duodenal ulcers/ erosions, with or without complications
2	Gastric mucosa-associated lymphoid tissue (MALT) lymphoma
3	Early gastric cancer after resection
Supportive evidence of clinical benefits	
1	Gastric cancer prevention in high risk populations
2	Uninvestigated dyspepsia
3	Functional dyspepsia
4	Patients' wishes
5	Family history of gastric cancer
6	Atrophic gastritis
7	Patients on aspirin or non-steroidal anti-inflammatory drugs
8	Patients with GERD requiring long term proton pump inhibitors
9	Other intestinal and extra-intestinal diseases: unexplained iron deficiency anaemia, idiopathic thrombocytopenic purpura, lymphocytic gastritis, gastric hyperplastic polyps, Menetrier's Disease

Other indications for treatment have supportive evidence of clinical benefits (Table 1). These include (1) early gastric cancer after resection, (2) gastric cancer prevention in high risk populations, (3) uninvestigated dyspepsia, (4) functional dyspepsia, (5) patients' wishes, (6) first degree relatives with gastric cancer, (7) patients on aspirin or non-steroidal anti-inflammatory drugs.

Other indications are not so well supported, including patients with atrophic gastritis or intestinal metaplasia, patients with gastro-oesophageal reflux disease requiring long term proton pump inhibitors, and those with extra-intestinal diseases as listed in Table 1.

Diagnosis

The choice of test for pre-treatment or never treated patients consists of non-invasive tests and invasive tests (Table 2). The non-invasive tests include carbon-13 urea breath test, serology for anti-H. pylori antibody, stool for H. pylori antigen, and urine for anti-H. pylori antibody. The invasive tests used during an upper endoscopy and biopsy include rapid urease test [with the commercial CLO test most commonly used], histology, culture, and polymerase chain reaction, with the later two very seldom performed.

Table 2. Diagnostic tests for Helicobacter pylori infection

	Principle	**Post-treatment**	**Cost (a)**	**Near patient test (b)**	**Remarks (c)**
Invasive Tests					
1.Rapid urease test	urease ctivity	+/-	+++	Yes	
2. Histology	pathology assessment	+	++++	No	
3. Culture	Microbiology	+	++++	No	Antibiotic sensitivity
4. PCR	Genome	+	++++	No	Research
Non-invasive Tests					
1. 13C-Urea breath test	urease activity	+	++	Yes/No	
2. Stool	Hp Antigen	+	+	No	
3. Serology	Hp antibody	-	+	No	Need validation
4.Whole blood	Hp antibody	-	+	Yes	Need validation
5. Urine	Hp antibody	-	+	Yes	Need validation

a. Cost of invasive tests includes cost of upper endoscopy. b. Near patient test means test that can be done within the doctor's office and can provide immediate result. c. Tests that rely on antibody need to be locally validated in Hong Kong. The accuracy may vary widely.

The method of choice for non-invasive tests include urea breath test and stool antigen test. The serology tests rely on the accuracy of the test kit and not all test kits perform with the same accuracy. These tests are based on the ELISA method

that requires the use of antigen epitopes from H pylori during production. Unfortunately H pylori from different countries or races have very diverse genomic variations. So some of the tests manufactured in USA or Europe based on Caucasian H pylori strains yield a very low accuracy for testing in Hong Kong1,2. The other form of serology test is the whole blood near patient test. The test uses only one drop of blood to be placed onto the test kit and the doctor can read the result within minutes in the office.

These tests have the same principle as serology test and the accuracy must be locally validated.

The method of choice for invasive tests include the rapid urease test and histology. Since the density of H pylori in the gastric antrum is the highest in normal patients without drugs, an antral biopsy is usually taken. However in patients on proton pump inhibitors; there is reduced density of H pylori in the antrum but with a higher density in the body and fundus. Therefore patients on PPIs should have biopsies from both the antrum and body to increase the accuracy.

Recent intakes of PPIs and/or antibiotics produce false negative results for all tests except serology. False negative tests may result from these drugs that suppress bacterial growth. PPIs should be stopped at least 2 weeks before performing the tests. Nowadays more and more patients are already receiving long term PPIs and cannot be withheld for various reasons. In this case, a locally validated serology test should be used.

Post-treatment testing is generally performed 4-8 weeks after stopping all PPIs and antibiotics, the longer the better. Hence if there is no urgent need to perform the test, it should be done at 8 weeks after stopping treatment. For patients who have used both bismuth and PPIs in the treatment regime, most commonly in a second line treatment of H pylori, the test should be performed 8-12 weeks after stopping treatment, preferably 12 weeks. The test of choice is the urea breath test. An alternative is the stool Hp antigen test. Serology tests should never be used in post-

treatment testing, as the antibody level will only be decreasing slowly despite successful treatment. In post-treatment testing for patients on long term PPIs, we still should not use serology test for the above mentioned reason. There is no single best method for these patients and clinical judgment is required in each scenario.

Treatment

Standard First Line Treatment

For years, the use of triple therapy is the gold standard for first line treatment of H pylori infection. There are several recent guidelines with detailed description of the different regimens3,4,5. In principle, the eradication rate of any first line regimen should be above 90% by per protocol analysis (PP), or 80% by intention to treat analysis (ITT). The best regimen for most Asian countries is probably a PPI plus amoxicillin plus clarithromycin (Table 3). We have recently completed a local study and the combination of a PPI plus amoxicillin plus clarithromycin for 7 days is still the best regimen in Hong Kong with an eradication rate of 92.7%. Some guidelines recommend the treatment period be extended from 7 days to 10 days or even 14 days, hoping to increase the eradication rate. Meta-analysis has shown that this approach yields only small benefit, and yet the cost effectiveness, side effects and cost may need to be considered carefully.

Treatment for Patients Allergic to Penicillin

For patients allergic to penicillin, the regime of choice will be a PPI plus clarithromycin plus metronidazole for 7 days. Due to increasing use of clarithromycin or metronidazole in monotherapy against other bacterial infections, it leads to increasing prevalence of antibiotic resistance in H. pylori. In Hong Kong, the antibiotic resistance of H pylori to clarithromycin and metronidazole is around 10% and 40% respectively and has remained stable in recent years. However we should be closely monitoring the pattern of resistance in future. The alternative for patients allergic to penicillin will be to use the quadruple therapy in the first line

setting for 7 days. This will avoid the problem of resistance to clarithromycin and metronidazole, but carries a risk of very limited options remaining if the treatment is not successful.

Other Options

In view of increasing prevalence of resistance to clarithromycin and metronidazole, some countries have advocated the use of levofloxacin-containing triple therapy in first line treatment. We have completed a local study to assess the use of PPIs twice daily plus amoxicillin twice daily plus levofloxacin 500mg once daily. The eradication rate was 85.3% only6. Hence we concluded that levofloxacin-containing triple therapy is not suitable for use in Hong Kong as first line treatment at this moment.

Second Line Treatment

For second line treatment of H pylori infection, the classical quadruple therapy is still the regimen of choice (Table 3). Our local study showed that the classical quadruple therapy with PPIs, bismuth subcitrate 240mg bid, metronidazole 400mg tds and tetracycline 500mg qds has an eradication rate of 88%. The use of a PPI plus bismuth plus amoxicillin 1000mg bid and levofloxacin 500mg bid has an eradication rate of only 73% ($P<0.05$)7. The other rescue therapy is a PPI, rifabutin 300mg daily, levofloxacin 500mg daily for 7 days. It had an eradication rate of 91%8. However rifabutin may have a rare chance of neutropenia and thrombocytopenia which restrict its use in this setting.

Table 3. Treatment regimes for H. Pylori infection	
First line treatment	
1	PPI standard dose + amoxicillin 1 gram + clarithromycin 500mg, all twice daily for 7 days (up to 14 days)
2	PPI standard dose + metronidazole 400mg + clarithromycin 500mg, all twice daily for 7 days, (up to 14 days) (for patient allergic to penicillin)

3	PPI standard dose + amoxicillin 1 gram + metronidazole 400mg, all twice daily for 7 days, (up to 14 days)(for patients allergic to clarithromycin, or cost concern)
4	PPI standard dose twice daily + bismuth 240mg twice daily + metronidazole 400mg three times daily + tetracycline 500mg four times daily for 7 days (up to 14 days) (for patient allergic to penicillin)
Second line treatment for H. Pylori infection	
	PPI standard dose twice daily + bismuth 240mg twice daily + metronidazole 400mg three times daily + tetracycline 500mg four times daily for 7 days (up to 14 days)
PPI standard dose: Omeprazole 20mg, lansoprazole 30mg, pantoprazole 40mg, rabeprazole 20mg, esomeprazole 20mg	

In this regard, it is of importance to emphasise good compliance during both first and second line treatment. Most of the drop outs are usually due to minor adverse effects such as loose stool, altered taste, malaise etc. It is important to encourage the patients to complete the whole course of treatment and reassure them that these minor adverse effects are tolerable, and will disappear after finishing the regimen. Patients should be reminded to contact the physician urgently if there is profuse watery diarrhoea during the course of treatment.

Conclusion

Although there are several new regimens proposed for the treatment of H pylori infection, the classical triple and quadruple therapy are still the best for first and second line treatment respectively. It is important to ensure patient compliance to enhance the high eradication rate.

Pharmacology Management of Pityriasis versicolor

Contributed by Minychel wale, from ALERT center email Minychelwale77 @ gmail.com

Introduction

Pityriasis versicolor is a common skin complaint in which flaky discolored patches appear mainly on the chest and back. The term 'pityriasis' is used to describe skin conditions in which the scale appears similar to bran. The multiple colours arising in the disorder give rise to the second part of the name, 'versicolor'. It sometimes called 'tinea versicolor', although the term 'tinea' should strictly refer to infection with a Dermatophyte fungus.

Pityriasis versicolor (PV) that develops in people with dark skin may result in the loss of skin color. This condition is known as **hypo pigmentation**. Some individuals who develop tinea versicolor do not have any significant changes in their skin color or appearance. In addition to changes in the skin, you may also experience increased sweating and itchy skin.

Pityriasis versicolor (PV) is a common, chronic disease caused by an overgrowth of the yeast fungus called Pityrosporum ovale and P. or biculareal so called Malassezia furfur. P. ovale is a member of the normal flora of skin. This causes the person no problems unless it starts to grow excessively. P. ovale also play a role in the development of cradle cap (seborrheic dermatitis). Little is known about its etiology but PV is very common in subtropical and tropical parts. It is liable to flourish during the summer in our country. Profuse perspiration and high production of sebum make it easier for the fungus to grow in the skin. Immunodeficiency, for example HIV infection also makes it easier for the fungus to spread. It is commonly seen as well defined, pale, red or brownish, scaly uneven patches which often merge into big blotches looking like maps. It is usually located on the upper part of the back and on the chest, but can be found on the entire body. People who suffer from profuse sweating or high production of sebum, for instance teenagers are prone to develop this disease. Many other skin diseases, which require a completely different treatment, may mimic PV. So it is very important that the diagnosis is confirmed by identification of fungal spores and hyphae by microscopy and cultivation in the laboratory. P. ovale gives yellow-green or red-brown florescence when exposed to ultraviolet light (Wood's light examination). PV is usually treated with antifungal creams or sprays as Clotrimazole, Miconazole nitrate, Ketoconazole, terbinafine or Whitfield's ointment. The outbreaks may be treated with selenium-sulfide or

antifungal shampoo. The shampoo is applied to the body and removed after thirty minutes, every day for a week. In severe and resistant cases, treatment with systemic azole antifungal compounds (Ketoconazole, Itraconazole, and Fluconazole) is quite effective. This treatment should also be followed up by preventive treatments in the subsequent years.

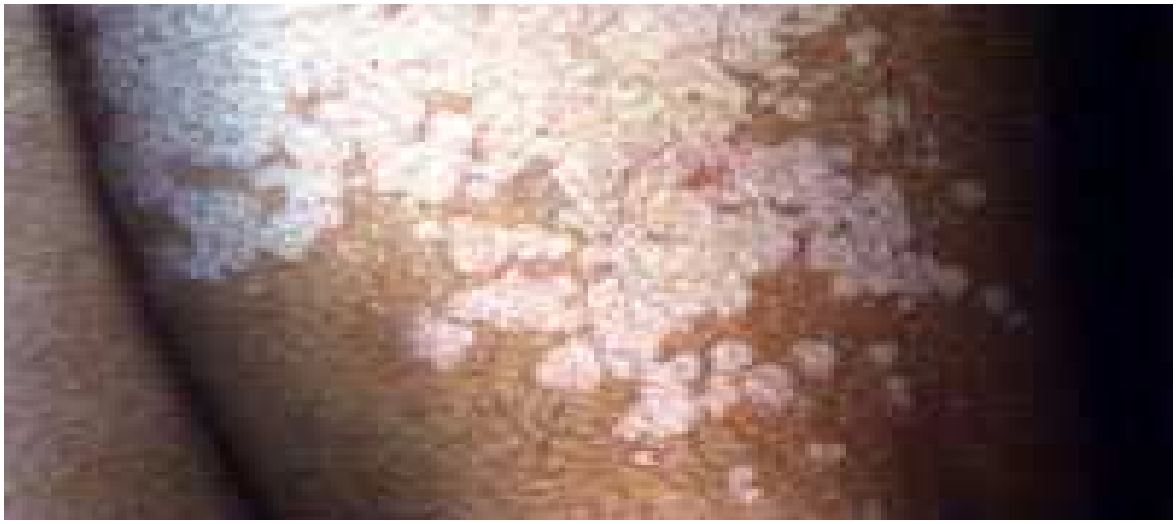

Fig 1 Pityriasis versicolor

Clinical features of pityriasis versicolor

Pityriasis versicolor affects the trunk, neck, and/or arms, and is uncommon on other parts of the body. The patches may be pink, coppery brown or paler than surrounding skin. They may be mildly itchy. Pale patches may be more common in darker skin; this appearance is known as pityriasis versicolor Alba and is less likely to itch. Sometimes the patches start scaly and brown, and then resolve through a non-scaly and white stage.

Pityriasis versicolor is more common in hot, humid climates or in those who sweat heavily, so it may recur each summer. Pityriasis versicolor does not appear to predispose affected areas to sunburn even when it causes pale white marks.

What is the cause of pityriasis versicolor

Pityriasis versicolor is caused by yeasts of the genus Maladdezia which may also be found on normal skin. Usually *Malassezia* species grow sparsely in the seborrheic areas (scalp, face and chest) without causing a rash. In some individuals they grow more actively on the skin surface, for unknown reasons. It is easier to demonstrate the yeasts in scrapings taken from the brown type of pityriasis versicolor than from the white type. The pale type of pityriasis versicolor is thought to be due to a chemical produced by *Malassezia* that diffuses down and impairs the function of the pigment cells in the underlying skin.

What Are the Symptoms of Pityriasis versicolor

The most noticeable symptom of tinea versicolor is the development of discolored patches of skin. These patches may:

- be lighter or darker than the surrounding skin
- be pink, red, tan, or brown in color (darkening of skin color is known as hyper pigmentation)
- be dry, itchy, and scaly
- be more prominent with tanning
- disappear in cooler, less humid weather

Diagnosis of Pityriasis versicolor or tinea versicolor

It was aided by Wood's light examination and confirmed by direct microscopy of KOH preparation. Obtained form skin lesion. Wood's light examination revealed yellow fluorescence over lesions showing also the extent of disease on body. For fungal microscopy, scales were scraped from four different diseased sites on glass slides with help of surgical blade. These were treated with 10% KOH and examined under microscope after about 30 minutes which showed characteristic hyphae and spores (spaghetti with meatball appearance). A yellow-green fluorescence may be observed on examination of affected areas with a Wood's light (long wave ultraviolet A).

Treatment of Tinea Versicolor with Topical Antifungal

Topical antifungal medications are the treatment of choice for tinea versicolor. The following topical antifungal treatment regimens have been shown to produce a greater than 70% clinical response rate:

- 2% Ketoconazole cream applied once daily for 11-22 days
- 2% Ketoconazole shampoo regimen (lathered over affected and surrounding areas and left on for at least 5 minutes before rinsing) applied once daily for 3 consecutive days
- 1% Terbinafine solution applied twice daily for 1 week
- 1% Clotrimazole solution applied once daily for 1 week

Treatment of Tinea Versicolor with Oral Antifungal

Oral antifungal medications can cause side effects such as nausea or reversible liver damage, but these side effects are not common with the short courses of therapy used for tinea versicolor. Oral Grisofulvine and oral terbinafine are not effective treatments for tinea versicolor. The following oral treatment regimens have been shown to produce a greater than 70% clinical response rate:

- Itraconazole 200mg every other day for 7 days
- Ketoconazole 400mg single dose
- Fluconazole 400mg single dose
- Fluconazole 150mg or 300mg weekly for 4 weeks

Treatment of Tinea Versicolor with Dandruff Shampoos

Until recently, dandruff shampoos were the mainstay of treatment for tinea versicolor. They are less effective than the antifungal medications and can cause skin irritation, but they are available over the counter and are less expensive. The following regimens have been shown to be effective:

- 2 – 10 % Salicyclic acid shampoo/Lotion applied nightly as a lotion for 1 week
- Zinc-pyrithione shampoo regimen (applied daily as a lotion and left on for 5 minutes before rinsing) for 2 weeks

- Selenium sulfide 2.5% lotion regimen (applied daily as a lotion and left on for 10 minutes before rinsing) for 1 week

How Can Pityriasis versicolor

Preventing a recurrence of the condition can be difficult. If you are diagnosed with tinea versicolor and successfully treated, there are steps that you can take to prevent future infections. These include:

- avoiding excessive heat
- avoiding tanning or excessive sun exposure
- avoiding excessive sweating
- taking prescribed medication

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Obituary

EPA deeply regrets the loss of its members this year and wishes strength to their families and friends.

May their soul rest in peace in Heaven