Message from the President of EPA

As President of the Ethiopian Pharmaceutical Association (EPA), it is gratifying for me to see the current strength of our association and the enormous efforts that has been invested over the course of years that lead us to the current level of development. The achievement are immense but can only serve as a stepping stone to move forward to the next phases as there are a lot more yet to accomplish. EPA is an association representing pharmacists working in a highly complex system and diverse areas of practice and hence will continue to work hard to satisfy the evolving needs of its members and the pharmaceutical sector at large.

The pharmaceutical sector is a multifaceted and technically complex arena that requires highly skilled personnel and a standardized operational infrastructure. The pharmaceutical sector of countries all over the world is responsible for serving society with the provision of medicines and associated pharmaceutical services that are an essential component of overall health care services. Therefore, the task of managing the pharmaceutical sector should be taken as top priority in order to ensure that it is institutionally sound and operates efficiently and in harmony with other healthcare systems. Medicines are key health products that can translate into tangible benefits for numerous acute and chronic health conditions. Policy makers need to ensure that medicines are appropriately manufactured, supplied, and used. One of the key elements to ensure this is governance of the pharmaceutical sector. Flaws in the structure and management of the pharmaceutical sector can limit the population's access to quality pharmaceuticals and the corresponding pharmaceutical services, thereby depriving society of the health gains associated with these life-saving products

A significant portion of all health expenditure is related to the pharmaceutical sector and, for this reason, health planners, whether within the context of health sector reform or not, should be concerned about the governance and management of their pharmaceutical system. Improving access to services, and therefore medicines, is one of the main goals of most health sector reforms and as such, malfunctions in the pharmaceuticals sector performance can severely

compromise this goal. Cognizant of the significance of this sector, the Ethiopian Drug Policy outlines relevant policy directions and strategies on key elements including pharmaceutical products, personnel for provision of pharmaceutical services and key institutional framework and processes required to ensure access to medicines to the population. The ultimate goal of implementing this policy is making medicines and pharmaceutical services more accessible to all Ethiopians. In order to meet the objectives of expanding access to quality services and increase efficiencies, there needs to be appropriate structural arrangements, at all levels of the health care system, with the necessary resources that enable implementation of each components of the national drug policy.

For the drug policy to be implemented effectively and efficiently the sequential operation of five primary areas of activity are required: medicines registration, medicines selection, medicines procurement, medicines distribution, and medicines use. The last area of activity i.e. medicines use encompasses the whole range of activities that includes prescribing and dispensing. The provision of pharmaceutical care, clinical pharmacy services, extemporaneous compounding, medicines use education, dispensing, adherence counseling, medicines use review/monitoring, drug information services, pharmaceutical research, etc… are all combined together under the umbrella of pharmaceutical services. As such pharmaceutical service provision is a key component of overall health care services and is essential for a successful treatment outcome. Therefore reforms in the health sector should be able to address pharmaceutical services in order to ensure that success registered in medicine regulation and supply chain are finally reflected in the outcomes of treatment at the end user.

Unfortunately, there is a persistent misconception that pharmaceutical services comprise only procurement and supply of 'health commodities'. This arrangement cannot be appropriate for efficient management of the pharmaceutical sector in the 21st century. The numerous changes observed in the sector over the course of years which include commercialization and globalization of trade in pharmaceuticals; intellectual property provisions and their implications on access to medicines; increasingly complex issues of quality and safety (of products & services); spread of counterfeits and other illegal practices; spread of antimicrobial resistance, increased sophistication of disease management with associated costs; increasing demand for information and advice on appropriate medicines use; and the enhanced role of the pharmacist in public health and in the clinical environment requires a special emphasis in the management of the sector. As a result current practices and international management trends are towards clear separation of pharmaceutical policy development/revision/implementation, regulation and supply functions.

Pharmacists working in Ethiopia should take the prime responsibility to fully implement the Ethiopian drug policy. In an attempt to achieve this, pharmacists should be aware of international best practices and strive to adapt it to our situation taking into account the local context. Whenever there are practices that are believed to impede progress towards these accomplishments, pharmacy practitioners, at all levels of the health care system, should generate evidence to guide policy makers take appropriate decisions and/or actions.

During the past one year, EPA with the effort of its members, has managed to accomplish remarkable results in project management, systems development, human resource strengthening, and development of its financial capacity. Apart from consolidating its reform activities, EPA has also expanded its scope of global partnership and has managed to demonstrate excellence in project development by winning different projects including those at an international level. EPA is working hard to generate evidence that can be of significant importance in shaping policy decisions regarding the pharmaceutical sector. I hope that, you all will play your own role in making our efforts highly productive and successful. Lastly, I would like to extend my sincere gratitude and appreciation to all individuals and institutions who have partnered with EPA and contributed to the successes we have achieved thus far.

With Best Wishes,

Hailu Tadeg (BPharm, MSc, MPH)
President

Message from Editors

Pharmacy is undergoing enormous change as the nature of health care systems and the technologies change. Task shifting in the practice of pharmacy particularly in the developed nations have prompted changes in the way pharmacy education is delivered and how pharmacy is practiced in the healthcare settings. With this, of course, comes applying evidence based information in the care of patients. It also requires one to have a good knowledge of the clinical aspects of pharmacy and keeping abreast of the current developments in the area of pharmacy.

In Ethiopia there are now efforts underway to implement clinical pharmacy in healthcare settings and as pharmacy professionals brace to accept this new responsibility, we should be ready to confront the challenges in terms of the difficulties faced while trying to introduce a new concept which may not be well known to other healthcare professionals. The preparations require gearing up in terms of updating/educating ourselves in the area of therapeutic management of diseases to make ourselves better pharmacy professionals who can provide evidence based drug information to other healthcare professionals and patients. For this, as pharmacy professionals, we need to be informed with the latest news and events in the area of the profession. Pharma forum is one way, among others, through which the Ethiopian Pharmaceutical Association provides information to pharmacy and other healthcare professional.

The Pharma Forum Editorial Committee is continuing its commitment to the continuous publication of the bi-annual Pharma forum bulletin and EPA Newsletter, which is issued quarterly. With the launching of the EPA's website, the issue of both publications are available on the website (on the following address: www.epaethiopia.org).

Finally, please feel free to give us your feedback on our content. We value our readers' input; your feedback helps us to continually improve the content of our publication.

Sincerely,

Yours in EPA

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NEWS

Continuing Pharmacy Education on Professionalism and Regulation of Pharmacy Practice

The Ethiopian Pharmaceutical Association (EPA) in collaboration with MSH/SPS & the school of Pharmacy, Addis Ababa University organized a Continuing Pharmacy Education (CPE) entitled "**Professionalism and Regulation in Pharmacy Practice: International Perspectives'** which was attended by 48 pharmacists working in different sectors. The training took place on March 12, 2011 at Global hotel and was given by Dr Heather Boon, an associate professor at Leslie Dan Faculty of Pharmacy, University of Toronto. The occasion had helped the trainees to recognize the inseparable nature of professionalism and regulation, whether this is self imposed (as in the case of the "code of Ethics and Standards of Practice for Pharmacists practicing in Ethiopia" of EPA) or regulated by the state. Dr Boon also spoke about Pharmaceutical care indicating its current status and the different components of the patient care processes to which the pharmaceutical care is applicable in different sectors of the profession.

The long standing partnership between EPA, MSH/SPS and the School of pharmacy, AAU in organizing such events is expected to move ahead with introduction of a standardized CE, whose preparation is currently underway.

Some of the trainees and the trainer Dr Boon

A Continuing Medical Education on TB/HIV Co-infection Updates offered

The Ethiopian Pharmaceutical Association (EPA) in collaboration with the Ethiopian Medical Association and other members of the consortium of health professionals association conducted continuing medical education on TB/HIV Co-infection Updates on May 15, 2011 at Axum Hotel, Mekele. 135 participants (Pharmacists, Physicians, Health Officers, Pharmacy Technicians, Nurses and Medical Laboratory Technicians) from health facilities in Mekele and its surroundings attended the CME.

The subjects covered included Epidemiology of TB/HIV Co-infection, TB Infection Control in the era of HIV/AIDS, Updates on Laboratory Diagnosis of TB with HIV Co-infection, Managing Drug Interactions in the Treatment of TB/HIV co-infection, and Status of Multi Drug Resistant TB (MDR TB) in Ethiopia.

The session was possible through the financial assistance of the Center for Disease Control and Prevention (CDC)-Ethiopia/PEPFAR.

Training on Misoprostol & Mifepristone Use

Unsafe abortion is very common and exacts a heavy toll on women in Ethiopia. To reduce maternal death due to this cause, the Federal Ministry of Health has issued the necessary Legal Code and Implementation Guidelines on safe Abortion Services in Ethiopia. Associated with unsafe abortion is postpartum hemorrhage (PPH) which is a serious cause of maternal deaths in Ethiopia. The situation has demanded the training of Pharmacy professionals on the role of Misoprostol and Mifepristone in medication Abortion and PPH. Accordingly, a nationwide training with the title "***The Pharmaco-therapeutic application of Mifeprisone and Misoprostol in Reproductive Health***". was offered to 914 Pharmacy professionals (majority of whom were Pharmacists). The training ran from April to May 2011 and was held in Jimma, Diredawa, Mekelle, Dessie, Hawassa, Adama and Addis Ababa. This is the third in a series of trainings offered in collaboration with DKT-Ethiopia-an indicator of the growing partnership between EPA & DKT-Ethiopia.

EPA has an observer status at United States Pharmacopeial Convention (USP)

The Ethiopian Pharmaceutical Association (EPA) has been a member of the International Pharmaceutical Federation (FIP) since 1996 and the association's international link has now moved one step further by enabling it to assume an observer status at United States Pharmacopeial Convention (USP).

USP is a scientific, nonprofit, standards-setting organization that improves the health of people around the world through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. Its standards are relied upon and used globally. USP's work supports regulatory agencies, manufacturers, and healthcare providers in their efforts to ensure access to good quality medicines.

The observer status at USP Convention will help EPA to contribute for import and manufacture of quality medicines in the country.

EPA's constitution under revision

The association's tasks are governed by the constitution which was revised only once in 2006 after its inception in 1974. Considering the increased membership size, the increased scope of activities, and improved administrative structures and also in meeting the requirements set by the Charities and Societies agency of the Ministry of Justice it has become necessary to revise the existing constitution. Accordingly, a draft constitution from the taskforce was enriched by a group of senior Pharmacy professionals during a workshop held on March 19, 2002. The draft is available for comment on the association's website and is expected to be endorsed during the 31st annual scientific conference.

School of Pharmacy, Addis Ababa University provides community service

The Addis Ababa University, School of Pharmacy has recently conducted a health screening and public education in the areas of diabetes and high blood pressure. The event was organized in collaboration with the Ethiopian Diabetes Association and was the first in the history of the school. About 700 individuals received the service. Services provided during the event included blood sugar, blood pressure, body mass index, and waist circumference measurements. Diabetes is becoming a threat to the nation and involvement of pharmacists is key in order to improve treatment outcomes in patients with diabetes. During the event, individuals were given education on the importance of early screening (esp. for those who have a family history) and good glycemic control and exercise and healthy eating for those who have a diagnosis of diabetes. Medication reviews were also conducted for those who came with their own medication.

The School has also provided, through volunteer students drawn from its regular undergraduate program, an education in five high schools in Addis Ababa city about antimicrobial resistance (AMR) and the importance of proper use of these classes of medications in order to avoid/control the spread of antimicrobial resistance. Related with this, an educational video on AMR was prepared and was shown to the public during the health screening event. "The School has plans to continue such activities in the future in order to educate the public specifically on

issues related to medications and health promotion in general" explained Mr. Ephrem Abebe, the coordinator of the events.

Consultative Workshops on the development of a National Pharmacovigilance Framework and standardization of course contents

Two separate Consultative workshops one on the development of a National Pharmacovigilance Framework and another on standardization of the course content of Teaching Institutions regarding Pharmacovigilance were carried out on June 20, and 21, 2011 respectively by the Food, Medicine and Health Care Administration and Control Authority (FMHACA) in collaboration with Management Sciences for Health/Strengthening Pharmaceutical Systems (MSH/SPS).

Twenty six participants were present at the workshop for the development of a national pharmacovigilance framework. The participants were from different sectors (pharmaceutical Importers and wholesalers, health facilities, professional Associations, pharmaceutical manufacturer, teaching institutions, experts from FMHACA). A draft framework document was presented to the participants for comment. The framework identified capacity building, collaboration, active surveillance system, public health programs, communication, research and education as key strategic elements to strengthen the pharmacovigilance system. The participants appreciated the initiative taken to develop a National framework and wished for its successful implementation promising their full participation.

The second part of the workshop aimed at standardizing course contents of the teaching institutions in the country regarding information they are delivering on Adverse drug event monitoring to their students during pre- service training. Twenty participants of whom 13 instructors from government medical and pharmacy schools, 4 instructors from private medical and pharmacy colleges and the remaining 3 from regulatory information development and dissemination team of FMHACA attended the workshop. The participants strongly agreed on the relevance of including information about adverse events monitoring and related issues in the pre-service training course content of health professionals. There was a detailed discussion especially on which course to include it and the time to be allocated to the topics when incorporated in the existing syllabus.

National Workshops held on revision of pharmaceutical standards.

The Food, medicine and healthcare Administration & control Authority (FMHACA), under the Ministry of Health has undergone various reforms as part of the Ethiopian Government's response to the structural adjustment of the health care system. Key components of the Business Process Reengineering include strong regulatory review and implementation of strategies that will deliver effective and efficient health care service.

The provision of complete health service by each level of healthcare facility necessitates the availability of safe, effective and affordable medicines of the required quality, in adequate quantity at all times. In order to meet the objective of providing complete healthcare service by the different levels, the FMHACA strives to identify the challenges of the healthcare system and strongly works on setting and revising standards, among other activities, to improve the quality of medicines availed to the population. The standards for medicines imported and distributed has been serving as means by which the quality and efficiency of the health care regulation is measured. Hence, The Authority conducted workshops to revise the standards for P*harmaceuticals Importers, Distributors and Exporters and Medicines Retail Outlets***.** Different stakeholders from public and regulatory bodies participated in the workshops and discussed on the revised standards. The purpose of this revision was to include current improvements in the above areas. The standards were revised taking in to account the changing priorities for public health action, epidemiological conditions as well as progress in pharmacological and pharmaceutical knowledge. The issues addressed were related to licensure requirements for importers, distributors, exporters, and retail outlets in relation to the premises, product, professional competence, and practice.

Jimma University graduated the first 12 clinical Pharmacists

School of pharmacy, Jimma University graduated the first 12 clinical pharmacists with MSc degree, in June 2011, the first of its kind in the history of pharmacy education in Ethiopia.

About three years ago, the School of Pharmacy, Jimma University took a decision to commence clinical pharmacy education. Jimma University is a pioneer innovative community-oriented health professionals training institute of higher learning in Ethiopia. The initiative to launch a clinical pharmacy education came to light in an attempt to improve pharmacy services in general, and minimize drug related problems in particular. The decision was based on scientific evidence, outcomes of need assessment, and experiences shared from other countries.

A national curriculum workshop and clinical pharmacy sensitization forum were conducted prior to launching of the program which was possible through the financial assistance of MSH/SPS. The program began with enrollment of 12 pharmacists from the academia and was supported by different institutions and individuals.

Jimma University appreciates all aspects and levels of contributions made by individuals and institutes /organizations.

Training to private Pharmacy practitioners on rational dispensing and handling of Anti-malarial drugs

The Ethiopian Pharmaceutical Association (EPA) in collaboration with MSH/SPS offered a training on rational dispensing and handling of antimalarial drugs to sixty-one private sector Pharmacy practitioners. The training was held on August 14 and 15, 2011 at Nekemt Desslaegn Hotel and was intended to increase the trainees awareness of the National Policies and Guidelines vis-à-vis the disease. The training moreover had allowed the practitioners to refresh their knowledge on the various anti-malarial agents while letting them to comprehend the significance of Artimisinin Combination Therapy (ACTs) in the current treatment armament. Included in the training were also the concepts of Rational Drug Use (RDU); clients counseling and the Pharmacovigilance of anti-malarials and other drugs.

Partial view of the training participants

EPA won FIP TB Project

EPA had won an FIP TB project entitled "FIP Challenge on TB Round 1" following its submission of a proposal by a title of "**Maximizing the role of pharmacists on TB prevention and control in Ethiopia**". The award brings EPA to an international scene. As per the MoU to be signed between FIP and EPA, the project involves training of 80 pharmacy practitioners divided into two groups and the first round of the training is scheduled for October 7, 2011.

EPA Conducted a CME in Collaboration with Sanofi-aventis

EPA conducted a half-day continuing education session on respiratory conditions and its management. Two topics, namely, Respiratory Diseases and its management and the clinical pharmacology of Respiratory drugs were delivered by Dr Amsalu Mekonnen (a pulmonologist) & Professor Eyasu Mekonen respectively. The session was held on 16th of July 2011 at Intercontinental Hotel and was attended by 93 Pharmacy practitioners.

Some of the training participants

CURRENT ISSUES

The Growth and Transformation Plan and the Pharmaceutical Sector

As part of the plans to achieve broad-based, accelerated and sustained economic growth, meet the Millennium Development Goals (MDGs) by 2015 and its longer term vision of being a middle income country by 2020 – 2023, Ethiopia has formulated the five year Growth and Transformation Plan (GTP) (2010 – 2014/15) which envisages the realization of better results in all sectors, including the health and industrial sectors.

Plans in the health and pharmaceutical sector

According to the GTP, health centers (HCs) will serve as a first curative referral center for health posts (HPs) through ambulatory and some cases of inpatient admissions. HPs and HCs will be equipped and staffed as per the standard and expanded in all Woredas. The total number of health centers planned to be available at the end of the plan period is 3299 including the 99 planned for Addis Ababa. The GTP also gives due emphasis to the expansion of higher quality hospital services. The government plans to allocate adequate budget to ensure sustainable national pharmaceutical and service supplies to health facilities at all levels. The plan is to ensure 100% availability of essential drugs at health facilities. There is also a plan to capacitate and motivate private healthcare providers to provide quality health service.

Private pharmaceutical factories will be given much emphasis by providing incentives to sustainably produce and deliver quality pharmaceuticals. The objectives for the pharmaceutical industry are to create the capacity to produce essential pharmaceutical products that substitute imported products and supply export markets. This will be achieved by improving the utilization of existing capacity and the establishment of new industries (> 10 planned). The share of the

domestic market held by local pharmaceutical and medical supplies manufacturers is planned to be raised to 50%.

Implications for the pharmaceutical sector

Pharmaceutical wholesaler and importer companies

The quest of the government, via the Pharmaceutical Fund and Supply Agency (PFSA), to fully supply all public health facilities in the country including the more than 3000 HCs and more than a hundred hospitals with essential medicines needs an expanded pharmacy workforce in different parts of the country. It would of course need the strong partnership of locally registered pharmaceutical manufacturers and suppliers to fulfill its missions. It should also be noted that in supplying public health facilities, PFSA would focus on a limited list of essential medicines which leaves out others considered 'nonessential' to be supplied by private wholesale companies. More importantly, the ever expanding private pharmaceutical retail outlets and hospitals need the private sector to fulfill their high needs of pharmaceuticals.

Community pharmacies

Along with the expansion and upgrading of the health services, an even more increased demand for pharmaceuticals which play a large role in healthcare delivery is expected which cannot be fully met by the public facilities' pharmacies. It should be expected that while the government promises to make increased efforts to avail essential pharmaceuticals, it may not meet all the needs of the facilities and especially those individuals who can afford to go to the private clinics and be prescribed medicines that will have to be obtained from the nearby community pharmacies. A greater demand for community pharmacies all over Ethiopia is also expected with the projected per capita GDP growth especially in the towns and cities.

Pharmaceutical industry

The Ethiopian pharmaceutical industry has been in existence for nearly half a century; however, its development has not been as much as it should have been. The government seems to have realized this and the huge potential that the pharmaceutical industry can play in the Ethiopian economy. Increased attention and higher incentives are therefore expected to be given to local manufacturers to realize government intents of curtailing the hard currency expended for the pharmaceuticals. Should the objectives set for pharmaceutical industry proceed well, it will have positive implications for enhanced technology transfer, research and job opportunities in the pharmaceutical sector.

By Bruck Messele, School of Pharmacy, Addis Ababa University.

Lecturer and PhD student.

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The Pharmaceutical Industry: Perspectives on the Global and Local Scenarios

The global pharmaceutical industry looks like the epitome of a modern, matured industry that has found a comfortable way to make profits by the billions; it is global, hi-tech and has the ultimate customer, the healthcare budget of the world's richest countries. The industry is however characterized by highly risky and lengthy research and development (R & D) processes, intense competition for intellectual property right, stringent government regulations and powerful purchaser pressures.

The origins of modern pharmaceutical industry can be traced to the late 19th century, when dyestuffs were found to have antiseptic properties. Roche, Ciba-Geigy and Sandoz all started out as family dyestuff companies based in Switzerland which moved to synthetic pharmaceuticals and eventually became global players. Penicillin was a major discovery for the emergent industry and during the 1940s and 1950s, R&D became firmly established with in the sector. The industry expanded in the 1960s benefiting from significant new discoveries with permanent patent protections. Regulatory controls on clinical development and marketing were light and healthcare spending boomed as economies prospered.

In the late 1960s and early 1970s, two important developments that defined the directions of the global pharmaceutical industry became apparent. Firstly, the Thalidomide tragedy (where the drug given for pregnant women caused birth defects in newborns) led to much tighter regulatory controls on clinical trials, greatly increasing drug development costs. Secondly, enactment of legislations to set a fixed period on patent protection, typically 20 years from initial filing as a research discovery led to the appearance of "Generic" medicines. The impact of generic entry is illustrated by Bristol Myers Squibb's Glucophage, (a brand for metformin) which generated US sales of $2.1billion in 2001. Following loss of the patent in January 2002, brand sales plunged to $69m for the first quarter. The introduction of generics, however, was very beneficial for society: valuable medicines became extremely cheap. Indeed, health economists have estimated that the social returns from pharmaceutical R & D exceed that appropriated by firms by at least 50 to 100 per cent.

From the year 1998 to 2005, the global pharmaceutical sales showed more than a double increase from $298 billion to $602 billion. The average growth during these periods was strongest in North America (12.6% per year) compared to 9.3% in Europe and 2.9% in Japan. North America accounts for the largest proportion of the world's pharmaceutical market (45%) followed by Europe (including the UK) which accounts for 23% of the total global sales. Australia represents 1% of the global pharmaceutical market and the rest of the world including Africa, Asia (excluding Japan), Latin America and the Oceania altogether take 21%.

France, Italy and Poland are the three leading countries in terms of the expenditures on pharmaceuticals. France and Italy each spent an average of 1.9% of their GDP on pharmaceuticals during the 2002 to 2007 fiscal years.

In most developing countries, 20-50% of their annual healthcare budget is spent on procurement of pharmaceuticals. In Ethiopia, compiled data on most of the pharma-economics are rare. It can, however, be said that the country doesn't have a developed pharmaceutical industry, but only few and small factories which mainly manufacture generic products using a commissioned master formula developed elsewhere. These factories produce some 25-30% of the essential drugs that the health sector of the country needs. The remaining 70-75% of the country's medicines market has been left vacant for imported products, principally for the low cost generics from micro-drug factories from Asia, mainly India and China.

A study jointly published by the Federal Ministry of Health of Ethiopia and the World Health Organization (WHO), publicized that, before five years, the allocated drug budget was inadequate as revealed by a very low per capita government drug budget of ETB 1.60 ($0.18 by the then exchange rate). This was indicated to be the lowest even by the sub-Sahara African standards and the WHO's recommendation of $ 1.00. But until recently, Ethiopia used to put high tax burden on pharmaceutical raw materials imported from abroad which now seems to have eased a little bit. For Ethiopia to be self-sufficient not only in food security but also in medicines, it has to figure out on the ways of developing a vibrant local pharmaceutical industry which can supply the local demand with quality and efficacious medicines and also contribute to the national GDP by replacing the poor quality products imported at high cost of the hard-earned foreign currency.

By Girma Belachew Gutema (Lecturer, Mekelle University)

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PHARMACY PRACTICE

The Ethiopian Hospital Reform: a tool for improving the Pharmacy service

In an attempt to improve the quality and accessibility of services at all levels of the country's health system, Ethiopia's Federal Ministry of Health (FMOH) has initiated a sector-wide reform in the country's health care system. Accordingly, health facilities in the country are working for more efficient service streamlining of their operational processes.

The reform is aimed to ensure patients obtain comprehensive quality health service they require in line with the principle of "one-stop-shopping". Accordingly a guideline, namely, the Ethiopian Hospital Reform Implementation Guideline (EHRIG) has been developed to help hospital managers and health providers in steering the consistent implementation of the reform processes. The focus of EHRIG includes hospital governance, service quality, patient flow, medical records, pharmacy services, laboratory services, infection prevention, nursing care, human resources, facility and equipment management, finance management, as well as monitoring and reporting. Although EHRIG is primarily intended for Hospital services the guideline is useful across all levels of the national health system

As essential component of hospital care, pharmaceutical services make a full-fledged chapter of the EHRIG. Effective pharmaceutical services promote the safe, rational, and cost effective use of drugs, therefore, maximizing health gain and minimizing risk to patients. Furthermore, well organized pharmaceutical services ensure the continuous availability of pharmaceuticals required for patient care.

The pharmacy chapter of EHRIG contains the following 12 operational standards.

1. A Drug and Therapeutics Committee (DTC) for a rational and cost-effective use of medicines.
2. Facility specific Medicines Formulary listing which is subject for revision every year
3. Outpatient, inpatient, emergency pharmacies and a central medical store each directed by a registered pharmacist.
4. A proper documentation /recording system of all types of drug transactions and patient medication information
5. Standard Operating Procedures (SOPs) for all compounding procedures
6. Enabling access to drug information to health care providers and patients to optimize drug therapy

7. Having policies and procedures for identifying and managing drug use problems, including: monitoring adverse drug reactions, prescription monitoring and drug utilization monitoring.
8. A drug procurement document which describes methods of quantification, prioritization, drug selection and ordering in line with the national guidance and which is approved by the facility DTC.
9. An inventory system (paper based or computerized) to reduce the frequency of stock-outs, wastage, over supply and drug expiry.
10. A physical inventory of all pharmaceuticals in the store and each dispensing unit at a minimum once a year.
11. Proper and safe disposal of pharmaceutical wastes and expired drugs.
12. Personnel, equipment, premises and facilities adequate enough to carry out compounding, dispensing, and counseling services.

Hospitals have started implementing the operational standards of pharmacy services since EHRIG was officially launched in March 2010. Applying the EHRIG standards have profound importance for the improvement of the pharmaceutical service and the public health at large. The implementation of the standards is expected to lead to minimization of wastage and pilferage, reduction in the expiry of drugs, increased drug availability, improved use of drugs, improved adherence, minimization of drug toxicity, increased treatment outcomes, improved drug information to the medical staff and to the society. It also improves overall accountability in handling drugs and managing drug transactions in health facilities. Hospital Reform becomes one of the most important tools to promote rational use of drugs. However, the Hospital Reform of the pharmacy service provision has not yet been fully implemented in most public health facilities in Ethiopia. Therefore, a lot is desired to have the full advantage of the reform. But it is encouraging to know that hospitals such as Tikur Anbessa ,Debre Berhan, Amanuel, ALERT, Assela, St Paul, Hawasa, Yirgalem, Woldya, Debre Tabor, Nekemte, Debre Markos Hospitals have started implementing the guideline. Some health centers, such as Bole Health Centre, are also implementing EHRIG.

With the new standard, hospital pharmacies in the country are reorganized by case teams: out-patient, inpatient and emergency pharmacy services. Each of the pharmacy services will be run by a pharmacist as a lead. Hospital pharmacies are organized as follows:

A. The Out-Patient Pharmacy Service: this service has one to four units depending on the type of the Hospital. These units may include:
    - Chronic care pharmacies; one for antiretroviral services and another for other chronic diseases like hypertension, diabetes, epilepsy and others
    - Main outpatient pharmacy unit for cash payers
    - Main outpatient pharmacy unit for credit users

B. The Emergency Pharmacy Service: this unit will cater to the medication related needs of patients eligible for emergency medical services.

C. The Inpatient Pharmacy Services: this service ranges from only one in-patient pharmacy unit for all wards up to one unit for each ward.

D. Pharmacy warehouses: the stores are led by a drug supply management case team process owner, who is a pharmacist and quantification is made based on the Integrated Pharmaceuticals Logistic System (IPLS). This helps to ensure continuous supply and availability of pharmaceuticals.

Team work, dedicated CEOs, and courageous and hard working pharmacists were shown to be very crucial for successful implementation of EHRIG.

By Ayalew Adinew, MSH/SPS

CONTINUING EDUCATION

Drug Use in Chronic Kidney Disease

Measuring renal function

True Glomerular Filtration Rate (GFR)

GFR is accepted as the best overall measure of kidney function. Normal values are related to age, gender and body size, and are typically 130mL/min/1.73m2 in young men and 120mL/min/1.73m2 in young women. The true GFR can be measured as the urinary or plasma clearance of an exogenous marker. However, this is difficult and expensive, and exposes patients to radioisotopes or iodine-based contrast material and is therefore impractical at a population level.

Estimating GFR

Serum creatinine concentration has traditionally been used as a proxy for GFR. However, this concentration is determined not only by the rate at which creatinine is excreted by the kidney, but also by its rate of production, which is dependent on dietary intake and muscle mass.

Therefore, serum creatinine concentration may be above the upper limit of the reference range in adult patients with normal kidney function but who have higher than average muscle mass (e.g. young body builders).

Conversely, it may remain within the reference range despite marked CKD in adults with low muscle mass. With such points in mind, the GFR can be estimated from serum creatinine concentrations, using equations that take into account key factors such as age, gender, racial origin, and body weight. Two standard equations used are the Cockcroft-Gault and Modification of Diet in Renal Disease (MDRD) formulae. Both have been validated against measurement of kidney function using clearance of isotopes, and aid recognition of CKD.

The Cockcroft-Gault Equation:

$$\text{Estimated CrCl (mL/min)} = \frac{(140-\text{age(years)}) \times \text{Weight (Kg)}}{\text{Sr.Cr(mg/dL)} \times 72}$$

Multiply the whole equation by 0.85 if subject is female

Abbreviated MDRD Formula:

186 X [SCr (mg/dL)]-1.154 X [age (years)]-0.203 X [0.742 if female] X [1.212 if black]

The Cockcroft-Gault formula (which was published in 1976) sometimes overestimates GFR; does not adjust for body surface area; is not appropriate for children; and appears less accurate than the MDRD formula in older or obese people, or as GFR falls. The MDRD formula (developed in 1999) is a more accurate estimate of GFR. For adults, 90% of the GFRs estimated by the formula to be below 60mL/min/1.73m2 are accurate to within 30% of the true value. The MDRD equation is well validated in people of white or black American ethnic origin. It is less well validated in people of Chinese origin, and few validation data are available for other ethnic groups. It is not validated for use in children, patients with acute renal failure, pregnancy, edematous or muscle wasting disease states, amputees or those who are malnourished.

About Chronic Kidney Disease (CKD)

Definition

A classification of CKD based on e-GFR was proposed in 2002, with the publication of the American National Kidney Foundation Kidney Disease Outcome Quality Initiative (KDOQI) and has now been widely accepted internationally and is shown in the table below:

Table: CKD Stages

Stage	Description	GFR (mL/minute/1.73 m2)	Management
	At increased risk	>90 (CKD risk factors)	Screening CKD risk reduction
Stage 1	Kidney damage with normal or increased GFR	>90	Diagnosis and Rx CVD risk reduction
Stage 2	Mild reduction in GFR	60-90	Estimating progression
Stage 3	Moderate reduction in GFR	30-59	Evaluating and treating complications
Stage 4	Severe reduction in GFR	15-29	Preparation for kidney replacement therapy
Stage 5 (ESRD)	Kidney failure	<15 or dialysis	Replacement, if uremia is present

An e-GFR of 60–90mL/min/1.73 m2 does not, on its own, indicate CKD. To be diagnosed with CKD stage 1 or 2 (i.e. early kidney disease), the patient must have evidence of kidney damage for 3 months or more as defined by pathological abnormalities or markers of damage (e.g. microalbuminuria; proteinuria; haematuria; structural abnormalities of the kidneys demonstrated by imaging; chronic glomerulonephritis proven on biopsy).In stages 3–5, a reduced e-GFR for over 3 months is sufficient for diagnosis. The diagnosis of CKD should not be made on a single e-GFR.

Who gets CKD?

Individuals most likely to develop CKD include elderly people, in whom co-morbidities and use of multiple drugs are common, and those with diabetes mellitus, hypertension or primary kidney disease (e.g. glomerulonephritis). Other conditions that can lead to CKD include bladder outflow obstruction (e.g. due to benign prostatic hypertrophy in older men), structural urinary tract abnormalities, reflux nephropathy, neurogenic bladder and drug-induced nephrotoxicity.

What are the health implications?

While CKD is a long-term condition, only a minority of people in stage 1 or 2 go on to develop more advanced disease. From stage 3 onwards, CKD is associated with an increased risk of cardiovascular events and death. Cardiovascular disease is the commonest cause of death in people with CKD, while renal failure accounts for a minority of deaths in such patients

Pregnant women with CKD are at increased risk of preeclampsia, fetal loss, premature delivery, and long-term deterioration in renal function, and the risk is higher with moderate or severe renal disease than with mild disease. Ideally, young women with known kidney disease should be assessed prior to pregnancy, so that blood pressure and other potential risk factors can be optimized to help to achieve a successful outcome. People with CKD are also at higher risk of adverse drug reactions.

Implications of CKD for drug therapy

Many commonly used drugs are metabolized or excreted by the kidney, and this has particular significance for people with CKD. Impaired renal function alters drug pharmacokinetics, potentially changing drug efficacy and increasing the likelihood of unwanted effects, including renal toxicity.

Drugs affected by pre-existing kidney disease

Renal excretion of a drug is dependent on glomerular filtration (and therefore the GFR), and on the balance between any secretion and reabsorption of the drug in the renal tubules. When renal function is impaired, clearance of a drug by the kidney is decreased and the plasma half-life prolonged.

Therefore, patients with CKD on such drugs will require reductions in dose or frequency of administration. Key examples include the following:

- beta-blockers (e.g. atenolol)
- digoxin
- some analgesics (e.g. codeine)
- some antimicrobial drugs (e.g. amoxicillin, cephalosporins, ciprofloxacin, clarithromycin, acyclovir)
- certain cytotoxic drugs (e.g. cyclophosphamide, melphalan, methotrexate).

Vitamin D requires hydroxylation by the kidney to its active form, and this means that the hydroxylated derivatives alfacalcidol or calcitriol should be prescribed in patients with severe renal impairment who require vitamin D therapy.

Drugs that may impair kidney function

Patients with CKD may be more susceptible to the renal effects of certain nephrotoxic drugs. Drugs can be nephrotoxic through a variety of pathophysiological mechanisms, including effects on glomerular filtration (e.g. NSAIDs); tubular function (e.g. lithium, gentamicin); vascular damage (e.g. ciclosporin); interstitial nephritis (e.g. allopurinol, vancomycin); and obstructive nephropathy (e.g. acyclovir).

A key point to bear in mind is that patients may be taking over-the-counter medicines (e.g. ibuprofen), as well as prescribed treatments.

Specific patient factors can compound the effect of CKD in increasing the inherent drug-related risk of nephrotoxicity. Examples include dehydration, pre-existing heart failure and concomitant drug therapy.

Principles of drug use in CKD

Clinical assessment

The patient's current medication list (including any over-the-counter and herbal treatments) should be reviewed for drugs which are affected by, or can adversely affect, renal function, or any possible drug interactions. Combinations of drugs (e.g. diuretics, NSAIDs and ACE inhibitors or angiotensin II receptor antagonists) may impair renal function by a variety of mechanisms. It is also important to check the patient's blood pressure, and for any evidence of hypovolaemia or oedema.

Measuring and interpreting e-GFR

If the patient is already known to have CKD, or if acute renal failure or chronic renal impairment is considered likely on clinical grounds, renal function should be checked before giving any drug which might require dose modification. There may be an urgent need to initiate or modify such medication in a patient with CKD, for example, certain types of antibacterial therapy for acute infection. In such circumstances, a baseline serum creatinine concentration (with e-GFR) can prove useful to indicate a potential need for dose adjustment, comparison with subsequent measurements, and monitoring of the drug's effects. Dose adjustments are usually done using the estimated creatinine clearance calculated using one of the methods described above. Such dosing recommendations can be obtained in most standard drug information books or in medicine package inserts.

Can treatment be avoided altogether?

Assessment of the patient and the potentially nephrotoxic therapy may make it obvious that the risks outweigh the benefits and the treatment should not be used. Combinations of nephrotoxic drugs should be avoided if at all possible. Also, patients should be informed about potential dangers from nephrotoxic non-prescription medicines and alternative remedies, such as over-the-counter NSAIDs. When treatment is mandatory, preventive measures such as adequate hydration of patient may also be required.

The table below lists some of the most commonly used classed of medications with examples that might require dosing adjustment and or avoidance in patients with renal disease:

Drug Classes	Examples	Recommendations
Analgesics (NSAIDs and Paracetamol)	Ibuprofen	No dosage adjustment is recommended for patients with renal dysfunction or failure; May impair renal function in during chronic use
	Diclofenac sodium	No specific dosage adjustment for diclofenac is necessary in renal impairment; May impair renal function in during chronic use
	Paracetamol	It has been recommended to increase the dosing interval to every 4 hours in patients with mild renal failure (GFR greater than 50 mL/min), every 6 hours in patients with moderate renal failure (GFR 10 to 50 mL/min), and every 8 hours in patients with severe renal failure (GFR less than 10 mL/min); generally safer for use in CKD than NSAIDs
Antihypertensives	Thiazide diuretics	Avoid if GFR is < 30 mL/min/1.73m2 for most.
	ACE Inhibitors and Angiotensin receptor blockers	Monitor for hypotension, esp. during initiation of therapy. Potassium levels may rise.
Antimicrobial agents	Amoxicillin	Generally, dose reduction is not required for renal impairment unless severe
	Metronidazole	No dosage adjustment is necessary for patients with mild to moderate renal failure (GFR greater than 10 milliliters/minute).
	Doxycycline	Dosage adjustments are not required for patients with renal impairment.
Antidiabetic medications	Sulfonylureas	Most eliminated renally and thus risk of hypoglycemia with renal impairement. Dose reduction indicated.
	Metformin	Risk of lactic acidosis.
	Insulin	Dose reduction required with renal impairement
Anticoagulants	Low molecular weight heparins (E.g., Enoxaparin)	Dosage adjustments required with impaired renal function.
	Unfractionated heparin (Heparin Sodium)	No dosage adjustment of heparin is necessary in patients with renal failure. Safer than LMWHs in renal failure.
	Warfarin	No specific dosage adjustment of warfarin is necessary in patients with renal dysfunction

Note: The reader is advised to refer to standard drug references to obtain a full list of recommendations for drug dosing in renal impairment.

Conclusion

Practitioners need to be aware of drugs that are affected by reduced renal function, and the increased risks of drug-induced nephrotoxicity in people with CKD. Whenever possible, they should take steps to minimize these risks, either by avoiding the drugs, or by using reduced doses or administrative frequency, or increasing monitoring of renal function. Sources such as the Ethiopian National Drug Formulary (ENDF) provide summaries of product characteristics, drug information services and consultant nephrologists should be consulted for further advice.

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Obituary

Manalebish Delebo

Manalebish Delebo was born in 1945 E.C in Mizan Teferi Town. She graduated in 1969 E.C from nursing program of the Ethiopian Red Cross Society and graduated with B.Pharm from the School of Pharmacy , Addis Ababa University in 1975 E. C.

She served in Dilla Hospital, at Wonji, Metehara Sugar Factory, World Vision, and World Lutheran Federation and at Shashemane Kenema Pharmacy, Nazareth Pharmacy & Bethel teaching general hospital as a pharmacist & department head with a cumulative service of 33 years.

W/rt Manalebeish passed away on June 23, 2003 E.C. The Ethiopian Pharmaceutical Association extends its condolence to her family and colleagues.

May her soul rest in peace

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