Ethio-Morph launched

The famous 17th Century English Physician Sydenham said, “Among the most powerful remedies that God bestowed to mankind in order to ease our suffering, none is as efficient or as universal as opium”.

Ethio-Morph syrup (morphine sulphate) was officially launched on October 9, 2010 on the occasion of the WHPCD 2010. The formulation process was undertaken by the Research & Development Department of the Ethiopian Pharmaceutical Company (EPHARM). EPHARM has adhered to all the national regulation for manufacturing and marketing pharmaceutical products by conducting both “accelerated” and “real time” stability studies. Ethio-Morph was registered by the Quality Assessment Directorate of DACA with a license issued to be marketed with an expiry period of 2 years. Ethio-Morph will be supplied in strengths 5, 20, 30 and 50 mg/5ml concentrations /125 ml bottles. The product comprises the essential components of cost effectiveness, quality assurance, research, and sustainability. Oral solution formulations have enhanced bioavailability, shorter onset of action, suitable pediatric formulation, and a measurable formulation for dose modification (dose titration). Morphine is a cost effective medication and the “gold standard” of pain medications in chronic and intractable pain. This makes it indispensable to apply the WHO analgesic ladder. Experience and published data confirm that its appropriate use revolutionizes pain management. Over the last twenty years, the INCB, WHO and other international bodies have repeatedly reminded countries of their obligation to ensure adequate availability of opioids for the treatment of pain.

National PC Professionals

Drs Wondimagegne Tegeneh, Aynalem Abraha and Dagnachew H/ Mariam were the 1st batch of national professional in Palliative Medicine. They have successfully completed a post graduate Diploma in Palliative Medicine at the University of Cape Town. This makes them the only three Palliative Medicine professionals in a nation of close to 80 million! Drs Wondimagegne and Aynalem are senior oncologists while Dr Dagnachew is an MD with extensive experience in HIV care. All three physicians provide services at Tikur Anbessa Specialized Hospital (TASH). CDC/PEPFAR implementing University partners, I TECH, UCSD-E and JHU-TSEHAI, the Observatory of End of Life Care and University of Cape Town jointly sponsored the training. Both Dr Aynalem and Dr Dagnachew will continue their education for a Masters-MPhil in Palliative Medicine in the next year. The good news is that the Federal Ministry of Health has recognized Palliative Medicine as a medical specialty! As Dr Wondimagegne puts it “There is no need for the discovery of a wonder drug for the establishment of effective palliative care and effective pain relief! There is need for learning and sharing experience...
In recent years, there has been growing awareness of the need to provide better pain and symptom management, particularly for patients with chronic painful diseases. The development of the National Pain Management Guideline (NPMG-2007) reflects a heightened awareness and commitment to a most neglected need. To its credit, the Ethiopian government i.e. DACA had created a conducive policy environment for promoting pain management by including opioids in LIDE and issued 2 national guidelines - Guideline to control and promote proper use of Narcotic Drugs & Psychotropic Substances 01/2003 & Guideline to control narcotic and psychotropic substances prescription papers, DACA Jan 2004.

PC and Pain relief as a human right

Under international human rights law, governments must address a major public health crisis that affects millions of people every year—PAIN! Many international organizations such as the World Health Organization, the International Association for the Study of Pain (Annexed), the Worldwide Palliative Care Alliance, and other PC advocates have developed a number of declarations calling for PC and pain relief as a human right—Freedom from pain should be regarded as a human right’s issue (WHO 1998). This includes the right to essential medicines for the relief of pain. A right to palliative care and access to pain treatment is further protected by the right to freedom from cruel, inhuman and degrading treatment. Model pain and PC programs in Uganda, India and in other resource constraint settings have demonstrated the feasibility of providing pain and symptom relief including opioid treatment, safely, effectively, and inexpensively. The correct diagnosis and proper treatment of pain should be an important public health concern, even in low resource settings. A lack of the prioritization of pain management is not a result of the low prevalence of pain but of the invisibility of its sufferers, which results in unnecessary human suffering.

National Pain Management Guideline

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World Hospice and Palliative Care Day 2010

World Hospice and Palliative Care Day 2010 was celebrated on October 8 at the Telemedicine Facility building of the Black Lion hospital under the theme Sharing the Care. WHPCD is an awareness day for anyone and everyone who cares about or is involved in pain relief and palliative care anywhere in the world.

“......... We need to step out and work with our neighbors. Partnerships can be mutually beneficial and empowering – we need to share ideas, information, skills, experience and knowledge........

Source: Sharing the Care – World Day Report The Worldwide Palliative Care Alliance (WPCA)

Present were representatives of government and other national and international stakeholders in pain relief and palliative care. The 3 national professionals in palliative care were introduced to the audience and congratulated. Dr. Bogale Solomon, Radiotherapy Unit Director at the Black Lion Hospital said that “with the availability of morphine, health care providers will no longer turn away chronically ill patients since they can now manage their pain.” Dr. Nigist Tesfaye, head of the Urban Health Promotion and Prevention Department at the Ministry of Health, emphasized the urgent need of PC services.

Dr. Yoseph Mamo, PC and Pre-Service Advisor at UCSD-E (University of California San Diego)–Ethiopia, said that “......although the production of domestic oral morphine solution in Ethiopia is a great achievement in terms of its sustainability and cost effectiveness there is need for a strategic approach to opioid scale-up. All strategies and programs to expand opioid use should be evaluated to ensure that “lessons” can be replicated/adapted for use in other sites. There is still no estimate on the amount of morphine tablets or solution that will be required to meet needs at the

The ‘Merriman Model’

With dedication and medications, 95 percent of pain can be controlled 95 percent of the time!........ A patient can get enough morphine for 10 days for the same price as half a loaf of bread.

A Liverpool physician who has dedicated her career to caring for the dying in Africa, Dr Anne Merriman is world-renowned for her pioneering work and influential research into palliative care in developing countries in Africa, enhancing the treatment of the dying and working tirelessly to make morphine available to those in need. In Audacity to Love (launched in July of 2010) Dr. Merriman tells the story of Hospice Africa, from the spiritual development of Hospice, its religious associations with the early Catholic Church, to the roots of the creation and development of Hospice Africa today. “Imagine a world where the only pain relief is paracetamol .......” she says. This was the situation in most of sub-Saharan Africa in 1993 until she came along with a vision – of bringing affordable pain relief to dying patients throughout the poorest countries in Africa. Dr Merriman is responsible for the ‘Merriman Model’ – a PC programme devised during her work in Nairobi Hospice in Kenya. It was here that she witnessed terrible suffering of terminally-ill cancer patients without access to proper oncology treatment

WHO uses morphine consumption statistics as a broad indicator of progress to improve pain relief. As shown in the graph, in 2003 Ethiopia had one of the lowest morphine /capita consumption 0.0005mg compared with the global mean of 5.85mg. Again in 2006, the consumption was reported as 0.0002mg /capita; Uganda 0.3136mg/capita; Mali 0.0181mg /capita; Sudan 0.0230mg/capita; Kenya; 0.1292mg/capita. Ethiopia’s low consumption of morphine is indicative of the poor availability of pain control and palliative care. Suddenly, in 2008, there is a surge. This can be attributed to the importation of powder morphine to reconstitute the oral solution and also to increased importation by PFSA of morphine tablets that is supplied to TASH.
The WHO 3-step Analgesic Ladder

PAIN MANAGEMENT PROTOCOL

The World Health Organization (WHO, 2002) has devised guidelines for the management of pain related to cancer or HIV/AIDS. This is often used as a framework for the management of other types of pain. Its advantages include: Simplicity, as only a few widely-known cheap analgesic groups are used; Applicability to a wide variety of situations and prescribers worldwide; Flexibility to a large variety of pain situations and also to prescribers globally. By referring to drug classes, rather than specific drugs, the ladder maintains a level of flexibility that allows clinicians to work within their set regulations and limitations; Safety, in that safest drugs are used first in their lowest effective dose; Emphasis on multimodal analgesia - the concept that pain is best treated, not by a single drug or therapy, but by combinations, which maximize efficacy whilst keeping side-effects low. This stepped approach of administering the right drug, in the right dose, at the right time is inexpensive and generally effective in managing pain.

Pain Management - Challenges

The effective relief of pain depends not only on the availability, accessibility or affordability of pain relieving drugs but also on the health sectors capacity to use those drugs efficiently. One of the biggest obstacles to provision of good pain treatment is the lack of training of health care workers. There is inadequate teaching of undergraduate doctors and nurses in pain management. The majority of health professionals do not know how to holistically assess and control pain. Only an insignificant number familiar with the WHO pain management protocol. In clinical settings much of the professional focus is on treatment—the curing of disease— without addressing the care of the suffering and the pain that goes along with the disease and treatment. Inaccurate information, myths, rumors, fear, and cultural issues also contribute to inadequate pain management. Oral morphine is most often considered the “gold standard” of pain medications in chronic pain management. However, physicians still hold exaggerated and unjustified concerns ‘opiophobia’ about the risk of opioid abuse, addiction, and diversion. Effective provider education on the policies that govern pain management and clarify the philosophy and intent of the use of analgesics, particularly opioids in treating pain, should help reduce or eliminate fears as a primary barrier to appropriate pain medication prescribing practices.

Cont from page 2 .. National PC professionals

home based care is confused with the provision of PC services. “Care and support” without pain relief is not PC. The effort should start from the premises and awareness that physical suffering is avoidable when health care providers have basic pain management skills, have access to medications like morphine, and have institutional structures, and processes in which to implement it. Such a process will also start a series of activities to initiate common protocols and generate information and data in which to implement it effectively. As such, it will deliver sustainable outputs to highlight the problem of unrelieved pain.

“... With dedication and medications, 95 percent of pain can be controlled 95 percent of the time!.... ”

Cont from page 3 .... The Merriman Model’

or pain relief. Using Uganda as a pilot, she rolled out the model to health services in several other African countries, ultimately creating the affordable and accessible cancer treatment that was made available on the continent during the 1990s. In 1998, Uganda became the first nation in Africa to list palliative care as an essential clinical service. Pioneers in cost effective oral morphine solution formulations like Uganda have been inspiration to initiatives such as those in Ethiopia. Dr Merriman has made repeated visits to Ethiopia to encourage and assist the national initiative in various capacities.
The Ethiopian Pharmaceutical Share Company (EPHARM)

Pharmacy is a profession involved/can be involved at every level of drug use from drug discovery and development to the use of these drugs by the patient. Pharmacy professionals are critical in basic and applied researches during drug discovery, in pharmaceutical industries where they work as experts of formulation technology. This has been reflected by the formulation of the first oral morphine solution in Ethiopia at Pharmaceuticals Manufacturing, Sh.Co (EPHARM). EPHARM is the leading government owned company supplying the Ethiopian market with essential generic medicines. Its range of products includes tablets, capsules, syrups, vials, ampoules, ointments, and oral powders. For the most part, in countries where usage is thought to be low and bureaucracy potentially cumbersome, many pharmaceutical companies are not interested in manufacturing morphine or in obtaining a license for their formulation. It was against this background that EPHARM came forward with the interest and commitment to formulate, register and distribute it for free!! (Refer to page 1 -Ethio-Morph). Oral solution formulations are inherently more complex and challenging than solid dosage forms. This is due to the requirements of taste-masking - (bitter-taste), flavoring and preservation as oral solutions are multi-use products. The management of EPHARM has indicated that the production of drugs such as will oral morphine syrup will considered under the category of social responsibility drugs without any profit considerations. Central manufacturing has also an added advantage in terms of standardization.

Institute of Palliative Medicine — WHOCC

Institute of Palliative Medicine, Kozhikode, INDIA has been designated as a WHO Collaborating Centre (WHOCC) for Community Participation in Palliative Care and Long Term Care. A WHOCC is an institution designated by the Director-General of the WHO to form part of an international collaborative network carrying out activities in support of the WHO’s program at all levels. WHOCC in Kozhikode India is the first one to be based in the developing world. This designation is especially relevant to the national initiative in prompting PC and pain management in Ethiopia. An Ethiopian delegation of 4 attended the 2nd NNPC Conference on (January 2009). In April 2009 a team from University of California – San Diego conducted a study tour. Dr Anil Kumar Paleri. Dr. K. Suresh Kumar—Director, Institute of Palliative Medicine and Dr Cherian M Koshy (Left to right to R ) were recruited from a pool of train-
Development of Palliative Care Philosophy

"We have to concern ourselves with the quality of life as well as its length."

Dame Cicely Saunders (June 22, 1918–July 14, 2005) founded the modern hospice and started a worldwide movement to provide compassionate care for the dying. A nurse, social worker and doctor, she established new methods of pain control and a multi-faceted, holistic approach to care giving. This led to the development of a new medical specialty, palliative care, and the contemporary hospice. Her belief that dying is a phenomenon "as natural as being born," was at the heart of a philosophy that sees death as a process that should be life-affirming and free of pain. Dame Cicely saw dying as an opportunity to say "thank you" and "sorry" to family and friends. One of her legacies is the change in pain management. Saunders’ questioned practitioners’ fear that their dying patients would become addicted to medications. Rather than respond to pain with intermittent sedation, Saunders’ novel method of pain control provided a steady state in which a dying patient could remain conscious and maintain a good quality of life. Moving beyond physical pain, one of her lasting contributions to health care was her concept of “total pain.” This included physical, emotional, social, and spiritual elements. She focused on caring for the whole person and enfolding their family and friends within that care. This led to the development of a new medical specialty, palliative care.

Articulating Palliative Care

Multidisciplinary Professionals and stakeholders deliberating the concept and philosophy of Palliative Care

Recommended Minimum Drugs required for Pain Management & Palliative Care

A national list of basic PC Drugs is necessary to implement effective pain management and PC services has been drafted. The list was drawn from the IAHPC List of Essential Medicines for Palliative Care (PC), 2004; the List of World Health Organization Essential Medicines (15th edition, March 2007); and Palliative Medicine, Pain, and symptom control in the cancer and HIV/AIDS patient in Uganda and other African countries, 2006. Panel of Physicians from referral hospitals in Addis Ababa and trainers at the Basic pain course in essentials of pain management (July 20-26, 2009). This was submitted to government for review.
The African Palliative Care Association (APCA) was founded in 2003 to help support and promote the development of palliative care and palliative care professionals throughout Africa. APCA is committed to increasing availability of palliative care drugs for all in need, promoting training programmes, and standard guidelines for palliative treatment throughout Africa, and working with governments to mainstream appropriate palliative care into each country’s health services. Also integral to APCA’s work, is its efforts to establish networks of palliative care associations. It encourages and supports the establishment of National Palliative Care Associations in all African countries, and assists organizations to share best practices and training methods. As Ethiopia moves towards the establishment of a national grassroots association - the Pain and PC Society-Ethiopia - the support and guidance of APCA will be indispensable.

As part of the initiative to scale up PC services in Ethiopia UCSD-E has established a small PC Resource Unit. These include books, publications, journals, audiovisuals, brochures, articles, policy documents, training modules, manuals, PowerPoint presentations etc.

As per the formulation, quality assurance, distribution, storage and control. The initiative will be sustained by government, a partnership of PFSA and EPHARM. EPHARM was awarded a Certificate of acknowledgement & appreciation in recognition of its outstanding contributions. Feasibility study for domestic manufacturing of normal release morphine sulphate tablets is underway. Re-starting domestic production of codeine phosphate, a 2nd step analgesic in the WHO pain management protocol is also being looked into. The widespread access to oral opioids will depend on the development of new systems, such as community or hospital-based palliative care networks.

The costs of changing national policy toward opioids is substantial in terms of cost, time, expertise, and leadership. The time expended is an opportunity cost, but it may be amortized over a long time if the effort succeeds.

Mrs. Diana Mattanovich, Country Director of UCSD-Ethiopia, expressed her deepest gratitude to the strong commitment and hard work of all involved in making oral morphine production a reality in Ethiopia. The event was organized by UCSD-E, JHU/TSEHAY, and Black Lion Hospital. This is the 4th such event celebrated in Ethiopia.

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set up. Careful planning and forecasting will be needed to ensure sufficient supplies are always available and also that stock does not expire.

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We take this New Year opportunity, to thank all the volunteers for their continued enthusiastic support in relation to past and present issues and for the many helpful suggestions.

The NL will make all efforts to track, vet, and disseminate information and research findings related to PC and pain management initiative and activities in national and other resource constraint settings as they become available.

We apologize for the delay of this issue. It is not bilingual due to time and technical constraints. Articles to contribute, especially in Amharic are not only most welcome but much needed.

Please share or send this NL to friends and colleagues who care as much as you do about the suffering people are facing in Ethiopia. Until our next issue which we hope will be soon ..........

Have a happy, healthy, productive and peaceful New Year and we invite you to join us in the establishment of the "Pain & Palliative Care Society – Ethiopia" in the coming year........only together can we make this vision a reality!!

Contact us @ advpalliativecare_eth@yahoo.com
or
(00251-1 554444 Ext. UCSD-E Palliative Care Program or Dr Dagnachew Haile Mariam— Tikur Anbessa Specialized Hospital Pain & Palliative Care Society- Ethiopia-Interim coordinator

"Suffering is by no means a privilege, a sign of nobility, a reminder of God. Suffering is a fierce, bestial thing, commonplace, uncalled for, natural as air. It is intangible; no one can grasp it or fight against it; it dwells in time – is the same thing as time; if it comes in fits and starts, that is only so as to leave the sufferer more defenseless during the moments that follow, those long moments when one relives the last bout of torture and waits for the next."

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