PALLIATIVE CARE ASSOCIATION OF MALAWI

Quantifying morphine use in Malawi – averting a further national crisis

PI 1 : Mercy Pindani: Kamuzu College of Nursing, University of Malawi, Lilongwe Campus, P/Bag 1, Lilongwe, Malawi.

PI 2 : Kathryn Hamling: NdiMoyo Palliative Care, PO Box 84, Salima, Malawi

CO-PIs: Lameck Thambo: Palliative Care Association of Malawi.
Jane Tauzie: Palliative Care Association of Malawi.
Glenda Winga: Palliative Care Association of Malawi.
Suave Gombwa: St Gabriel Hospital, Private Bag 1, Lilongwe. Malawi.
Catherine Chiwaula: Ministry of Health (Nursing Directorate), Box 30377 Lilongwe, Malawi
Chilenje Chipala: Pharmacy, Medicines, and Poisons Board

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

ART/ARV	:	Antiretroviral Therapy/Drugs
CHAM	:	Christian Health Association of Malawi
CMS	:	Central Medical Stores
DHO	:	District Health Officer
INCB	:	International Narcotics Control Board
MOH	:	Ministry of Health
MCM	:	Medical Council of Malawi
NGO	:	Non Governmental Organizations
PI	:	Principal Investigator
PMPB	:	Pharmacy Medicines Poisons Board
WHO	:	World Health Organization

Quantifying morphine use in Malawi – averting a further national crisis

Abstract:

Although pain amongst those living with HIV/AIDS and other life-limiting diseases can be effectively managed, the availability of opioids remains a particular challenge in Malawi. This study set out to identify current drug availability, use of morphine/morphine products throughout Malawi and examine potential barriers to their accessibility and prescribing. This will help inform the quota for opioid import and so help prevent repeated national morphine stock-outs.

Background and introduction:

Palliative care is advocated by the World Health Organization (WHO 2013) for the 22.4 million people in sub-Saharan Africa who live with HIV infection, the 1.4 million of those who die annually and the 542,000 patients who die of cancer annually (Selman et al 2011; Harding et al 2011). In Malawi, out of a total population of approximately 13.5 million, 12% of 15-49 year olds are infected with HIV and an estimated 61,000 deaths are attributed to AIDS annually (MoH 2008). The WHO analgesic ladder, initially developed in 1986, advocates the use of morphine as the analgesic of choice for severe pain in cancer and has been recommended in the management of pain in other conditions such as HIV/AIDS (Huang 2013). The Malawian Ministry of Health has incorporated this guideline into its management of HIV-related diseases since 2004.

International health and drug regulatory authorities acknowledge that analgesics (especially opioids) are insufficiently available for pain management in many countries (International Narcotics Control Board (INCB) 2008). In 2006, the vast majority of morphine was consumed in industrialized countries;in Africa, the regional mean was only 0.33 mg per person/year compared with the global mean of 5.98 mg. WHO estimates that each year 5·5 million patients with terminal cancer and 1 million with end-stage HIV/AIDS die without access to adequate pain treatment (Wakeham et al 2010). Although advances have been made pursuing this inequality in Africa, access to opioids remains problematic.

Common factors hampering opioid availability include supply and legislation.Central Medical Stores were reported as not stocking adequately, having unreliable stocks and insufficient numbers of dispensers.Punitive and prohibitive regulations, lack of national policies on opioid use and poor educationhave hampered the appropriate use of opioid drugs.Other practical issues such as storage requirements and not enough prescribers have also impacted negatively on the availability and accessibility of morphine (Powell etal2010, Bates et al 2008; Harding et al 2007).

Since 2004 morphine sulphate tablets (MST, a modified release formulation) were made available to centres providing anti-retroviral therapy through the Global Fund but due to inadequate reporting to the INCB, ongoing stock provision failed in 2006. Although the situation has now improved, imported morphine products via this fund are still not being distributed to palliative care centres not attached to ART clinics.Oral morphine solution, made in-country initially by Lighthouse Trust in Lilongwe, then more recently by Central Medical Stores, using imported morphine powder, is available to the small number of palliative care centres/clinics throughout Malawi but this too has been subject to stock-outs.Poor regulation, planning and reporting have at timesled to the import quota ceiling being breached. Reporting has now improved, led by the Pharmacy, Medicines and Poisons Board (PMPB), but stock outs are still occurring; the most recent being in July 2013. Palliative care centres and clinics are considered to be the highest users of morphine in the control of both pain and breathlessness in advanced disease so are often the areas where stock-outs have the most impact.

Whilst strides are being made to address many of these factors such as education and raising awareness of the benefits of palliative care under the leadership of the African Palliative Care Association, the Palliative Care Association of Malawi (PACAM) and the Ministry of Health (MoH) in Malawi, little is currently known about the actual annual use of morphine.This makes it difficult to plan and address needs and,consequently, impossible to prevent stock outs of morphine in the country. It is evident that work needs to be done to quantify when and where morphine products are being stored and used to improve equitable

access to this essential medicine for those most in need.

Literature Review

A literature search utilizing CINHAL,MEDLINE, and Embase databases was carried out using key words 'Opioids/morphine, Palliative Care, Sub-Saharan Africa, accessibility, challenges/barriers', looking at key publications from 2000-2013, written in English. Theresults of the search identified that there is a growing body of literature focusing on the burden of palliative care needs in Sub-Saharan Africa and noted similar problems in accessing adequate analgesia in relation to need.

Morphine regulations

Much of the literature focuses on the global inequality of access to opioid analgesics. Liberman et al (2010) comment that in 2008 13% of the world population consumed more than 90% of the morphine consumed globally. The study cites that the INCB, which oversees the controlled use of morphine, has focused more heavily on preventing its misuse than on ensuring its availability. Amon et al (2009) suggest this fact alone has added to the 'fear element' of prescribing in many instances, a point also noted in studies by Logie & Harding (2005), Harding et al (2007), and Bates et al (2008).

There was a recurring theme of problems in opioid availability and accessibilityacross the African continent throughout the literature review. Logie & Harding (2005) list supply blockages in Uganda at various points in the regulatory framework including lack of capacity in Central Medical Stores, morphine for NGO/mission hospitals needing to be obtained via District Hospital pharmacy (therefore depending on the cooperation of the pharmacist/dispenser), and inadequate storage facilities at local health centres. The regulations dictate that morphine must be double locked in a secure cupboard attached to the wall. Pharmacy rooms were often inadequately sized or cupboards too small. Harding et al (2010) detailed the challenges in purchasing opioids as overwhelming cost, scarcity of opioids, single source of supply, unreliable supply, and too many

restrictions. They further summarized production challenges as government embargos making it hard to produce and source enough with a potentially expanding patient base, and lack of pharmacists. Jagwe & Merrimen (2007) comment that drug availability, is one of the main hindrances to the rolling out of palliative care services, for which access to morphine is seen to be essential. However, Uganda has demonstrated how easily morphine powder can be purchased, reconstituted and delivered when led by Hospice Africa Uganda (Merrimen 2006). With regard to drug availability, particularly opioids, APCA is currentlyworking alongside six East and Central African countries to remove governmental policy impediments that render opioids inaccessible. Participating countries, including Malawi, have reported significant movement on appropriate drug availability for pain management.

Underuse of morphine

Logie & Harding (2005) point out that although morphine can be used safely and effectively with antiretroviral drugs (ARVs), chemotherapy and traditional medicines; it is underused largely due to professional fears which included fear of respiratory depression and addiction. The study in Malawi in 2008 by Bates et al., concurs with this. Harding et al (2010) again detailed dispensing and prescribing issues as heavy restrictions in progressing palliative care in their study covering 12 African countries. They cite a lack of pharmacists, too many professionals not knowing how to prescribe, a lack of education, a lack of staff in rural areas, and gross under use largely due to fears and myths, both on the part of practitioners and patients. The slow development of hospice and palliative care organizations is clearly reflected in the low level of opioid use across the continent (Clark et al 2007). The key to this issue lies in the education of health professionals with training introduced both within national curriculum for Nursing and Medical training, alongside a rolling palliative care education programme designed for those practitioners in the field (Jagwe & Merrimen 2007).

Access and availability of morphine

Althoughstill limited, efforts are being made to ensure palliative care is being delivered in a range of settings, and rolled out for greater coverage, but opioid accessibility is key. All integrated services should be able to offer care for those with advanced disease e.g. advanced HIV and cancer, including access to opioids where appropriate. The prescribing of morphine has recently been reviewed by the Ministry of Health and PACAM, and it has been informally agreed this can now be done by clinicians and nurses trained in Palliative Care following Hospice Africa Uganda's lead. To date however the Malawi Council of Nurses has not legislated for this change, leaving nurses unclear of their roles within a specialty where they continue to be the key care providers. Working in partnership with the Ministry of Health, PACAM has introduced a five-day course for health care workers, which more than 500 individuals have now completed.The course includes modules on pain assessment and the safe and appropriate use of morphine in its management (Bates et al 2008). Palliative care is a relatively new approach to the care of those with advanced disease in Malawi but it is a growing one. Morphine use will increase alongside this, so if the growing needs in Malawi are to be addressed it will be necessary to harmonize morphine availability in the system to achieve wider impact on those with palliative care needs (Clark et al 2007).

The aim of this study is to provide an evidence base of opioid availability and accessibility across Malawi and its use in palliating those with advanced disease. It is hoped that providing a clearer more realistic quota will be the first step in encouraging expansion of palliative care services in which supply and needs are better matched.

Objectives

Overall Aim

To review the procurement, supply and use of morphine in Malawi to help inform authorities in the setting of realistic quotas for the import of morphine/morphine products.

Specific Objectives

1. To review the supply of morphine/morphine products to Central, District and CHAM Hospitals, Health Centres and Palliative Care Clinics throughout Malawi.

2. To review the prescribing and use of morphine/morphine products in Central, District and CHAM Hospitals, Health Centres and Palliative Care Clinics throughout Malawi.

METHODOLOGY

Study design

The study employedboth a quantitative and a qualitative approach.The quantitative approach was utilized to gather information on the actual quota of opioid import, the regulations governing this,and to quantify where morphine products were procured and usedthroughout the country.Qualitative research is a systematic, subjective approach used to describe and promote understanding of life experiences and situations, and give them meaning (Burns & Grove, 2011). This method was chosen because it enabled the exploration of participants' experiences concerning morphine use with further abstraction and interpretation by the researchers based on researchers' theoretical and personal knowledge.

Study setting

This study took place in Central, District and CHAM Hospitals, Health Centres and Palliative Care Clinics throughout Malawi,sites where either liquid or Morphine tablets are used in a palliative care setting.

Study population

The target population for this study were clinicians (doctors, clinical officers, nurses and pharmacists)from the hospitals and palliative care sites where morphine is procured, dispensed, prescribed and used. It was estimated that there were twenty eight (28) district hospitals, four (4) central hospitals, nine (9) CHAM hospitals, seven (7) Non Governmental hospitals and twenty (20) Palliative care sites that stock and use morphine in Malawi (PACAM 2013).

Information on the study was provided in advance to all sites and those who agreed to participate signed the prepared consent form (Appendix A & B).

Sample Size

According to Sandelowski (1986) in Laverty (2003)the number of participants necessary for qualitative studies varies depending on the nature of the study and the data collected along the way. DeGagne & Walter, (2010)state that a sample size of 12 may be big enough to derive significant outcomes for a study. In this study, purposive sampling technique was used to select a qualitative sample offour hospitals and sixpalliative care sites where a focus group discussion per site was conducted comprising of 6-10 health professionals. Three in-depth interviews were held with personnel from each of the regulatory bodies (MCM, PMPB & CMST). Random sampling technique was used to obtain twenty-four sites for quantitative data collection.

Inclusion criteria

- Health professionals that had an experience and training in managing patients with pain using morphine.
- Health professionals who are willing to participate in the study

Ethical Approval

The study proposal gained ethical approval fromthe Health Sciences Research Committee of Malawi.

Data collection

Quantitative data was collected from the 4 Central Hospitals in Malawi(Queen Elizabeth, Zomba, Kamuzu, and Mzuzu); 13 District Hospitals, 5 Mission hospitals and 2 independent (NGO) palliative care sites using the designed questionnaire (Appendix...). This allowed measurement of the procurement and use of morphine products across the selected sample of palliative care providers in Malawi, 2009-2013.Individual in-depth interviews were held with personnel within The Medical Council for Malawi (MCM), The Pharmacy, Medicine and

Poisons Board (PMPB) and Central Medical Stores Trust (CMST). These interviews were guided by the questionnaire (Appendix C, D, E) whilst open questions allowed further probing of challenging areas. Extensive notes were recorded during these interviews and the information collated allowed a deeper understanding of issues within the country in the ordering process, and reporting to the International Narcotics Board allowing quotas to be set.An interview guide (Appendix F) also helped direct focus group discussion at the 4 Central Hospitals, and 6 palliative care sites – 4 Mission (CHAM) Hospitals and 2 independent (NGO) sites. The guide was developed and administered in English although use of local languages was allowed to help participants express their real experiences if required. The focus group discussions allowed collection of qualitative data, which helped validate some of the quantitative data.All focus group discussions were recorded using a digital recorder, whilst field notes and reflective journals were utilised in recording observations and personal feelings. Within each region (Northern, Central and Southern) a team of three from the research group undertook the qualitative data collection. Each team concurrently analysed the responses, which helped inform the next day's discussion with topics to potentially explore. On completion of the data collection in all three regions, all materials were collected centrally. The taped interviews were transcribed verbatim.

Data analysis

Strauss and Corbin (1998) state that data analysis is the process of breaking down, examining, comparing, conceptualising and categorising data (as cited in Schmidt & Brown, 2012 p 341). Descriptive statistics were computed for the demographic variables and the qualitative data wasanalysed based on the phenomenological method adapted from Colaizzi (1978) cited by Parahoo (2006):-

- The transcripts were read alongside extensive field notes in order to gain an overall view and feeling of the subject in discussion
- Significant statements were extracted and listed
- Formulated meanings were agreed and extracted

- Formulated meanings were clustered into themes
- The themes were validated and cross-checked

Both quantitative and qualitative data analysis was carried out by two of the team (KH/GW), which helped to sort, decipher and interpret the responses. Rigour in the process was ensured by meeting with the research team to discuss the recorded findings and add clarity to some of the issues raised about the interpretation of the recorded scripts, especially where language challenges added a different slant on potential meaning.

Klapowitz (2000) noted in his study that individual interviews were 'more likely to raise socially sensitive discussion topics than focus groups' but in this project it was considered that all respondents/participants were keen to give information and support each other when discussion turned to challenges faced in the ordering, procuring, delivery and use of morphine.This is supported in the common themes which emerged. These themes were coded and then listed to help add detail to the phenomenon and are described in the narrative below. Quantitative data was collated on spread-sheets and information cross-checked where both types of data collection took place on the same site. Quantitative date is described in the narrative below and added clarity given with the use of graphs and tables.

Results

Pharmacy, Medicine and Poisons Board

The in-depth interview with PMPB informed on the regulations around importing narcotics, the licensing of these products and highlighted the issues of limited resources in terms of reviewing and reporting. Those licensed to prescribe morphine were listed as trained pharmacists and doctors registered with the Medical Council of Malawi (MCM).It was noted that only two district hospitals have registered pharmacists (others reliedwholly on Pharmacy Technicians), whilsta number of districts are also without medical doctors. It was highlighted that reporting on morphine use is not well done across many sites, especially government led facilities. The Board also has a role in monitoring and regulating

use of morphine in all health facilities.However, resources do not allow for individual visits to establishments and there is a reliance on obtaining information by phone or email, reducing the accuracy of monitoring and potentially increasing the incidence of abuse.

Quotas for the country are set by the INCB who monitor a country's use. As demand increases, the country is 'red flagged' and a check is undertaken. Malawi has had an annual increase in its quota which is believed to be an indicator of the spread of palliative care in the country. This quota has risen from 10kg in 2009/10 to 25kg in 2012/13 but maintaining this is reliant on the receipt of quarterly consumption reports following which authorisation is given for the import licence. Currently CMST is the only facility licensed to reconstitute morphine. Although the import of donated morphine products is included in the country's quota, these products are not always available to those who use most morphine i.e. the independent palliative care centres, as they do not feature on the distribution list of the antiretroviral services.

Challenges to the system included PMPB being too small a department to cope with the monitoring of the consumption of morphine. Estimates received did not always match consumption, making reporting to the International Board difficult andmaking the time lapse betweenidentified need to actual increased quotas unacceptable, so increasing the risk of national morphine stock outs.

Central Medical Stores Trust

Data from CMST was collected through in-depth interview with the Quality Assurance manager. He confirmed that the role of CMST was to procure morphine powder and produce, store and distribute strong and weak morphine solution throughout the country. The amount procured by CMST has risen steadily since 2010 from 1kg to 7.98kg in 2013, all of which was procured from a supplier in the United Kingdom (UK). It was stated that a maximum of 8 weeks was expected between ordering and receiving stock. Complete stock-outs of morphine powder were recorded in 2009, 2011 and 2013.

Challenges noted included delays in the process due to processing through PMPB, lack of sufficient human resources in the reconstitution and delivery processes, and fluctuating ordering patterns when donated morphine was available free of charge in the country making planning and reconstitution difficult to estimate and resulting in some stock not being collected within the 'use-by' dates.

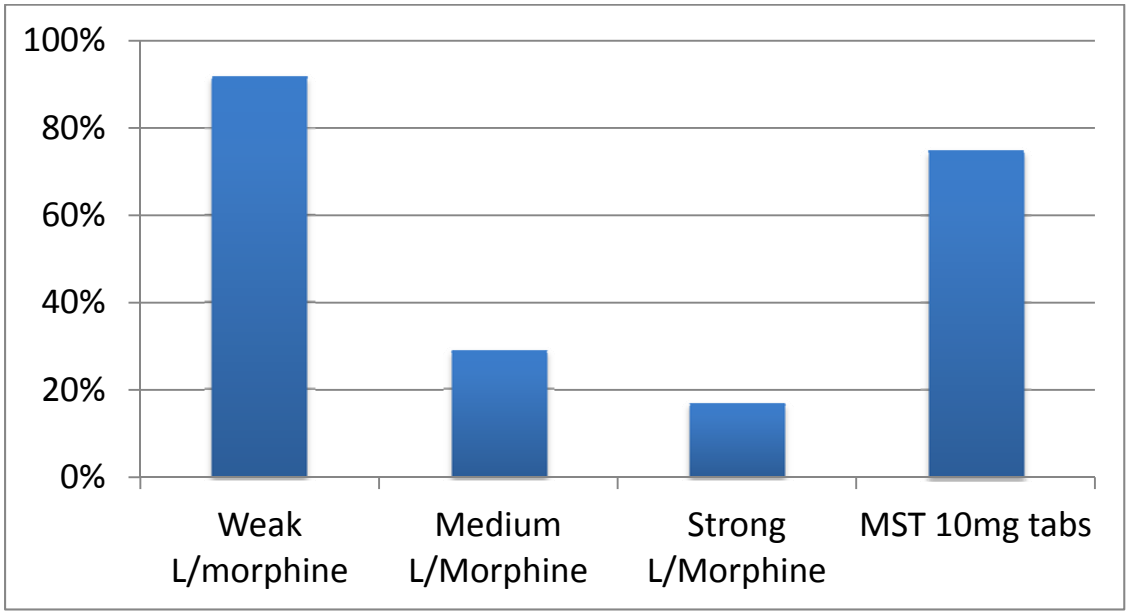
Medical Council of Malawi

The in-depth interview held with the Assistant Registrar of the MCM clarified the role the Medical Council played regarding morphine use in Malawi. The Council ensures the medical prescribers of all drugs, including opiates, are taught during their generic medical training; a curriculum vetted by MCM. In the previous 5 years 371 Medical Doctors, 481 Clinical Officers and 31 Surgeons had been registered by Council as practitioners in Malawi. There are no rules governing up-dating prescribing practice as that was generally done 'on the job', but there was an acknowledgement that further training could be beneficial for all medical staff. It was noted that in the previous ten years approximately 10 medical professionals had been reported regarding misuse of morphine and been disciplined, treated and/or suspended.

Quantitative Data results

In total twenty-four (24) hospitals and palliative care sites were visited and quantitative data collected regarding morphine products procured, prescribed and dispensed within the hospital. The majority of the responders to the quantitative questionnaire were pharmacist technicians (n=16) or pharmacy nurses (n=8). All (n=24) included morphine in their usual drug stock at the time of the visits, and only one admitted to being out of stock at that time. Four different types of morphine were recorded as stocked with the majority, 92% (n=22) stocking weak liquid morphine (5mg/5mls), whilst 17% (n=4) stocked strong

morphine (50mg/5ml) and 75% (n=18) held Modified Release Morphine (MST 10mg) tablets (Graph 1)

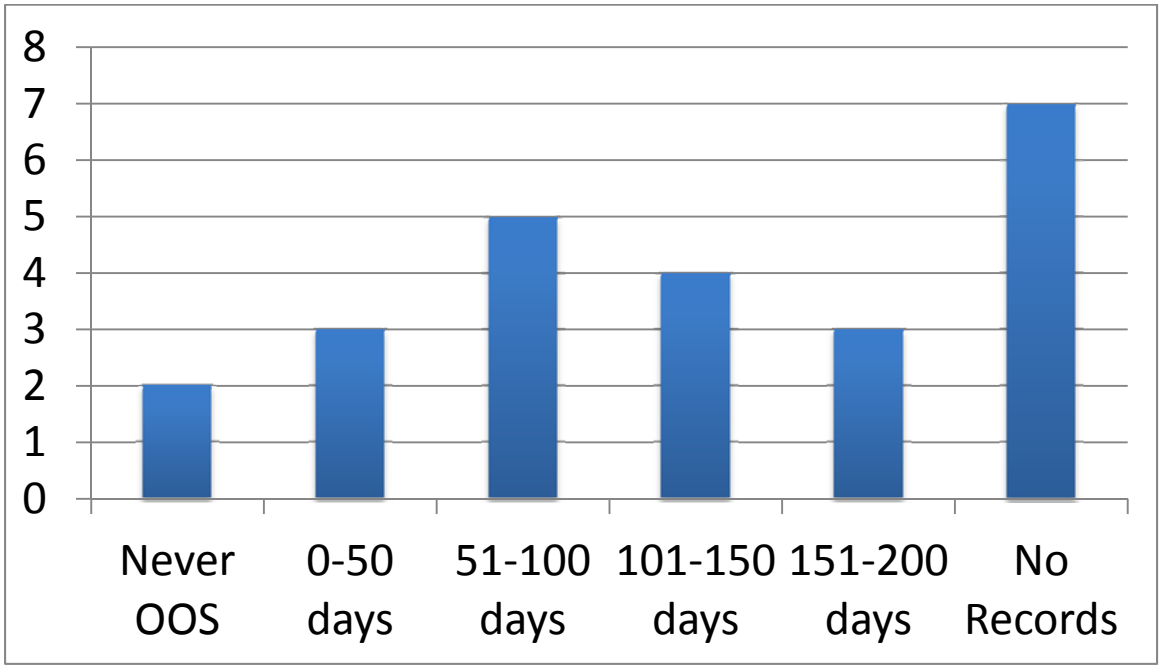


Graph 1: Morphine products stocked

Almost one third (29%) held a stock of pre-packaged morphine (10mg/5ml) strength, a donated form of morphine which is included in the Global fund ante-retroviral supplies and is therefore generally only accessible to hospitals which run an ART service, and not independent palliative care services. Of those respondents who held records, the average monthly use of morphine reported was weak, 29 litres; strong, 1 litre; MST 1050 tablets; and 2 litres of the 10mg/5ml strength.

Poor record keeping and/or limited access to archived records made some of the data collection difficult. Few of those questioned knew how long their health facility had stocked morphine, and even fewer had an understanding of the minimum stock level maintained by that establishment. Only two centres had never been stocked out of morphine in the last five years. Two hospitals had no records and could not respond but of the other respondents (n=20) all reported product stock outs were an annual event they had come to expect and accept.

The average number of days stocked out was 68 days/year but the range was 39-180 days/year.



Graph 2: Days whenmorphine was out of stock(OOS) in 2013 at participating centres

The respondents confirmed that all units questioned received their liquid morphine supplies from Central Medical Stores Trust (CMST), with eleven facilities (47%) also getting their MST supplies from the HIV Unit. Four facilities reported getting their morphine supplies at times from Lighthouse, Tiyanjane, or Ndi Moyo (specialist HIV and/or Palliative Care Centres) especially when CMST were slow in delivery times, or there was no morphine available at the time. This could at times cause pressure on the provider units who were keen to ensure no one was in pain but who then felt vulnerable with their own supplies. One site reported purchasing morphine supplies via a private pharmacy.

Responsibility for ordering morphine in the majority of cases (97%) was that of the pharmacist/senior pharmacist technician. The palliative care co-ordinator appeared to have the main non-pharmacy role in monitoring stocks and raising the need for the order. Again pharmacy technicians and nurses did the majority of the dispensing alongside, when available, the Clinical Officers. In all units

prescribing morphine was carried out by a Clinical Officer although in 65% of the facilities, nurses who had extra training in Palliative Care also prescribed, and one facility reported that Medical Assistants, where overseen by a Medical Doctor, could also prescribe. Where there was a medical doctor present, 27%of sites questioned, they too prescribed, but where a palliative care service was available within the establishment, they often deferred prescribing issues to the palliative care team.

All facilities, except one, stated that they maintained a morphine register although not all registers were available for checking.

Qualitative Data from focus groups

Focus group discussions were held out at ten sites throughout the country – 4 Central Hospitals, 4 CHAM Hospitals and 2 NGO organisations, where there were established palliative care services running. Participants were Clinical Officers, Palliative Care Nurses, and where available (Central Hospitals), Medical Doctors. Discussion was led by the devised guide (Appendix F) but open discussion was encouraged to explore the issues and challenges faced in procuring, prescribing and using morphine. Three themes emerged from the data - Challenges involving ordering, delivery & storage; Knowledge and skills needed for prescribing morphine; Perceived challenges in treatment effectiveness. Quotes from the discussions are added where appropriate to illustrate the points in discussion.

Challenges involving ordering, delivery and storage

There appeared to be no clear pathway involved in ordering morphine for the individual hospitals and at times the process was complex, involving up to 3-4 different people, and therefore lengthy given the time to chase this up. For the independent palliative care centres, ordering had to be done via the nearest District or Central hospital where morphine was not always stocked and appeared not to warrant priority. Time from raising a requisition request to getting one signed could take up to four weeks if the people involved were busy or away.

In the palliative care clinics within Central hospitals or attached to a District Hospital, the process was more straight forward but often this process was only started when the morphine stock was low and delays often resulted in periods of stock out. In hospitals that stocked a supply of morphine tablets, information on their use appeared to be collated by the ART departments and there was an automatic top up procedure, but not all palliative care clinics had access to these.

Problems with procurement were reported to have increased since Central Medical Stores became a trust. It was felt the process has slowed considerably with late deliveries and short use-by dating adding to the challenges. Questions were raised by many as to why only CMST in the Southern region were the only centre for reconstitution of morphine powder to liquid.

"...there were fewer problems I think before CMS became a Trust...still stock outs...but fewer issues getting the supplies here. Now we have to wait for a van coming from Blantyre..." (FGD 1)

"..it was better when (Morphine) was made at Lighthouse...for this area anyway...we knew the people involved better..." (FGD 5)

Issues around the 'use-by' dating system was highlighted in a number of the focus groups especially around recent decisions to increase the date by three months to six months from reconstitution. Although all providers had been informed the changing of labels on already delivered stock made some feel unsure about using what should have been out-dated stock.

"… the morphine they had was labelled expired in January but then they were told to use it until April but not told why…" (FGD 2)

Challenges lay in some provider clinics in having sufficient space to store the morphine as it is required (a locked cupboard within a locked cupboard) and some clinics admitted to failing to comply with this legislation.

Knowledge and skills needed for prescribing morphine

Although the majority of those taking part in the discussions felt confident in prescribing, much of which was attributed to improved training on palliative care, issues remain with those who do not work in palliative care full time or are infrequent prescribers.

"...I have no fear now of using morphine although before working here I might have had. We use it every day and it is good to see how much it can help with some ofour patients. That is why we worry so much when stocks are low or there is a crisis...not for here but for others elsewhere..." (FGD 6)

Despite training many stated they still felt unsure of when to initiate morphine and there was still an underlying fear of encouraging addiction despite the fact that only one group reported any knowledge of abuse of morphine amongst patients and/or staff over the preceding five years. Hastening death by suppression of the respiratory system was also noted as a fear in prescribing.

"...I did my course three years ago and hardly used morphine for a long time so it took a while to feel I would not kill someone if I give them the morphine..." (FGD 9)

"...I still prefer my colleague with me before I give morphine...I don't want to be accused by the family of killing someone" (FGD 7)

"...I am still a little concerned...just because I do not have much experience. I know that morphine can be addictive and can cause breathing to stop...I feel fear at times and unsure about using...some of my colleagues are better at it..." (FGD 10)

It remains unclear in some establishments as to who can prescribe morphine. Some units thought only Clinical Officers or Medical doctors could prescribe

whilst others thought nurses who had undertaken training in palliative care were able to prescribe, although what level of palliative care training was also unclear/unknown. Many expressed the thought that palliative care nurses were often more knowledgeable about morphine prescribing and use so felt negative if they had to wait for a Clinical Officer to be available who often did not know the patient and who's knowledge of prescribing was lesser.

"*…what do you do when there is no Clinical Officer and yet a patient is there with a (pain) score of 3/5 and above and a nurse with palliative care training?..." (FGD 4)*

Frequent errors such as prescribing MST once daily, incorrect conversion of doses when the product being prescribed changed e.g. weak to strong morphine or in the use of the pre-packaged medium strength morphine of 10mg/5mls, were reported to have occurred. During the last national stock out period a consignment of the medium-strength (10mg/5mls) morphine, pre-packaged in 100ml bottles was sourced via the HIV Unit. This eventually became available to all palliative care provider sites but many professionals felt there was no orientation in using the new strength and their ability to convert from weak liquid morphine normally used was limited and cases of over and under-dosing were reported.

"…*2mg/ml was not well orientated to prescribers…there was a need for better communication rather than just telling the 'in-charges'…" (FGD 3)*

Training issues were raised for community-based workers who often were involved in the care of patients taking morphine in the home setting. Some areas where this was in place commented that this had improved patient compliance to treatment and ability to access further supplies of needed medication.

Even in hospitals where there was an established palliative care clinic there seemed to be a lack of knowledge in other departments of this clinic. One medical doctor commented that they had not been informed of such a service.

"… I have only found out at this discussion there IS a clinic! Why is that not known…we need this information…" (FGD 1)

Perceived challenges in treatment effectiveness

A number of groups discussed challenges faced in not being able to follow up patients once discharged from hospital. There was no directory of palliative care services, which might help referral onwards in the community to which these patients were returning. As a result many patients only got an initial dose of morphine unless they were able to afford transport back to the dispensing service.

"…*patients fail to access morphine due to their transport challenges…once discharged most do not come back…" (FGD 1)*

"…only those with money go back for refill... so they ARE dying in pain" (FGD 9)

In hospitals where prescriptions were written in the palliative care clinic but collected at the main hospital pharmacy, concern was raised that patients were turned away when the drug was out of stock but no one was informed and patients were not advised to return to get an alternative prescription from the clinic, so went home without the necessary medication.

During the long periods of national stock out (most years) clinics accepted that no morphine was available and there was limited networking to see if other units could help. Those units who had done this were the ones where no or minimal stock out periods occurred. During these periods, in many units, patients were in severe pain which nurses found distressing but helpless to change. This was

also the case when patients were discharged with no referral on to other palliative care providers for follow up treatment.

"….it is very hard as a nurse when you know what should be given and you have to say to the patient we are out of stock…come back next week … and they do and still there is nothing…" (FGD 8)

Many providers also complained that they often experienced difficulties in accessing other medication especially laxatives which are recommended to be co-prescribed with morphine. Again it was considered that CMST were responsible for stock-outs of these drugs.

"*…you cannot prescribe morphine without Bisacodyl so BOTH have to be available but Bisacodyl often is not…" (FGD 6)*

Despite all the challenges faced the over-riding note gained from the collective focus group discussions was one of optimism that things were slowly improving and for each difficult case described their were many very positive stories shared.

"…this place used to have terrible difficulties having morphine and we felt no one cared. Now, we have six nurses who have done the course although not all use the knowledge…but at least now our patients have some chance and we are working hard at making sure this carries on…" (FGD 2)

"…having placements in other places makes you see what can be done. I have been to Ndi Moyo and Tiyanjane and see the difference they make and I know that we should be able to do that here too…" (FGD 4)

Discussion

This study looked at a sample of all hospitals, government and private, and independent palliative care providers to identify current availability and use of

morphine throughout Malawi. With repeated efforts by PACAM working collaboratively through the Ministry of Health, and with the support of APCA, in running palliative care introduction courses, palliative care is seen to be a growing area of interest in Malawi.In practice many gaps remain, not least the disharmony between supply and demand for the essential medicines, particularly morphine. This study demonstrated that there is a growing awareness of the need for morphine and there is a growing confidence in its use but much more work is required. Those involved in the supply chain acknowledged the challenges facing them, largely in terms of lack of resources, financial and human, but they are trying to close some of these gaps. A good supply of morphine powder is now available in the country.The INCB have increased the quota in Malawi to better match demand but there still remain challenges in reconstitution and delivery in a timely manner which needs to be addressed by both the organisation responsible and the government department which funds it. Currently reconstitution is carried out in only one area (CMST South) but it may benefit all if each region had its own centre, reducing transport costs and availability, but quality assurance would need to be managed and overseen.

Although there are still myths and fears surrounding the use of morphine, with extended training and more frequent use, these seem to be reducing and most of those who were questioned stated they were increasingly confident in this process. However the groups involved in the discussion groups came from well established palliative care units and may not reflect the experience of practitioners working in less specialised areas. Access to morphine was improved by having close proximity to the Central or District hospitals, especially where a good relationship existed between the procurers and those who needed to sign the requisition requests. The mission hospitals and independent palliative care units had more challenges in this and often were at the mercy of the personalities or whims of the signatories needed. Overall, it was felt a universal system of procurement needed to be agreed, where established palliative care providers could order directly from CMST. Uncertainty still exists regarding the supply of morphine products via the Global Fund and its availability, distribution

and proper use by non-palliative care trained providers. The feeling was expressed that a new distribution list needed to be drawn up by the HIV Unit to ensure palliative care services not linked to ART clinics could have equal access to Global Fund donationsas MST was too expensive to purchase privately via the commercial pharmacies.It was also noted that the use of morphine products by some ART clinicians, not experienced in palliative care, needed more close monitoring.

Collection of data at times was difficult due to inadequate records of morphine supplies and use. Few units held the MoH “Dangerous Drugs Register” and in some palliative care clinics, although the quantities of morphine dispensed were recorded, no note was made of the individual to whom it was actually dispensed.

Confusion remains as to who is ‘legally’ allowed to prescribe morphine. Although there has been an informal agreement that nurses trained in palliative care can prescribe, this has not yet been adopted by the Nurses Council in Malawi.This needs to be addressed as a matter of urgency.

It must also be encouraged that those staff who have undertaken training and are practising palliative care be allowed to remain working within that field (unless they choose otherwise) to help build core competencies especially within each government hospital palliative care department or clinic. Communication issues between the palliative care units and other departments within many of the hospitals needs to be improved to ensure equity of access for all patients in need at whatever entry point is made into the system.

It is noted that since this research project started PACAM has set up a Task Force to improve monitoring of access and availability to morphine across the country and deal with the challenges as they arise. There is now a Drug Monitoring Lead and whilst this is progress, more authority to deal with the challenges is needed. It would appear that in mid 2014, there is plenty of morphine in Malawi but as this report is being completed a number of hospitals

across the country are stocked out of the drug due to disputes/inadequacies within CMST. Further work is needed to resolve the reconstitution and distribution of liquid morphine.

Unfortunately the question which drove this research project - finding how much morphine is needed in order to avert a further national shortage - has been left largely unanswered. Quantifying the amounts individual units ordered, used and needed was difficult to determine due to the often haphazard way morphine was acquired and to a basic lack of recording. This was disappointing on many levels but has raised awareness that much work is still needed in the training and mentoring of palliative care providers, and in the support and involvement of the procurers of the product within their establishments.

Recommendations

- Tightened control on the recording of morphine procured and prescribed at local level.
- Direct ordering from CMST of morphine by CHAM hospitals and independent palliative care sites.
- Clarity in the position of nurse prescribing of opioids and the training required to allow this.
- Astudy looking at the feasibility of reconstituting powdered morphine in one centre in each of the three regions of Malawi, with overall monitoring of quality by CMST, to be carried out.
- HIV Unit to continue purchasing and supplying morphine products through the Global Fund but better consistency in terms of the supply to palliative care units not immediately linked to ART clinics.
- Improved communication between palliative care providers and the hospitals/clinics/communities they work alongside.
- Consideration by the MoH that staff trained in Palliative Care be allowed to continue working in units where their skills can be used.

- Development of a palliative care service provider register to help with follow up care of patients discharged from hospitals into their own communities.

Conclusion

Morphine is acknowledged as the analgesic of choice for severe pain in cancer and HIV/AIDS but its accessibility in many instances remains sub-optimal. This study of the availability, accessibility and use of morphine products in Malawi highlights many challenges within the current system at all stages of the process from quota setting to prescribing. If the needs of those with advanced disease are to be met there will need to be better engagement between all parties from government through the regulatory bodies and the palliative care providers to improve the procurement, reporting and prescribing of opioids. Important steps are being taken but these must be embedded in the national health system to achieve meaningful coverage of sustainable palliative care services for those most in need.

APPENDICES

APPENDIX A: PARTICIPANTS INFORMATION SHEET

STUDY TITLE: ***Quantifying morphine use in Malawi – averting a further national crisis***

You are invited to take part in a research study on Quantifying morphine use in Malawi – averting a further national crisis.Before you decide to participate in the study, it is important to understand why the research is being conducted and what will be involved. You are free to ask questions if you are not clear or else you need more information. Participation is voluntary and you can decide to stop participating in the research at any time if you feel so.

THE PURPOSE OF THE STUDY

The aim of the study is to review the procurement, supply and use of morphine in Malawi in order to help inform authorities in the setting of realistic quotas for the import of morphine and morphine products.

The findings will help to identify current drug availability and use of morphine/morphine products throughout Malawi. It will also examine potential barriers to morphine accessibility and prescribing in Malawi. Additionally, findings will enhance improvement in Palliative Care and will assist policy makers in formulation of policies as regards to use of morphine in Malawi.

PARTICIPATION IN THE STUDY

Participation in this study is voluntary. Therefore everyone is free to take part or not or to withdraw at any time they feel like even without giving reasons. Refusal to take part in the study will not affect anything. If you agree to take part you will be asked to sign a consent form. Information about you will be confidential and no one will identify who answered which questions as no names will be written on the interview guides. In addition, no names will be mentioned during the

interviews to ensure anonymity, and interview responses will be destroyed at the end of the study.

POSSIBLE RISKS FOR TAKING PART

There are no known risks associated with this study.

BENEFITS OF TAKING PART IN THE STUDY

There will be no immediate benefits to you for taking part in the study. However, findings will assist in identifying current drug availability and use of morphine/morphine products throughout Malawi thereby improving Palliative Care services in Malawi.

CONCERNS

If you have concerns, please forward your complaints to the Chairperson of National Health Sciences Research Committee. You may also contact Palliative Care Association of Malawi. In case of further information on the study, please contact Mercy Pindani on 0888 896970 or Kathryn Hamling on 0997683946.

APPENDIX B: CONSENT FORM

STUDY TITLE: Quantifying morphine use in Malawi – averting a further national crisis

READ AND SIGN THIS FORM IF YOU ARE TAKING PART IN THIS STUDY

I have read the attached information sheet for this study and have understood the purpose of the study and the problems involved. I agree to voluntarily participate in the study, be interviewed and respond to the best of my knowledge. I understand that I am free to withdraw at any time without giving reasons. My information will be kept confidentially and will only be accessed by the researcher or those people directly concerned with this study. I will not benefit financially or be given gifts in materials. I know that the study will not injuries or harm me in any way. The information that I will give to the researchers will not be used against me in future. I have been advised on whom to contact in case of any problem.

I voluntarily agree to take part

Participant's Name	Signature	Date
……	……	

Name of the interviewer	Signature	Date
……	……	

APPENDEX C: INTERVIEW GUIDE

Quantifying morphine use in Malawi – averting a further national crisis

In- depth interviews with a representative of regulatory body responsible for Morphine prescription in Malawi - **Medical Council of Malawi**.

Interview guide number…….....CODE NO. ……..

Participant's number…… Date……

Name of Facility

.....

Designation of Respondent

.....

1. What is the role of this board regarding morphine use in Malawi?

   .....

   .....

2. Who is licensed to prescribe morphine?

   .....

   .....

3. How many medical doctors, surgeons and clinical officers were registered in Malawi from 2009 to 2012 ?

   .....

4. What is the requirement for a health professional to be licenced to prescribe morphine?

   .....

5. How does the board distribute morphine to the hospitals?

   .....

6. What challenges does the board experience in regards to morphine prescription?

.....

.....

7. What would be your recommendation regarding the challenges experienced?

……

APPENDEX D: INTERVIEW GUIDE

Quantifying morphine use in Malawi – averting a further national crisis

In- depth interviews with representative(s) of **Central Medical Stores Trust** responsible for Morphine procurement and distribution in Malawi.

Interview guide number…….....CODE NO. ……...
Participant's number…… Date…….

Name of Facility
.....
Designation of Respondent
.....

1. What is the role of this board regarding morphine accessibility and availability in Malawi?
   .....
   .....
2. How much morphine has been procured for the past four year (2009 – 2012) both powder and tablets respectively?.
   .....
   .....
3. Where do you order morphine from (both powder and Tablets)?
   .....
4. How long does it take from the time you submit the order to the time you get the consignment?
   .....
   .....

5. How does the board distribute morphine to the hospitals?

   .....

   .....

6. When was morphine out of stockbetween 2009 to 2012.

   .....

   .....

7. What is the minimum stock level (in months/amount) of morphine that triggers the initiation of the procuring process?

   .....

   .....

8. How does the CMST determine/set such minimum levels?

   .....

   .....

9. How does the CMST know that the minimum level has been reached?

   .....

   .....

10. What challenges does the board experience in regards to procurement, reconstitution and distribution?

    .....

    .....

    .....

11. What would be your recommendation regarding the challenges experienced?

    .....

    .....

APPENDEX E: INTERVIEW GUIDE

Quantifying morphine use in Malawi – averting a further national crisis

In- depth interviews with representative of regulatory body responsible for Morphine Licensing and reporting in Malawi - **Pharmacy, Medicine and Poison Board**.

Interview guide number…….....CODE NO. ……..

Participant's number…… Date…….

Name of Facility

.....

Designation of Respondent

.....

1. What is the role of this board regarding morphine accessibility and availability in Malawi?

   .....

   .....

   .....

2. How much morphine has been procured for the past four year (2009 – 2012) both powder and tablets respectively?.

   .....

   .....

   .....

3. What is the requirement for a health facility to be licensed for Morphine?

   .....

   .....

4. What were the past four year's morphine estimates quota in Malawi (from 2009 – 2012) respectively

   .....

   .....

5. Who is licensed to reconstitute and dispense morphine?

   .....

   .....

6. How does the board regulate the availability of morphine and control the usage?

   .....

   .....

7. What challenges does the board experience in regards to regulating and controlling the use of morphine?

   .....

   .....

8. What would be your recommendation regarding the challenges experienced?

APPENDEX F: INTERVIEW GUIDE

Quantifying morphine use in Malawi – averting a further national crisis

Focus Group Discussion with health professionals.

Interview guide number…….....CODE NO. ……...

Participant's number…… Date…….

Name of Facility

.....

1. Does the hospital stock Oral Morphine?

2. If yes, is it available today? If no when was it last available?

3. When did the hospital start procuring morphine?

4. What forms of morphine does the hospital stock?

5. Who is responsible for ordering of morphine?

6. Where does the hospital get it's morphine from?

7. What is the ordering process?

8. Who prescribes morphine at this hospital?

9. How do you feel prescribing or administering morphine for patients?

10. At this hospital where do patients get their prescribed morphine from?

11. When was morphine out of stock in this hospital/clinic between 2009 to 2013?

12. What is the procedure for morphine ordering (to be responded by pharmacy technician)

13. Did the hospital experience any form of abuse of Morphine at any point? .

14. What are the challenges that the hospital experience with morphine procurement?

15. Do you have any question or comment regarding the subject discussed?

References

Amon J, Lohman D, Thomas L. (2009) Access to pain treatment a luxury for most. Lancet 374 (11)

Bates J, Gwther L, Dinat N. (2008)“Morphine: Friend or foe?” Malawi Medical Journal; 20(4) 112-4

Burns…, Grove,,(2011)

Colaizzi P (1978) Psychological research as the phenomenologist views it. In Valle R & Kings M (Eds) Existential Phenomenological Alternative for Psychology. Oxford University Press: New York

Clark D, Wright M, Hunt J, Lynch T. (2007) Hospice and Palliative acre Development in Africa:A multi-method review of services and experiences. Journal of Pain & Symptom Management 33(6) 698-710.

DeGagne.., Walter.. (2010)

Harding R, Powell RA, Kiyange F, Downing J, Mwangi-Powell F. (2007) Pain-relieving drugs in 12 African PEPFAR countries: Mapping current providers, identifying current challenges, and enabling expansion of pain control provision in the management of HIV/AIDS. Kampala, Uganda: African Palliative Care Association

Harding R, Selman L, Agupio G, et al.(2011) The prevalence and burden of symptoms amongst cancer patients attending palliative care in two African countries. European Journal of Cancer;47:51e56.

Huang Y (2013) Challenges and responses in providing palliative care for people living with HIV/AIDS. International Journal of Palliative Nursing 19(5) 218-225

International Narcotics Control Board. (2008) Narcotic drugs: estimated world requirements for 2008- statistics for 2006. New York: United Nations,.

Jagwe J, Merrimen A.(2007) Uganda: Delivering Analgesia in Rural Africa:Opioid

Availability and Nurse Prescribing. Journal ofPain & Symptom Management 33(5) 547-51

Klapowitz M.D. (2000) Statistical analysis of sensitive topics in group and individual interviews. Quality and Quantity 34 pp419-31

Liberman J, O'Brien M, Hall W, Hill D.(2010) Ending inequities in cancer to effective pain relief? Lancet 376 pp856-7.

Logie D, Harding R. (2005) An evaluation of a morphine public health programme for cancer and AIDS pain relief in Sub-Saharan Africa. BCM Public Health 5 (82)

Merriman A. (2006) Pain and symptom control in the cancer and/or AIDS patient in Uganda and other African countries, 4th, ed. Kampala, Uganda: Hospice Africa Uganda

Ministry of Health. (2008) ARV Guidelines, Malawi (Version 3).

Parahoo K. (2006) Nursing Research: Principles, Processes and Issues. 2nd Ed. Palgrave Macmillan

Powell R.A, Kay R.M, Ddungu H, Mwangi-Powell F. (2010) Advancing drug availability-Experiences from Africa. Journal of Pain & Symptom Management 40(1) 9-12,

Selman LE, Higginson IJ, Agupio G, et al. (2011) Quality of life among patients receiving palliative care in South Africa and Uganda: a multi-centred study. Health Quality Life Outcomes;9:21.

Strauss.. Corbin.. (1998)

Wakeham K, Harding R, Bamukama- Namakoola D, et al. (2010) Symptom burden in HIV- infected adults at time of HIV diagnosis in rural Uganda. Journal of Palliative Medicine;13:375e380.

World Health Organization (2013) Palliative Care.www.who.int/hiv/topics/palliative/palliativecare/en. Accessed Sept 2013