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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

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Rationale

1) Pain is a significant and distressing problem experienced by people living with HIV/AIDS. In order to adhere to the World Health Organisation's (WHO) pain ladder, it is essential that HIV care providers can access opioid analgesia for their patients. Although palliative care is defined by its multidimensional focus on physical, emotional and spiritual pain, the lack of access to opioids in Sub-Saharan Africa has been identified as a major challenge. This study aimed to identify current opioid prescribing services and regulatory bodies within 12 PEPFAR countries, and to describe barriers to, and potential for, expansion in the number of opioid providers, for people with HIV/AIDS.

Methods

2) A cross sectional survey questionnaire was distributed to palliative care sites in 12 countries, and a telephone interview conducted with International Narcotics Control Board (INCB) competent authorities in each. The data were analyzed and integrated to identify potential strategies for opioid expansion.

Main findings

Site configuration and activity

3) The majority of the sample (56.4%) were 'integrated' Non-Governmental Organisations (NGOs) offering a range of HIV services, including a component of palliative care. These services focused on general counseling, family/community education, food parcels/ grants/income generation, HIV prevention and testing. The palliative-only services (35.5%, e.g. hospices) stressed bereavement counseling, family support, spiritual care, professional education and advocacy.

4) All sites concurred with the WHO definition of palliative care, with no deviations or adaptations.

5) Although palliative care should be offered alongside antiretroviral therapy (ART), only 11 sites (17.7%) were ART providers, and 5 (8.1%) had no local access at all, the remaining 40 (64.5%) having nearby provider access for their patients.

6) Palliative-only services cared for significantly fewer patients per year than did the integrated NGOs and were significantly more likely to prescribe opioids to both adult and child patients while under their care.

7) Comparing palliative-only to integrated services, there was no significant difference in the number of clinical staff, nor in the proportion of staff able to prescribe opioids. However, the palliative-only services had a significantly higher proportion of clinical staff trained in palliative care.

Opioids

8) 36 sites (58.1%) were currently dispensing opioids. Less than constant supply of analgesia was reported by sites at all three levels of the WHO Pain Ladder. Seven sites reported less than constant supply of Step 1 analgesics.

9) 18 sites did not report access to an agent for the management of neuropathic pain, a common symptom of HIV disease and an ART side-effect. Again, there were breakages in the supply of antiemetics (11 sites), anxiolytics (7 sites) and neuropathic pain treatments (7 sites).

10) The common factors hampering opioid provision were: **Supply** (e.g. central stores not stocking adequately, overly tight control, unreliable stocks, few dispensers); **Legislation** (e.g. regulations, lack of national policy on opioid use, bureaucratic processes); **Education** (e.g. existing clinicians do not know how to assess and treat pain, fear of addiction, poor patient compliance, palliative care stresses its specialty to the point of exclusion, doctors lack interest in dying patients); **Practical** (e.g. costs, storage requirements, not enough prescribers, unqualified staff in home-based care, poor infrastructure to follow discharged patients home, lack of sugar for making up syrup, and short shelf-life of morphine).

11) Responses suggesting mechanisms to assist more providers to access opioids: **Advocacy** at governmental and public levels on the need for opioids, and on lifting restrictive legislation; **Collaboration** with prescribing doctors, across primary and secondary care, with hospital

pharmacies; **Training** in pain assessment and management, in all curricula, on palliative rather than supportive care, and shorter courses for prescribing; **Coverage** to rural and home-based care services.

12) The identified challenges to expansion were: **Political**, achieving motivation; political will and to support opioid use **Educational**, challenging myths, teaching that HIV requires Step 3 pain management, and achieving medical cultural change; **Resources**, time for doctors to prescribe, drug costs, storage facilities, number of pharmacists, supply breaks, building up rural services, and the number of prescribers.

13) The suggested methods to overcome the challenges included: **Education**, training for health care workers, input to medical curricula, teaching for HIV services, and the development of shorter courses; **Advocacy**, support through APCA, and government lobbying; **Organisational**, central supply of drugs and collection points to be facilitated by government, and better linkages with hospices; **Resources**, funding for drug storage facilities, increase in hospice capacity, more pharmacists, and the employment of professional staff in home-based care (HBC) organisations.

Regulation

14) There was considerable difficulty with Ministries identifying and contacting their INCB competent authorities, which suggests potential problems when addressing one of the key mechanisms for expanding opioid access, i.e. advocacy through governmental and other bureaucratic organisations.

15) In each of the five countries, the INCB competent authority cited specific opioids they believed to be available in the country that were never cited by any site in the survey provider data.

16) The majority of INCB competent authorities felt that the current regulatory procedures were working well, which contradicts the provider data.

17) All INCB competent authorities except one felt that there were currently adequate numbers of opioid prescribers in their country.

18) While there is a consensus within the palliative care movement that access to opioids should be widened, this was not reflected in the INCB data. INCB competent authorities stated doubts regarding their capacity to regulate increasing numbers of services, and questioned the competence of current prescribers.

19) The majority view among INCB competent authorities was that access could be expanded through education: increasing numbers of medically trained personnel, addressing opioid fears among existing personnel, and improving the caliber of those currently able to prescribe.

Recommendations
For sites and HIV care practitioners

1) While the presence of both specialist and integrated centers should be encouraged, it is essential that each can offer the basic service elements of the other when needed. Examples of this from our data would be expansion of bereavement care and family support in integrated services, and economic support activities in palliative-only centers. However, this expansion of core skills and service components should occur with the proviso that specialist palliative-only centers have referral criteria and capacity to offer care for more complex cases.

2) Referral networks between ART sites and palliative care services should ensure that not only are patients under palliative care referred for ART, but that mechanisms of clinical support and consultancy are offered so that ART sites can access palliative care when treatment is initiated, maintained and discontinued.

3) With the wide range of distressing and burdensome HIV and treatment-related symptoms, practitioners should remember to assess and treat the full spectrum throughout the disease trajectory including ART treatment. Also, any side-effects of opioids must be constantly monitored and controlled, and drugs made available to achieve this.

4) Where opioid access is poor, networks should be established with current hospice and governmental providers to establish routes for dispensing.

5) Rural and HBC services should consider their potential routes to palliative care drugs when arranging palliative care training for their staff, as spiritual and emotional pain cannot be optimally managed without the control of physical pain.

For educators

6) All services, whether palliative-only, integrated NGO or government facilities, must ensure that all clinical staff are trained in palliative care to a basic agreed level. This would assist staff to assess palliative care needs, to provide general palliative care, and be aware of when to make appropriate referrals for specialist input.

7) Training and education providers should form collaborative teaching activities with current clinicians. Those in practice require ongoing professional education to improve the pain control of those living with HIV, and to meet the needs of the dying.

8) Training and education providers should form collaborative teaching activities with future clinicians. The inclusion of palliative care in medical school curricula should be a goal for all countries.

9) Education must take a long-term view of the process of teaching, and mechanisms put in place to ensure follow-up to support the application of skills learned.

10) Shorter palliative care courses that focus on prescribing should be considered for current clinicians.

11) Educators need to redouble efforts to address the public fears of opioids. A potential means to achieve this may be through the existing significant global networks for HIV advocacy groups such as ICW and GNP. Currently the issues of palliative care and opioid use are not campaigning issues by advocacy groups of people living with HIV/AIDS.

12) There may be educational opportunities to work with INCB competent authorities to demonstrate the successes of opioid use and the current limitations that could be addressed. Such consultation may also offer INCB competent authorities an opportunity to share their concerns. Interactive education and sharing of viewpoints may offer better potential for feasible and acceptable strategies for opioid expansion.

For funders

13) Funders must take account of the high burden of pain and symptoms that affect quality of life and allocate resources to ensure that these manageable problems are adequately controlled.

14) Patients should have local access to antiretroviral therapy at all services that offer palliation whatever disease stage the service focuses on. Referral and co-management care pathways should be in place to ensure that even if palliative care and therapy are not available at the same site, they are co-ordinated to ensure that they can be integrated across services.

15) Currently, palliative-only services see fewer patients. While not all people living with an incurable life-limiting disease should require specialist palliative care, and not all people at the end of life should or could access hospice care, resources are required to increase the capacity of these institutions to enhance their educative, advocacy and specialist role for complex case management.

16) Funding for clinically trained staff is essential in HBC HIV sites, as opioids cannot be utilized without staff able to prescribe.

17) Funders should consider the structural requirements of sites, e.g. the essential current problems of adequate opioid storage facilities and pharmacy facilities, in addition to staff and training costs.

18) Funders should consider those analgesics beyond opioids, i.e. neuropathic pain agents, which are essential for pain that often cannot be controlled with opioids.

Executive Summary

For policy makers and regulators

19) The current opioid (and non-opioid) drug supply systems experience a number of blockages and uncertainty in supply. Any expansion will require identification of the strongest routes, and to strengthen these further, before expanded drug supply can be achieved.

20) The emphasis on expanding opioid supply is being pursued to enhance adherence to the WHO pain ladder. It is clear from the data that this requires attention at all steps of the ladder, including in some cases provision of Step 1 pain-relieving drugs.

21) Policies to expand opioid access must carefully balance the need for expansion with the threat of additional pressure on unreliable current purchase, production and dispensing. Expansion should not be at the cost of reliability to existing providers.

22) Any strategy for expansion must take account of the concerns of INCB competent authorities with respect to regulation. Advocacy and lobbying must convince this essential stakeholder group of the feasibility of expansion programs, as current INCB skepticism may prove a significant barrier. INCB's need adequate resources to monitor and support existing and new opioid providers.

23) The synergies of strengthening supply systems for opioids can also enhance other symptom-controlling drugs, such as antiemetics and anxiolytics, which are also essential for this population.

24) Any strategic approach to opioid expansion must use a multi-pronged approach taking account of: supply (e.g. ordering and stocking, consistency of availability), legislation (e.g. regulations on storage and prescribing), education (i.e. ensuring that opioids are used appropriately) and practical site-specific support (e.g. adequate numbers of trained and able-to-prescribe staff, funds and storage facilities). Failure to address each of these areas is unlikely to achieve sustainable success.

25) Each country should undertake a wide-ranging consultation process to appraise its current legislation and identify the potential to pilot and test safe, feasible and practical legislation for the prescribing and dispensing of opioids.

26) Policy change, across the legislative and regulatory settings, can only be achieved through co-ordinated advocacy that takes account of governmental disinterest and professionals' fears of opioid use.

27) Current funding goals to increase the numbers of patients accessing palliative care should take account of the current limitations on opioid use and supply, and address the likely pressure on existing infrastructure.

28) In order to address the current weaknesses in supply, and build capacity for expansion, greater emphasis and capacity needs to be placed on training and employing pharmacists.

For researchers

29) In the light of different models of care and numbers of trained staff and patients seen according to service model, multidimensional outcome evaluations are required, including measurement of pain and symptom control.

30) Evaluative studies should compare both economic costing and levels of analgesia available, taking account of comparative baseline patient need across models.

31) Referral criteria and care networks should be examined to understand the movement between sites as patients move up and down the pain ladder.

32) All strategies and programs to expand opioid use should be evaluated at the site/country level to ensure that lessons can be replicated/adapted for use in other sites.

33) Longitudinal evaluation of education for initiatives in opioid use should be conducted to measure practice outcomes.

Background

Defining palliative care

The World Health Organisation (WHO) describes the goal of palliative care as aiming to improve:

'the quality of life of patients and families who face life-threatening illness, by providing pain and symptom relief, spiritual and psychosocial support from diagnosis to the end of life and bereavement'. (1)

The holistic nature of palliative care

As demonstrated above by the WHO definition, palliative care is concerned with pain in all its manifestations among patients and families affected by life-limiting incurable disease. This embraces physical, emotional and spiritual pain (13). Palliative care can only be said to be present if this 'total care' package is evident in whatever format is feasible and appropriate in the local setting. Pain control without good psychosocial care may be termed anesthesiology; psychosocial care without adequate pain control is supportive care. This study focused on the physical pain control tasks of palliative care as this component has been identified as a particular challenge in the African context. However, we recognize that there is equally important research to be undertaken into the provision of control of emotional and spiritual pain, and family support as well as distressing symptoms other than pain, and in training initiatives.

Why do we need PC as we roll out access to antiretrovirals?

Although palliative care is based on a multi-disciplinary family-based approach to care and support, the defining feature of palliative care that distinguishes it from supportive care is the element of pain and symptom control. Given that pain is experienced throughout the HIV disease trajectory from the point of diagnosis (2), and that severe pain is experienced by approximately 80% of those with advanced HIV disease at the end of life (3), palliative care has been advocated by the WHO as:

'an essential component of a comprehensive HIV care package because of the variety of symptoms they can experience – such as pain, diarrhea, cough, shortness of breath, nausea, weakness, fatigue, fever, and confusion. Palliative care is an important means of relieving symptoms that result in undue suffering and frequent visits to the hospital or clinic. Lack of palliative care results in untreated symptoms that hamper an individual's ability to continue his or her activities of daily life. At the community level, lack of palliative care places an unnecessary burden on hospital or clinic resources.' (4)

A recent systematic review of patient outcomes in HIV palliative care found significant improvements in pain and symptom control, anxiety and patient insight (6).

Palliative care in Sub-Saharan Africa

To achieve adequate patient care, the WHO recommends a three-part strategy for developing a cancer pain relief program (7). This strategy can be transferred to other life-limiting illnesses, including pain management for HIV/AIDS. The three step-strategy states:

(a) **Government policy** – the national government health and regulatory authorities should establish and support a policy that makes pain relief a high priority in the health care system;

(b) **Education/training** – the public, policymakers, and regulators should be informed that pain can be relieved, and health care professionals should be trained to manage pain using the three-step ladder; and

(c) **Drug availability** – analgesics, including opioids such as morphine, should be made available.

Current provision of palliative care in Africa is patchy and is often thought to be provided from centers of excellence rather than integrated into the health care system. Home-based care (HBC) (the prime modality of African HIV care provision) has been criticized for the often inadequate pain control clinical skills and use of appropriate pain-controlling drugs (5). A current challenge to improve patient outcomes is to disseminate lessons learned by those who have pioneered palliative care and to balance expansion of coverage with quality (8).

Providers of end-of-life care have identified pain control availability as a primary challenge (9). The need for adequate pain control will increase as antiretroviral therapy is rolled out across the region,

because side effects can be highly prevalent and burdensome (10) and need to be managed to enhance adherence, while the emergence of other life-limiting co-morbidities require palliative therapy as the chronic disease phase increases in length (11) (12).

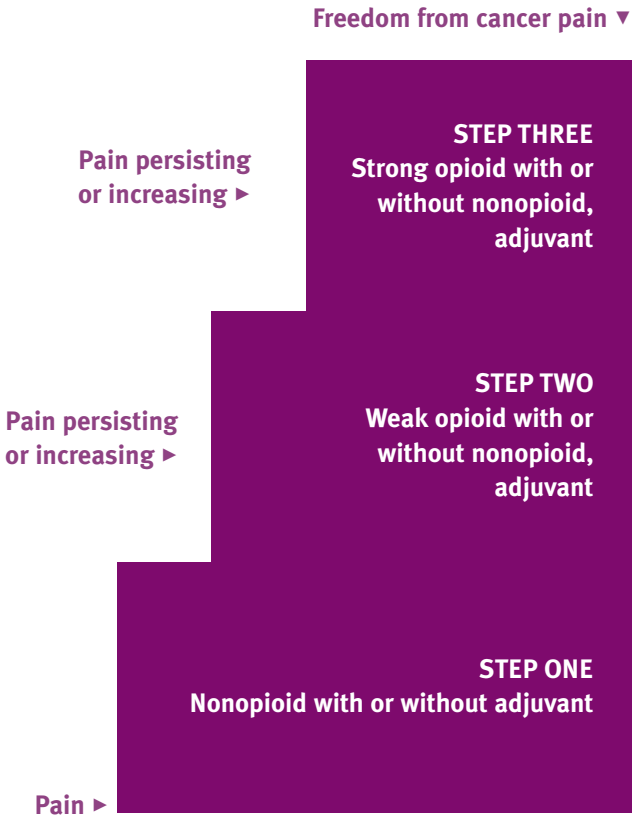
The growth of awareness of the need to expand palliative care in Sub-Saharan Africa, and increasing availability of funds available, have been major developments in patient care in recent years. Increasing numbers of HIV care providers are demanding to acquire palliative care skills, and the means to support this growth need to be identified.

Opioid availability

Opioids are essential for the management of severe pain, and can effectively control the vast majority of pain presented. It is not possible to control the range pain intensity in the clinical care setting without access to the Pain Ladder, i.e. drugs from paracetamol to codeine to morphine. The WHO Expert Drug Committee on essential drugs has designated morphine, codeine and other opioids as essential drugs, defined as those that satisfy the health care needs of majority of the population, that should therefore be available at all times in adequate amounts and in appropriate dosages. Oral opioid analgesics such as codeine, fentanyl, hydromorphone, morphine, and oxycodone are considered to be the cornerstone of good pain management. Drugs from these classes of analgesic must be made available for medical use if a comprehensive palliative care program is to succeed. According to the WHO pain ladder, opioids must be available to manage pain in patients whose pain has not been adequately controlled by the use of non-opioids, weak opioids and the addition of adjuvants (see Figure 1). In addition, it is required that opioids are delivered:

- 'by the ladder', i.e. according to Figure 1
- 'by the clock', i.e. titrated for consumption at regular intervals to avoid the unnecessary and distressing experience of breakthrough pain
- 'by the mouth', i.e. oral morphine for simple self administration in the home setting, and absorbed to avoid peaks in the analgesia levels.

Figure 1
The WHO Pain Ladder



Source: www.who.int/cancer/palliative/painladder/en

These drugs have, however, proved extremely difficult to obtain in many African countries. Although in theory many countries permit importation and distribution of the drugs, it can be impossible in practice to obtain the necessary authority from regulating bodies to prescribe these drugs. Indeed, the International Narcotics Control Board (INCB, the global authority which monitors the control and supply of narcotics) found that one of the biggest obstacles to the use of opioids was the fear among health professionals of legal action that might be taken against them if they prescribed these drugs.

There is little or no use of morphine in nearly half of the countries in the world. Almost all morphine is consumed in developed countries. Indeed, in many parts of Africa, there is limited availability of even simple pain-relieving drugs. Opioids in countries like Kenya, Malawi and Zambia are only accessible or imported within very tight regulatory frameworks. Since access to appropriate medication for pain

relief and opportunistic infections is central to palliative care, identifying the means to increase the numbers of HIV care providers who can offer adequate pain relieving drugs, and have the necessary palliative care skills, is a key stage in scaling-up palliative care in the region.

Barriers to opioid availability

International health and drug regulatory authorities have recognized that opioid analgesics are not sufficiently available for the treatment of pain in many places throughout the world. The INCB has asked all countries to take the necessary steps to assure that opioids are available for pain management.

A number of economic and historic factors contribute to the current lack of oral opioid availability. Many countries do not have the resources and health care infrastructure to produce and distribute medicines. Traditionally, the treatment of pain has not been as high a priority as the treatment of disease. Injectable morphine has long been recognized as a potent analgesic, but the broader realization that oral morphine is also very effective is more recent. Although the international narcotics control treaty has recognized for many years that opioids are indispensable in the management of pain, some countries have drug legislation that prohibits or restricts the availability and medical use of opioids. In addition, misunderstanding and fear of addiction impede the rational use of opioids in pain relief throughout the world.

The global barriers to opioid availability can be summarized as:

- Stringent and outdated laws and regulations for importation of opioids.
- Bureaucracy involved in obtaining authority from regulating bodies to prescribe drugs.
- Fear of addiction to opioids among health professionals.
- Poor or no health infrastructures.
- Cultural attitudes that make pain relief less of a priority.
- Ignorance of the availability and potency of oral morphine, although the potency of injectable morphine is known.
- Inadequate numbers of properly trained staff to asses and treat pain.
- Inadequate resource allocation of medications.
- Low funder priority for pain and symptom control.
- Lack of training in paediatric palliative care, and lack of availability of drug formulations for children.

Symptoms other than pain

People living with HIV disease experience a range of symptoms beyond pain, and these can be very distressing and may appear to clinicians to be untreatable. These symptoms can appear early in the disease trajectory, and may also be a result of treatment. Symptoms can include diarrhea, rash/itching, anxiety and depression, sexual dysfunction, and fatigue 1-5 6. Therefore, it is essential that clinicians are able to assess and treat the full range of symptoms, which includes having access to symptom controlling drugs.

Study Aim

This study aimed to identify current opioid prescribing services and regulatory bodies within 12 African PEPFAR (Presidents Emergency Plan for AIDS Relief) countries, and to examine the barriers to, and appraise the potential for, expansion in the number of opioid providers, for people with HIV/AIDS according to the WHO pain ladder.

Study objectives

The three study objectives were:

1. To identify the policy and practice context, and the necessary steps for providers to incorporate step 3 analgesics prescribing in 12 PEPFAR countries.

2. To identify current challenges, practice and opioid supply issues, and practical steps for expanding the number of palliative care providers in the 12 PEPFAR countries.

3. To describe the country context of opioid prescribing, the current opportunities and blockages in opioid prescribing, and identify steps that services in the 12 countries can take to integrate palliative pain control into their existing HIV care services.

Study design

The study utilized a cross-sectional survey methodology, collecting data from palliative care providers and INCB competent authorities, integrating and comparing findings at the country and continent levels.

Methods

Procedure

The study population was defined as services currently in operation defined by the African Palliative Care Association (APCA) as a palliative care service. A clear definitional framework was utilized (see Appendix 1), with any service that operated at Levels 2, 3 or 4 included. Therefore, according to the APCA classification, the minimum service package that met the inclusion criteria was use of health care professionals as well as community health workers, and delivery of clinical and supportive opportunistic infection management, and at least Step 1 analgesics.

Recruitment and data collection

A comprehensive list of potential palliative care service providers was compiled from:

- The APCA contact list.
- The International Observatory, University of Lancaster.
- USG representatives and their partners.
- The Hospice Africa Uganda Distance Learning Diploma and other contacts.
- University of Cape Town MSc in Palliative Care.
- Mildmay Uganda contacts from their training courses.
- Further contacts proposed by the project's Steering Group members.

All services identified as meeting the study inclusion criteria were contacted initially by email. The questionnaire was formatted electronically and attached to the mailing. Contact details were identified for services without electronic contact details and these were telephoned. Hard copies were printed and posted to those without access to email facilities, and hard copies delivered by hand to those services that were visited by the APCA team during the period of data collection.

The INCB competent authorities were identified through each country's Department of Health and contacted by telephone to ask for participation.

Where telephone appointments were refused, the survey was sent electronically for self-completion.

Reminder emails and telephone calls were made to non-responders periodically throughout the data collection period, which ran for a period of 8 months from August 2005-March 2006.

Survey items

For the provider survey, the items addressed their operational definition of palliative care, service components and activity, ARV use, health care professional staffing, analgesia and symptom control prescribing and dispensing, the national legislative framework for opioid use, and challenges to opioid provision.

INCB competent authorities questions investigated opioid availability, essential drug lists, legislative restrictions, and current challenges.

Data processing and analysis

Data were entered into SPSS V.12® for cleaning, checking and analysis. To ensure the anonymity and confidentiality of responding services, the coded data was subjected to restricted access; completed questionnaires were stored in a secure location.

The inputted data were subjected to profiling descriptive statistics, and inferential statistics, in particular, the Chi-square (x^2) test for categorical data, and the *t*-test and the ANOVA for continuous data to determine statistically significant differences. Where open-ended questions had been asked, post-hoc coding frames were developed to present data thematically.

Palliative care sites

Site sample characteristics

Sixty-two sites participated, a response rate of 61%, with responses broken down by country as follows:

Table 1 Country of respondents

	Frequency	Percent
Botswana	1	1.6
Cote d/Voire	1	1.6
Ethiopia	1	1.6
Kenya	6	9.7
Mozambique	1	1.6
Namibia	1	1.6
Nigeria	3	4.8
Rwanda	1	1.6
South Africa	27	43.5
Tanzania	4	6.5
Uganda	8	12.9
Zambia	8	12.9
TOTAL	**62**	**100**

The sites categorized themselves as either 1) a palliative care-only service (e.g. Hospice), 2) a non-governmental organisation (NGO) offering a number of services including palliative care (i.e. integrated care), 3) or as a Governmental service (e.g. Hospital or clinic). In addition, they were asked to list the main service components that they provide, which are presented in Table 2 overleaf according to category of service. In addition, participants described their sites of care (Table 3).

Responding sites were required to categorise themselves as 1 of the following:

1) A palliative care-only service – These services can be characterized as providing solely specialist palliative care. The most common example of this is the Hospice (which may provide home, daycare and inpatient care), although there are other specialist palliative care teams, for example those based in hospitals offering consultancy.

2) An NGO offering a number of services including palliative care – These services can be characterized as providing a range of HIV care services of which one is palliative care although this is usually integrated throughout the

services offered. Therefore, the service is likely to offer care from the point of diagnosis.

3) A governmental service – These services can be characterized as primary or secondary and form part of the state facility network.

Table 2 Components of care described by sites

Category of site:	Palliative care only (e.g. Hospice)		Non-Governmental care provider offering more than palliative care		Government service facility (e.g. Govt. hospital/clinic)	
Number of services in category	n=22 (35.5%)		n=35 (56.4%)		n=5 (8.1%)	
Service components (no. of times mentioned)	Bereavement counseling	11	Bereavement counseling	6	Bereavement counseling	0
	Counseling	5	Counseling	14	Counseling	2
	Family/community education	5	Family/community education	10	Family/community education	0
	Family planning	0	Family planning	1	Family planning	0
	Family support	4	Family support	1	Family support	0
	Food parcels & grants	6	Food parcels & grants	10	Food parcels & grants	0
	HIV testing	1	HIV testing	9	HIV testing	0
	Hospice mentoring	1	Hospice mentoring	0	Hospice mentoring	0
	Income generation	1	Income generation	6	Income generation	0
	Nutrition support	0	Nutrition support	5	Nutrition support	0
	Orphan care	9	Orphan care	15	Orphan care	0
	Pain & symptom control	4	Pain & symptom control	2	Pain & symptom control	3
	Palliative care advocacy	5	Palliative care advocacy	1	Palliative care advocacy	0
	Primary prevention	1	Primary prevention	6	Primary prevention	0
	Professional Education & Training	10	Professional Education & Training	6	Professional Education & Training	1
	Psychosocial support	3	Psychosocial support	4	Psychosocial support	1
	Rehabilitation	1	Rehabilitation	1	Rehabilitation	0
	Resource centre	1	Resource centre	0	Resource centre	0
	Respite	1	Respite	2	Respite	0
	Social work	2	Social work	4	Social work	0
	Spiritual care	4	Spiritual care	3	Spiritual care	1
	Terminal care	3	Terminal care	1	Terminal care	0

All sites reported that they concurred with the WHO definition of palliative care, with none offering a deviation or adaptation. The data in Table 2 demonstrate different foci between the service models:

- Palliative care-only services (e.g. hospices) more often sited a focus on bereavement counseling, family support, spiritual care, professional education and advocacy.
- Integrated NGOs more often described their focus on general counseling, family/community education, food parcels/grants/income generation, HIV prevention and testing.
- Government hospital services described service components of pain and symptom control in addition to screening, medical, and surgical input. However, there were only five services in this category.

Disease groupings served and antiretroviral therapy provision

There were observed differences in the proportions of each category of site with respect to the disease group served and provision of ART (Table 4). The majority of each service type provided care for both HIV and cancer, and none provided care for cancer patients alone. A similar proportion of palliative-only and integrated services were unable to provide ART, either in-house or from other local agencies.

Excluding government facilities due to the low number of cells, a chi-square was not significant when testing for a difference in the availability of ART between palliative-only and NGO integrated services. However, it is notable that only 11 services were ART providers, and 5 had no local access at all. It is a strength that the majority (40) sites had local access, but it is unclear from the remit of this study whether ART sites request palliative care support for those initiating and maintaining therapy.

Table 3 Sites of care

	Palliative care only (e.g. Hospice)	Non-Governmental care provider offering more than palliative care	Government service facility (e.g. govt. hospital/clinic)
Sites of care			
Inpatient care	N=7 (31.8%)	N=18 (51.4%)	N=5 (100%)
Home care	N=21 (95.5%)	N=33 (94.3%)	N=1 (20%)
Day care	N=16 (72.7%)	N=22 (62.9%)	N=4 (80%)
Hospital consultancy	N=15 (68.2%)	N=16 (45.7%)	N=5 (100%)
Outpatient care	N=13 (59.1%)	N=22 (62.9%)	N=5 (100%)

While the palliative-only services and integrated NGO's were broadly similar in the sites of care provided, the government facilities appeared to be less likely to provide home care, although the small numbers prevent statistical testing.

Table 4
Disease groupings and antiretroviral therapy

	Palliative care only (e.g. Hospice)	Non-governmental care provider offering more than palliative care	Government service facility (e.g. govt. hospital/clinic)
Diseases cared for			
Cancer only	0	0	0
HIV only	N=1 (4.5%)	N=2 (5.7%)	N=0 (4.8%)
HIV and cancer	N=21 (95.5%)	N=33 (94.3%)	N=5 (95.2%)
ART availability			
We provide ART	N=3 (13.6%)	N=8 (22.9%)	N=1 (25.0%)
We don't provide ART but work with providers to gain access for pts	N=17 (77.3%)	N=23 (65.7%)	N=2 (50.0%)
We don't provide ART have no access to other providers	N=2 (9.1%)	N=3 (8.6%)	N=1 (25%)

Number of adult and child patients seen

Table 5 below demonstrates that palliative care-only services provide care for a statistically smaller number of patients per year than either integrated NGOs or governmental facilities, and that both their adult and child patients are statistically significantly more likely to be prescribed opioids at any point under care.

Table 5 Number of patients seen per year

	Palliative care only (e.g. Hospice)	NGO offering more than palliative care	Government facility (e.g. govt. hospital/clinic)	
No. of patients cared for per year	Mean (SD)	Mean (SD)	Mean (SD)	
Adults	985 (1150)	1593 (2076)	2705 (1900)	ANOVA: F=1.878, p=0.164
Children	83 (126)	368 (620)	450 (87)	ANOVA: F=2.521, p=0.091
Proportion of patients at any time prescribed opioids				
Adults	67% (32)	24% (33)	35% (35)	ANOVA: F=8.619, p=0.001***
Children	47% (45)	11% (20)	20% (22)	ANOVA: F=5.073, p=0.012**

** Significant at the 0.01 level
*** Significant at the 0.001 level

Clinical staff on service

The clinical staff mix for each service category is described in Table 6. To statistically compare the staff mix, the governmental services were excluded due to the low number of sites (i.e. N=5).

Interestingly, although the palliative-only services saw fewer patients (Table 5), they did not have significantly fewer clinical staff (no tests for comparison of means were significant for each of the staff levels). This reflects the nature of multi-dimensional and holistic specialist care, which has been shown to offer greater time per patient and family and is reflected in the data in Table 2, which shows a greater focus on bereavement counseling, family support, spiritual care and education.

When the *proportion* of each grade of clinical staff *able to prescribe opioids* was compared (excluding Government facilities), there was no significant difference between palliative-only and integrated services.

When the *proportion* of each grade of clinical staff *trained in palliative care* was compared, it was found that palliative-only services had a significantly greater proportion of trained nurses (68% v 45%, t=2.147 p=0.037) compared to integrated services. Therefore, comparing palliative-only to integrated services, staff numbers and prescribing ability do not differ, although the proportion of nurses trained in palliative care is higher, fewer patients are seen, and they are more likely to be prescribed opioids in the palliative-only services.

Table 6
Clinical staff mix and opioid-prescribing staff

Clinical staff:	Nurse			Medical Officer			Doctor			Clinical Officer		
	A	B	C	A	B	C	A	B	C	A	B	C
Palliative care only (e.g. Hospice)	8.25 (1-33)	1.65 (0-17)	5.83 (0-33)	1.64 (0-8)	2.23 (0-11)	1.46 (0-11)	1.47 (0-5)	1.44 (0-5)	1.19 (0-5)	0.73 (0-3)	0.44 (0-2)	0.50 (0-2)
NGO offering more than palliative care	11.53 (1-110)	0.45 (0-4)	3.53 (0-38)	1.33 (0-13)	1.30 (0-13)	0.70 (0-13)	0.94 (0-6)	0.61 (0-2)	0.33 (0-2)	0.85 (0-4)	0.33 (0-4)	0.33 (0-3)
Government facility (e.g. hospital/clinic)	7.0 (4-10)	0.60 (0-2)	1.0 (0-2)	3.75 (2-5)	3.75 (2-5)	1.67 (0-3)	3.33 (0-5)	3.33 (0-5)	0.33 (0-1)	1.0 (0-2)	1.0 (0-2)	0.67 (0-1)

A= Mean number of staff (range)
B= Mean number able to prescribe
C= Mean number trained in palliative care

Pain and symptom control prescribing and dispensing

Thirty-six sites (58.1%) were currently dispensing opioids, and they were dispensed in the following formulations: liquid (oral) n=29 (46.8%), tablets n=20 (32.3%), injectable n=17 (27.4%). [1]

The specific drugs prescribed for each step of the WHO ladder are described in Table 7. The number of times each drug was mentioned is listed after each drug name.

Table 7 Analgesics prescribed, dispensed and supply continuity

	Drug name prescribed	
Step 1 (non-opioid)	NSAIDs	88
	Paracetamol	64
	Aspirin	22
	Nimesulide	4
	Tricyclic	3
	Benzodiazipine	1
	Steroids	2
	Ciclofenal	1
	Buscopan	1
	Periactin	1
	Stopain	1
NO RESPONSE n=4 SERVICES		
TOTAL = 188 DRUG RESPONSES		
Step 2 (weak opioid)	Codeine	33
	Dihydrocodeine	11
	Tramadol	14
	Dextropropoxyphene	6
	Anti-epileptics	1
	Co Dydramol	1
	Anti-depressant	1
	Coproxamol	1
NO RESPONSE n=19		
TOTAL= 73 DRUG RESPONSES		
Step 3 (strong opioid)	Morphine	57
	Pethidine	6
	Fentanyl	4
	Duragesic	3
	Pethilofan	1
	Pentazome	1
	Valaron	1
	Tilidine	1
	Methadone	1
NO RESPONSE n=19		
TOTAL= 69 DRUG RESPONSES		

Of the Step 1 analgesics listed, 156/180 responses indicated that they were dispensed onsite. Forty-two services indicated that Step 1 analgesics were available 100 % of the time, the remaining 7 ranged from only 10-95 % (9 missing).

[1] This question had a multiple answer format, hence the responses do not add up to 100 percent.

Of the Step 2 analgesics, 52/73 drugs cited were dispensed onsite. Twenty-one services indicated that Step 2 analgesics were available 100 % of the time, the remaining 7 ranged from only 10-75 % (15 missing).

Of the Step 3 analgesics, 45/69 drugs were dispensed onsite. Twenty-eight services indicated that Step 3 analgesics were available 100% of the time, the remaining 7 ranged from only 5-90 % (8 missing).

Therefore, although the majority had access onsite to Step 1 analgesics, fewer had access to Step 2 and 3 analgesics. However, those that listed Step 2 also were likely to have Step 3.

For those who dispensed opioids, they were obtained from the following sources:

Table 8 Opioid sources

Opioid Sources	
Joint Central Medical Stores	9
Government hospital	8
Private pharmacy	7
Pharmaceutical supplier	5
Hospice	1
Locally from pharmacy in powder form	1
Manufacturers	1
Cancer Institute	1
Patients buy from outside hospital	1
Import from UK	1
Missing	1
TOTAL 36	

The most common sources of opioid supply were governmental, i.e. via Joint/Central medical stores and government hospitals, with private pharmacies the next most common source.

The prescribed symptom control drugs are described in Table 9.

Table 9 Symptom control drugs prescribed, dispensed and supply continuity

	Drug name prescribed	
Antiemetics	Metachloperamide	43
	Phenothiazines	19
	Haloperidol	18
	Cyclizine	9
	Promethizine	9
	Bonamine	1
	Ondansetron	2
	Stemetic	1
	Emeset	1
	Eyelezine	1
	Motilium	1
	Ondansetron	1
	Decedron	1
	Maxaton	1
NO RESPONSE n=13 SITES		
TOTAL= 109 DRUG RESPONSES		
Management of neuropathic pain	Amitriptyline	34
	Carbamazapine	19
	Phenytoin	9
	Vit B	7
	Steroid	5
	Gabapentin	4
	Tricyclic antidepressant	3
	Phenothiazine	2
	Morphine	2
	NSAID	2
	Paracetomol	1
	Haloperidol	1
	Bamezapine	1
TOTAL= 90 DRUG RESPONSES		
NO RESPONSE n=18 SITES		
Anxiolytics	Benzodiazapine	48
	Lorazepam	11
	Amitriptyline	5
	Haloperidol	4
	Chlorpromazine	2
	Phenothiazine	1
TOTAL= 71 DRUG RESPONSES		
NO RESPONSE n=17 SITES		

Of the antiemetics listed, 81/109 responses indicated that they were dispensed onsite. Seventy responses indicated that the drug was available to be dispensed 100 % of the time, the remaining 32 ranged from only 20-90 % (7 missing).

Of the agents listed for the management of neuropathic pain, 68/90 of the cited drugs were dispensed onsite. Sixty-three responses indicated that neuropathic pain agents were available to be dispensed 100 % of the time, the remaining 20 ranged from only 5-95 % (7 missing).

Of the anxiolytics listed, 51/71 drugs cited were dispensed onsite. Forty-one responses indicated that anxioloytics were available 100 % of the time, the remaining 16 ranged from only 1-95 % (14 missing).

Government, country and policy context

Each respondent identified whether opioids were on their essential drugs list. Also they were asked to describe the legal requirements for obtaining, producing, storing and prescribing opioids, and the main factors hampering opioid provision within their country (see Table 10).

The data shows that, although some countries such as Uganda have made advances in opioid provision in comparison to others, there is a remarkable similarity in the identified factors hampering opioid provision. They can be summarized as:

- **Supply**
  E.g. stores do not stock, overly tight control, unreliable stocks, and few dispensers.

- **Legislation**
  E.g. regulations requiring 7-days only for prescribing, lack of national policy on opioid use, and bureaucratic processes.

- **Education**
  E.g. existing clinicians do not know how to assess and treat pain, fear of addiction, poor patient compliance, palliative care stresses specialty to the point of exclusion, and doctors are less interested in dying patients.

- **Practical**
  Costs, storage requirements, not enough prescribers, inadequate staff in HBC, poor infrastructure to follow patients home, lack of sugar for making up syrup, and short shelf-life of morphine.

There was concordance between sites with regard to whether opioids were on the country essential drugs list, with the notable exception of Zambia.

Table 10 Opioids, essential drug lists and legal requirements

	Opioids on essential drugs list?		Legal requirements	Main factors hampering opioid provision	Oral morphine on essential drugs list?	
	Yes	No			Yes	No
Botswana	1 (100%)	0	■ Opioids supplied by Central Medical Stores	■ Lack of professional knowledge of pain relief for HIV patients ■ Lack of training ■ Central Medical Stores don't provide oral morphine ■ Logistical supply problems ■ Lack of political will	1 (100%)	0
Cote d'Ivoire	1 (100%)	0	■ Supply, stock and dispensing tightly controlled ■ Only doctors can prescribe, with specific prescription forms and for 7 days	■ Doctors fear of opioids ■ Lack of availability country-wide	1 (100%)	0
Ethiopia	1 (100%)	0	■ No idea because although it is on essential drugs list it is not available in the country		1 (100%)	0
Kenya	0	6 (100%)	■ A license is required for handling drugs ■ Only hospices can purchase, store and dispense ■ Must have a strong room ■ Ordered by doctor, administered by a registered nurse, checked by second nurse, recorded in book, locked in cupboard	■ Lack of knowledge of opioids ■ Lack of national policy ■ Non-availability in most settings ■ Not recognized as a need ■ Few dispensers ■ Costs ■ Doctors fear addiction ■ Scarcity of supply ■ Lack of supervisory staff ■ Long & tiring bureaucratic processes ■ Lack of training ■ Lack of storage facilities	0	6 (100%)
Mozambique	1 (100%)	0	■ Only doctors can prescribe	■ Fear of misuse ■ Over centralized control	1 (100%)	0
Namibia	1 (100%)	0	■ Only doctors can prescribe; only available through hospitals	■ Lack of trained medical staff ■ Public misunderstanding	0	1 (100%)

Table 10 Opioids, essential drug lists and legal requirements – continued

	Opioids on essential drugs list?		Legal requirements	Main factors hampering opioid provision	Oral morphine on essential drugs list?	
	Yes	No			Yes	No
Nigeria	2(66.7%)	1(33.3%)	■ Current government embargo on use	■ Lack of staff and facilities ■ Lack of supply ■ Legislation ■ Fear of addiction ■ Lack of training programs	0	1 (100%)
Rwanda	0	1(100%)	■ None yet	■ Palliative Care National Association is newly formed ■ No national policy ■ Lack of programs	0	1 (100%)
South Africa	24(88.9%)	DK 3(11.1%)	■ Need a dispensing license ■ Strong opioids on named patient basis only from licensed pharmacist ■ Only doctors can prescribe ■ Constant evaluation of effect ■ Daily count of locked stores ■ No NGO/CBO allowed to store, hospital dispenses ■ Prescription not repeatable ■ Obtain from a registered pharmacy ■ Store behind 2 locks ■ 2 nurses witness dispensing ■ Strength frequency and route stated in words and figures	■ Prescribing restrictions ■ Availability ■ Cost ■ Cultural acceptance of pain ■ Distance from suppliers ■ Health care staff lack confidence ■ Ignorance of pain in HIV ■ Poor clinical training ■ Lacking full time prescriber ■ Morphine myths ■ Sustainability of supply ■ Lack of political support ■ Lack of doctor presence in HBC ■ Storage difficulties ■ Lack of knowledge of pain ladder ■ Respiratory depression fears ■ Poor pain assessment work ■ Poor patient compliance ■ HIV complications (e.g. vomiting)	25(92.6%)	DK 1(3.7%)
Tanzania	1 (25%)	3 (75%)	■ Lack of national availability ■ Difficulties in meeting government requirements	■ Lack of knowledge and skills ■ Lack of places for making up powdered morphine ■ Access ■ Fears ■ Lack of suppliers/dispensers ■ Lack of bureaucratic support ■ Pain assessment skill problems ■ Lack of clinical will and support ■ Lack of education opportunities ■ Lack of knowledge of effectiveness	1 DK	3 (75%)

	Opioids on essential drugs list?		Legal requirements	Main factors hampering opioid provision	Oral morphine on essential drugs list?	
	Yes	**No**			**Yes**	**No**
Uganda	8(100%)	0	■ Registered pharmacy adhering to Class A policy inc prescribing, pharmacy & ward rounds, storage ■ Register with National Drugs Authority ■ Must have letter by medical superintendent/pharmacist to collect with written authority ■ Be party to internal convention ■ Be registered with medical council to prescribe ■ Duplicate prescription with patient/carer signature ■ Double locked cupboard ■ Keep record of stock ■ Need license to produce morphine solution	■ Nurses not being able to prescribe ■ Lack of pharmacists ■ Doctors: unwilling, lazy, lack of interest in dying patients ■ Chronic lack of education ■ Staff do not want to explain and write proper prescriptions ■ Inadequately trained staff ■ Myths/fears ■ Illiteracy ■ Poor infrastructure to follow patients home ■ Poor side-effect monitoring systems ■ Cultural beliefs ■ Morphine roll-out needs to reach more districts ■ Need more providers of training ■ Unreliable supply (distribution, stocking, shelf life) ■ Palliative care specialists over-emphasise the specialist nature and exclude others ■ Morphine has short shelf-life	7(87.5%)	missing n=1
Zambia	3(37.5%)	1(12.5%) DK 4(50%)	■ Nurses can not prescribe ■ Only hospitals can stock ■ Government medical stores must distribute through the main hospital pharmacy ■ Prescribe only by doctors ■ Under Dangerous Drugs Act	■ Government regulations ■ Poor access ■ Funds ■ Legislation/restrictive policy ■ Doctors will not prescribe to those in need ■ Professionals fear addiction ■ Lack of pharmacists ■ Myths ■ Lack of qualified personnel ■ Poor knowledge of opioid use in HIV ■ Lack of numbers of prescribers ■ Lack of sugar for mixing oral morphine ■ Poor pain assessment skills ■ Inadequate dosing and not by the clock	2(25%)	4(50%) DK 2(25%)

Opioid training, expanding access and current challenges

Respondents indicated whether they felt there were adequate opportunities for staff training in the use of opioids, what mechanisms they recommend for expanding access to a greater number of HIV care providers, and what challenges they envisage in achieving this (see Table 11).

Again, despite there being some disparity in the progress being made between individual countries within the region, there were notable similarities with respect to their views.

In terms of *assisting more providers in accessing opioids*, the suggestions were:

- **Advocacy:** at government and public levels on the need for opioids, and on lifting restrictive legislation.
- **Collaboration:** with prescribing doctors, across primary and secondary care, and with hospital pharmacies.
- **Training:** in pain assessment and management, in all curricula, on palliative rather than supportive care, and a shorter course for prescribing.
- **Coverage:** to rural and HBC services.

With respect to potential *challenges to expansion*, the difficulties were:

- **Political:** achieving sufficient motivation.
- **Educational:** challenging myths, teaching that HIV requires Step 3 pain management, and achieving medical cultural change.
- **Resources:** time for doctors to prescribe, drug costs, storage facilities, number of pharmacists, supply breaks, building up rural services, and the number of prescribers.

The suggested methods to overcome the challenges were as follows:

- **Education:** training for HCW, input in to curricula, teaching for HIV services, and developing shorter courses.
- **Advocacy:** support through APCA, and government lobbying.
- **Organisational:** central supply of drugs and collection points facilitated by government, and better linkages with hospices.
- **Resources:** fund storage, increase hospice capacity, more pharmacists, and employ professional staff in HBC organisations.

Table 11 Opportunities and challenges:expanding opioid provision

	Adequate training opportunities?		How can more providers access opioids?	What would the challenges be?	How could they be overcome?
	Yes	No			
Botswana	0	1(100%)	■ Work with MoH to raise awareness and advocate for morphine use, public education	■ Motivating the MoH and planners of health care provision	■ Train HCW with help from APCA, train more nurses and doctors, educate the public on palliative care in cancer and HIV
Cote d'Ivoire	0	1(100%)	■ Advocate for use of opioids, increase country-wide availability ■ Change prescribing rules	■ Fear of opioid abuse	■ Increase advocacy
Ethiopia	1(100%)	0	■ Closer working with Ethiopian doctors	■ For doctors to comply in working with HIV care providers. Doctors do not seem to have the time to work with providers and this stops patients getting effective pain relief	■ Better education for doctors
Kenya	DK 1(16.7%)	5(83.3%)	■ Order in opioids from current stockists ■ Government change restrictive rules ■ Purchase privately ■ Better training in pain assessment and management/dispensing ■ Collaboration with hospices ■ MoH support	■ Cost ■ Government acceptance of morphine use for HIV and license morphine ■ Inadequate supply and lack of prescribing personnel ■ Lack of pharmacists to reconstitute, and lack of storage facilities ■ Lack of pharmacy stocks ■ Government policy	■ Centralize purchased and collection points and cost reduction. Government should facilitate this process ■ Better supply, training, increase hospice capacity ■ Government legislation change ■ Advocacy with MoH/Government ■ Training for staff on prescribing & dispensing, and reduce tough importation rules ■ Better use of available pharmacists, more storage cupboards
Mozambique	1(100%)	0	■ The individual is the only way to advocate successfully and change policy	■ Need to strengthen advocacy organisations ■ Ministry understanding	■ Advocacy is the only way
Namibia	0	1(100%)	■ Need doctor and nurse training to assess and prescribe, better supervision of volunteers	■ Government policies	■ Education & lobbying

Table 11 Opportunities and challenges:expanding opioid provision – continued

	Adequate training opportunities?		How can more providers access opioids?	What would the challenges be?	How could they be overcome?
	Yes	**No**			
Nigeria	0	3(100%)	■ Better availability of opioids ■ Incorporation into health worker curriculum ■ Government life embargo	■ Supply ■ Costs ■ Government willingness to allow use ■ Personnel	■ Advocacy, education ■ Government advocacy ■ Availability in the districts ■ Training for all HCW
Rwanda	0	1(100%)	■ Political will and advocacy		
South Africa DK 2 (7.4%)	14(51.9%)	10(37%)	■ Access to state hospital pharmacies ■ Advocacy ■ Government & private partnerships ■ Availability even in rural hospitals ■ Restrictions lifted on only doctors prescribing ■ Better liaison with hospitals ■ Lobbying by PWAs ■ Nurse access to opioids ■ Government hospitals need better regular pharmacy supply ■ Better networking across primary and secondary care	■ Providing palliative care in hospitals ■ Threat of abuse ■ Better education for patients and carers on administration of opioids ■ Better professional education ■ Get opioids into clinics and HBC ■ Advocate for nurse prescribing ■ Reduce professional ignorance ■ Lack of trained doctors in palliative care ■ Revising the law ■ Safe storage ■ Poverty and geographic limitations ■ Professional resistance in use of opioids ■ Safe storage ■ Costs ■ Lack of pharmacists ■ MoH apathy ■ Increase training facilities	■ Increase government funding to maintain stocks ■ Workshops & capacity building, better policies on pain control, nursing license to prescribe ■ Training ■ Policy change ■ Professional education ■ Increase number of pharmacists to improve supply ■ Focus on holistic care ■ Involvement of rural clinics ■ Better family education ■ Research to link theory of opioid expansion to practice

Table 11 Opportunities and challenges:expanding opioid provision – continued

	Adequate training opportunities?		How can more providers access opioids?	What would the challenges be?	How could they be overcome?
	Yes	**No**			
Tanzania		4(100%)	■ Getting training in palliative rather than supportive care ■ Train in opioid use beyond cancer ■ Reduce government restrictions	■ Fears of prescribing and using opioids ■ Costs ■ Human resources ■ MoH/Medical Schools must include in curriculum ■ Government bureaucracy ■ Reduction of restrictions	■ Advocacy and external assistance ■ Sensitize policy makers ■ Medical schools scale-up training ■ Training for HIV care providers on palliative care ■ Government recognition of palliative care training courses
Uganda	5(62.5%	2(25%)	■ Improve network between trained prescribers and HIV care organisations ■ Grafting palliative care onto existing services, especially pain and symptom control ■ Relax prescribing requirements without compromising control ■ Non-specialists should be given a shorter course to enable them to prescribe ■ RN or CO to attend prescribing course at HAU rather than only doctors ■ Liaise with hospices	■ Finance/costs ■ Record keeping ■ Fear of opioids ■ Bureaucracy in being a provider ■ Having enough medical staff ■ Not all districts trained and sensitized ■ Doctor reluctance to prescribe/prescribe incorrectly ■ Not enough prescribers ■ Better organisational management	■ Develop shorter training courses ■ Harmonize existing training to incorporate morphine ■ Education ■ Advocacy ■ Current centers take responsibility for rolling out into districts ■ Linkages with hospices ■ Expand base of prescribers i.e. non-doctors ■ Institutions given storage facilities ■ Sensitize police and government ■ Understand the training needs
Zambia	2(25%)	8(75%)	■ Employ personnel who can prescribe ■ Train HBCs and MoH approve opioid use ■ Advocate to Government ■ Train clinical officers and nurses to prescribe as they are closer to the community ■ Policy change ■ Obtain opioids through private importer or through University teaching hospital ■ Opioid clinics in hospitals	■ Fear of abuse ■ Change legislation ■ Train in prescribing and pain management ■ Poor availability of morphine powder ■ Funding ■ Doctors are resistant to change ■ Training costs ■ HBC services sometimes lack health care staff ■ Government persuasion	■ Advocacy to Government ■ Policy change ■ Sourcing funding for opioids ■ Train non-professional staff ■ Encourage HBC services to have professional staff ■ Increase opioid supply ■ Weak opioids should be available to clinical officers/nurses who are trained in opioid prescribing without need for an on-site pharmacist

Current challenges: purchasing, producing, dispensing and prescribing

Finally, respondents described current challenges in the purchasing, production, dispensing and prescribing or opioids (see Table 12).

The **Purchasing** issues can be summarized as:

- Overwhelming cost due to new taxes; expensive and scarce single source of supply; lack of funds; unreliable supply; distances; too many restrictions.

The **Producing** issues can be summarized as:

- None produced due to government embargo; hard to produce and source enough due to expanding patient base; lack of pharmacists; limits on sugar supply to make up syrup.

The **Dispensing** issues can be summarized as:

- Restrictions to hospitals and hospices mean patients do not get access; massive delays between scripts and dispensing; lack of pharmacists.

The **Prescribing** issues can be summarized as:

- Being the sole prescriber; heavy restrictions; professionals do not know how to prescribe; lack of education; refusal to prescribe for children; lack of rural staff; gross underuse due to fears and myths.

Table 12 Current issues in opioid provision

	Purchasing		Producing		Dispensing		Prescribing	
	None	**Issues**	**None**	**Issues**	**None**	**Issues**	**None**	**Issues**
Botswana	1(100%)		0(0%)	■ None is produced in Botswana	1(100%)		1 (100%)	
Cote d/Voire	1(100%)		1(100%)		0(0%)		0 (0%)	■ Only doctors can prescribe and for 7 days at a time
Ethiopia	1(100%)		1(100%)		1(100%)		N/A	
Kenya	2/6(33%)	■ Cost has almost doubled due to new tax laws on drugs ■ Drug companies do not stock enough opioids	1/6(16.7%)	■ Hard to source enough to provide for expanding patient base due to Government restrictions on import ■ Not all companies can produce	3/6(50%)	■ Mostly dispensed in hospitals and hospices so many patients do not get access	3/6 (50%)	■ Restrictions on prescribing ■ Most professionals do not know how to prescribe
Mozambique	1(100%)		1(100%)	■ Not sure if they have the conditions to produce	1(100%)		1 (100%)	
Namibia	–	–	–	–	–	–	–	
Nigeria	1/3(33%)	■ Can only be purchased at National Drug Store ■ Scarce and expensive	1/3(33%)	■ Not produced in country ■ Only produced centrally	2/3(66.7%)	■ Only doctors can prescribe	3/3 (100%)	
Rwanda	–	–	–	–	–	–	–	

Table 12 Current issues in opioid provision – continued

	Purchasing		Producing		Dispensing		Prescribing	
	None	**Issues**	**None**	**Issues**	**None**	**Issues**	**None**	**Issues**
South Africa	12/27 (44.4%)	■ Cannot purchase without prescription ■ Not enough funding to purchase ■ Black patients cannot source morphine outside the private system ■ Essential drugs not always available at public health facilities ■ Lack of doctors ■ Distance to dispensers	12/27 (44.4%)	■ Few qualified pharmacists ■ Lack of doctors to prescribe ■ New regulations are limiting spread of opioids across the country ■ Lack of prescribers in rural areas ■ Cost	9/27 (33.3%)	■ Need dispensing license ■ Need correct scripts from doctor ■ Can take 3-week delay between script writing and morphine delivery from dispensary ■ NGO status debars from dispensing ■ No dispensing from premises	13/27 (48.1%)	■ Takes too long to get morphine, especially in rural areas ■ Doctors need education in morphine use ■ Doctors refuse to prescribe morphine for children ■ Patient/family fear of addiction ■ No license ■ Rural areas do not have doctor available to write scripts ■ Nurses need to be able to prescribe
Tanzania	4(100%)		2(50%)	■ No local production	2(50%)	■ Too few pharmacists ■ Staff inadequately trained in pain assessment and management	2(50%)	■ Too few prescribers ■ Only doctors, and not all doctors, know how to prescribe
Uganda	6(75%)	■ Drugs run out of stock ■ Cost ■ Despite us requesting quarterly in advance, Medical Stores do not order in time	4(50%)	-	8(100%)		7/8(87.5%)	■ I am the only person able to prescribe!
Zambia	3/8(37.5%)	■ Too many restrictions	2/8(25%)	■ Reliance on sugar to make powder into syrup ■ Limited pharmaceutical industry	3/8(37.5%)	■ Restrictions to hospitals only ■ Only available in major hospitals ■ Storage restrictions limit access	2/8(25%)	■ Grossly underused due to fears of addiction ■ Can not prescribe outside hospitals

INCB competent authorities data

Respondents

Despite significant efforts over a period of eight months, five interviews were achieved. This was due, in large part, to considerable confusion within Ministries as to whom the appropriate person was and a lack of accurate contact details for the identified individual.

The interviews that were achieved were:

- Ethiopia
- Kenya
- Namibia
- Tanzania
- Uganda

Current opioid supply and regulatory system

All five stated that opioids were currently on their respective country's essential drugs list and available in country for pain relief.

In Table 13, it is notable that the majority of INCB competent authorities were satisfied with the functioning of the current regulatory system, contrary to provider data. INCB competent authorities also felt (with the exception of Uganda) that there were currently adequate numbers of opioid providers. An important finding from these interviews is that INCB competent authorities feel that they may not be able to offer adequate regulation and monitoring for increased numbers of providers, and that they question the skills of those already prescribing opioids.

Table 13 INCB competent authorities views: current opioid supply and regulation

	What are the blockages and problems?	How would a site become a provider	Are there enough providers?	Does the regulatory system work well?	Difficulties & challenges to regulatory system	Systems & resources needed to increase no. of providers
Kenya	Due to the punitive nature of the 1994 Act, most providers have shied away from selling opioids.	Apply for a license from the Pharmacy & Poisons Board and employ legally recognized staff.	Yes	Yes	None, pharmacy & Poisons Board Inspectorate operates efficiently.	We need to improve the quality of prescribing personnel through training not increase the numbers.
Ethiopia	The fears around prescribing may be due to the regulation. There is a lack of awareness of appropriate opioid use among those able to prescribe.	Register with DACA, and either use drugs on the essential drug list OR work with existing government facilities who have access.	Yes	Yes	The policy and regulatory environments are enabling, the problem arises from people not prescribing drugs because they lack knowledge and do not stimulate demand.	Better training of those able to prescribe, review the regulatory environment, review curricula, improve estimation system.
Tanzania	Professional fear of transcribing.	Apply for permit from TFDA.	Yes	Yes	The current system works well but do need to improve inspection, and to raise awareness among providers.	Increase medical student intake, and motivate prescribers to be active in all areas.
Uganda	Stringent laws on importation. Dispensing pharmacies and health care facilities fear stocking opioids due to tough requirements. Too few prescribers.	Grant authorization from MoH, organisation is surveyed for suitability.	Too few	No	Too few personnel to conduct surveys and monitoring for the whole country.	Integrate training so any qualifying clinical staff are confident to prescribe.
Namibia	Availability of doctors to prescribe and pharmacists to dispense.	Need a doctor to prescribe and a pharmacist to dispense and register with Government.	Yes BUT not enough to really cope with HBC	No	Lack of staff to regulate! The powder it is made from is a Schedule 7 drug, also need compounding equipment etc. Shelf life is only 1 month.	If nurses were to prescribe we'd need to change current legislation, expand training, and improve monitoring.

Comparison to site responses

The data from INCB competent authorities and the data from care sites were integrated and compared to appraise the congruity of their perspectives on opioid availability.

It is noteworthy in Table 14 that although the Ethiopian INCB competent authority reported that opioids were available in the country, the respondent said that while they were on the essential drugs list, they were unavailable anywhere. In every country without exception, INCB competent authorities cited specific opioids that they believed to be available in-country that were never cited by any service within that country.

Table 14 Comparison of INCB competent authorities and provider data: opioid availability

	Morphine	Pethadine	Codeine	Tramadol	Nitrazepam	Methadone	Fentanyl	Tilidine	Etorphine
Kenya	• ✓	• ✗	• ✓	• ✗			• ✓		
Ethiopia	• ✗	• ✗	• ✗						
Tanzania	• ✓	✓	• ✓	✓					• ✗
Uganda	• ✓		• ✓	✓	• ✗				
Namibia	• ✗	• ✗	• ✗			• ✗	• ✗	• ✗	

• Noted by INCB comp auth as present in country
✓ Mentioned by at least one service in country
✗ Not mentioned by any service

Discussion

Definitions and components of palliative care

Palliative care is delivered in an increasingly diverse range of settings, with the potential for generalist palliative care to be rolled-out more easily than the specialist care which offers expert management of complex cases. Our data offer two important and fundamental opportunities for opioid expansion for people living with HIV in Sub Saharan Africa.

Firstly, all the respondents reported that they define palliative care in exactly the same way as the WHO 2002 definition. As a common thread throughout the data is the need for education and collaboration to increase opioid access, the united acceptance of the WHO definition will make the roll-out, monitoring and provision of opioids to common objectives easier to achieve. As the PEPFAR legislation has been designed to operationalize this definition, in particular the WHO pain ladder, then scale-up strategies can more easily embrace the range of services with the knowledge that a common definition is shared.

Second, the range of services offered by the 3 categories of provider demonstrate clear differences in focus, with palliative-only services stressing bereavement counseling, family support, spiritual care, professional education and advocacy, while more integrated NGOs offer general counseling, family/community education, food parcels /grants/income generation, HIV prevention and testing. This probably reflects the needs of the patient population referred to these types of provider, suggesting that the palliative-only service provides a more end-of–life focus (i.e. hospice) while the integrated service cares for a wider disease-spectrum population. However, it is not possible for palliative-only services to care for all dying patients, and integrated services should be able to offer advanced disease care (including opioids) for those who need it, and further research is required to map referral criteria for the management of complex cases which may require a more specialist palliative care setting.

Antiretroviral therapy

Of the sample, six had no local access to ART for their patients, although all were PEPFAR countries. ART is an essential complement of palliative care, even for those with late-stage infection and an inadequate response to therapy (14). While it is not necessary for all sites to provide ART, it should be available for co-management between providers. Also, all sites should have access to the full range of pain and symptom-controlling drugs and trained staff to provide skills in managing the side effects of therapy and immune reconstitution events among ART-referred patients, as the majority of respondents did not provide ART for their patients but worked with ART sites to gain access.

Patient population

The data show that the palliative-only services see significantly fewer patients, and that they are more likely to be prescribed opioids while on service. This is unsurprising as specialist palliative care usually offers more detailed assessments, offers longer contact per consultation, and if more patients are prescribed opioids then closer monitoring is required. Also, as these patients are likely to be nearer to the end of life, their needs can be expected to be greater, as are those of the family. Therefore, it is essential to recognize that the smaller number of patients, while not reflected in smaller staff numbers, is likely to be a function of the type of care provided and patient need, a view supported by the data describing service components and the proportion of patients prescribed opioids. However, the possibility that the data might suggest under-use of opioids in integrated services cannot be discounted, particularly as these staff are significantly less likely to be palliative-trained.

Staff skills

While the number of staff did not differ in line with the site patient population size, the proportion of palliative-trained staff was significantly lower for the integrated NGOs. While it is expected that an integrated service has more components of care and so fewer palliative-specific staff, it is important that *all* staff can recognize palliative need and can provide generalist palliative care during their patient interaction, and refer appropriately, and so we recommend that all staff in an integrated service have at least some basic training. The number of staff able to prescribe did not differ between services, which suggests that there are adequate numbers of staff on service in integrated services who could prescribe if they received adequate training in the assessment and management of pain.

Analgesia and symptom controlling drug availability

Firstly, looking at Step 1 analgesics, it is concerning that even among these participating a significant number had problems in accessing Step 1 analgesics. These are the least complex in terms of legislative bureaucracy and control, and so challenges here suggest an inability to even begin to use the WHO ladder with certainty of continuity. Also, a small number of services were unable to dispense Step 1 analgesics, and while it is not necessary for all services to dispense Steps 2 and 3 (e.g. South African hospices tend not to dispense opioids), the prevalence of pain and lack of policy restraints suggest that any site should be able to provide Step 1 analgesia.

Looking at Step 2 and 3 analgesics, both were dispensed by fewer sites and supply was an increasing issue. Less than half the sites were currently prescribing opioids of any strength, and those that did were mainly relying on Joint Medical Stores and Government Hospital pharmacies. Clearly, while reliance is on these sources, any strategy to increase the number of providers must take account of how best to assist these centers in offering continuing supply. The data identified a number of alternative methods, such as direct importation from the UK, and these centers should be investigated more closely in the search for reliable mechanisms of supply.

Neuropathic pain is a common, distressing and challenging presentation among people with HIV disease, and can be a result of the underlying disease or a side-effect of antiretroviral therapy. The most effective drugs, such as Gabapentin, are expensive, and this is reflected in the low number of services that cited its use. Antiemetics and anxiolytics are also essential drugs in the management of patients with HIV disease, and further problems were identified with these both in availability and supply continuity. Although opioids often have an anxiolytic effect, they should always be available for patients with advanced disease. Nausea and vomiting are common side effects of both opioid and ART use, and so antiemetics should always be available. The data demonstrate some systemic problems that suggest that opioid supply issues are not solely related to this class of drugs but are compounded by the legislative framework, and that less controlled drugs such as antiemetics experience similar problems. Therefore, while lobbying for opioid availability is a clear and essential task, there are issues beyond this that speak to drug supplies across the formulary spectrum.

The service perspective on opioid access: factors hampering provision, expanding access and facing challenges

The sample represents diverse countries in terms of progress towards opioid availability for a true public health approach to palliative care provision, from the well-recognized Ugandan experience, the governmental/hospice links across South Africa, to the challenges of Ethiopia. However, it is notable that despite these significant differences, the data offers common themes to guide a strategic approach to opioid scale-up. To aid identification of feasible and appropriate strategies for opioid expansion, the data have been integrated from Tables 10-12 demonstrating the commonalities across themes and countries (See Figure 2).

Figure 2
Challenges and responses: data integration

Factors hampering roll out & challenges	Suggested responses & solutions to challenges
Political ■ Store supplies are unreliable ■ Lack of political will ■ Motivating MoH ■ Lack of national policy ■ Bureaucracy	**Political** ■ Advocacy to MoH to raise awareness ■ Public education ■ Change prescribing rules ■ PWA lobbying ■ Government take responsibility for central purchase & distribution ■ License nurses to prescribe ■ Legislative change
Clinical ■ Professionals lack knowledge on HIV pain, assessment, management ■ Professionals fear opioids ■ Lack of professional training ■ Lack of clinician interest in the dying ■ Public opioid fear	**Clinical** ■ Focus on training palliative not supportive care ■ Focus on training in opioid use in HIV not just cancer ■ Graft onto existing providers ■ Provide a shorter prescribing course for non-specialists ■ Better HBC training
Site-specific ■ Lack of storage facilities ■ Rural distance from suppliers ■ Specialist palliative care excludes other organisations	**Site-specific** ■ Closer collaboration with doctors ■ Improve clinical training ■ Better clinical supervision ■ Access to state pharmacies ■ Roll-out to rural areas ■ Improve primary / secondary integration ■ Improve networking with existing prescribers ■ Increase hospice capacity ■ Better pharmacy links ■ More storage cupboards
Resources ■ Lack of prescribers and pharmacists ■ Costs ■ Lack of facilities to follow patients home	**Resources** ■ Identify sources of opioid funding ■ More pharmacists ■ Evaluation of opioid expansion

The INCB competent authorities and provider data: common goals and disparate perspectives

The INCB competent authorities and provider data: common goals and disparate perspectives
It is very illuminating to compare the data from the provider sample to the INCB sample. Although this could only be conducted for 5/12 countries, the contrast in the data suggests some conflicting views on the current provision of opioids.

Advocacy for greater access

A first point is that despite the need to lobby through government and achieve policy, legislative and bureaucratic change, it was extremely difficult for APCA (the principal advocacy body in Africa) to even identify and then make contact with INCB competent authorities in the majority of countries.

Second, among INCB competent authorities, the majority felt that a) the current bureaucratic process works well and, b) that there are adequate numbers of providers currently.

Third, it is important to recognize that any expansion in opioid availability carries implications for the regulatory bodies (i.e. the Ministry and INCB competent authorities), and these resource restrictions were noted by the respondents.
There was a far from clear view that expansion was possible, with fears expressed that the current cadre of prescribing professionals should be further trained and improved before more prescribers are trained. Indeed, the regulatory and legislative frameworks were described by INCB competent authorities as 'enabling', with many comments focusing on the weaknesses of existing prescribing staff.

However, despite these concerns, it should be noted that there were important areas of congruence between care sites and INCB competent authorities. These were: recognition that legislation has caused a reluctance to prescribe opioids; the need to review medical training curricula; and a need for an increase in medical school intake.

Drug availability: INCB competent authorities and site views

The availability of drugs, both opioids and other symptom-controlling drugs, was a constant theme throughout the data. However, the integration of data from care sites and INCB competent authorities highlights a disparity in the understanding of the availability of specific drugs. Table 14 demonstrates that in every country, the INCB competent authority named a drug that was not listed by any service in that country. It may be that the low number of respondents in some countries led to an under-reporting of some drugs at sites, but these sites were identified by APCA as the most prominent and accessible palliative care providers, and if they do not have access then this suggests under-supply.

Limitations

There are several limitations to our findings. Firstly, the lists of potential contacts may have excluded a number of providers, but was composed of every service known to the funders, research centre and APCA, and so we believe it was an inclusive and exhaustive recruitment procedure.

Secondly, significant difficulties were experienced in the data collection phases, mainly logistical challenges (including failing power, telecommunications, lost emails and unobtainable contacts) that may have reduced the response rate. The significant challenges of undertaking primary research in Africa, which are well recognized (15), were compounded by our aim of collecting data in 12 countries.

Thirdly, the sample was weighted towards South Africa, and although it would be useful to compare the findings according to country, there are currently insufficient operational services to allow this.
The low number of palliative care providers and patchy coverage disallow the potential to generalize from a random sample, and therefore we attempted to contact all services according to the APCA Classification (Appendix 1).

Fourthly, the focus is solely on opioids. As a defining feature of palliative care that separates it from those services unable to control pain this is useful. However, opioids alone do not constitute a palliative care service. It is not possible to deliver a full investigation of palliative care in this study, and other data sources are available. The focus will be central to delivering the stated outputs. A further exclusion is education, an important activity that cannot be given full consideration. It is however included as a variable.

Fifth, the inclusivity and thoroughness of the contact list was central to sampling and the generalisability of the data. We designed the list of potential participants in collaboration with country representatives to ensure that all relevant people are involved. We acknowledge that in South Africa opioids are "essential drugs" and as such are usually available in public health care facilities. The scope of this small-scale exercise did not allow all such facilities to be included and focuses instead on the perspective of palliative care services that may or may not have access to opioids.

Conclusion

A key finding from this study has been that while there are common issues raised by services and INCB competent authorities, it is clear that these key stakeholders have concerns regarding the potential roll-out of opioids. A number of very practical suggestions have been made, all of which must be taken into account in any strategic plan to enhance pain relief, as strategies that target change in the domains of education, resources, bureaucracy, legislation and provider sites cannot achieve the goal in isolation.

The data suggest similar numbers of clinical staffing and different domains of care between integrated and palliative-only services, while the latter offers care to fewer patients with a greater likelihood of opioid use and staff who are trained in palliative care. Each may have its merits, and further attention should be paid to networks of referral to ensure access appropriate to patient need, as well as the development and use of multi-dimensional outcome evaluations to appraise the resource implication costings in the light of varying outcomes. The question of education has not been addressed in this study, and was a constant theme in discussion of solutions to opioid use. The educative role of 'specialist' centers should not be underestimated, and evaluative studies should take account of the education activities and outcomes of these services.

Finally, previous work reviewing evidence and outcomes for palliative care in Africa has identified the need to balance quality and coverage. This study shows that opioid expansion needs to balance supply and skills: there are currently not enough staff to prescribe and supply is unreliable, and any efforts to expand supply should ensure that it does not weaken current systems.

Recommendations

For practitioners

1) While the presence of both specialist and integrated centers should be encouraged, it is essential that each can offer the basic service elements of the other when needed. Examples of this from our data are expansion of bereavement care and family support in integrated services, and economic support activities in palliative-only centers. However, this expansion of core skills and service components should occur with the proviso that specialist palliative-only centers have referral criteria and capacity to offer care for more complex cases.

2) Referral networks between ART sites and palliative care services should ensure that not only are patients under palliative care referred for ART, but that mechanisms of clinical support and consultancy are offered so that ART sites can access palliative care as treatment is initiated and continued.

3) With the wide range of distressing and burdensome HIV and treatment-related symptoms, practitioners should remember to assess and treat the full spectrum throughout the disease trajectory including ART treatment. Also, any side-effects of opioids must be constantly monitored and controlled, and drugs made available to achieve this.

4) Where opioid access is poor, networks should be established with current hospice and governmental providers to establish routes for dispensing.

5) Rural and HBC services should consider their potential routes to palliative care drugs when arranging palliative care training for their staff, as the management of spiritual and emotional pain cannot be achieved without the management of physical pain.

For educators

6) All services, whether palliative-only, integrated NGO or government facilities, must ensure that all clinical staff are trained in palliative care to a basic agreed level. This would assist staff to assess palliative care needs, to provide general

palliative care, and be aware of when to make appropriate referrals for specialist input.

7) Training and education providers should form collaborative teaching activities with current clinicians. Those in practice require ongoing professional education to improve the pain control needs of those living with HIV, and to meet the needs of the dying.

8) Training and education providers should form collaborative teaching activities with future clinicians. The inclusion of palliative care in medical school curricula should be a goal for all countries.

9) Education must take a long-term view of the process of teaching, and mechanisms put in place to ensure follow-up to support the application of skills learned.

10) Shorter palliative care courses that focus on prescribing should be considered for current clinicians.

11) Educators need to redouble efforts to address the public fears of opioids. A potential means to achieve this may be through the existing significant global networks for HIV advocacy groups. Currently the issues of palliative care and opioid use are not championed by people living with HIV/AIDS.

12) There may be educational opportunities to work with INCB competent authorities to demonstrate the successes of opioid use and the current limitations that could be addressed. Such consultation may also offer INCB competent authorities an opportunity to share their concerns. Interactive education and sharing of viewpoints may offer better potential for feasible and acceptable strategies for opioid expansion.

For funders

13) Funders must take account of the high burden of pain and symptoms that affect quality of life and allocate resources to ensure that these manageable problems are adequately controlled.

14) Patients should have local access to antiretroviral therapy at all services that offer palliation whatever disease stage the service focuses on. Referral and co-management care pathways should be in place to ensure that even if palliative care and therapy are not available at the same site, they are co-ordinated to ensure that they can be integrated across services.

15) Currently, palliative-only services see fewer patients. While not all people living with an incurable life-limiting disease should require specialist palliative care, and not all people at the end of life should or could access hospice care, resources are required to increase the capacity of these institutions to enhance their educative, advocacy and specialist role for complex case management.

16) Funding for clinically trained staff is essential in HBC HIV sites, as opioids cannot be utilized without staff able to prescribe.

17) Funders should consider the structural requirements of sites, e.g. the essential current problems of adequate opioid storage facilities and pharmacy facilities, in addition to staff and training costs.

18) Funders should consider those analgesics beyond opioids, i.e. neuropathic pain agents, which are costly, but essential for pain that cannot be controlled with opioids.

For policy makers

19) The current opioid (and non-opioid) drug supply systems experience a number of blockages and uncertainty in supply. Any expansion will require identification of the strongest routes, and to strengthen these further, before expanded drug supply can be achieved.

20) While there is emphasis on expanding opioid supply, this is being pursued to enhance adherence to the WHO pain ladder. It is clear from the data that this requires attention to all steps of the ladder, including in some cases provision of Step 1 pain-relieving drugs.

The INCB competent authorities and provider data: common goals and disparate perspectives

21) Policies to expand opioid access must carefully balance the need for expansion with the threat of additional pressure on unreliable current purchase, production and dispensing. Expansion should not be at the cost of reliability.

22) Any strategy for expansion must take account of the concerns of INCB competent authorities with respect to regulation. Advocacy and lobbying must convince this essential stakeholder group of the feasibility of expansion programs, as current INCB skepticism may prove a significant barrier.

23) The synergies of strengthening supply systems for opioids can also enhance other symptom-controlling drugs, such as antiemetics and anxiolytics, which are also essential for this population.

24) Any strategic approach to opioid expansion must use a multi-pronged approach taking account of: supply (e.g. ordering and stocking, constistency of availability), legislation (e.g. regulations on storage and prescribing), education (i.e. ensuring that opioids are used appropriately) and practical site-specific support (e.g. adequate numbers of trained and able-to-prescribe staff, funds and storage facilities). Failure to address each of these areas is unlikely to achieve sustainable success.

25) Each country should undertake a wide-ranging consultation process to appraise its current legislation and identify the potential to pilot and test safe, feasible and practical legislation for the prescribing and dispensing of opioids.

26) Policy change, across the legislative and regulatory settings, can only be achieved through co-ordinated advocacy that takes account of governmental disinterest and professionals' fears of opioid use.

27) Current funding goals to increase the numbers of patients accessing palliative care should take account of the current limitations on opioid use and supply, and address the likely pressure on existing infrastructure.

28) In order to address the current weaknesses in supply, and build capacity for expansion, greater emphasis and capacity needs to be placed on training and employing pharmacists.

For researchers

29) In the light of different models of care and numbers of trained staff and patients seen according to service model, multidimensional outcome evaluations are required, including measurement of pain and symptoms.

30) Evaluative studies should compare both economic costing and levels of analgesia available, taking account of comparative baseline patient need across models.

31) Referral criteria and care networks should be examined to understand the movement between sites as patients move up and down the pain ladder.

32) All strategies and programs to expand opioid use should be evaluated to ensure that lessons can be replicated/adapted for use in other sites.

33) Longitudinal evaluation of education should be conducted to measure practice outcomes.

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The participating sites were:

- AFXB
- AIDS Care Training and Support (ACTS) Initiative
- Associacao Nacional dos Enfermeiros de Mocambique (ANEMO)
- Bamalete Lutheran Hospital
- Breede River Hospice
- Camdeboo Hospice
- Catholic AIDS Action
- Catholic Diocese of Ndola, Integrated AIDS Program
- Chatsworth Regional Hospice
- Chipata Diocese
- CHU de COcody
- Coast Hospice
- Cotlands Western Cape
- Cradock Hospice (Good Samaritan Home)
- Eldoret Hospice
- Estcourt Hospice
- Federal Medical Centre, Abeokuta, Hospice and Palliative Care Services
- Golden Gateway Hospice
- Good Shepherd Hospice
- Grahamstown Hospice
- Highway Hospice
- Holy Cross AIDS Hospice
- Hospice Africa Uganda
- Hospice East Rand
- Hospice Rustenburg
- Hospice Viljoenskroon
- Howick Hospice
- JOY Hospice (Deliverance Church Medical Services)
- Kara-Ranchod Hospice
- Kara Counseling and Training Trust
- Khanya Hospice Association
- Kisumu Hospice and Palliative Care
- Kitovu Mobile AIDS Home Care and Orphans Program
- KNYSNA Hospice
- Ladybrand Hospice
- Little Hospice Hoima
- Meru Hospice
- Mildmay International
- MMM Counseling and Social Service Centre
- Mobile Hospice Mbarara
- Moretele Sunrise Hospice
- Mother of Mercy Hospice Trust
- Muheza Hospice Care
- Nairobi Hospice
- Nyeri Hospice
- Ocean Road Cancer Institute
- Palliative Care Initiative
- PASADA
- Pretoria Sungardens Hospice
- Radio and Oncology Centre, Ahmadu Bello University Teaching Hospital
- Rays of Hope Hospice Jinja
- Selian Lutheran Hospital Hospice
- South Coast Hospice
- St Joseph's Care and Support Trust
- St Nicholas Children's Hospice
- Stellenbosch Hospice
- SWAA-Rwanda
- Tapologo Hospice
- Tikondane Home-Based Care Foundation
- Tygerberg Hospice

Department of Palliative Care, Policy and Rehabilitation, King's College London

Our mission is to produce cutting edge innovative research to improve care for patients and families affected by progressive life limiting disease, and discover more humane and effective care and treatment. We have special expertise in those groups who have been neglected or who have problems we continue to struggle to alleviate.

The Department is multi-professional, comprising 2 clinical Professors, 2 Clinical Senior Lecturers, 3 Lecturers, 2 Senior Research Fellows and around 20 multi-professional research, education and support staff and consultants in the three main hospitals to which our Medical School is partnered, Guy's and St Thomas' NHS Trust, and King's College Hospital. We also have collaborations and shared appointments with many palliative care teams, hospices and related services in the UK and overseas and with colleagues in Schools throughout King's College London, including Medicine, Biomedical Sciences, Dentistry, Nursing and Midwifery, Law and Ethics, the Institute of Psychiatry and the Humanities.

Our portfolio of work in palliative care research in Sub-Saharan Africa, and our history of research into care for people with non-malignant diseases including HIV/AIDS, has resulted in a number of teaching and research projects in the region, including the generation and appraisal of original research.

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African Palliative Care Association

The mission of the African Palliative Care Association (APCA) is to promote and support affordable and culturally appropriate palliative care throughout Africa. APCA was provisionally established in November 2002, and formally established in Arusha, Tanzania, in June 2004. Its aim is to contribute to the African response to the HIV/AIDS epidemic by scaling-up palliative care provision across Africa through a culturally appropriate public health approach that strives to balance quality with coverage. Its broad objectives are to:

- Promote the availability of palliative care for all in need, including orphans and vulnerable children.
- Encourage governments across Africa to support affordable and appropriate palliative care which is to be incorporated into the whole spectrum of health care services.
- Promote the availability of palliative care drugs for all in need.
- Encourage the establishment of national palliative care associations in all African countries.
- Promote palliative care training programmes suitable for African countries.
- Develop and promote quality standards in palliative care training and service provision for different levels of health professionals and care providers.

To achieve these objectives, APCA employs a fourfold approach in their work that includes:

1. Working in collaboration with those organisations and individuals championing palliative care service provision in Africa to ensure governments and other international donors accept palliative care as a vital component in the care of people with life-limiting illnesses (including HIV/AIDS) and incorporate budget lines for dedicated funding that will be used to build palliative care capacity across the region.

2. Providing technical assistance to non-governmental organisations and Faith-based organisations working on HIV/AIDS to help them integrate palliative care into existing work programmes, thereby ensuring palliative care is recognized as part of the spectrum of responses for effective HIV/AIDS management.

3. Supporting identified champions of palliative care (both individual and organisational) in positions that can influence national policy so that:

- Palliative care is included in the curricula for all medical and nurse training, thereby increasing the existing skills base so that palliative care provision in the region can be sustained;
- Palliative care is incorporated into the national health plans of African governments;
- Appropriate drugs for the alleviation of pain and to combat opportunistic infections are made available.

4. Developing a mentorship programme for new organisations with ongoing technical support to ensure initiatives are sustainable.

As implied above, APCA does not provide direct clinical care to people living with life-limiting illnesses. Rather, it plays a facilitative role, working collaboratively with existing and potential providers of palliative care services to help expand the scale of service provision by training existing and potential service providers, providing support for effective advocacy work and offering a mentorship program to support emerging initiatives; and to improve the quality of care provision by the introduction of a quality assurance and standards of care program.

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Appendix 1

APCA's Tool for the Classification of Palliative Care Activities

Organisational Capacity Level	Qualifying Criteria for Organisational Capacity Level
Level 1 ***Not palliative care***	1. Relies mainly on community health workers (CHW)/volunteers 2. Includes basic administrative structures 3. Provides supportive care 4. Does not provide basic OI and/or pain assessment and management services
Level 2	1. Relies on CHW/volunteers and part-time qualified health professionals 2. Includes basic administrative structure and procedures (e.g. job descriptions) 3. Provides support and basic clinical services for OI, WHO level 1 pain assessment and management
Level 3	1. Relies on CHW/volunteers and full-time qualified health professionals 2. Includes managerial and administrative structure and procedures (management, technical and support staff 3. Relies on multidisciplinary team approach for service delivery 4. Uses protocols for support and clinical services for OI and pain assessment and management 5. Provides support and clinical services for OI and at least WHO level 2 pain assessment and management 6. Manages a basic referral network for provision of essential palliative care components
Level 4 **Centre of Excellence**	1. All the above 2. Manages a proactive referral network 3. Provide support and clinical services for OI and WHO level 3? pain assessment and management 4. Provide technical assistance and training to partner organisations 5. Recognised palliative care champion

Notes

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