Original Article

Barriers to Accessing Internationally Controlled Essential Medicines in Uganda: A Qualitative Study

Gaby Isabelle Ooms, MSc, Paul Klatser, PhD, Hendrika A. van den Ham, PhD, and Tim Reed, PhD

Health Action International (G.I.O., T.R.), Amsterdam; WHO Collaborating Centre for Pharmaceutical Policy and Regulation (G.I.O., H.A.v.d.H.), Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University, Utrecht; and Vrije Universiteit (P.K.), Amsterdam, The Netherlands

Abstract

Context. Access to internationally controlled essential medicines is a problem worldwide. More than five billion people cannot access opioids for pain and palliative care or do not have access to surgical care or anesthetics, 25 million people living with epilepsy do not have access to their medicines, and 120,000 women die annually owing to postpartum hemorrhage. In Uganda, access to controlled medicines is also problematic, but a lack of data on factors that influence access exists.

Objectives. The objective of this study was to identify the social, cultural, and regulatory barriers that influence access to internationally controlled essential medicines in Uganda.

Methods. Semistructured interviews with 15 key stakeholders with knowledge on controlled medicines from relevant institutions in Uganda. Interviews were transcribed verbatim and analyzed using the *Access to Medicines from a Health System Perspective* framework.

Results. Barriers in accessing controlled medicines were experienced owing to lack of prioritization, difficulties in finding the balance between access and control, deficiencies in the workings of the estimate and distribution system, lack of knowledge, inadequate human resources, expenses related to use and access, and stigma. It was believed that some abuse of specific controlled medicines occurred.

Conclusion. The findings of this research indicate that to improve access to internationally controlled essential medicines in Uganda, health system strengthening is needed on multiple fronts. Active engagement and concerted efforts are needed from all stakeholders to ensure access and prevent abuse. J Pain Symptom Manage 2019;■:■–■. © *2019 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.*

Key Words

Controlled medicines, essential medicines, access to medicines, drug control, opioid analgesics, psychotropic substances

Introduction

The World Health Organization (WHO) Model List of Essential Medicines (EML) contains medicines that aim to satisfy the priority health care needs of the population, and they ought to be available at all times.[1,2] The EML also includes medicines controlled by law through the Single Convention on Narcotic Drugs of 1961, the Convention on Psychotropic Substances of 1971, and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988.[3-6] Controlled medicines are subjected to stricter regulatory practices than noncontrolled medicines owing to their potential for abuse.[4-6] On the 20th EML, 14 medicines are controlled under one of the conventions.[7] These internationally controlled essential medicines (ICEMs) are used as anesthetics, anticonvulsants, topical anti-infective, oxytocic, anxiety disorder medicines, for opioid agonist treatment, and for pain and palliative care (see Table 1).[7]

Address correspondence to: Gaby Isabelle Ooms, MSc, Health Action International, Overtoom 60-2, 1054 HK Amsterdam, The Netherlands. E-mail: gaby@haiweb.org

Accepted for publication: July 3, 2019.

0885-3924/$ - see front matter
https://doi.org/10.1016/j.jpainsymman.2019.07.002

Table 1
Controlled Medicines Listed on WHO EML

	Therapeutic Use							
Medicine	Anesthesia	Anticonvulsant	Anxiety Disorders	Management of Cancer Pain	Opioid Agonist Treatment	Oxytocic	Pain and Palliative Care	Topical Anti-infective
Buprenorphine					■			
Codeine							■	
Diazepam		■	■					
Ephedrine	■							
Ergometrine						■		
Fentanyl				■				
Hydromorphone							■	
Lorazepam		■	■					
Methadone					■		■	
Midazolam	■	■	■					
Morphine	■						■	
Oxycodone								
Phenobarbital		■						
Potassium permanganate								■

Shaded area signifies the corresponding therapeutic use of an ICEM.
WHO = World Health Organization; EML = Model List of Essential Medicines; ICEM = internationally controlled essential medicine.

Globally, five billion people are unable to access essential opioids or anesthesia if needed, and more than six million people die in unbearable pain annually; more than 25 million people living with epilepsy do not receive the medicines they need; and 120,000 women die annually owing to postpartum hemorrhage.[8-11] Meanwhile, 92% of morphine is consumed by just 17% of the global population, all living in high-income countries.[8,12]

Difficulties accessing ICEMs are partly because of the strict regulation surrounding these medicines.[8,13] Legal restraints are further augmented by Article 39 of the Single Convention, which allows countries to adopt more severe measures than those provided in the Single Convention on Narcotic Drugs.[4] In many countries, this leads to a stronger focus on preventing illicit drug trafficking than on ensuring availability of these medicines.[14]

Although Uganda is heralded as an example for other countries due to, among others, local manufacturing of oral morphine, availability of hospice and palliative care services, and nurse prescribing, access to controlled medicines remains problematic.[15,16] A study on opioid availability in Africa showed that in Uganda, methadone was unavailable, and only codeine and injectable or immediate-release oral morphine were occasionally available at facilities.[17] Major problems for patients were also experienced in accessing pharmacies that prescribe these medicines, as only hospital pharmacies are allowed to handle opioids.[17] Furthermore, other ICEMS have not received a similar level of attention as opioids; data are lacking on their day-to-day availability in Uganda, as well as on the factors that inhibit their accessibility. Consequently, action to improve access is difficult, highlighting the need for detailed data on access to controlled medicines in Uganda.[18-21] The aim of this research is to identify the factors that influence access to ICEMs in Uganda, using semistructured interviews.

Methods

Study Design and Population

This qualitative study consisted of semistructured interviews with key experts. Mapping was done through document desk review, and in consultation with the Ministry of Health (MoH), the National Drug Authority (NDA), and a nongovernmental organization (NGO) to conceptualize the supply chain and service delivery of ICEMs. The process identified 11 relevant stakeholder groups, including MoH, NDA, the police, manufacturers, distributors, health care professionals, and NGOs and civil society organizations. Stakeholders were selected based on the following criteria: 18 years or older; capacity to give informed consent; knowledge on access to ICEMs; ability to communicate in English.

Data Collection

Interviews were conducted between August 2, 2016, and August 27, 2016. Fourteen were completed face-to-face and one used video-calling. Biases were believed minimal between the two methods as video-calling also allows face-to-face interaction and thus facilitates trust-building. The face-to-face interviews were conducted at a place chosen by the respondents to ensure they felt comfortable. Interviews were semistructured, meaning questions were asked in a systematic and consistent order, but

Table 2
Characteristics of Interviewed Stakeholders

No	Discipline	Profession	Gender
1	Health care provider	Specialist physician	Male
2	Health care provider	Specialist physician	Female
3	Health care provider	Senior pharmacist	Male
4	Health care provider	Senior pharmacist	Male
5	Local manufacturer	Senior advisor	Male
6	Local manufacturer	Senior advisor	Male
7	Distributor	Senior advisor	Male
8	Distributor	Senior advisor	Male
9	Civil Society Organization	Director	Male
10	Civil Society Organization	Senior advisor	Female
11	Non-Governmental Organization	Senior advisor	Male
12	Non-Governmental Organization	Director	Male
13	Ministry of Health	Senior advisor	Male
14	Ministry of Health	Senior advisor	Male
15	National Drug Authority	Senior advisor	Male

allowed for follow-up questions if relevant to the topic of study. This allows for flexibility that reflects awareness that respondents understand the research topic in various ways.[22]

An interview guide was developed containing questions pertaining to respondents' knowledge and perceptions on the social, cultural, and regulatory factors that influence access to ICEMs in Uganda. Examples of questions are as follows: "What factors influence access to ICEMs?"; "Can you tell me about the enforcement of the regulatory practices concerning ICEMs?"; "What are the challenges surrounding the supply and distribution of ICEMs?"; and "What do you think are the main challenges experienced by patients in accessing ICEMs?" For more information, see Appendix. The interview guide was tested in a pilot interview with a health care professional. Consequently, minor modifications in phrasing were made to improve comprehensibility.

Respondents were provided with a participation information sheet and asked to sign an informed consent form. All interviews with the exception of one, due to the wishes of the respondent, were recorded. During the interviews, field notes were collected, capturing mood and expressions of the respondents. Interviews lasted from 40 to 75 minutes.

Data Management and Analysis

Analysis of the interviews was done using the program MAXQDA version 12. Data was entered manually. Textual data from interview transcripts and field notes were collected, organized, and cleaned. Transcripts were transcribed verbatim and coded deductively and inductively into themes using the *Access to Medicines from a Health System Perspective* framework.[23] This framework argues that access to medicines barriers function at the local, national, and international level and that health system building blocks are not separate factors, but interactions exist between these blocks.[23] The framework was adapted during the research to the contextualization of the controlled medicines situation. The researchers (G. I. O. and T. R.) coded the first transcript separately to generate code categories independently. After, the researchers reviewed the separately coded transcripts together to reach consensus on the final code-categories to be used for the analysis of the transcripts.

Quality Assurance

This research used the COREQ framework for reporting methods and findings.[24] In this research, credibility and dependability were taken into consideration through the consensual coding, and peer-debriefing during the writing process as done by the coauthors (T. R., P. K., and H. A. v. d. H.). Informant triangulation occurred through the inclusion of different stakeholders in the research. Transferability was considered through purposive sampling and thick descriptions of the data collection process, such as how and where the interviews were conducted. Confirmability was achieved by considering the aforementioned considerations and by ensuring the researchers' neutral, objective stances through reflectiveness on the manner of data collection.[25] The study was approved by Makerere University School of Health Sciences Research and Ethics Committee, approval number 2016−29.

Results

Fifteen of 19 stakeholders contacted participated. Stakeholders interviewed are shown in Table 2. Topical saturation was reached; the last three interviews did not yield new concepts.

An account is given of the stakeholders' perceptions regarding the factors influencing access to ICEMs in Uganda. An overview of the findings is shown in Fig. 1. The results are categorized according to the components of the adapted framework. Themes more often mentioned in interviews are shown as bigger boxes. Key themes were as follows: regulation—access vs. excess, availability, and illicit use.

International Level

Multiple respondents stated international control bodies guide control at country level. Uganda has to justify the use of ICEMs to these bodies, and its legislation and control is also based on the bodies' principles. However, ability to meet the requirements of the control bodies is difficult, influencing availability of the ICEMs at the national level.

> … Countries tend to adopt global norms. If the control is right from the global level, it is likely

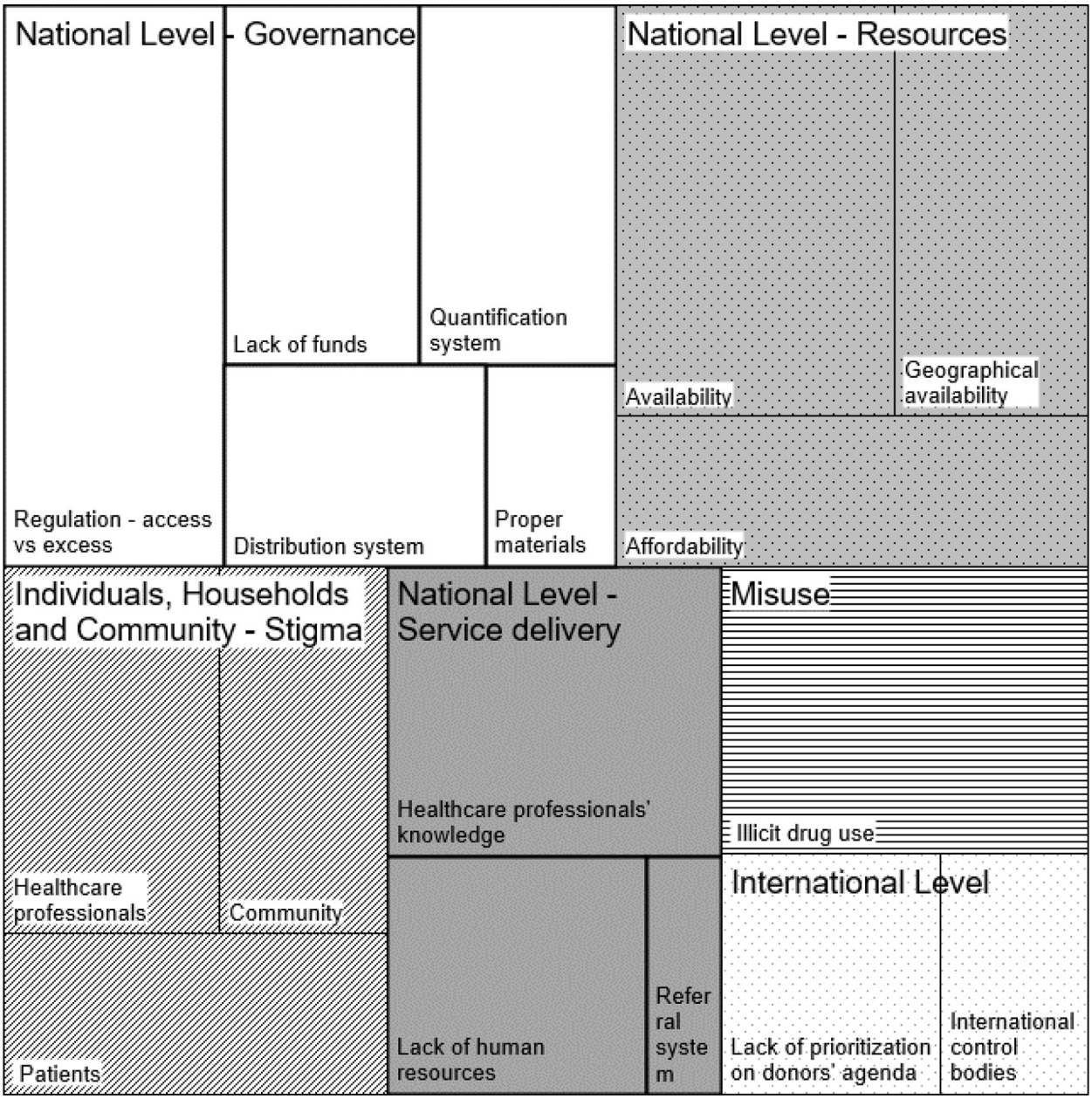

Fig. 1. Treemap chart. Overview of the factors influencing access to ICEMs. ICEMs = internationally controlled essential medicines.

the countries are going to have control systems, that inevitably influences access, inevitably. (R12)

Respondents believed that ICEMs were not a donor priority. They agreed that donor funding might help improve access but raised the question of sustainability of donor-supported programs. Donor funding alone was thought to not be enough to meet the needs.

National Level

Governance. The MoH's budget was argued to be inadequate to meet the population's needs, resulting in prioritization of certain health themes. The disease fields related to ICEMs were argued not to be prioritized in terms of budget allocation, causing the central procurement agency to be unable to guarantee supply of the medicines. This resulted in stock-outs and insufficient quantities at health centers.

Respondents often referred to the necessity of drug control. Although some believed ICEMs regulations were in line with their potential for abuse, other respondents mentioned regulations were a barrier. It was stated that it caused extra work, such as the necessity of additional documentation books and special licenses for prescribing opioids. Furthermore,

some prescribers fear the threat of legal sanctions, such as license revocation, influencing prescribing practices.

However, participants also stated that some abuse of ICEMs occurred in Uganda. For instance, diazepam was argued to be available without a prescription and was used by parents to calm children so they could work uninterrupted. According to respondents, they were unaware of side effects:

> Many parents tend to use it because it […] calms down the children and sedates them. The children can then sleep, and then the parents go to do their work. But the parents are not aware about the negative effects of the diazepam. (R15)

Respondents stated that for other ICEMs, abuse was limited because the formulations available are not easily abused. Interestingly, some respondents mentioned abuse of pethidine, which is a controlled medicine but is not listed on the WHO EML. Linked to the fear of abuse, use of opioids for opioid agonist treatment is illegal. The reasoning is that although it could be used for treatment, opioids are also injected by persons suffering from addiction.

The information system, specifically the estimates system, was also believed to hamper access. Quantities of ICEMs listed on the Single Convention allowed into a country are based on a country's annual requests to international control bodies. Respondents stated Uganda has no system to document the use and need of ICEMs. Instead, quantification is based on estimates, leading to inadequate quantities and stock-outs:

> There is no logistics management information system that can be used to […] document the cases that are being seen and then also to build in a forecast factor and say two years from now, this is what we need. So it is very difficult to do that type of quantification. (R6)

Another problem with the estimates system was related to human resources. Respondents argued that problems were exacerbated by health care providers' lack of knowledge on how to quantify the needs:

> The other aspects would be the personnel at the health centers, are they available, who adequately quantify the need that they require […]? If you cannot quantify your need from the health center, then how are you able to indicate to the person supplying you the medicines that this is what you need? (R7)

The distribution system was also thought to be a barrier. Respondents said that when health centers order a certain quantity of ICEMs, they sometimes only receive a fraction of the order due to problems experienced by the distributor or due to practical delivery issues.

Service Delivery. Uganda has a special morphine prescribing policy, which allows nurses to prescribe morphine. This policy was a response to the shortage of doctors able to prescribe opioids. However, the number of prescribers was argued to still be insufficient to treat those in need. Moreover, respondents mentioned human resources are unequally distributed across Uganda as health care providers preferred to work where remuneration for their services was best; this is not in rural areas or the public sector. Besides, respondents argued that many health care providers allowed to prescribe ICEMs were in practice not adequately skilled to do so because they lacked training and knowledge. Related, even when they had received training on ICEMs, respondents mentioned that the addictive qualities and side effects were overemphasized, leading to fears:

> The issue is […] the reluctance of prescribers to prescribe controlled medicines. But like morphine, people didn't want to prescribe it. They say no-no-no-no, people get addicted to these medicines. (R1)

Finally, information sharing between health centers was thought inadequate. Uganda's health system consists of seven levels of health service delivery: Health Center I (village health teams); Health Center II (first point of contact between patient and formal health care services); Health Center III (first-line health services); Health Center IV (secondary and emergency care); General Hospital (services offered at HC IV, and training and consultations); Regional Referral Hospital (services offered at general hospital, additionally specialized services); National Referral Hospital (regional referral hospital, additionally teaching and research hospital).[26] Referral of patients was argued to often not occur because contact between the different levels was thought to be lacking: lower level centers were unaware of ICEMs availability at higher levels, hampering service delivery.

> So you find at times, when they're in a health center II, they don't want to refer you to a health center III because I don't know whether they have it. So we just tell you that the medicine is not there. But if there is a strong referral system and I know that this health center III has this, then it makes it easier. (R5)

Resources. An important obstacle to accessing ICEMs was affordability. Many voiced that patients often have to travel far to access medicines, costing money. ICEMs were also not always available in the public sector, where all medicines are free to the patient, forcing patients to seek care from the private sector where costs are

substantial. Patients might also have a chronic need for medicines, exacerbating financial hardships:

> Well they can't afford it. I think you need to look at the poverty situation in this country. Sometimes critical medicines are not available in the system, and the patients have to buy. […] They have to sell their property, just to get some basic treatment. (R12)

Discrepancies in the availability of specific ICEMs were identified by respondents. Respondents also referred to the lack of availability of different formulations and the substantial gap between need and actual availability:

> When you look at our consumption on the global map, we're still very low compared to other countries in terms of consumption. So we need to do a lot in terms of improving this availability, and ensuring that these medications are available for those who need them. (R4)

Geographical availability also affected accessibility because it was believed that rural areas had more difficulties with access than urban areas owing to longer distances and lesser facilities.

Individuals, Households, and Communities

Respondents reported beliefs and attitudes of the community and patients negatively influenced use of ICEMs. They stated communities associated ICEMs with diseases that are "in bad faith," and patients known to be taking medicines for such diseases are socially excluded and isolated, such as is the case for epilepsy. Owing to stigma, persons using anti-epileptics did not want to take them in public.

Not surprisingly, patients also held stigmatizing views. Respondents argued patients feared addiction, and they associated some ICEMs with death because patients with end-stage diseases received palliative care, which sometimes includes opioids, to alleviate their pain.

> For the patients, what is happening is that you know most people who are having cancer and are near death, most of them are the ones taking morphine. So many of them are now associating the use of the narcotic to death, and not to the cancer. (R3)

Discussion

This is the first study that provides qualitative insights into access to ICEMs in Uganda from a multiple-stakeholder perspective that not only focuses on access to opioids for palliative care. Barriers experienced were due to the controlled status of the medicines, while some were also barriers that were experienced by medicines in general. For instance, barriers that were experienced accessing ICEMs that also influence access to medicines in general were the use of an estimate system to quantify medicine needs, practical and logistical issues of supply, lack of human resources, expenses related to use and access, and physical and geographical availability. ICEM-specific barriers in Uganda were due to nonprioritization of ICEMs, difficulties in finding a balance between control and access, lack of knowledge among health care providers and the population, and stigma. In addition, some abuse of specific controlled medicines was mentioned.

This research on access to ICEMs upholds findings of previous research in a specific country context—that of Uganda. The finding that a lack in budget provisions for ICEMs in Uganda was an impediment to access is supported by previous research. In India, no budget was allocated to palliative care, and in many African countries, where epilepsy is often also categorized as a mental health disorder, no specific health budget is allocated to mental health.[27,28] The present research suggests lack of budget provisions plays a role in the availability of ICEMs and that international focus might contribute to more attention for these medicines.

The extra documentation books and special licenses necessary for opioid prescription in Uganda was thought to influence access negatively as health care providers were thought to be more reluctant to prescribe opioids. Similar problems hampered the prescription of opioids, as well as anti-epileptics, in other African countries.[17,29] The research further showed that reluctance to prescribe ICEMs due to fear of potential legal sanctions existed among health care providers. These fears were found to impede access of ICEMs in other countries as well.[12,30] Interestingly, legal sanctions were thought to not be overly restrictive by Ugandan policy makers, raising the question whether the offenses are in truth not too restrictive, and what can be done to allay the fears of health care providers.

Furthermore, respondents raised the issue that a lack of knowledge among health care providers might affect sufficient caregiving. Past research supports these findings, showing that many health care providers have little knowledge or understanding of controlled medicines.[8,12-14,31] The finding that health care providers are at times reluctant to prescribe ICEMs because they fear the addictive qualities were also found in previous studies.[8,30-33] Similar beliefs and stigmatization were thought to be present in communities and among patients in Uganda, which is supported by other research.[8,12,30,33,34] These findings suggest that in Uganda, lack of proper knowledge on ICEMs among health care providers, communities, and patients might lead to beliefs and attitudes that adversely affect the use and prescribing of ICEMs.

The research also showed that needs for ICEMs in Uganda are based on estimates and not on actual

Table 3
Recommendations to Improve Access to ICEMs in Uganda

Recommendations	
Policy • Ensure compliance to regulation Estimates and distribution system • Estimates system based on documentation • Strengthen distribution system Service delivery • Increase ICEMs prescribing possibilities for health care providers based on the opioid nurse prescribing policy • Integrate ICEMs service delivery into existing programs to ensure prioritization	Human Resources • Include/increase training on ICEMs in medical curricula Affordability • Ensure ICEMs availability in the public sector Community • Implement stigma-reduction programs • Develop information campaigns

ICEMs = internationally controlled essential medicines.

need. These estimates might already have been inadequate, as was found in other research.[8,13,30,31] One study showed that in Uganda, the actual availability of morphine covered only 2.3% of the population's needs.[35] Two other studies found that ephedrine was never available to 28% of anesthetists, and two-thirds of health centers IV had not been supplied with ergometrine for at least one-quarter of the year.[21,36] The ICEMs treatment gap in Uganda thus remains substantial.

Previous research studies further found that indirect costs and out-of-pocket expenses for ICEMs are high in many low- and middle-income countries.[12,13,34] This research found that in Uganda, most ICEMs are affordable in the public sector because they are subsidized by the government. Nevertheless, when they are unavailable there, patients need to visit the private sector where direct and indirect costs can be substantial.

Abuse of ICEMs was argued to not be a significant problem in Uganda. Nevertheless, some abuse was thought to occur, specifically of diazepam. Literature on this problem seems to be lacking, demonstrating a need for more research. Furthermore, an unexpected finding was that in Uganda pethidine, a medicine listed on the EMLU but not on the WHO EML was mentioned to be abused by health care providers.[7,37] Similar abuse was found in studies in Ghana.[38] Pethidine was removed from the WHO EML because it was considered inferior to morphine due to its toxicity and costs.[7,39] The WHO recommended it be removed from national lists and that countries focus on ensuring availability of morphine.[39] This research thus highlights a point of contention between the WHO EML and the EMLU, and a need for review of pethidine on the EMLU.

Some limitations to this research should be noted. One interview was not recorded owing to the respondent's wishes. Furthermore, the patient perspective was not included, while this perspective would have provided valuable, experiential knowledge. This perspective would be interesting to research in a separate study to provide it the importance it deserves. The researchers were also unable to interview stakeholders from private sector facilities or the procurement agency. These perspectives would have been a valuable component to the knowledge base which we have lain now; comparing access to ICEMs barriers between the public and private sector might have yielded additional insights.

Based on this research, multiple recommendations were formulated to improve access to ICEMs in Uganda (see Table 3). Health system strengthening, and active engagement and concerted effort of the government, regulators, suppliers, educational institutions, patient organizations, advocacy groups, NGOs, and health care providers, is needed. Health system strengthening is needed at the level of human resources, service delivery, policy, and the estimates and distribution system. Affordability of ICEMs and community education are also crucial to ensure access.

Conclusion

Access to ICEMs in Uganda is hindered by multiple aspects, among which health system barriers are one of the most important. Barriers were experienced owing to lack of prioritization, difficulties in finding the balance between access and control, deficiencies in the workings of the estimate and distribution system, lack of knowledge, inadequate human resources, expenses related to use and access, and stigma. The findings of this research indicate that to improve access to ICEMs in Uganda, health system strengthening with active engagement from all stakeholders is needed.

Disclosures and Acknowledgments

The authors declare that there is no conflict of interest. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

References

1. World Health Organization. Essential Medicines [Internet], 2016. Available from http://www.who.int/medicines/services/essmedicines_def/en/. Accessed January 24, 2016.

2. Jafarov A, Schneider T, Waning B, Hems S, Laing R. Comparative table of core and complementary medicines on the WHO Essential Medicines List from 1977-2011 [Internet], 2016. Available from www.who.int/medicines/publications/essentialmedicines/EMLsChanges1977_2011.xls. Accessed February 15, 2016.

3. World Health Organization. Access to Controlled Medications Programme. [Internet]. Geneva: World Health Organization, 2007:46.

4. United Nations. Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs. New York: United Nations Treaty Series, 1961:520:151. Available from https://treaties.un.org/doc/Treaties/1964/12/19641213%2002-14%20AM/Ch_VI_15.pdf. Accessed February 15, 2016.

5. United Nations. Convention on Psychotropic Substances. Vienna: United Nations Treaty Series, 1971. 1019:175. Available from https://treaties.un.org/doc/Treaties/1976/08/19760816%2008-16%20AM/Ch_VI_16p.pdf. Accessed February 15, 2016.

6. United Nations. United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. Vienna: United Nations Treaty Series, 1988. 1582:95. Available from https://treaties.un.org/doc/Treaties/1990/11/19901111%2008-29%20AM/Ch_VI_19p.pdf. Accessed February 15, 2016.

7. World Health Organization. WHO Model List of Essential Medicines: 20th List, 20th ed. Geneva: World Health Organization; 2017. Available from https://apps.who.int/iris/handle/10665/273826. Accessed December 18, 2017.

8. International Narcotics Control Board. Availability of internationally controlled drugs: Ensuring adequate access for medical and scientific purposes - indispensable, adequately available and not unduly restricted. New York. New York: United Nations, 2016:1–99.

9. Meara JG, Leather AJM, Hagander L, et al. Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development. Lancet 2015;386:569–624.

10. Tran DN, Bero LA. Barriers and facilitators to the quality use of essential medicines for maternal health in low-resource countries: an Ishikawa framework. J Glob Health 2015;5:1–9.

11. World Health Organization. Epilepsy: a public health imperative. Geneva: World Health Organization; 2019.

12. Global Commission on Drug Policy. The negative impact of drug control on public health: the global crisis of avoidable pain. Rio de Janeiro: Open Society Foundations, 2015:1–28.

13. Human Rights Watch. "Please, do not make us suffer any more …": access to pain treatment as a human right. New York: Human Rights Watch, 2009:46.

14. Lohman D, Burke-Shyne N. The impact of international drug policy on access to controlled medicines. New York: Open Society Foundations, 2015:1–17.

15. Jagwe J, Merriman A. Uganda: delivering analgesia in rural Africa: opioid availability and nurse prescribing. J Pain Symptom Manage 2007;33:547–551.

16. Lohman D, Schleifer R, Amon JJ. Access to pain management as a human right. BMC Med 2010;8:8.

17. Cleary J, Powell RA, Munene G, et al. Formulary availability and regulatory barriers to accessibility of opioids for cancer pain in Africa: a report from the Global Opioid Policy Initiative (GOPI). Ann Oncol 2013;24(supplement 11):xi14–xi23.

18. Choi Y, Ametepi P. Comparison of medicine availability measurements at health facilities: evidence from Service Provision Assessment surveys in five sub-Saharan African countries. BMC Health Serv Res 2013;13:266–274.

19. Cameron A, Bansal A, Dua T, et al. Mapping the availability, price, and affordability of antiepileptic drugs in 46 countries. Epilepsia 2012;53:962–969.

20. Harding R, Simms V, Penfold S, et al. Availability of essential drugs for managing HIV-related pain and symptoms within 120 PEPFAR-funded health facilities in East Africa: a cross-sectional survey with onsite verification. Palliat Med [internet] 2014;28:293–301.

21. Hodges SC, Mijumbi C, Okello M, Mccormick BA, Walker IA, Wilson IH. Anaesthesia services in developing countries: defining the problems. Anaesthesia 2007;62:4–11.

22. Witzel A. The problem-centered interview. Forum Qual Soc Res 2000;1.

23. Bigdeli M, Jacobs B, Tomson G, et al. Access to medicines from a health system perspective. Health Policy Plan 2013;28:692–704.

24. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research: a 32-item checklist for interviews and focus groups. Int J Qual Heal Care 2007;19:349–357.

25. Anney VN. Ensuring the quality of the findings of qualitative research: looking at trustworthiness criteria. J Emerg Trends Educ Res Policy Stud 2014;5:272–281.

26. Uganda Ministry of Health. Health sector strategic & investment plan: promoting people's health to enhance socio-economic development 2011/12 - 2014/15. Kampala 2010.

27. Rajagopal MR. The current status of palliative care in India. In: Magrath I, ed. Cancer Control: Cancer Care in Emerging Health Systems. Brussels. INCTR, 2015:57–62.

28. Jenkins R, Baingana F, Ahmed R, McDaid D, Atun R. Health system challenges and solutions to improving mental health outcomes. Ment Health Fam Med 2011;8:119–127.

29. Chomba EN, Haworth A, Mbewe E, et al. The current availability of antiepileptic drugs in Zambia: implications for the ILAE/WHO "out of the shadows" campaign. Am J Trop Med Hyg 2010;83:571–574.

30. Berterame S, Erthal J, Thomas J, et al. Use of and barriers to access to opioid analgesics: a worldwide, regional, and national study. Lancet 2016;387:1644–1656.

31. Harding R, Powell RA, Kiyange F, Downing J, Mwangi-Powell F. Provision of pain- and symptom-relieving drugs for HIV/AIDS in sub-Saharan Africa. J Pain Symptom Manage 2010;40:405–415.

32. O'Brien T. Cancer pain and opioid use: a global issue. Q J Med 2013;106:603–605.

33. Bosnjak S, Maurer MA, Ryan KM, Leon MX, Madiye G. Improving the availability and accessibility of opioids for the treatment of pain: the International Pain Policy Fellowship. Support Care Cancer 2011;19: 1239–1247.

34. Milani B, Scholten W. The world medicines situation 2011: access to controlled medicines. Geneva: World Health Organization, 2011:1–22.

35. Seya M-J, Gelders SFAM, Achara OU, Milani B, Scholten WK. A first comparison between the consumption of and the need for opioid analgesics at country, regional, and global levels. J Pain Palliat Care Pharmacother 2011; 25:6–18.

36. Atukunda EC, Brhlikova P, Agaba AG, Pollock AM. Civil Society Organizations and medicines policy change: a case study of registration, procurement, distribution and use of misoprostol in Uganda. Soc Sci Med [Internet]. Elsevier Ltd; 2015;130:242–249.

37. Uganda Ministry of Health. Essential Medicines and Health Supplies List for Uganda 2016. Kampala; 2016.

38. Asare JB, Addae AA. Substance use disorders in Ghana. In: Changing Trends in Mental Health Care and Research in Ghana. Legon-Accra: Sub-Saharan Publishers, 2014:83–98.

39. World Health Organization. The Selection and Use of Essential Medicines: Report of the WHO Expert Committee, 2003. Geneva: World Health Organization, 2003:128.

Appendix.

Interview Guide

Introduction

1. As an introduction, could you tell me a bit about yourself and your position at … … … … … … … …?
2. As I've explained, we are doing research on the availability and accessibility of essential controlled medicines. So what are your thoughts on the current situation in Uganda concerning availability and accessibility of controlled medicines?

Regulation

3. What are your views on current laws on controlled medicines, regulation and policies in Uganda? (probe on laws which respondents refer to)
4. In your opinion, how do these above laws affect availability, accessibility and affordability?
5. Can you think of any other factors that in your opinion influence accessibility and availability of ICEMS? (probe further on how the factors influence access)
6. In your opinion, what needs to be changed on a regulatory level to improve the access to ICEMs?

Enforcement

7. Can you tell me about the enforcement of the regulatory practices concerning ICEMs?
8. What are your views on the legal sanctions surrounding the use and misuse of ICEMs?
9. The WHO states that a balance should be found between protecting people from abusing controlled medicines and providing people with the needed controlled medicines. Would you say this is the case in Uganda?

Supply Chain and Distribution

10. Can you tell me about the process of the supply chain/distribution system of ICEMs? (procurement, manufacturing, distribution)
11. What are the challenges that are being experienced? (provision, quantities)
12. Are there differences between the private and public sector?
13. I know that health facilities must make an estimation of the needed ICEMs, do you believe this system functions well?

International level

14. In your opinion, do donors and international priority and attention influence accessibility and availability of ICEMs in any way?

Patient Experience

15. What do you think are the main challenges experienced by patients in accessing controlled medicines?
16. Do you believe stigma is a factor that plays a role in the accessibility and availability of ICEMs? Why (not)?

Conclusion

17. In your opinion, what are the main strengths in the provision of controlled medicines in Uganda?
18. In your opinion, what are the main challenges Uganda faces?
19. Is there anything you would like to add?