

## Review

## Barriers to accessing internationally controlled essential medicines in sub-saharan Africa: A scoping review



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## ABSTRACT

**Background:** Access to internationally controlled essential medicines (ICEMs), medicines that are listed on both the World Health Organization's Essential Medicines List and one of three international drug control conventions, remains problematic in Sub-Saharan Africa (SSA). Previous reviews have focused only on specific ICEMs or ICEM-related healthcare fields, but none have focused on all ICEMs as a distinct class. This scoping review therefore aims to identify the barriers to accessing ICEMs across all relevant healthcare fields in SSA.

**Methods:** A scoping review was conducted across indexing platforms Embase, PubMed, Scopus and Web of Science of studies published between January 1 2012 and February 1 2022. Articles were eligible if they mentioned barriers to accessing ICEMs and/or ICEM-related healthcare fields, if studies were conducted in SSA, or included data on an SSA country within a multi-country study. The review was guided by the Access to Medicines from a Health System Perspective framework.

**Results:** The search identified 5519 articles, of which 97 met the inclusion criteria. Many barriers to access were reported and were common across the ICEMs drug class. Main barriers were: at the individual level, the lack of knowledge about ICEMs; at the health service delivery level, low availability, stockouts, affordability, long distances to health facilities, insufficient infrastructure to store and distribute ICEMs, and lack of ICEM knowledge and training among healthcare workers; at the health sector level, lack of prioritisation of ICEM-related healthcare fields by governments and subsequent insufficient budget allocation. Cross-cutting, governance-related barriers pertained to lack of proper quantification systems, cumbersome procurement processes, and strict national laws controlling ICEMs, leading to overly restrictive prescription practices.

**Conclusion:** This review showed that there are a multitude of barriers to accessing ICEMs in SSA across all health system levels. Many of the barriers identified are applicable to all ICEMs, highlighting the importance of tackling barriers for this entire class of drugs together.

## Introduction

According to the World Health Organization (WHO), essential medicines are those that "satisfy the priority healthcare needs of the population" (World Health Organization, 2021a). These medicines should therefore always be available with guaranteed quality and at an affordable price. In 1977, the WHO adopted the WHO Essential Medicines List (EML), which includes medicines that are selected because of their relevance to public health, efficacy and safety, and comparative cost-effectiveness (World Health Organization, 2021a). The

most recent list is the 22<sup>nd</sup> edition, published in 2021 (World Health Organization, 2021b).

Some of the medicines listed on the WHO EML are also listed on one of three United Nations (UN) drug control conventions, namely the UN Single Convention on Narcotic Drugs of 1961, the Convention of Psychotropic Substances of 1971 and the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988. This is due to their potential risk for non-medical use and dependence, or because they are a precursor for illicit drugs (United Nations, 1971, 1972, 1988). Medicines

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**Table 1**  
Internationally controlled essential medicines and their therapeutic use.

Therapeutic use	Medicine
Anaesthesia	Lorazepam, midazolam, morphine
Anti-epileptic	Diazepam, lorazepam, midazolam, phenobarbital
Anxiety disorders	Diazepam, lorazepam, midazolam
Hypotension (anaesthesia)	Ephedrine
Opioid agonist treatment	Buprenorphine, methadone
Pain and palliative care	Codeine, diazepam, fentanyl, hydromorphone, methadone, midazolam, morphine, oxycodone
Procedural sedation	Fentanyl, lorazepam, midazolam
Topical anti-infective	Potassium permanganate
Uterotonic	(Methyl)ergometrine

listed on these conventions are ‘controlled’ and are consequently subject to strict regulations. When medicines are listed on the WHO EML and one of the three conventions, they are identified as internationally controlled essential medicines (ICEMs). Currently, fourteen medicines are ICEMs, and they are used for the management of pain and palliative care, epilepsy, anaesthesia, mental health, obstetric care, and opioid agonist treatment (OAT), for which methadone and buprenorphine are commonly used (see Table 1). The aim of the drug control conventions is to protect the health and wellbeing of people by ensuring availability of substances for medical and scientific purposes while at the same time preventing diversion and non-medical use (International Narcotics Control Board, 2019). However, access to ICEMs remains problematic for many in need of medical treatment worldwide.

The availability of ICEMs in low- and middle-income countries (LMICs) is extremely poor and does not meet the medical needs of their populations. The International Narcotics Control Board (INCB) estimated that 92% of morphine is consumed by people living in high-income countries, who represent only 17% of the world population (International Narcotics Control Board, 2016). While the United States is facing a so-called opioid crisis, with more than 130 people dying of an opioid overdose every day, it is estimated that each year, more than 20 million people living in LMICs die while suffering extreme pain because of lack of access to opioids (Centers for Disease Control and Prevention, 2021; Knaul et al., 2017). International guidelines for pain management are currently lacking after the retraction of WHO guidelines in 2019 (World Health Organization, 2020). Availability of psychotropic substances used for mental health and neurological disorders is also problematic; it is estimated that the prevalence of epilepsy is 9.39 per 1,000 population in Sub-Saharan Africa (SSA), while studies showed that 75% of people living with epilepsy (PLWE) and about 80% of people with mental disorders living in LMICs do not receive treatment (International Narcotics Control Board, 2016; World Health Organization, 2022). Phenobarbital is the cheapest treatment option available for epilepsy (Catalao et al., 2018; Hunter et al., 2016). The controlled status of some of these medicines might partly explain this situation.

Sub-Saharan Africa is one of the regions where many suffer needlessly because access to ICEMs is known to be inadequate (International Narcotics Control Board, 2019; Namisango et al., 2018). For example, Uganda and Nigeria have a reported unmet need for opioids for palliative care of 89.0% and 99.8%, respectively (Knaul et al., 2017). Many challenges exist in the region, some of which are specific to ICEMs, but others relate to all essential medicines and are inherent to weak health systems more broadly (Berterame et al., 2016; Knaul et al., 2017). To enable targeted action to improve access to ICEMs in SSA, it is imperative to have a detailed overview of all the barriers faced by people when trying to access them. Previous reviews have focused only on single ICEM-related healthcare fields; mostly on pain and palliative care (Agom, Onyeka, Iheanacho, & Ominyi, 2021; Rhee et al., 2017), and to a lesser extent on epilepsy (Ba-diop et al., 2014; Mbuba, Ngugi, Newton, & Carter, 2008) or anaesthesia (Grimes, Bowman, Dodgion, & Lavy, 2011). However, no reviews have focused on all ICEMs or ICEM-related healthcare fields together, or the barriers that exist to accessing

them in SSA. Importantly, by treating ICEMs as one class of drugs, such a review might inform government and patient strategies to improve access to all ICEMs across the entire health system. This scoping review therefore aims to identify the barriers described in literature to access ICEMs across all related healthcare fields in SSA.

## Methods

Our study design was guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR; Tricco et al., 2018) checklist and the methodological framework for scoping studies proposed by Arksey and O'Malley (Arksey & O'Malley, 2005) and elaborated by Pollock et al. (Pollock et al., 2022). Specifically, they guided the development of the research question, identification of relevant literature through electronic database searches and reference checking, inclusion and exclusion criteria, extraction of the data, and reporting of the results (Arksey & O'Malley, 2005; Pollock et al., 2022).

## Search strategy and study selection

A search of literature indexing platforms Embase, PubMed, Scopus and Web of Science was conducted on February 1 2022. To ensure up-to-date information, only studies published from 1 January 2012 to the search date were included. Key search words included all the countries of the Sub-Saharan region, terms related to barriers, such as: “treatment gap” OR “barriers” OR “challenges” OR “access” OR “availability” OR “accessibility” OR “affordability” OR “drug control” OR “drug policy”, and the names of the ICEMs, the healthcare fields in which they are used, and related terms used to describe ICEMs, such as: “controlled drugs” OR “controlled medicines” OR “controlled substances”. The full search syntax used across the literature indexing platforms can be found in Supplementary File 1. References of the selected studies were examined for additional literature.

Articles were deemed eligible if they mentioned any barriers to access to ICEMs and/or related healthcare fields. Study populations were limited to persons aged 18 year or older, as access to ICEMs for children encompasses additional barriers and dimensions. Only studies conducted in SSA, or multi-country studies with specific data on an SSA country, were selected for inclusion. Studies were restricted to the English language. All types of articles were included, with the exception of conference abstracts, historical reports and protocols. Articles were not excluded based on study design.

## Data extraction and analysis

The search results of the literature indexing platforms were downloaded into a Reference Manager database (Mendeley). Duplicates were removed, after which all titles were screened for eligibility in a step-wise approach (see Fig. 1). The screening and preselection of the studies, based on the title and abstract, was conducted by one author (GIO). To ensure the quality and reliability of the search protocol, full articles

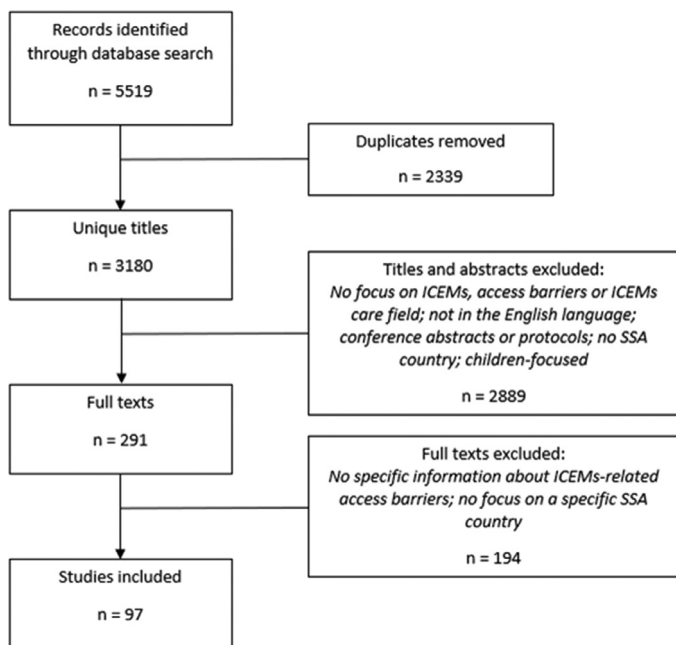


Fig. 1. PRISMA-ScR article selection process.

were then screened independently by two authors (GIO and JO) to determine their inclusion in the study. When the authors had different opinions about inclusion or exclusion of an article, the article was reviewed together to reach consensus. Data was analysed deductively using the *Access to Medicines from a Health System Perspective Framework*, in which the components of the framework functioned as categories for data extraction (Bigdeli et al., 2013). To increase the quality and reliability of the analysis, a data extraction form was created based on Arksey and O'Malley's framework, comprising the following information: author, year of publication, study location, study design, study population and sample, healthcare field, and main findings related to access barriers (Arksey & O'Malley, 2005). Included literature were not assessed for quality due to the range in scope and design of included studies.

The barriers to accessing ICEMs in SSA are presented per the five main levels of the *Access to Medicines from a Health System Perspective* framework: (I) individuals, households and community; (II) health service delivery; (III) health sector level; (IV) national level; (V) international level, as well as the cross-cutting category of governance (Bigdeli et al., 2013).

## Results

### Characteristics of included articles

The search generated a total of 5519 articles; 1463 citations from PubMed; 2809 from Embase; 717 from Web of Science and 530 from Scopus. Of the 5519 articles, 2339 were duplicates. After screening titles and abstracts based on inclusion criteria, 291 were included for full-text assessment. Full-text assessment led to the inclusion of 97 articles for data extraction (see Fig. 1). Characteristics of the included articles are summarised in Supplementary File 2. No additional papers were found after screening the references of the included papers.

The articles consisted of quantitative studies ( $n = 35$ ), qualitative studies ( $n = 20$ ), mixed-methods studies ( $n = 17$ ), expert pieces ( $n = 10$ ), reviews ( $n = 8$ ) and other studies such as programme evaluations, simulated client visits or health system assessments ( $n = 7$ ). Twenty-four studies were carried out in multiple countries, while 74 studies concerned country-specific research. These studies were carried out in Kenya ( $n = 10$ ), Ethiopia ( $n = 9$ ), Tanzania ( $n = 8$ ), Uganda ( $n = 8$ ), South

Africa ( $n = 6$ ), Ghana ( $n = 4$ ), Madagascar ( $n = 4$ ), Nigeria ( $n = 4$ ), Liberia ( $n = 3$ ), Botswana ( $n = 2$ ), Mozambique ( $n = 2$ ), Rwanda ( $n = 2$ ), Sierra Leone ( $n = 2$ ), Zimbabwe ( $n = 2$ ), and single studies from the Democratic Republic of the Congo (DRC), Eritrea, Malawi, Senegal, Somalia, Eswatini and Zambia. Studies covered all healthcare fields, including pain and palliative care ( $n = 45$ ), anaesthesia ( $n = 19$ ), epilepsy ( $n = 11$ ), OAT ( $n = 7$ ), mental health ( $n = 3$ ), obstetric care ( $n = 3$ ), ICEMs in general or multiple healthcare fields ( $n = 8$ ), and non-medical use of ICEMs ( $n = 1$ ). An overview of the barriers to access to ICEMs in SSA is given in Fig. 2.

### Individuals, households and community

Examination of included studies indicates that at the individuals, households and community level, access to ICEMs was influenced by multiple factors. Public knowledge about ICEMs and related healthcare fields was commonly reported to be lacking. For instance, knowledge about causes and treatment of epilepsy and mental disorders was often minimal, with people believing epilepsy to be incurable, contagious or caused by supernatural forces (Catalao et al., 2018; Dolo et al., 2018; Koltai et al., 2020; Ooms, Klatser, van den Ham, & Reed, 2019; Prevett, 2013), and being sceptical about the efficacy of anti-epileptic medication such as phenobarbital (Dolo et al., 2018). However, having positive experiences with anti-epileptic medication increased their acceptability, both at the individual (Catalao et al., 2018; Dolo et al., 2018) and community level (Catalao et al., 2018). Similarly, lack of knowledge about palliative care was commonly reported (Agom et al., 2021; Kamonyo, 2018). A number of studies also reported patients feared becoming addicted to opioids (Aregay, Oconnor, Stow, Ayers, & Lee, 2020; Bond & Knopp, 2018; Eshete et al., 2019; Ooms et al., 2019), and associated them with death because patients with end-stage diseases are the ones who commonly receive them (Dekker, Amon, le Roux, & Gaunt, 2012; Ooms et al., 2019). In Kenya, for example, 29% of surveyed religious leaders believed that use of opioids hastened death, and 8% believed the use of opioids to alleviate a patient's pain was morally the same as killing a patient (Rialem et al., 2020). It was also reported that in some SSA countries it was discouraged to complain or talk about pain, as some level of pain is believed to be acceptable (Eshete et al., 2019; Nchako, Bussell, Nesbeth, & Odoh, 2018).

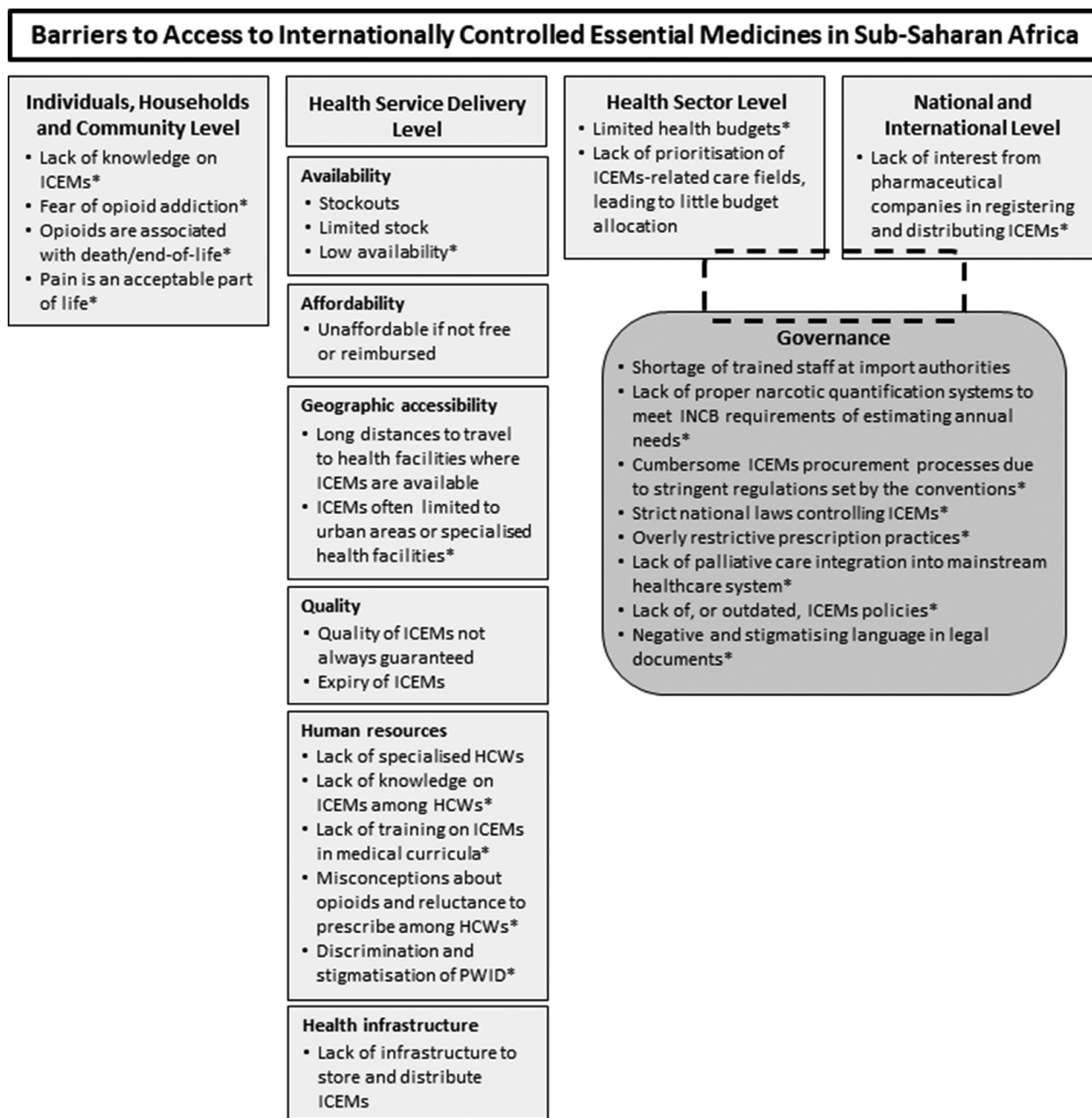
In the case of OAT, one paper that specifically looked at women in Tanzania found that enrolment for women was negatively influenced by being in a violent relationship and having a partner who was also using drugs; 83% of surveyed women who were injecting drugs who were not enrolled in an OAT programme, were in a relationship deemed to be violent (Balaji et al., 2017). Conversely, studies indicated that in Kenya, for both men and women, the financial, emotional and psychosocial support of family facilitated continued OAT enrolment (Guise et al., 2019; Ndimbii et al., 2021).

### Health service delivery

At the health service delivery level, access to ICEMs was influenced by their availability, affordability, geographical accessibility, quality, human resources, and health infrastructure, including weak supply chains.

### Availability

As shown in Table 2, a large number of studies reported that availability of ICEMs remains problematic in SSA as they were often unavailable or stocked out (Agom et al., 2021; Ba-diop et al., 2014; Baxter et al., 2017; Bitta, Kariuki, Chengo, & Newton, 2017; Bond & Knopp, 2018; Burke et al., 2014; Cleary et al., 2013; Eshete et al., 2019; Jakub Gajewski et al., 2020; Gwaikolo, Kohrt, & Cooper, 2017; Hamdi et al., 2018; Hartwig et al., 2014; Jost et al., 2016; Kananura, Kiwanuka, Ekirapa-Kiracho, & Waiswa, 2017; Knowlton et al., 2013;



\*: ICEMs-specific barrier.

Fig. 2. Barriers influencing access to ICEMs in SSA.

Koltai et al., 2020; Lavigne, Gaolebale, Maifale-Mburu, & Grover, 2018; Linden et al., 2012; Lonnée et al., 2021; Lyon et al., 2016; Marshall et al., 2021; Maseko, Pfaff, & Mwisongo, 2018; Mihretu, 2021; Namisango et al., 2018; Nyirigira et al., 2018; Odinkemelu et al., 2021; Onsongo, 2020; Ooms et al., 2019; Oppong, Kretchy, Imbeah, & Afrane, 2016; Prevett, 2013; Rhee et al., 2017; Salifu, Almack, & Caswell, 2021; Selman et al., 2013; Sisay, Amare, Hagos, & Edessa, 2021; Wagenaar et al., 2015; Zamudio-Haas, Mahenge, Saleem, Mbwambo, & Lambdin, 2016). In Zambia and Madagascar, for instance, phenobarbital was available at only 20% and 36% of surveyed pharmacies, respectively (Ba-diop et al., 2014; Jost et al., 2016). In a survey among 109 physicians from across SSA, 49% indicated they did not have access to liquid opioids (Tadipatri et al., 2021). In Eswatini, mor-

phine was not available at health centres; patients had to be referred to a higher-level facility (Maseko et al., 2018). Only one government facility in Nigeria and Cameroon stocked oral morphine in 2018 (Nchako et al., 2018), and 50% of nurses in Eritrea indicated that lack of opioids was a barrier to access (Kahsay & Pitkäjärvi, 2019). Stockouts were a problem in Zambia, where 45% of surveyed hospitals indicated that morphine had been stocked out for at least 90 days (Frett Utter et al., 2019). In Zimbabwe 22% of surveyed healthcare workers (HCWs) indicated opioids had been stocked out in the last three months (Tapera & Nyakabau, 2020). Methadone for OAT was also unavailable in many countries (Marks, Scheibe, & Shelly, 2020; Ooms et al., 2019; Zamudio-Haas et al., 2016). For instance, in Tanzania while a publicly-funded OAT program exists, access is very limited (Zamudio-Haas et al., 2016).

**Table 2**  
Availability of ICEMs, per country.

Country	Availability (%)										
	Codeine	Diaze-pam	Ephe-drine	Ergo-metrine	Fenta-nyl	Loraze-pam	Metha-done	Midazo-lam	Mor-phine	Oxy-codone	Pheno-barbital
Ethiopia (Bashford, 2014; Mihretu, 2021; Sisay et al., 2021)	33, 82 <sup>a</sup> , 90 <sup>b</sup>						90 <sup>b</sup>	27, 63 <sup>a</sup>			
Kenya (Burke et al., 2014)								25			
Liberia (Gwaikolo et al., 2017; Odinkemelu et al., 2021)	26 <sup>c</sup> , 92				12	26 <sup>c</sup>	12	35			26 <sup>c</sup>
Madagascar (Baxter et al., 2017; Jost et al., 2016)	90		81				5	38			36
Malawi (Kayambankadzanja et al., 2020)	78							9			
Mozambique (Wagenaar et al., 2015)	75						4				63
Sierra Leone (Lonnée et al., 2021)	85			80	15		30	45			
Tanzania (Mikomangwa et al., 2019)	91			18				70 <sup>d</sup>			
Uganda (Epiu et al., 2017; Kananura et al., 2017)	55				9				9		20
Zambia (Ba-diop et al., 2014; Frett Utter et al., 2019)	36										

ICEMs: Internationally Controlled Essential Medicines.

<sup>a</sup> Availability of benzodiazepines in general.

<sup>b</sup> Availability of either diazepam or midazolam.

<sup>c</sup> Availability of psychotropic medicines in general.

<sup>d</sup> Availability of opioids in general.

Studies reported that an inconsistent availability of ICEMs forced patients to switch to alternative medications, go without until a new supply arrived, or buy them from private suppliers (Dolo et al., 2018; Marks et al., 2020; Oppong et al., 2016). Further, even when ICEMs were available, stock was often limited. For instance, when phenobarbital was available in Madagascar, pharmacies only stocked one to two boxes of it, and the phenobarbital prescribed often covered only 7 days of treatment (Jost et al., 2016; Nizard et al., 2016). The inconsistent availability of ICEMs impacted treatment adherence; patients were more likely to discontinue their treatment due to unavailability of their medications (Koltai et al., 2020).

Numerous studies demonstrate that some countries did reach the WHO benchmark of at least 80% availability for some ICEMs, as can be seen in Table 2 (Bashford, 2014; Baxter et al., 2017; Epiu et al., 2017; Kayambankadzanja et al., 2020; Lonnée et al., 2021; Mihretu, 2021; Mikomangwa et al., 2019; Odinkemelu et al., 2021; Wagenaar et al., 2015). However, often availability differed depending on health facility level. In Mozambique, for example, diazepam was available at 55% of surveyed rural facilities, and at 83% of more specialised rural facilities (Wagenaar et al., 2015). In 2014, morphine was not available in any surveyed clinics or health centres in Kenya, but it was available in all surveyed secondary hospitals (Burke et al., 2014). In Malawi, opioids were available at 31% of all hospitals, but only 2% of lower level health facilities (those not defined as hospitals nor routinely providing in-patient care) (Kayambankadzanja et al., 2020).

#### Affordability

In some SSA countries ICEMs were provided free of charge in the public sector (Aregay et al., 2020; Cleary et al., 2013; Dika, Nkola, Iddi, Magwiza, & Kongola, 2021; Gwaikolo et al., 2017; Kamonyo, 2018; Ooms et al., 2019; Oppong et al., 2016). In Ethiopia for instance, patients' medication fees were waived if they were in possession of a fee waiver card, which was available to the poorest in the population (Catalao et al., 2018), and in Kenya, Malawi and Uganda, morphine was available free of charge to patients (Aregay et al., 2020; Kamonyo, 2018; O'Brien et al., 2013). In some countries insurance schemes are being rolled out, which cover healthcare costs such as medication purchases (Catalao et al., 2018). However, reimbursement of health facilities through such insurance schemes is not without problems, resulting in stockouts, and patients still resorting to the private sector for their medicines, where affordability was an issue (Agom et al., 2021; Brouillette et al., 2017; Dika et al., 2021; Dolo et al., 2018; Eshete et al., 2019; Jost et al., 2016; Koltai et al., 2020; Marks et al., 2020; Namisango et al., 2018; Ooms et al., 2019; Oppong et al., 2016; Salifu et al., 2021; van der Plas, Benjamens, & Kruijff, 2020).

Phenobarbital is the cheapest treatment option available for epilepsy in SSA, and can cost as little as USD 10 per year (Catalao et al., 2018; Hunter et al., 2016). In Madagascar, a 30-day treatment of phenobarbital nevertheless can cost a patient more than 10% of their monthly salary, while a box of phenobarbital can cost more than USD 20 in the DRC (Dolo et al., 2018; Nizard et al., 2016). Further, research conducted by Mbuba et al. (2012) indicated that even when the ICEM itself was affordable, indirect costs such as those for transportation to the health facility could make it unaffordable. Unaffordability of ICEMs can lead to treatment discontinuation in the case of epilepsy (Dika et al., 2021; Dolo et al., 2018); in Rwanda, 74% of patients indicated they discontinued treatment due to financial reasons (Ba-diop et al., 2014). Similar problems were reported when seeking pain management (Nchako et al., 2018). In Zimbabwe, 76% of surveyed HCWs indicated that most patients had to buy their opioids themselves (Tapera & Nyakabau, 2020).

In the case of OAT, methadone and buprenorphine are, as of 2020, not reimbursed in South Africa as they are not included on the national EML, meaning patients have to pay out-of-pocket (Abagiu et al., 2014; Marks et al., 2020). This makes it unaffordable to a significant part of the population, especially since OAT is almost 30 times more expensive

in South Africa than other middle-income countries, such as Georgia and the Ukraine (Scheibe et al., 2017).

#### Geographical accessibility

Distance to health facilities or pharmacies where ICEMs were available was a repeatedly cited barrier (Cleary et al., 2013; Namisango et al., 2018; Preveit, 2013). In Ethiopia and Nigeria about half of surveyed patients discontinued their treatment with phenobarbital within a year, with the most commonly given reason being difficulty travelling to the health facilities (Preveit, 2013). Another study found that in 14 of 20 SSA countries, accessing a pharmacy that dispensed opioids was difficult (Cleary et al., 2013), and a scoping review found that only about 20% of SSA countries provided palliative care in primary healthcare settings (Agom et al., 2021). In the DRC, Equatorial Guinea and Madagascar there was only one hospice or palliative care service, serving populations of more than 92 million, 1.4 million and 28 million, respectively (Agom et al., 2021; The World Bank, 2022a). Research also showed that in many countries, accessing ICEMs in rural areas is even more problematic (Reid, Gudina, Ayers, Tigineh, & Azmera, 2018). In Ghana, accessing morphine outside a hospital is difficult (Salifu et al., 2021), and in South Africa, Tanzania, Zambia and Zimbabwe, morphine availability was limited to the bigger cities (Aregay et al., 2020; Dekker et al., 2012).

In South Africa, for 32% of patients in one study who had successfully accessed OAT, it had been difficult to find a doctor who could provide the treatment (Abagiu et al., 2014). Forty-eight percent indicated they would have started OAT earlier if there had been better treatment availability and if more information about it was available (Abagiu et al., 2014). However, an evaluation of an OAT programme in Durban showed that once people who inject drugs (PWID) were enrolled in the programme, retention at 12 months was high (74%) (Marks et al., 2020). Multiple studies show that in Kenya, OAT clinics had fixed opening hours and clients had to visit the clinic each day for their methadone dose, which was a barrier to clients due to the distance, transportation costs, as well as the loss of income due to the daily visits (Guise et al., 2019; Ndimbii et al., 2021). Fixed clinic hours were reported as a barrier to women engaged in sex work, who worked at night and therefore had difficulty accessing the clinics in the morning (Ndimbii et al., 2021).

#### Quality

A number of studies indicated that ICEMs bought on both the licit and illicit market did not always meet quality standards (Preveit, 2013; Salifu et al., 2021). In Madagascar 18% of phenobarbital samples bought at a pharmacy did not meet quality standards, nor did the diazepam bought on the illicit market (Nizard et al., 2016). All 15 ergometrine injections bought by researchers in Tanzania, and all 55 injections bought in Ghana, from both public and private pharmacies, did not meet quality standards (Kaale et al., 2016; Stanton et al., 2012). Further, some facilities faced expired ICEMs (Oppong et al., 2016; Rhee et al., 2018). In Ghana, HCWs explained expired medicines were a consequence of HCWs not prescribing psychotropic medicines, or medicines from donor agencies being near expiry when they were received (Oppong et al., 2016).

#### Human resources

One cross-cutting issue for the ICEM-related healthcare fields reported in a large number of studies was the lack of appropriately trained HCWs (Agom et al., 2021; Berterame et al., 2016; Bitta et al., 2017; Bruno et al., 2017; Chao et al., 2012; Dekker et al., 2012; Elkheir et al., 2014; Epiu et al., 2017; Fraser et al., 2018; J Gajewski et al., 2017; Kahsay & Pitkääjärvi, 2019; Kamonyo, 2018; Knowlton et al., 2013; Koltai et al., 2020; Linden et al., 2012; Lourens, Hodgkinson, & Parker, 2020; Low et al., 2018; Lyon et al., 2016; Mihretu, 2021;

Mojapelo, Usher, & Mills, 2016; O'Brien et al., 2013; Ooms et al., 2019; Penoyar et al., 2012; Petroze, Nzayisenga, Rusanganwa, Ntakiyiruta, & Calland, 2012; Preveit, 2013; Umutesi et al., 2019; Vaughan et al., 2015). In Liberia for instance, the anaesthesiologist and nurse anaesthesiologist workforce densities are 0.02 and 1.56 per 100,000 population, respectively (Odinkemelu et al., 2021). The shortage of appropriately trained HCWs is especially common in rural areas, where there are few specialised doctors (Bitta et al., 2017; Lyon et al., 2016; Namisango et al., 2018; Ooms et al., 2019; Preveit, 2013). In Mozambique, 77% of anaesthesiologists work in Maputo, where only 5% of Mozambique's population lives (Lyon et al., 2016). In Kilifi County, Kenya, only mental health nurses, social workers and occupational therapists were available at mental health outpatient facilities, and were not allowed to prescribe psychotropic medicines (Bitta et al., 2017). Indeed, a number of studies indicated that many HCWs across SSA lacked the knowledge and skills to properly treat patients. Instead, health-care was provided by untrained or undertrained HCWs (Dagnew & Tewabe, 2021; Elkheir et al., 2014; Eshete et al., 2019; J Gajewski et al., 2017; Knowlton et al., 2013; Koltai et al., 2020; Nchako et al., 2018; Onsongo, 2020; Penoyar et al., 2012; Preveit, 2013; Umutesi et al., 2019).

One study showed that in Botswana, nurses felt like they lacked the knowledge and training to be able to advocate for prescription of opioids in outpatient settings (Mojapelo et al., 2016). In Eritrea, a knowledge-attitude survey found that almost 60% of nurses had answered less than 50% of the questions on opioids correctly (Kahsay & Pitkääjärvi, 2019). In Nigeria only 24% of surveyed physicians had received more than 2 hours of training on pain management at undergraduate level, 92% of surveyed HCWs had not received any formal training on pain management, and 51% indicated they only treated pain when patients complained (Ogboli-Nwasor, Makama, & Yusufu, 2013; Suleiman, Wahab, & Kolawole, 2016).

Multiple studies indicated that the lack of appropriately trained HCWs was fuelled by the lack of training opportunities within countries (Cheptum, Chemuttai, Nyambane, & Chelagat, 2016; Frau et al., 2021). Uganda did not have a neurology specialty within their medicine curriculum, while Mozambique had no formal exposure to anaesthesiology within the curriculum (Koltai et al., 2020; Lyon et al., 2016). In 2017, a review of palliative care education in 13 African countries found that only Kenya, South Africa, Uganda and Tanzania provided postgraduate education in palliative care (Rhee et al., 2017). In Ethiopia, HCWs and hospital officials indicated pain was neglected in undergraduate medical education, and 71% of surveyed health facilities also rarely or never provided HCWs with continuous professional development and medical education (Eshete et al., 2019; Mihretu, 2021). Studies also indicated that some countries did include palliative care in educational curricula. In Botswana, palliative care is included in 90% of medical and nursing education (Lavigne et al., 2018). In Sierra Leone, 86% of surveyed nurse anaesthesiologists had attended training (Vaughan et al., 2015).

Even when HCWs had received training on ICEMs, oftentimes the addictive qualities of the medicines were overemphasised (Ooms et al., 2019). Relatedly, misconceptions about palliative care and a reluctance to prescribe opioids because of opiophobia, fear of addiction or side effects, and lack of knowledge how to handle it, existed in many countries (Agom et al., 2021; Aregay et al., 2020; Berterame et al., 2016; Bond & Knopp, 2018; Chao et al., 2012; Court & Olivier, 2020; Eshete et al., 2019; Etafa et al., 2020; Fraser et al., 2018; Matula, 2019; Mojapelo et al., 2016; Nchako et al., 2018; Nyirigira et al., 2018; O'Brien et al., 2013; Ogboli-Nwasor et al., 2013; Onsongo, 2020; Rhee et al., 2018; Zubairi et al., 2017). In Kenya, 96% of surveyed HCWs believed opioids cause addiction (Zubairi et al., 2017), and Kenyan nurses at a tertiary hospital admitted they adjusted opioid doses or substituted them for weaker analgesics (Onsongo, 2020). Among surveyed Ethiopian nurses in one study, 82% believed drug addiction to be a major problem in patients who use morphine long term (Etafa et al., 2020), and 70% believed that elderly patients cannot tolerate opioids and that

patients should be withheld opioids for as long as possible (Dagneu & Tewabe, 2021). In Nigeria, 70% of surveyed physicians who treat patients with moderate to severe pain reported having rarely or never prescribed opioids, with the most common reasons being fear of respiratory depression (87%) and fear of addiction (85%) (Suleiman et al., 2016). Interestingly, 85% of surveyed Nigerian pharmacists did not believe that long-term use of opioids often induced addiction in patients (Adisa & Anifowose, 2019). Some HCWs in Kenya and also believed that the use of opioids accelerated death (Onsongo, 2020; Zubairi et al., 2017). HCWs in Uganda also reported a reluctance to discuss end-of-life care (Low et al., 2018).

Some research also indicated many HCWs did feel confident about their knowledge of opioids and their prescription. In Uganda for example, 100% of doctors interviewed at the Uganda cancer institute reported they felt confident prescribing opioids, and 80% reported they felt confident in symptom assessment and management (Low et al., 2018). In South Africa, even though 91% of surveyed pharmacists indicated they had a lack of training about opioids, 81% reported they felt comfortable providing pain management to patients, and 71% and 62%, respectively, reported they had good knowledge and a positive attitude regarding palliative care and opioids (Inderlall & Naidoo, 2021). A scoping review of 47 African countries found that Kenya, Uganda and Zambia had a broad awareness of palliative care among HCWs (Agom et al., 2021).

Lastly, in the case of OAT, some studies indicated that PWID were often discriminated against by HCWs in general healthcare settings, making them distrustful of formal healthcare, and forming barriers to receiving OAT (Balaji et al., 2017; Zamudio-Haas et al., 2016).

#### Health infrastructure

Examination of included studies indicates that many countries in SSA had a lack of infrastructure to properly store and distribute opioids (Agom et al., 2021; Fraser et al., 2018; O'Brien et al., 2013). In Uganda for instance, health facilities must be accredited to provide morphine, with an accreditation requirement including the presence of an eligible prescriber and a safe storage location. Consequently, less than 50% of facilities are accredited to provide palliative care services (Kamonyo, 2018). In some countries distribution of opioids is centrally controlled by the government, limiting non-medical use but also the availability for medical use (van der Plas et al., 2020).

#### Health sector level

Findings from multiple studies indicates that in many SSA countries, governments have limited budgets that cannot cover all the healthcare needs of their populations. Infectious disease are often prioritised, resulting in little budgetary allocation and attention from policy makers to chronic non-communicable diseases, anaesthesia or palliative care (Agom et al., 2021; Berterame et al., 2016; Bond & Knopp, 2018; Brouillette et al., 2017; Epiu et al., 2017; Frau et al., 2021; Kahsay & Pitkääjärvi, 2019; Kamonyo, 2018; Merriman, Mwebesa, & Zirimenya, 2019; Namisango et al., 2018; O'Brien et al., 2013; Ooms et al., 2019; Prevett, 2013). In Ghana, HCWs surveyed in one study believed lack of government funding was part of the reason why shortages of psychotropic medications occurred (Oppong et al., 2016). In many SSA countries, palliative care is still largely funded by international aid, making it sensitive to fluctuations in donor priorities (Merriman et al., 2019; Rhee et al., 2018, 2017). Similarly, in South Africa, OAT is largely financed by donor agencies (Scheibe et al., 2017).

#### National and international level

A number of studies also indicated that in many SSA countries, the potential profits pharmaceutical companies and suppliers can make are low due to the low price of the medicine relative to the cumbersome

process and high registration costs, making it unattractive to register their products (Nchako et al., 2018; Nickerson & Chikumba, 2018; O'Brien et al., 2013). In Zimbabwe for example, ephedrine was not available due to this reason (Nickerson & Chikumba, 2018).

#### Governance

Analysis of included studies indicates that some of the main barriers to accessing ICEMs are related to governance, which cuts across the health sector level, national level and international level. How 'governance' impacts on access to ICEMs is explained in more detail below.

#### International conventions

Review of the literature indicates that many SSA countries struggled to meet the requirements set out in the international drug control conventions. As per the Single Convention on Narcotic Drugs, 1961, countries need to submit their annual needs for narcotics to the INCB (United Nations, 1972). However, many countries did not have a system to properly document the use of and need for narcotics, resulting in the quantifications being based on invalid estimates (Namisango et al., 2018; O'Brien et al., 2013; Ooms et al., 2019; Vitry, Forte, & White, 2021). In Kenya, for example, the average reported consumption from 2009-2011 was 26.7 kg, which would have provided morphine to 4300 patients, even though it was estimated that 92,000 patients were in need (Kamonyo, 2018). Further, in 2018, only 11 of 24 countries in West and Central Africa submitted estimates (Frau et al., 2021). In Mozambique, mandatory reporting was a challenge as there had been no staff with technical expertise for at least five years (Namisango et al., 2018). When a country exceeds its submitted estimates, a request can be made by the country to the INCB for additional narcotics. However, oftentimes this is not done, or only after a long period of time (Vitry et al., 2021).

Relatedly, wholesalers and procurers reported that the international conventions functioned as a barrier due to the requirements that needed to be met before ICEMs could be procured (Berterame et al., 2016; O'Brien et al., 2013; Vitry et al., 2021). In a study from Ghana, for example, HCWs referred to the cumbersome procurement process for psychotropic medicines as a reason for shortages, stating they led to delays in medicine delivery of up to two years (Oppong et al., 2016). Similarly, cumbersome requirements to import ICEMs in Uganda were said to deter some wholesalers from importing them (Vitry et al., 2021). For phenobarbital, the border regulations due to its controlled status were also reported as a barrier to their import (Ba-diop et al., 2014). Further, another study found that in 2019 the only available opioid in Nigeria was pentazocine due to the strict national laws controlling narcotic medicines (Anderson et al., 2019). Similarly, another study reported healthcare and relief organisations tend to use non-controlled medicines instead of ICEMs due to the challenges faced with importing controlled substances (Vitry et al., 2021).

A number of studies indicated that a shortage of staff at import authorities, and their lack of training on how to properly issue import authorisations also impeded access to ICEMs, resulting in long import times due to delayed or erroneous authorisations (Frau et al., 2021; Ooms et al., 2019; Vitry et al., 2021). Moreover, a recent study reported that generally, it took three to twelve months to obtain the export and import authorizations in LMICs in SSA (Vitry et al., 2021).

#### Regulatory practices

A number of studies reported overly restrictive prescription practices were common in many SSA countries (Aregay et al., 2020; Berterame et al., 2016; Bitta et al., 2017; Bond & Knopp, 2018; Cleary et al., 2013; Fraser et al., 2018; Hartwig et al., 2014; Kahsay & Pitkääjärvi, 2019; Lavigne et al., 2018; Matula, 2019; Namisango et al., 2018; Nchako et al., 2018; Ooms et al., 2019; Rhee et al., 2017; Selman et al., 2013). In Botswana, Kenya, Malawi and Nigeria only

doctors were allowed to prescribe psychotropic medicines (Bitta et al., 2017; Nchako et al., 2018; van der Plas et al., 2020). HCWs in Uganda reported difficulties prescribing opioids as they needed additional documentation books, special licenses to prescribe opioids, and feared losing their licenses if errors were found in their prescription behaviour (Ooms et al., 2019). Similarly, Cleary et al. (2013) found that of 20 SSA countries studied, 18 had restrictive laws for opioid prescribing, which included special prescription forms (11 countries) or the need for duplicate or triplicate forms (13 countries), with these forms not being readily accessible in many countries (Cleary et al., 2013). In Tanzania HCWs described difficulties in obtaining a license for opioid prescribing (Bond & Knopp, 2018). In Senegal, only 5% of doctors had the prescription pad necessary to prescribe opioids (Hamdi et al., 2018). In eight of 20 studied countries opioids could be dispensed for only a few days at a time, ranging from 2 days in Ghana to 14 days in Malawi (Cleary et al., 2013). Forty-eight percent of nurses in Eritrea indicated that the strict opioid regulations were a barrier (Kahsay & Pitkääjärvi, 2019). HCWs, even when permitted to do so, were also afraid to prescribe opioids due to the lack of legal protection or fear of legal sanctions within their country (Berterame et al., 2016; Eshete et al., 2019; Rhee et al., 2018). In Mozambique, Eswatini and Zimbabwe, stakeholders reported inclinations towards stringent storage and prescription regulations for ICEMs (Namisango et al., 2018).

The literature shows that not all countries adhered to the stricter regulation of dispensing ICEMs. In Mozambique, diazepam could be prescribed by a community health worker, and phenobarbital by a medical technician (Wagenaar et al., 2015). In Sierra Leone benzodiazepines were also provided by unauthorised HCWs (Lonnée et al., 2021). In Tanzania, 70% of surveyed pharmacies dispensed diazepam without requesting to see a prescription, opening the door for non-medical use (Mikomangwa et al., 2019). In Uganda, 21% and 41% of surveyed pharmacies, respectively, sold phenobarbital and diazepam without a prescription, and 41% sold codeine without a prescription (Kamba et al., 2020). Further, only 23% of these facilities complied to stock control requirements, such as having a controlled drugs prescription book to record sales; batch numbers of dispensed drugs and contact details of patients; dedicated files for archiving copies of opioid and psychotropic prescriptions (Kamba et al., 2020). Similarly, a lack of up-to-date record keeping for psychotropic medicines was found in health facilities in Kenya (Bitta et al., 2017).

### Policies

A number of policy-related barriers to ICEMs access were found in the surveyed literature. In Somalia, only 29% and 7% of surveyed health facilities had guidelines for anaesthesia or pain relief available (Elkheir et al., 2014). In most SSA countries, palliative care was poorly integrated into the mainstream healthcare system (Agom et al., 2021; Frau et al., 2021; Kamonyo, 2018). At the Uganda cancer institute, doctors reported that working together was more of a challenge than a benefit due to the challenges in coordinating care (Low et al., 2018). Further, it was reported in multiple studies that many SSA countries had a lack of guidelines for pain assessment and management (Eshete et al., 2019; Frau et al., 2021; Kahsay & Pitkääjärvi, 2019; Maseko et al., 2018) and that often, policies and legislation were outdated (O'Brien et al., 2013). Similarly, two studies reported that policies on palliative care or pain management, including the use of pain rating scales, were often lacking or unknown to HCWs in Ethiopia and Eswatini (Eshete et al., 2019; Maseko et al., 2018). In 14 of 20 studied countries, laws regarding opioids contained negative or stigmatizing language (Cleary et al., 2013). Moreover, some studies highlighted that often, coexisting goals of improving access to ICEMs for medical use and preventing illicit use were not balanced (Berterame et al., 2016; Namisango et al., 2018). For instance, in South Africa, methadone and buprenorphine were not listed as medicines for OAT on the country's EML (Marks et al., 2020; Namisango et al., 2018).

### Discussion

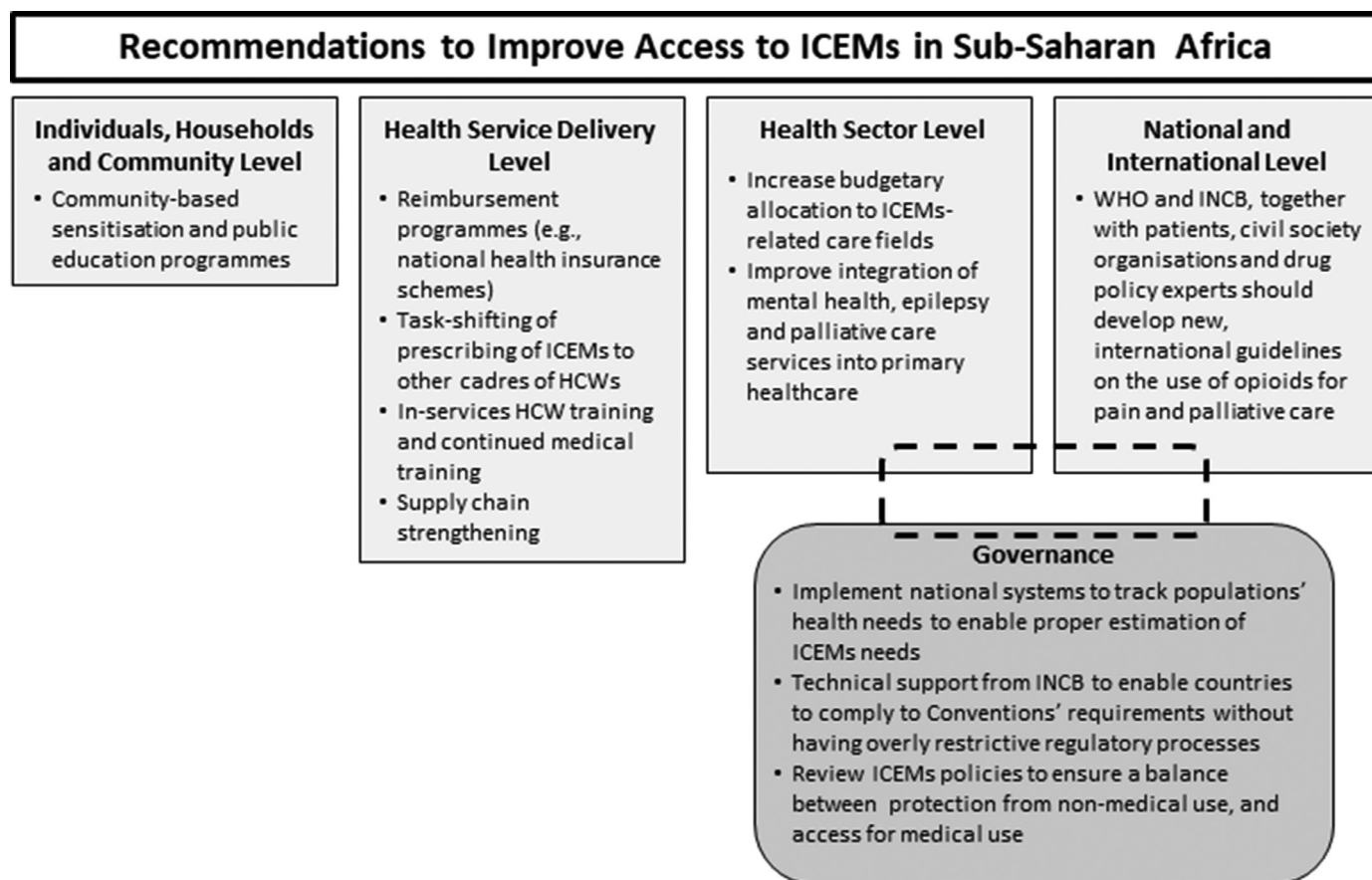
This scoping review presents an overview of the barriers to accessing ICEMs in SSA. The literature showed that many barriers to access exist and are common across the ICEMs drug class. While some barriers were specific to ICEMs, others were observed for non-controlled medicines as well. ICEM-specific barriers observed at the individuals, households and community level were: the lack of public knowledge about ICEMs; fear of opioid addiction; the association of opioids with death; and cultural acceptability of some level of pain in life. Barriers influencing access to both ICEMs and other medicines observed at the health service delivery level included stockouts, unaffordability, long distances to reach health facilities, medicine quality, lack of specialised HCWs, and a lack of infrastructure to store and distribute medicines. Low availability, an issue also experienced across other medicine groups, was exacerbated by the controlled status of ICEMs. Other ICEM-specific barriers were lack of knowledge and training on ICEMs among HCWs, which caused misconceptions about the medicines and discrimination and stigmatisation of PWID specifically. At the health sector level, there was a lack of prioritisation of ICEM-related healthcare fields, and due to the limited health budgets available in most of SSA, this led to low budget allocation to these healthcare fields. This is also an issue for other healthcare fields, and not limited to only ICEMs. At the national and international level, there was a lack of interest in ICEMs from pharmaceutical companies due to the cumbersome regulations and low profit margins for ICEMs in SSA markets. Cross-cutting governance-related barriers were mainly ICEMs-specific and pertained to: lack of proper quantification systems; cumbersome procurement processes due to the regulations set by international drug control conventions; strict national laws controlling ICEMs leading to overly restrictive prescription practices; and negative and stigmatising language in legal documents.

While many of the access barriers identified in this review were applicable across all ICEMs, the following were specific to opioids: the fear among HCWs and the community of the addictive quality of opioids; the requirement for national estimates of medical need for opioids as stipulated by the Single Convention on Narcotic Drugs, 1961 (United Nations, 1972). For the use of methadone and buprenorphine in OAT, a specific barrier is that PWID are discriminated against when seeking healthcare, which becomes a barrier to accessing ICEMs.

Based on this review, recommendations have been formulated to improve access to ICEMs in SSA, which are detailed below (see Fig. 3). Misconceptions and lack of knowledge on ICEMs and the diseases they treat was found to be an important barrier at the individuals, households and community level. To assuage this, community-based sensitisation and public education programmes are needed. A pre- and post-intervention study in Japan, evaluating a community intervention programme providing educational materials such as flyers, posters, booklets and public lectures, showed for example, that overall perceptions of palliative care and opioids improved significantly among both the general public and family members of patients with cancer (Akiyama et al., 2016). In a similar study completed in Saudi Arabia on epilepsy, significant improvements were found in the attitudes of the general public towards epilepsy and PLWE after an educational awareness campaign (Alaqeel et al., 2015).

Many of the barriers identified at the health service delivery level in this study are barriers that are not confined to ICEMs and should be viewed in the larger context of the weak health systems found in much of SSA. For instance, the unaffordability of medicines is a system-wide problem, with many of the medicines found on the national EMLs unaffordable when they are not available in the public sector, or not reimbursed (Bizimana, Kayumba, & Heide, 2020; Chow et al., 2020; Ewen, Joosse, Beran, & Laing, 2019; Khuluza & Haefele-abah, 2019). Rolling out reimbursement programmes, such as national health insurance schemes, which include ICEMs in their coverage package, might be a way to tackle affordability issues if the schemes are properly function-





HCW: healthcare worker; ICEMs: Internationally Controlled Essential Medicines; INCB: International Narcotics Control Board; SSA: WHO: World Health Organization.

Fig. 3. Recommendations to improve access to ICEMs in SSA.

ing and managed (Aji, De Allegri, Souares, & Sauerborn, 2013; Ku, Chou, Lee, & Pu, 2019).

Similarly, a lack of (specialised) HCWs is a region-wide problem: there are 0.2 physicians and 1.0 nurses and midwives per 1,000 people in SSA, which is below the WHO threshold of 4.45 HCWs needed to achieve universal health coverage (The World Bank, 2022b, 2022c; World Health Organization, 2016). The inadequate health workforce in the region is caused by a multitude of factors, including insufficient training capacity, migration of HCWs across continents, governance issues, poor health workforce retention, morbidity and mortality among HCWs, poor planning and limited funding, making it a complex issue (Ahmat et al., 2022). Further, as found in this review, there is an inequitable distribution of the health workforce, with the workforce skewed towards urban settings. This forces rural-dwelling patients to travel long distances to access medicines, especially those that are found only at more specialised health facilities. The WHO recommends a task-shifting approach as one of the tools to be used to tackle human resource issues. Task-shifting entails transferring tasks to other cadres of HCWs with less experience, or delegating certain tasks to HCWs who receive training to obtain specific skills (World Health Organization, 2008). Since nurses are one of the main cadres of the health workforce, allowing nurses to prescribe ICEMs would potentially increase accessibility of ICEMs. Uganda, for example, was the first country to introduce nurse-prescribing laws, allowing nurses and clinical officers to prescribe opi-

oids independently after completing a nine-month training course, increasing access especially in rural areas (Hannon et al., 2016; Jagwe & Merriman, 2007; Kamonyo, 2018; Rhee et al., 2018). By 2013, Kenya, Sierra Leone and Tanzania had also introduced nurse-prescribing with a special permit (Cleary et al., 2013). Nurse-prescribing programmes for epilepsy and mental health, along the lines of the opioid nurse-prescribing programme, can be a successful strategy to also increase accessibility to services for PLWE and people living with a mental disorder. In the United Kingdom, an epilepsy nurse specialist programme, in which nurses were allowed to prescribe anti-epileptics, increased access to services and medications (Goodwin, Higgins, & Lewis, 2011).

However, this review also showed that in the existing health workforce, a lack of knowledge about ICEMs, and subsequent negative misconceptions, were common and impeded access. This is in line with an INCB study, which found that, according to Member States, one of the most common impediments to accessing ICEMs was lack of HCW training and awareness about ICEMs (International Narcotics Control Board, 2016). Therefore, in order to properly train and prepare both their existing and future health workforces on ICEMs and related healthcare fields, governments should focus their efforts on in-service training and medical education, and the better inclusion of ICEMs and related healthcare fields in medical curricula.

Essential medicines regularly do not reach the 80% WHO availability benchmark in many SSA countries (Bizimana et al., 2020; Ewen et al.,

2019; Khuluza & Haefele-abah, 2019; Ooms et al., 2020). However, the controlled status of ICEMs generally leads to a significantly lower availability when compared to other essential medicines (Baxter et al., 2017; Jost et al., 2016; Kayambakadzanja et al., 2020; Mihretu, 2021; Odinkemelu et al., 2021). In Sierra Leone for example, morphine and fentanyl were shown to have an availability of 45% and 15%, respectively, while ketamine (anaesthesia) and tramadol (pain management), both non-controlled medicines, were reported to have an availability of over 90% (Lonnée et al., 2021). Availability of ICEMs is also impacted by stockouts. Stockouts of medicines are a global issue, and shortages have been increasing over recent years in high-income countries and LMICs (Shukar et al., 2021). Again, shortages are both a systems-wide issue, as well as exacerbated by the controlled status of the medicines. So, while strengthening the supply chain in general might increase the availability of ICEMs, to significantly increase their availability, targeted action needs to be taken.

One of the ICEM-specific barriers exacerbating availability and stock-out issues is related to the requirement that countries need to annually quantify and predict the amount of narcotic drugs their population will need, which many SSA countries are poorly equipped to do. Governments should put systems in place that track the needs of their population so sufficient estimates can be sent to the INCB. Further, this review also revealed that stringent import and procurement regulations hampered access to all ICEMs, as it demotivated manufacturers and wholesalers to import them. The INCB has an important role, and some would argue a responsibility, to support countries to meet the Single Convention on Narcotic Drugs, 1961 requirements (United Nations, 1972). In 2012, at the request of the Commission on Narcotic Drugs, and recognizing the additional workload of national competent authorities due to the regulations set by the international drug control conventions, the INCB developed an electronic management tool, the *International Import and Export Authorization System* (I2ES), which countries can use to monitor and manage the import and export of controlled medicines more easily (International Narcotics Control Board, 2022; The Commission on Narcotic Drugs, 2012). Nevertheless, many SSA countries are still under-resourced, and more technical support from the INCB is needed to ensure better accessibility of ICEMs.

In many SSA countries, HCWs fear legal sanctions due to the stringent laws on prescribing and handling of ICEMs, and subsequent disproportionately serious penalties for errors or mishandling. Similarly, a 2014 INCB report showed that in 81 countries, penalties for inadequate recordkeeping of ICEMs ranged from fines to license revocation and prison sentences (Burke-shyne et al., 2017). Governments should, guided by drug policy experts, civil society and HCWs, review their policies on ICEMs prescribing and handling, to ensure that while laws protect against diversion, they are not overly stringent and criminalise prescribers.

At the health sector level, mental health, epilepsy and palliative care are often underfunded and lack prioritisation. Governments should increase their budgetary allocation to the ICEMs-related healthcare fields. Better integration of mental health, epilepsy and palliative care services into primary healthcare is also recommended to decrease accessibility barriers, especially in rural locations where specialised health care is not easily accessed.

At the international level, clear guidance on the use of opioids is lacking. In 2011 the WHO published guidelines to this extent, titled "Ensuring balance in national policies on controlled substances: Guidance for availability and accessibility of controlled medicines". However, these were retracted in 2019, and until now, no new guidelines have been published to replace them (World Health Organization, 2020). The WHO and INCB should, together with patients, civil society organisations and drug policy experts, develop new guidelines that can help governments and policy makers navigate the international regulations and safety concerns surrounding opioids so they can offer the best health care available to those in need.

## Strengths and limitations

This is the first review that studied barriers to access to all ICEMs in SSA, and not only of one specific drug group or healthcare field. This review included both quantitative and qualitative studies, and due to the broad inclusion criteria, a large number of studies could be included, creating a detailed overview of the barriers found in SSA. However, some limitations of this study should also be noted. The majority of the articles found during the literature search pertained to palliative care and anaesthesia, while much less information was found on ICEMs used for epilepsy, mental health and OAT. This indicates a lack of research in these healthcare fields, implying future research ought to focus specifically on accessibility of ICEMs for these specific healthcare fields. Also, many SSA countries are not represented in this literature review as no literature was found about these countries. This gap in the literature is alarming since it may indicate an overall lack of attention to issues related to ICEMs accessibility in these countries. Further, since the literature search included articles over a 10-year period, some data might be outdated if recent studies had not been conducted in that location. Grey literature, such as reports from the WHO or INCB, were not included in the search, which might have led to some information being missed. In this review only articles in the English language were included. Since this is a scoping review, and the high number of included studies included a broad range of study designs and methodologies (quantitative and qualitative studies, mixed-methods studies, expert pieces and reviews, as well as programme evaluations, simulated client visits and health system assessments), it was not possible to apply standardised quality assessment criteria across all studies. Last, literature was searched in four international databases, but not in Africa-specific databases. However, due to the range of included journals in the international databases, as well as snowball sampling that was used, we believe most of the relevant literature on access to ICEMs in SSA has been covered by this review.

## Conclusion

This review showed that there are a multitude of barriers to accessing ICEMs in SSA across all health system levels. It further showed that while there are many barriers that are specific to ICEMs, access is also hampered by barriers that are generally encountered for all types of medicines. However, often the controlled status of the ICEMs exacerbates the situation. Further, many of the barriers identified in this review are applicable to all ICEMs, highlighting the importance of tackling barriers to access for this entire class of drugs together. Thus, to improve access to ICEMs in SSA, a multi-pronged strategy is needed for the entire class of ICEMs, consisting of community sensitisation and health system strengthening targeted at the health service delivery level, the health sector level, and governance at the national and international level.

## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## CRediT authorship contribution statement

**Gaby I Ooms:** Conceptualization, Methodology, Formal analysis, Investigation, Writing – original draft, Visualization. **Janneke van Oirschot:** Validation, Formal analysis, Writing – review & editing. **Denise de Kant:** Investigation, Writing – review & editing. **Hendrika A van den Ham:** Conceptualization, Methodology, Writing – review & editing. **Aukje K Mantel-Teeuwisse:** Conceptualization, Methodology, Writing – review & editing. **Tim Reed:** Conceptualization, Methodology, Writing – review & editing.

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