


RESEARCH ARTICLE

Access to opioid analgesics for medical use at hospital level in the Democratic Republic of Congo: An exploratory mixed-method study

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Abstract

Objective: To investigate the availability of and access to opioid analgesics at hospital level in the Democratic Republic of Congo.

Methods: Exploratory mixed-method study combining a descriptive survey of the availability of opioid analgesics at hospital pharmacies with a qualitative survey that explored the experiences and perceptions of healthcare workers, managers, patients and caregivers, by means of a short questionnaire and of semi-structured interviews. The study was conducted in a convenience sample of 12 hospitals, located in five different provinces, in 2021.

Results: The quality and completeness of stock data for opioid analgesics were generally poor. Stock-outs were frequent. Only five hospital pharmacies had records on prescriptions of opioids in 2020. In-patients and caregivers indicated they generally must purchase opioids out-of-pocket, sometimes far from the place of residence. Doctors and nurses confirmed that prescribed opioids are often unavailable at the hospital pharmacy. Furthermore, they suggested an important need of training in pain management with opioids, and of effective regulation to ensure opioid availability. Pharmacists and managers recognised important weaknesses in the processes of needs quantification, stock management, planning and supply.

Conclusions: Our exploratory study suggests the need of a complex set of coordinated actions to be undertaken by all relevant actors in DRC to correct the poor practices in opioids' management and to improve opioids' availability, affordability and adequate use. This will require a change of mindset to overcome the neglect of the health needs of persons with acute and chronic pain.

KEYWORDS

access to medicines, Democratic Republic of Congo, essential medicines, hospital, morphine, opioids, pain treatment, palliative care

INTRODUCTION

Opioid analgesics are needed for treating acute and chronic pain. Morphine, methadone, hydromorphone and oxycodone (for adults and children), and codeine and fentanyl (for adults only) are listed in the WHO Model Lists of Essential Medicines [1, 2]. They are 'controlled substances' under the International Single Convention on Narcotic

Drugs [3, 4]. International regulations aim at achieving a balance between access for medical needs, and prevention of abuse and diversion, but a huge access gap exists between high-income countries (HICs) and low- and middle-income countries (LMICs) [5, 6]: in 2015, 92% of morphine was consumed by just 17% of the world population, with consumption concentrated in the global North [7]. In 2019, the total consumption of morphine for medical and scientific

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purposes was 9200 defined daily doses per million inhabitants in Western Europe versus 90 in Africa [5, 8]. Of course, needs are high and thus not covered in Africa, for example, for pain management in cancer (more than 1.1 million cases and 700,000 deaths reported in 2020 [9]) and other conditions such as HIV/AIDS, childbirth [10] and sickle cell disease. Access barriers are located at various levels, including legislation and policies, financing, knowledge, cultural attitude, training and education [11, 12, 13] and weak palliative care systems [14].

In the Democratic Republic of Congo (DRC), the National List of Essential Medicines includes both *non-narcotic analgesics*, that is, the combination of paracetamol + codeine, and tramadol in different oral and injectable formulations; and *narcotic opioid analgesics*, that is, injectable morphine chlorhydrate; morphine sulphate as oral syrup; injectable fentanyl; injectable pethidine chlorhydrate; codeine as oral and injectable formulations and suppositories; and oral methadone chlorhydrate [15]. Like any other medicines, opioid analgesics are placed under the regulatory oversight of the Congolese Authority for Pharmaceutical Regulation (ACOREP) [16]. In addition, opioid analgesics are controlled substances, subject to special legislation. The Ministerial Order n°1250/CAB/MIN/SP/008/CPH/OBF/2015 of 28 September 2015 [17] regulates trade of pharmaceutical products and indicates in art. 30 the need to strengthen planning, management, and control of the import and export of narcotics [18]. The Ministerial Order n°1250/CAB/MIN/S/0002/DC/OWE/2021 of 2 March 2021 sets the conditions for medical and scientific use of narcotics and psychotropics, in accordance with Law n°18/035 of 13 December 2018 determining the basic principles regarding the organisation of public health [19]. However, past reports indicated weaknesses in the pharmaceutical system in general [20] and in the management of controlled substances in particular [21].

There are to the best of our knowledge very few publications on access to opioid analgesics in DRC. An assessment of palliative care services in Kinshasa, conducted in 2018 by the International Youth Association for Development with the International Union against Cancer and the United Nations Office on Drugs and Crime indicated the need to improve training in the monitoring and use of opioid analgesics [22]. Building on these findings, we conducted an exploratory mixed-method study in 2021 to investigate the availability of and access to opioid analgesics at hospital level in the DRC. Our aim is to inform policy-makers, regulators and other national and international stakeholders about any legislative, regulatory, educational and operational measures needed to improve access to these essential medicines.

METHODS

This is a mixed-methods study combining a descriptive survey of the availability of opioid analgesics with a qualitative survey that explored the experiences and perceptions of

healthcare workers, managers, patients and caregivers. It was conducted in a convenience sample of hospitals from September to December 2021.

Study settings and sample size

Hospital inclusion criteria were: (a) being member of the Plateforme hospitalière RDC (PH-RDC) [23], and/or being supported by one or more Belgian non-governmental organisations within the platform Hub-Santé [24]; and (b) being likely to have significant recent experience in pain management. For fulfilling the latter criterion, we included hospitals with all the following characteristics: an in-patient capacity of at least 100 beds, an average of at least five patients/month requiring opioid analgesics, at least four functional services among Internal Medicine, Surgery, Paediatrics, Intensive Care, Anaesthesia and Resuscitation, at least one specialist in Internal Medicine and one in Surgery, and a hospital pharmacy. Overall, 12 public and private confessional hospitals in 5 provinces were included (Table 1). Having dedicated palliative care services was not an inclusion criterion—and in fact, only 5 of 12 hospitals had one.

Quantitative data were collected from the hospital pharmacies. Qualitative data were obtained from hospital healthcare workers and managers, patients and caregivers, conveniently sampled from those present at the time of the interviews, and by taking into account the gender dimension; and from the hospital pharmacists and managers at provincial level of the healthcare system. The desired minimal sample was pre-determined for ensuring representativeness across all 12 hospitals: 36 doctors and 36 nurses (3 each/hospital); 12 pharmacists and 12 hospital managers (1 each/hospital); 24 patients (2/hospital); 12 caregivers (1/hospital); and 10 key-informants at provincial level. Further informal conversations took place with health managers at central regulatory level to verify and validate the information concerning the national laws and regulations.

Data collection

The data collection team consisted of nine interviewers, overseen by the principal investigator, two field supervisors and the data manager. Data collection tools were in French, and they were pre-tested in two hospitals not included in the study. Quantitative data on the availability of opioid analgesics and indicators of stock management were obtained at hospital pharmacies. Data were digitally collected by means of a structured observation grid developed in the ODK Collect v2021.2.4, installed in collectors' android phones, and connected to a kobotoolbox server.

At the start of the project, a short questionnaire with closed and open questions was presented to health professionals of the surveyed hospitals concerning knowledge, use of and training about opioid analgesics. Qualitative data were thereafter obtained through semi-structured interviews,

TABLE 1 Characteristics of the 12 hospitals included in the study

N°	Name	Province	Status	Urban/rural	Member of the hospital platform?	Supported by a Belgian NGO?	Number of beds
1	HGR N'djili	Kinshasa	Public	Urban	No	Yes	153
2	Hôpital pédiatrique Kalembe Lembe	Kinshasa	Public	Urban	Yes	Yes	144
3	Clinique universitaire de Kinshasa	Kinshasa	Public	Urban	Yes	Yes	565
4	Centre Hospitalier Monkole	Kinshasa	Private	Urban	Yes	Yes	106
5	Hôpital St Joseph	Kinshasa	Private confessional	Urban	Yes	Yes	264
6	Hôpital de Ngaliema	Kinshasa	Public	Urban	Yes	Yes	309
7	Institut Médical Evangélique de Kimpese	Kongo central	Private confessional	Rural	No	Yes	400
8	HGR Gombe Matadi	Kongo central	Public	Rural	Yes	Yes	123
9	HGR de Kisantu Saint Luc	Kongo central	Public	Rural	Yes	Yes	340
10	Hôpital de Mosango	Kwilu	Public	Rural	No	Yes	351
11	HGR Rutshuru	Nord Kivu	Public	Rural	No	Yes	319
12	Hôpital de Panzi	Sud Kivu	Public	Urban	No	Yes	450

Abbreviation: HGR, Hôpital Général de Référence (General Referral Hospital).

conducted in French for health professionals, and in the participant's preferred language (French, Kiswahili, Kikongo or Lingala) for patients and caregivers. Regarding healthcare providers, the interviews explored in greater depth issues such as knowledge of opioid analgesics, and perceptions related to their availability and use. For patients and for their caregivers, the focus was on experiences of pain management and access to opioid analgesics. For pharmacists and managers, the focus was on the availability, procurement and use of opioids, and on policies, laws and regulation.

Data analyses

The quality and completeness of the quantitative database was checked daily. Data were aggregated and imported into SPSS version 25.0 and cleaned. Descriptive statistics were used for analysing quantitative variables and calculating the indicators of availability and consumption, the unit selling price, and days of stock-out. Data for categorical variables were summarised as frequency tables, with calculation of proportions.

Qualitative interviews were recorded, except for two respondents who refused where notes were taken. All interviews from the first nine hospitals where data collection was completed were transcribed, translated into French when needed and cleaned. For the last three hospitals, the social science researcher selected the interviews to be transcribed based on the need to ensure representativity per category of respondents. Overall, 96 of 127 files were transcribed, imported and regrouped in N-vivo software. Data were coded, based on an ad hoc-generated codebook. The analysis was of a deductive thematic type.

Ethics

The study was approved by the Institutional Review Board of the Institute of Tropical Medicine, Belgium (no. 1522/21)

and by the Ethics Committee of the School of Public Health of University of Kinshasa, DRC (no. ESP/CE/153/2021) prior to the start of the surveys. Administrative authorizations were obtained from the Provincial Health Directorates and Hospital Management teams. All participants were over 18. Informed consent was obtained in written from healthcare staff and managers, and verbally from patients and caregivers in their own language (French, Kiswahili, Kikongo or Lingala). No incentives were offered for participating in the research. No personal identifiers were entered in the databases.

RESULTS

Quantitative data

Stock cards were used in 11 of 12 hospital pharmacies (91.7%); stock records in 8 (66.7%); and 8 pharmacies (66.7%) used a computerised stock management system. Only five pharmacies had sales books (41.7%), and only three had the 'register of use of essential medicines and receipts' (25%). All pharmacists knew that there exists a National Essential Medicines List. The inventory tools were not harmonised across pharmacies and products.

The quality and completeness of stock data for opioid analgesics were generally poor. As the dispensing data for 2020 in Table 2 show, products containing morphine, fentanyl, pethidine, codeine and tramadol were most often reported as available, but only one hospital had morphine in oral solution. Table 3 shows, for 10 hospitals only, the same data for the first 6 months of 2021 but extrapolated to a full year for comparability. The availability figures for 2021 were higher than for 2020, but samples are too small to draw any conclusions on patterns over time, and reported availability is contradicted by stock-out data. Even if obtained from 5 hospital pharmacies only (Table 4), these data show that products most affected by stock-outs were

TABLE 2 Number of hospitals per quantities of opioid analgesics dispensed between 1 January and 30 December 2020 ($n = 12$ hospitals; NA = information not available)

Medicine	Formulation	NA	Count of hospitals by number of units dispensed			
			0 units	1–100	100–1000	>1000
Morphine	Injectable	4		2	2	4
Morphine	Oral solution	11			1	
Fentanyl	Injectable	3	1	5	2	1
Pethidine	Injectable	10		1	1	
Tramadol Hydrochloride	Injectable	3	1		4	4
Tramadol	Oral (capsule or tablet)	5	1	1	1	4
Codeine	Oral (capsule or tablet)	10		1	1	

TABLE 3 Number of hospitals per quantities of opioid analgesics dispensed between 1 January and 30 June 2021 extrapolated to a full year ($n = 10$ hospitals; NA = information not available)

Medicines	Formulation	NA	Count of hospitals by number of units dispensed			
			0	<100	100–1000	>1000
Morphine	Injectable	1	1	2	5	1
Morphine	Oral (sirop)	8	1	1		
Morphine	Oral (tablets)	9		1		
Fentanyl	Injectable	3		1	3	3
Pethidine	Injectable	9			1	
Tramadol	Injectable	1	1		1	7
Tramadol	Oral (capsules)	3		1	3	3
Tramadol + paracetamol	Oral (capsules)	9				1
Paracetamol + codeine	Oral (solution)	9		1		
Paracetamol + codeine	Oral (tablets)	8		1		1

TABLE 4 Number of days of stock-outs in five hospitals (2020)

Hospital code	Medicine	Formulation	Dose	Number of days of stock-out	
HA4	Morphine	Injectable	10 mg/ml	30	
HA3	Tramadol Hydrochloride	Injectable	100 mg/ml	11	
		Tablet	50 mg	4	
		Capsule	50 mg	9	
HK1	Fentanyl	Injectable	100 mcg/2 ml	6	
		Tramadol	Capsule	50 mg	120
HE1	Morphine	Injectable	10 mg/ml	90	
		Injectable	20 mg/ml	30	
	Fentanyl	Injectable	100 mcg/2 ml	270	
		Codeine	Tablet	50 mg	30
			Pethidine	Injectable	100 mg/2 ml
HE2	Morphine	Injectable	10 mg/ml	300	

injectable forms of morphine (3/5 hospitals; for a median number of 60 days), fentanyl injections (2/5 hospitals, 138 days) and tramadol injections (2/5 hospitals, 10 days). Only five hospital pharmacies had records on the number of prescriptions of opioids in 2020.

We also assessed the reported prices per sale unit for 2020, but data were scarce, and four hospitals did not provide any at all. In Table 5, we show the price of products for which a comparison was possible. Some price differences should be investigated; for example, morphine oral solution

TABLE 5 Sale unit price in US dollar, for products with more than one price available

ICD	Formulation	Dosage	Unit price in \$									
			Sale unit	HA1	HA2	HA3	HA4	HB1	HB2	HK1	HE2	
Fentanyl	Injectable	100 mcg/2 ml	1 ampoule	3.5	5	4.9						3.8
	Injectable	50 mcg/ml	1 ampoule					6	6.1			
Tramadol	Injectable	50 mg/ml	1 ampoule	0.5	2.5						0.5	
	Injectable	100 mg/2 ml	1 ampoule					0.4	0.3	0.2		0.39
	Capsule	50 mg	1 blister 10 caps			4.5	1.5	0.8			1	
Morphine	Injectable	10 mg/ml	1 ampoule	4.8		5.4	4.8			2.5	2.5	
Morphine	Oral solution	50 mg/5 ml	1 bottle 500 ml	10			14.3					

was sold at a minimum of 10 and a maximum of 14.3 USD per unit.

Qualitative data—Patients and caregivers

Overall, we analysed the interviews from 23 adult patients and caregivers. Patients were admitted with conditions requiring therapy for acute or chronic pain, that is, trauma, surgical interventions, osteoarticular and rheumatic conditions, sickle cell disease, cancer, other pathologies causing chronic pain, gout and hemorrhoidal disease. Pain was interpreted in a broad socio-cultural context. The causes of pain associated with acute conditions were generally well-understood, and the recourse to biomedicine tended to be straightforward, as indicated by this patient: *‘They advised me to always follow the advice of the doctors, follow their guidance for this disease’*. Conversely, for pain associated to chronic illnesses, supernatural and spiritual causes were also invoked, for instance, by the mother of a sickle cell child: *‘Family members or relatives say that it was supernatural spirits that caused my child’s illness’*. Hospital-based medicine was not perceived as the only possible source of care. Many patients were encouraged by their entourage to pursue the medical management in hospital, while in other cases, conflicting opinions could disorientate the patient in his/her decision-making between hospital, local ancestral medicine, and self-medication. For instance, a caregiver stated *‘Some people referred me and suggested that after the treatment if I can go to a mother in our village who uses traditional products for fracture treatment but my wife refused this proposal because of the severity of the fracture’*. Self-medication was sometimes facilitated by using old prescriptions, as witnessed by a patient: *‘It’s myself when I feel the pain, I refer to the prescription from the other time to buy’*. Seventeen of 21 respondents (80.9%) indicated that they had to purchase the opioid analgesics out-of-pocket in the hospital pharmacy or in private pharmacies; only 4 (19.1%) received them for free. Two of seven patients who gave their opinion on affordability felt that the medication was too expensive: *‘It was not easy to access opioids because of the lack of financial means’*; *‘It was not easy for me, I had to fight to find the means to buy the products’*. In the absence of a health insurance

system, affordability seemed to largely depend on the patient’s and the household’s incomes, and on the pricing policy implemented by each hospital or the local pharmacies. Geographical accessibility can also be problematic: for instance, a patient indicated that it was necessary to travel from Central Kongo to Kinshasa to find the medicines.

Qualitative data—Healthcare providers

Overall, we analysed the interviews from 73 respondents: 26 doctors, 28 nurses, 11 hospital pharmacists and 8 pharmacists and managers at provincial level. They were evenly split between males and females (50% vs. 50%), with an average length of service of 11.87 years (minimum 0 and maximum 44 years and a SD of 11.16). The largest proportion (31.6%) had served 1 to 5 years in the hospital, followed by those who had worked there for 6 to 10 years (23.7%) and 10.5% who had 31 years or more of tenure.

Interviews of doctors and nurses: Knowledge about/training in opioid analgesics use

Most doctors had adequate theoretical general knowledge of (the use of) opioid analgesics, as reflected in the following statement: *‘Opioids for medical use are strong analgesics, used for severe pain according to the WHO stages. So, we use opiates when we are at the end of other methods that we can use, it is at this moment that we can use opiates to tranquilize a patient’*. The same applies to nurses, as reflected in the following statement: *‘Opioids are painkillers that we administer, as we say in level 3, according to the degree or level of pain, and they are medicines that are only given on medical prescription and also require medical and nursing supervision’*. Respondents generally concurred in that treatment should immediately be stopped if side effects occur, and that side effects must be managed on a case-by-case basis. A doctor stated: *‘So for the management of side effects, it’s case by case, we proceed either by a decrease in dosage, if we find that the decrease in dosage will not be effective, we change the molecules altogether’*, and a nurse stated: *‘If there is vomiting, we give ondansetron [anti-emetic] ... If respiratory*

depression, we give naloxone and ventilation; if pruritus-type allergy to tramadol, we give hydrocortisone or promethazine. The antidote for morphine is naloxone and resuscitation. For the others, I have no experience'. Most respondents noted that side effects can be adequately managed only if patients are intensively and continuously monitored (particularly in intensive care units). A doctor explained that '... those who monitor these patients are our friends the nurses, it's true that the doctor visits, but those who are really on duty are the nurses. For the patients in intensive care, there are the monitors, but the monitors have to be supervised; even if we, the doctors, are not next to the patient all the time, but we have to come and listen to their requests from time to time'. In palliative care units, emphasis should be on psychological support until the end of life: 'A patient in palliative care must be accompanied, a patient in palliative care is not taken to the Intensive Care Unit'. Many responders pointed at the psychological burden of managing pain with opioids: 'Often when you receive a patient with excruciating pain, the first thing is if you are not strong, you might even stress but with opioids, the ideal first thing is to relieve the patient'. They also shared their reasonings for prescriptions, for example, 'For all severe or moderate head and brain trauma patients, we resort to morphine analgesics, because it has been proven that pain is a negative factor in the evolution of this category of patients and causes the occurrence of cerebral oedema'. Most respondents felt they had insufficient training, and less than half reported having received some in-service training (generally supported by external national or international partners). A doctor noted that 'There is no training organized in this context; however, we still have patients who need to be followed up by staff trained in palliative care; often, the need exists but the service is not yet provided'.

Interviews with doctors and nurses: Features of/barriers to prescribing

Most respondents indicated that opioids are prescribed by experienced doctors. The medicines most commonly prescribed for pain management were tramadol and codeine, often co-formulated with paracetamol. Only a few respondents mentioned morphine, while others indicated non-steroidal anti-inflammatory medicines. The opioids most commonly prescribed as last resort were morphine and fentanyl. These findings could not be cross-checked with stock data. However, a doctor mentioned the use of a combination of paracetamol and tramadol as last resort, when strong opioids are not available; and many respondents mentioned the limited availability and stock-outs of strong opioids—particularly morphine—as obstacles to prescription. A doctor stated 'No, we prescribe. The big difficulty is when there is a stock shortage'. A nurse explained that 'The big difficulty is the non-availability of these medicines; we can prescribe them but the patient may not be able to find them if we don't have them here in the hospital ...'.

In other cases, doctors may be reluctant to prescribe opioids: '... even here in the hospital, there are many people who refrain from prescribing them because of their side effects'. Lack of experience can make prescribers hesitant: 'Yes, I would say that there is still a difficulty in prescribing opiates given that first of all it is a product that is not very familiar to the whole hospital and to all the clinicians. It is a product that is not very, very available that would give a certain difficulty in prescribing because we are not used to prescribing it'.

Interviews with doctors and nurses: Laws and regulations

The interviews revealed suboptimal knowledge, but also a high awareness of the need for adequate, effective regulation. For instance, a doctor mentioned that 'There should be a law to regulate all this, i.e. access should be limited and authorised to patients by a prescription issued by a doctor, with a signature and a serial number on the prescription, and this should make it possible to show traceability in case the need arose'. Some respondents expressed open dissatisfaction with the health sector in general ('We have the impression that the State has completely forgotten, resigned, and forgotten about health; therefore we must make our State responsible') and for access to opioids in particular. A paediatric nurse said: 'Let them legislate and let us have laws that deal with access to opiates for children'. Still another responder stated: 'I think that opioids should be available in the state structures. The government, through its supervisory ministry, must supply hospitals with opioids, not only opioids but also other medicines'. Others underlined the need for measures that favour achieving universal health coverage, informing communities on palliative care, training health-care workers on opioids, and making opioids continuously available for medical use; and that limit the misuse of opioids by rigorous monitoring and surveillance. A doctor synthesised these concerns: 'Quite simply, we must work to ensure that the country has the possibility of treating everyone. I would go in the direction of training health personnel who manage opioids and the availability of opioids, i.e. improving the availability of opiates in our environment'.

Interviews with pharmacists and managers

Most hospitals procure opioids by purchase, except in (rare) cases of donations from international organisations. The suppliers must be approved by the Provincial Health Division or by ACOREP. The range of potential suppliers is broader in urban areas, and particularly in Kinshasa. Seven of 12 hospitals primarily purchase at private wholesalers or outlets, and 5 at the regional distribution centres, which are private not-for-profit entities working in partnership with the state under Law n°004/2001 of 20 July 2001. The secondary suppliers are private wholesalers or outlets, and sometimes international NGOs or other partner organisations.

The respondents adequately described administrative and logistical requirements for stock management, for example, good reception and distribution practices, disposal of expired products, and the 'alert' stock system. Most of them also described a collaborative approach for preparing orders. However, the theoretical knowledge does not seem to match practices, as in the quantitative survey only five hospital pharmacies provided information on opioid stock-outs. Interviews revealed a lack of specific tools for opioids management such as dedicated forms, notebooks and registries, and procedures in case of loss or theft. In five hospitals opioid prescriptions were archived in the pharmacy; in three hospitals they were sent back to the prescribing department and in four hospitals they were not kept. Concerns were raised by a respondent on the oversight of the Bureau of Inspectors: *'There is a Bureau of Inspectors who are supposed to see if these opioids are well-managed. But in the field, there is the Drug Police who interfere without technical expertise and it becomes a hassle. These services should be working with the DPS but they just go and charge taxes and the "death shops" continue to operate ...'* Stock-outs of opioids are frequent. Reasons for stock-outs include the low national availability due to import restrictions and time-consuming procedures; and the difficulties in quantifying needs. As explained by a hospital manager, *'When you order, the product is not available. It takes a long time to get the import license in Kinshasa. Currently, marketing authorizations are also a problem. The lack of control over the quantification of medicines poses a problem, which is at the root of stock-outs of medicines, resulting in their non-availability in health facilities'*. Furthermore, provincial pharmacists are poorly informed on the availability of opioids: *'... I too was not paying too much attention to the availability of these products; it is still relevant, of course; but we were much more focused on all these medicines that are essential to act on specific programmes or on the general public, so public health in general'*. Stock-outs force patients to look for opioids at private pharmacies or to go back to the prescriber: *'... in the event of stock-outs, we advise the patient to return to the prescriber. He returns to the doctor who consulted him in order to change the molecule'*. The replacement can also be proposed by the hospital pharmacist him/herself: *'... they will resort to lower-tier molecules, tramadol for example, often they mix tramadol with anti-inflammatories, ibuprofen for example'*. Even when available at the pharmacy, opioids may be unaffordable for patients: *'... Yes, when we see the prescription, we serve really quickly and we serve only in relation to the money he has; the financial means with the population that has a purchasing power that is already too low [pose a problem]'*. Some respondents linked unaffordability to poverty and lack of health insurance; and some to the lack of a clear pricing policy (which is indirectly confirmed by the price variability observed, despite the small sample, in the quantitative survey). All this loudly resonates with the interviews with patients, caregivers and healthcare workers.

Knowledge and practice interviews of healthcare professionals

At the start of the project, a short questionnaire with closed and open questions was presented to 31 doctors, 34 nurses and 11 pharmacists or managers. Seventy-two of 76 respondents declared to be knowledgeable about opioid analgesics for medical use, and cited at least one, especially tramadol and morphine. Fentanyl, codeine, pethidine and pentazocine were cited by very few respondents, as was oxycodone (not in the national list). Some respondents, however, cited non-opioid analgesics instead, for example, non-steroidal anti-inflammatory drugs and others. To a question about which narcotics were most commonly used, some more problematic answers were: anaesthetics, benzodiazepines, barbiturates and others. The proportion of those who declared to know the side effects of opioids was large among both those with the right to prescribe (90.3%) and those without (91.1%). To answer a question on the frequency of side effects, the majority indicated digestive problems, followed by dependence, sleep disorders and respiratory problems. About 71% (22/31) of prescribers and 62.2% (28/45) of non-prescribers indicated that opioids can hasten death in patients. Almost 74% (56/76) of respondents indicated that they felt insufficiently trained in the use of opioids in pain management—especially nurses (75.6%) and doctors (71.0%). Only 38.7% (12/31) of prescribers and 44.4% (20/45) of non-prescribers said they had received some formal training—the most recent training dated back to <1 year for 62.5%. Forty of 76 respondents had some experience of prescribing opioids, but only half of these were officially allowed to prescribe medicines. Twenty-six reported barriers to prescribing opioid analgesics related to the doctor's role in diagnosing and prescribing (38.5%), need of monitoring (26.9%), non-availability of opioids (15.4%) and fear of dependence (15.4%). A few respondents also indicated the need of a special authorization for prescribing these products.

DISCUSSION

Management of opioid analgesics

In our study, stock-out data and prescription records were available at a minority of hospital pharmacies only. Unless due to a lack of willingness to share them, this is an indicator of poor stock management, which causes inadequate quantification, wrongly estimated orders, and new stock-outs—similar to the findings of Nurse-Findlay that inaccurate country forecasts and weak procurement systems compromise the availability of benzathine penicillin [25]. Inaccurate quantification of needs at local level may be enhanced by the lack of routine supervision from provincial level, and by the delayed supply from central level. The poor stock- and record-keeping is particularly alarming for opioids, which are subject to a special legislation, but it is also harmful for non-controlled products like tramadol—a

product in great demand with a high potential for misuse. The situation might be worse in facilities without authorised pharmacists (DRC only counted 1510 pharmacists in 2011, 1166 in 2015, and 2710 were inscribed at the Order of Pharmacists as of September 2022).

Our data suggest a need to correct the current poor practices in opioids management. As ACOREP is in charge of oversight of pharmaceutical regulation, stock management and stock planning, for opioids analgesics and for all essential medicines, it would seem urgent to increase its human, financial and infrastructural resources. This will require strong national political willingness and support of external partners and donors. The DRC recently joined the East African Community (EAC), and ACOREP could benefit from participation in the EAC Medicines Regulatory Harmonisation Programme for upgrading its skills and capacities [26].

Access to opioid analgesics for medical use

Even if we could neither check the exact quantities of opioids available at hospitals nor cross-check availability versus needs, our findings raise various concerns. First, stock-outs are under-reported but frequent at hospitals pharmacies, and the burden of searching for these essential medicines elsewhere is unfairly put on patients and their caregivers. They are pushed towards private outlets (often more expensive, and/or far from where the family lives), and possibly even towards the unregulated, riskier informal sector. Otherwise, doctors and pharmacists must provide alternative medicines, potentially suboptimal; for instance, high use of tramadol-containing products might be compensating morphine stock-outs.

Even if a majority of patients in our sample managed to purchase opioids in a hospital or private pharmacy, the interviews with healthcare staff suggest that affordability of opioid analgesics is poor, due to families low income and lack of health insurance, and because these products are not subsidised except in rare cases of donations. More qualitative research will be needed to understand the impact of the purchase of essential medicines for pain management on individual or household income and other health expenses. Price-setting mechanisms are not transparent and affected by mark-ups at different levels of distribution upstream from the hospital. It seems urgent that the government of DRC develop, via the Ministry of Health and ACOREP and with the support of external partners, a sustainable strategy for needs' quantification and supply, integrated in the state network of essential medicines supply centres. Pain management should be systematically included in universal health coverage policies and packages [27], and there should be a transparent, harmonised and fair pricing policy.

Training about opioid analgesics

Although we did not use formal knowledge assessment scores and did not assess the quality of prescriptions, we

identified important weaknesses in the knowledge of health-care workers about opioid analgesics and their use, in line with findings of Berdi [28] (who assessed in-hospital use of painkillers in Morocco) and Zubairi [29] (who assessed palliative care services in Kenya). Lack of knowledge may cause insufficient or inadequate prescriptions, for example, if doctors are not familiar with all the opioids in the national essential medicines list. Exaggerated concerns on side effects may lead to inadequate individual risk–benefit assessments. In fact, a third of the doctors in our sample had no experience in prescribing opioids, and the ‘role of the doctor’ was at the top of the list of difficulties in prescribing opioids. Inadequate knowledge of palliative care or pain management with opioids has been noted by several other authors, and often linked to structural gaps in medical education [30–33]. Most doctors, nurses and pharmacists in our sample felt insufficiently trained on the use of opioids; and a majority of prescribers and non-prescribers stated that they had not received any in-service training in pain management. These figures are in line with those of Tawi [34] who investigated providers' knowledge and perception of palliative care in the management of HIV patients in DRC, and found that only 32% had been trained in palliative care. They also echo our previous observations that such training is highly needed in most settings in West and Central Africa [13]. Academic institutions, medical professional associations, policy-makers and donors in DRC should prioritise the set-up and roll-out of training programmes on pain management, opioid use and palliative care.

Patient non-adherence did not emerge as a barrier to adequate pain management, but we learned that patients may opt for self-medication. This indicates a need of programmes to inform communities and patients/caregivers on the adequate and safe use of opioids. However, such programmes will not be successful if the needed opioids are not available and affordable at the health facilities.

Laws and regulations

Our study identified noncompliance with laws and regulations at different levels, including but not limited to poor record-keeping for opioid stocks and prescriptions; prescription by non-authorised healthcare workers; and a lack of routine monitoring of opioids at provincial level. Patient non-adherence did not emerge as a barrier to adequate pain management, but self-medication did. Self-medication is (also) made possible by weak oversight along the dispensing chain (e.g., dispensing without prescription, potentially up to illegal sales of opioids). The government of the DRC, through the Ministry of Health and ACOREP and with the support of external partners and donors, should invest in strengthening the legislative arsenal. In particular, it should finalise the adoption of a Ministerial Order (‘Arrêté Ministeriel’) for the implementation of Law N°18/035 of 13 December 2018; provide adequate resources to allow that all concerned workers are trained in relevant laws, regulations and directives that impact on the availability,

BOX 1 Recommendations emerging from the study, by stakeholders

What	How	Stakeholders	Essential pre-requirements
Improve availability of opioids	Improve stock management at local and national levels	ACOREP, Ministry of Health, Donors	Finalise the adoption of a Ministerial Order ('Arrêté Ministeriel') for the implementation of Law N° 18/035 of 13 December 2018. Provide adequate resources to train all concerned workers in laws, regulations and directives that impact on the availability, affordability and management of opioids. Ensure that laws and regulations are adequately implemented
	Improve the quantification of needs at local, provincial and national levels	ACOREP, Ministry of Health, Donors, Hospitals	
	Strengthen regulatory supervision along supply chain	ACOREP, DPS	
	Roll out training programmes on the quantification and management of opioids for pharmacists, health managers, inspectors and policy-makers	Academia, ACOREP, Professional Orders, Donors	
Improve affordability of opioids	Include essential opioids in health insurance packages and subsidisation programmes	Government, Donors	
	Include essential opioids in universal health coverage policies and packages	Government, Ministry of Health, Donors	
	Enforce a transparent, harmonised and fair pricing policy	Government	
Improve adequate use of opioids	Include pain management and palliative care in undergraduate and graduate medical curricula	Academia	
	Roll out training programmes on pain management, use of opioids and palliative care, for healthcare workers	Academia, Ministry of Health, Professional Orders, Donors, DPS	
	Roll out sensitization programmes for patients, caregivers and communities on the safe use of opioids	Ministry of Health, Professional Orders, Donors, Hospitals	
	Integrate palliative care in all hospitals	Government, Ministry of Health	

affordability and management of opioids; and ensure that these are adequately implemented.

Palliative care

Only 5 of 12 hospitals in our sample had dedicated palliative care services. The main barriers to integrating palliative care

into the health systems, as previously identified by scholars such as Masumbuku [35, 36], Tawi [34], and King [37], seem applicable in the DRC: a preponderant or exclusive focus on curative and preventive care by policy-makers and donors; cultural determinants; financial constraints; and the absence of palliative care in medical curricula. After the first Conference on Palliative Care organised in Kinshasa in 2013 [38], palliative care has been slowly developing through a

network of hospitals supported by international partners, but its integration into the health system seems still far to reach. Therefore, national policy-makers and donors should invest in the integration of palliative care in hospitals.

Study limitations

The main limitation of our study is the convenience sample of hospitals, all supported by national platforms or international donors and thus not necessarily representative of other hospitals in the country that do not benefit from external support. However, one can assume that the situation is similar, or worse, in less-resourced hospitals, and thus that our findings remain informative. Second, an ongoing strike in state hospitals may have limited access to some information and even to some potential respondents, and the selection of interviews before transcription may have introduced some level of subjective bias. Third, the lack of standardised and/or well-completed stock management tools across hospitals, and the fact that quantitative data declared by the pharmacists were not double-checked, prevented a more systematic and accurate analysis of stock data. Fourth, we may have missed information on opioid stocks and use when these medicines are managed elsewhere than in the hospital's pharmacy. Lastly, we obtained very little information related to pain management in children, which certainly requires further study.

CONCLUSIONS

Our exploratory study revealed significant problems in the availability, affordability and adequate use of opioid analgesics for pain management in DRC. Correcting this situation (Box 1) will require a change of mindset among government, policy-makers, international and national NGOs, donors active in DRC, and the 26 Provincial Health Divisions and hospitals themselves to overcome the current neglect of the health needs of persons with acute and chronic pain.

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CONFLICT OF INTEREST

Raffaella Ravinetta is the chairperson of Institutional Review Board of the Institute of Tropical Medicine, Belgium, but she was not involved in any ways in the review of this study.

DATA AVAILABILITY STATEMENT

The full study report in French, including the data collection tools, is available from the corresponding author.

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