



TRANSFORMING
THE SUPPLY CHAIN

Comparative Study of Pharmaceutical Waste Disposal in Ethiopia, Kenya, Sudan and Uganda

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Abstract

This report examines the pharmaceutical waste disposal systems of Ethiopia, Kenya, Sudan and Uganda in relation to the WHO guidelines for pharmaceutical waste disposal. It analyses pharmaceutical waste disposal at three levels of the Health Supply Chain: industry, community and household. First, the report establishes the recommended guidelines for pharmaceutical waste disposal. Then, it identifies the relevant national legislation in each country for pharmaceutical waste disposal. Finally, it uses a systematic literature review of the studies done in each case study country, paired with a survey and key informant interviews, to assess how pharmaceutical waste disposal functions in practice at each of the three levels of the Health Supply Chain. In this way, the report identifies gaps in policy and practice of pharmaceutical waste disposal in each case study country. Findings across the four countries include that although the guidelines for pharmaceutical waste disposal are generally comprehensive, enforcement could be stronger for each case study country. In addition, incinerators are commonly used at the community level (e.g. at hospitals), but they are of low quality and do not follow WHO-recommended guidelines, which can pose a danger for public health and the environment. Finally, it would be worthwhile to invest in education for staff at health-care facilities and for patients to increase awareness of proper pharmaceutical waste disposal techniques.

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Acronyms

EEFO	Earliest-expiry-first-out
EPISA	Ethiopian Pharmaceutical Supplies Agency
FDA	Food and Drug Administration
FIFO	First-in-first-out
FEFO	First-expired-first-out
FMHACA	Food, Medicines, and Health Care Administration and Control Authority
HCF	Health-care facility
HCW	Health-care waste
HCWM	Health-care waste management
IAPHL	International Association of Public Health Logisticians
ICRC	International Committee of the Red Cross
KEMSA	Kenya Medical Supplies Authority
KII	Key informant interview
LMIC	Low- and Middle-Income Country
MOH	Ministry of Health
NACWA	National Association of Clean Water Agencies
NDA	National Drug Authority
NMSF	National Medical Supplies Fund
NMPB	National Medicines and Poisons Board
NGOs	Non-Governmental Organisations
PPB	Pharmacy and Poisons Board
PPE	Personal Protective Equipment
WHO	World Health Organisation

1. Introduction

This paper explores the disposal of pharmaceutical waste in Ethiopia, Kenya, Sudan and Uganda. As a report from the International Committee of the Red Cross (ICRC 2011: 34) on hospital health-care waste management (HCWM) states, ‘Only too often, waste management is relegated to the rank of a menial task, whereas it ought to be valued and all actors in a hospital made to realize their share of responsibility’. Although the ICRC report focuses on hospital waste management, the principle of shared responsibility for waste management applies at all levels of the Health Supply Chain, including industries (manufacturers, donors and importers), community facilities (hospitals, health-care facilities, etc.) and households. Pharmaceutical waste emerges at these three levels, and it is important to account for each level when assessing the disposal waste practices of a country. The central challenge is to determine how to dispose of pharmaceutical waste in a manner that is safe for the environment and for public health, while still being affordable and effective.

Suitable pharmaceutical waste management is essential for environmental and public health, and although disposal is a critical step in the Supply Chain, low- and high-income countries alike struggle to implement a disposal system that is affordable, efficient and safe (Kamba et al., 2017). Indeed, many low- and middle-income countries (LMICs) do not have ‘established’ systems for pharmaceutical disposal (Bataduwaarachchi and Chamari, 2016). The World Health Organization (WHO) has guidelines for safe disposal of unwanted pharmaceuticals (WHO, 1999), and many countries have national guidelines as well, yet it is difficult to enforce these guidelines in every context and at each level of the Health Supply Chain. Therefore, in addition to analysing whether policies exist, it is essential to consider the extent to which policies are implemented at various levels of the Supply Chain.

This paper has four main objectives. First, to review the literature on pharmaceutical waste disposal and provide background on the general process. Second, to compare pharmaceutical waste disposal practices at the national level across the four case-study countries. Third, to examine waste disposal within each country at the industry, community and household levels of the Health Supply Chain; and fourth, to highlight gaps between the waste disposal policies and practices of each country at the three Supply Chain levels. Health-care waste, which is sometimes referred to as medical waste, is a broad topic that encompasses all waste produced in health-care activities (ICRC, 2011). However, the scope of this paper is limited to pharmaceutical waste specifically. Further, this report focuses on African countries in general, and the four case study countries in particular.

The remainder of this paper seeks to compare pharmaceutical waste disposal practices among Ethiopia, Kenya, Sudan and Uganda. The discussion is structured as follows: Literature Review (Section 2), Methodology (Section 3), Case Studies (Section 4), Conclusion (Section 5). Each case study is divided into two sub-sections: 1) an exploration of the national legislation in each location, and 2) an assessment of how pharmaceutical waste disposal occurs in practice in each country, comprised of a systematic literature review, survey responses, and key informant interviews (KIIs).

2. Literature Review

The Risk

Pharmaceutical waste represents an environmental and public health risk if it is not managed properly. Although most studies are concerned with the disposal of sharps because these can cause injuries and transmit infectious diseases if managed improperly (WHO, 2014), pharmaceutical waste, which makes up about 3% of all health-care waste, also poses a risk (WHO, 2004). Indeed, Udofia and Nriagu (2013) found that although African countries produce less health-care waste (HCW) than ‘developed’ countries, poor sorting practices mean that large amounts of waste become hazardous. This waste can be dangerous for public and environmental health if left unaddressed (Udofia and Niragu, 2013).

This paper focuses on three levels of pharmaceutical disposal across the Health Supply Chain: the industry level, including private wholesalers and public procurement agencies; the community level, including hospitals, pharmacies, and health-care workers; and the household level, including individual household disposal practices. It is important to differentiate these three levels to understand how waste disposal guidelines are adhered to at each level and identify where potential gaps exist. Furthermore, pharmaceutical waste constitutes a risk at each level. The industry level involves large amounts of pharmaceuticals, which can have significant environmental impacts if destroyed improperly. Next, assessing the community level can provide insight into how health-care facility (HCF) staff handle waste. For example, if pharmaceutical waste is mixed with municipal waste, this can prove to be an environmental problem and dangerous for scavengers who may come across the products. Finally, many of the studies show that the majority of households have left-over stocks of pharmaceuticals. Inappropriate household-level disposal may affect the immediate environment around the household and render it unsafe and unhealthy.

Defining Terms

The WHO refers to ‘pharmaceutical waste’ under the umbrella of ‘health-care waste’. Pharmaceutical waste can be defined as ‘expired, unused, spilt and contaminated pharmaceutical products [and] prescribed and proprietary drugs, vaccines and sera that are no longer required, and, due to their chemical or biological nature, need to be disposed of carefully’ (WHO, 2014: 5). Pharmaceutical disposal is complex and requires a ‘differentiated approach’ because ‘pharmaceutical waste’ is a broad term involving three categories of waste: non-hazardous, potentially hazardous and hazardous. Two types of hazardous drugs are genotoxic and cytotoxic drugs. Drugs that are genotoxic exhibit mutagenic properties, whereas cytotoxic drugs are used in chemotherapy and stop the growth of living cells (WHO, 2014: 29). ‘Antineoplastics’ is a term which is frequently used in the literature to refer to cytotoxic drugs (WHO, 2014: 5). Non-hazardous waste can be disposed of with general waste, therefore potentially hazardous and hazardous waste are of greatest concern in this paper (Secretariat of the Basel Convention, 2005).

Two major sources of pharmaceutical waste are products that expire and are recalled. A recall is an action ‘to remove a defective drug product from the market’ (FDA, 2020). It is important for countries to have recall procedures in place, and the Case Studies (Section 4) review country recall processes. An expired pharmaceutical product is one that was not used by the recommended date, meaning it may become less effective or even toxic. Pharmaceuticals may expire due to overstock, poor management of stock, or poor donation practice. Expiry can occur in warehouses, pharmacies, or other locations where drugs are stored.

Regulations

WHO (1999) provides guidelines for pharmaceutical waste disposal which should be followed if a country does not have national regulations. However, given the differentiated nature of the pharmaceutical industry, the number of stakeholders involved in the Supply Chain, and the cost of disposal, it is challenging to ensure compliance (Alnahas et al., 2020: 7). As Alnahas et al. (2020: 7) write, ‘There seem to be general recommendations grounded by global regulatory bodies, though still the handling and implementation differ on country bases.’ In addition, there are no international conventions that govern pharmaceutical product transport across borders (WHO, 1999: 11; Pinheiro, 2008). While national and international regulatory frameworks offer a number of recommendations that function as best practices, these are not strictly followed, resulting in a number of gaps between policy and practice.

These precautionary measures require financial investment and are therefore difficult to institute, especially in LMICs. The central reasons for lack of compliance to health-care waste policies include: little awareness of health-care waste's hazardous effects, low-quality training for waste management, inadequate human and financial resources, and health-care waste disposal not being considered a priority (WHO, 2018). Countries of varying income levels alike continue to work toward meeting the regulatory standards for pharmaceutical disposal and health-care waste management generally.

It is important to examine regulations at each level of the Health Supply Chain. Overall, the preferred method for addressing pharmaceutical waste in the long-term is to minimise pharmaceutical waste production (WHO, 2014). Second, many WHO guidelines recommend high-temperature incineration as a feasible method, although other guidelines say the WHO (2004) will support countries to move away from incineration in the long-term to reduce the harmful dioxins and furans that can be released during incineration. The method used for disposal depends on the context and resources available to those managing the waste. For example, WHO (1999) provides guidelines for pharmaceutical waste disposal in emergency contexts, when there may be limited options for waste management.

There are many potential methods of health-care waste disposal, including those defined below (WHO, 1999):

- **Landfilling:** There are various levels of engineered landfills. Landfills that are open and non-engineered are a last resort because scavengers may be exposed to pharmaceutical waste and chemicals may leach into water streams. Engineered landfills that are protected from water sources are preferred (WHO, 1999). Cytotoxic waste should never be landfilled (ICRC, 2011: 106).
- **Immobilisation:** Immobilised pharmaceuticals can be securely stored or dumped in landfills and covered with other waste to prevent scavenging (WHO, 2014). There are two main types of immobilisation: *encapsulation*, which involves containing pharmaceuticals in a solid block or steel drum, and *inertisation*, which requires that pharmaceuticals are ground into a paste and immobilised in cement.
- **Sewer:** Disposal through sewers is suitable for liquid pharmaceuticals in an emergency if they are diluted properly (WHO, 1999); however, this method is not recommended or feasible for most pharmaceuticals (WHO, 2014: 232).

- **Burning in open containers:** Burning pharmaceuticals at low temperatures releases harmful chemicals into the air and should not be used. Cytotoxic waste should never be burned in an open container (ICRC, 2011:106).
- **Medium-temperature incineration:** Medium temperature incinerators are preferred to dumping hazardous pharmaceuticals in a landfill (WHO, 1999). They should operate at a minimum of 850°C and are preferred in emergency contexts if a two-chamber high-temperature incinerator is not available. Cytotoxic waste should never be burned in a medium-temperature incinerator (ICRC, 2011:106).
- **High-temperature incineration:** Various forms of kilns disintegrate toxic organic compounds, and two-chamber incinerators meet European Union control standards (Council Directive 1994/67/EC). When a country does not have its own high-temperature incinerator it may be useful to use an industrial plant's incinerator. High-temperature incineration is effective, but it is expensive and can negatively impact the environment with the release of toxins and furans. It is important to ensure that incinerators meet international/national operating standards (WHO, 2014).

High-temperature incineration and immobilisation are two commonly recommended options for disposal in policy documents. However, incineration is considered to be a short-term solution because it still has some environmental impact with the release of dioxins and furans (National Research Council, 2000), and the most sustainable solution remains waste minimisation (WHO, 2014). At the industry-level, good medicines donation practice is essential for reducing pharmaceutical waste. This is especially relevant for LMICs, many of which 'have no choice but to rely on drug donations from high-income countries (Kamba et al., 2017: 594). Previous donated medicines have arrived in LMICs without proper documentation, in inappropriate quantities, with a short remaining shelf life, unlabelled or in a language that is not comprehensible (WHO, 2011a: 6). Therefore, WHO (2011a) has created guidelines for best practices for medicines donations. At the community level, practices such as waste segregation and sorting are encouraged at HCFs. Further, best practices include:

- Not issuing expired products or products with a remaining shelf-life that is too short for consumption;
- Earliest-expiry-first-out (EEFO), which is also known as first-expired-first-out (FEFO); and
- First-in-first-out (FIFO).

At the household-level, past guidelines have recommended that households dispose of pharmaceutical waste by flushing it down the toilet or washing it down the sink (NACWA, 2019). Those practices have been found to be environmentally harmful and therefore it is now recommended that households return expired medicines to pharmacies, and pharmaceutical take-back programmes are widely recommended to encourage safe disposal (Alnahas et al., 2020). Take-back programmes have been instituted in numerous countries, such as in Australia (called the Return Unwanted Medicines programme), Canada and throughout Europe (WHO, 2012). The presence of unused or expired pharmaceuticals in households is also a concern because there is a risk that children may consume them or individuals may use them to self-medicate (Angi'enda and Bukachi, 2016).

3. Methodology

Although this study set out to conduct a systematic literature review of academic and practice papers on pharmaceutical waste disposal at three different levels of the Health Supply Chain (industry, community and household), the literature was too vast to complete this review comprehensively. To maintain a reasonable focus, the scope of the systematic literature review is limited to the four case study countries. Following others who have previously conducted systematic literature reviews in these countries (Yazie et al., 2019), this study generally follows the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) system in reporting the literature (Moher et al., 2009). This paper includes published studies that were found using Google Search and Google Scholar with the following phrase combinations: “Ethiopia* healthcare disposal”, “Ethiopia* pharmaceutical disposal”, “Kenya* healthcare disposal”, “Kenya* pharmaceutical disposal”, “Sudan* healthcare disposal”, “Sudan* pharmaceutical disposal”, “Uganda* healthcare disposal”, and “Uganda* pharmaceutical disposal”.

Because pharmaceutical waste disposal is situated under the larger umbrella of health-care waste disposal, few studies, especially at the community level, focus explicitly on pharmaceutical disposal. Therefore, the review includes papers pertaining to health-care waste disposal more generally, as long as the paper deals with pharmaceutical disposal within the overarching topic of health-care waste. Results of the systematic literature review were also cross-checked with any existing systematic literature reviews for that country. This was the case for Ethiopia (Yazie et al., 2019) and Sudan (Hassan et al., 2018).

Studies were only included if they were published in English. In order to include a broad range of papers, this study also includes the relatively large number of papers that are available online but were published only as dissertations. These papers are referenced as dissertations where applicable using “*”. This study does not include papers that were under review. The goal of the systematic review is to identify trends in the research on pharmaceutical disposal in each case study country. This includes: the number of studies conducted at each level, the most studied geographical areas, and trends in study results. The aim of this process is to understand how pharmaceutical disposal is undertaken on the ground through second-hand sources.

The papers from the systematic literature review were then coded using a qualitative data analysis software, MAXQDA, through thematic analysis to determine trends in the findings across papers at each of the three levels of the Health Supply Chain. The findings from this exercise are reported under the ‘In Practice’ section of each case study and collated with survey responses and KIIs. This study draws on four KIIs with individuals who were selected to provide additional insight into the pharmaceutical disposal policies and practices within each case study country. KIIs involved semi-structured interviews of about thirty minutes each.¹ Informants worked in Uganda, Sudan and Kenya, and one informant worked for a medicines donation NGO and provided information via email. Unfortunately, due to time constraints we were unable to interview an individual knowledgeable of Ethiopian pharmaceutical disposal; however, a survey was published on the International Association of Public Health Logisticians (IAPHL) platform to elicit responses from practitioners in the field.² The majority of respondents worked in Ethiopia, which supplements for the lack of KII information on Ethiopia. The survey findings have been analysed and added to the case study findings where appropriate.

Policies are outlined under the ‘National Legislation’ sub-heading of each case study section. The national legislation sections are divided according to policies that pertain to specific aspects of pharmaceutical waste disposal (e.g. recall systems, policies to reduce waste, policies around incinerators, etc.). In each case study, ‘National Legislation’ is listed first, followed by ‘In Practice’, which highlights the findings from the systematic literature review, survey responses, and KIIs. Structuring case studies in this way highlights gaps between pharmaceutical disposal policy and practice.

¹ See Appendix A for interview questions.

² See Appendix B for survey questions.

Systematic Review

In total, the systematic literature review resulted in 79 papers relating to the four case study countries.

Fig. 1 Papers by Health Supply Chain level

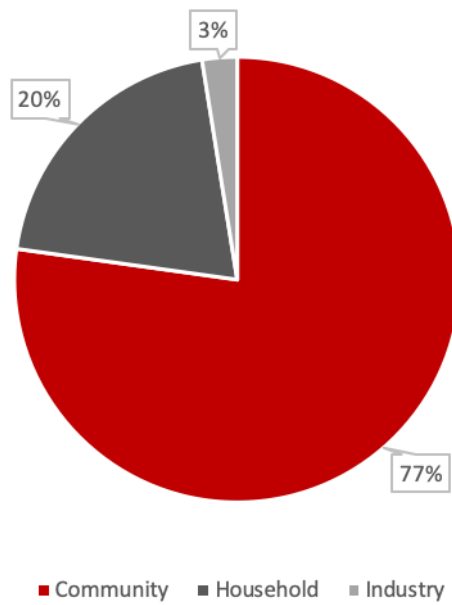
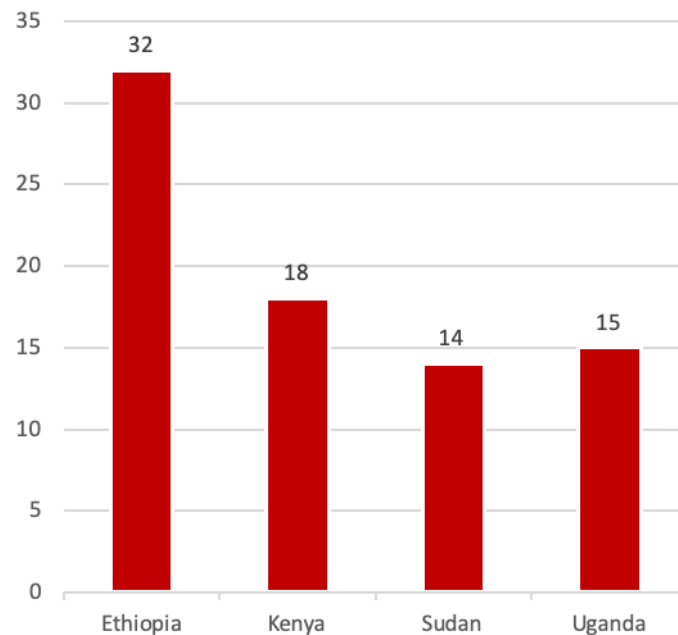


Fig. 2 Papers by country



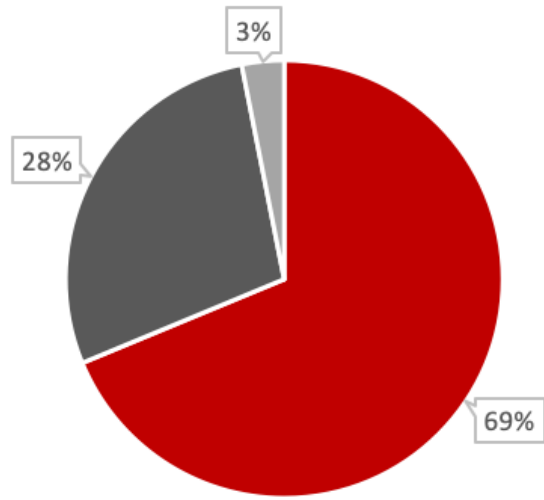
Across the four case studies, the majority of studies took place at the community level, followed by the household level and the industry level. The largest number of studies took place in Ethiopia, followed by Kenya, Uganda and Sudan. Across all papers, the two most popular journals were *BMC Public Health* and the *Journal of Environmental and Public Health*, which published four papers each that were included in the review.

Although the focus of this study is pharmaceutical disposal, few papers focused exclusively on pharmaceutical disposal; rather, pharmaceuticals were an element included in research on other aspects of the Health Supply Chain. For example, many studies at the community level assessed how a specific hospital dealt with its health-care waste. Pharmaceutical disposal may have been referenced relatively infrequently, but certain aspects gave insight into how pharmaceutical waste is dealt with; for example, the level of waste segregation that occurs in the hospital. The most common methodology used in the papers included in the systematic literature review was cross-sectional questionnaires to survey participants about disposal practices. However, because this review includes a wide range of papers, some studies also used quantitative methods such as sampling waste to determine its composition.

Trends for each country are reported in greater depth in the corresponding case study sub-sections (Section 4). Basic metadata are as follows:

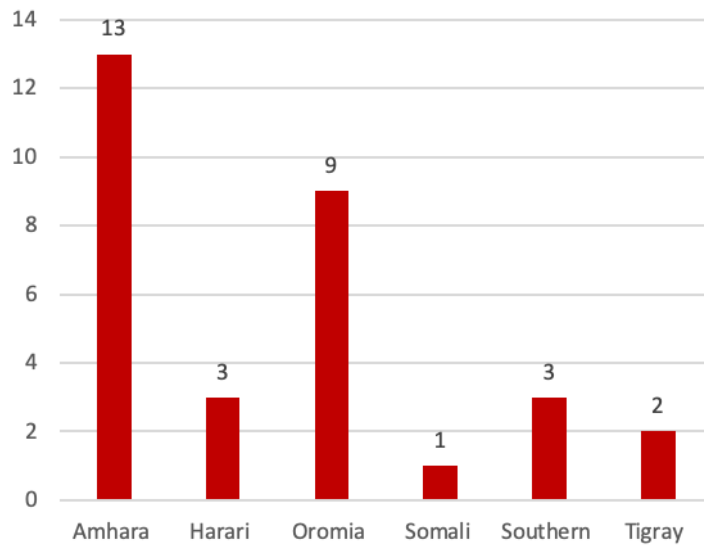
Ethiopia: 32 studies, none of which were dissertations.

Fig. 3 Ethiopia paper focus



■ Community ■ Household ■ Industry

Fig. 4 Most referenced Ethiopian regions



Kenya: 12 studies, five of which were dissertations.

Fig. 5 Kenya paper focus

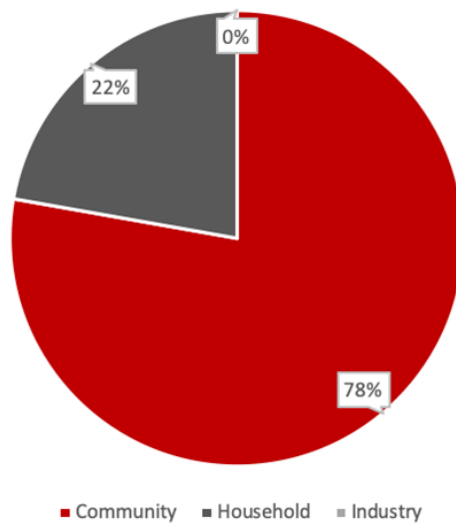
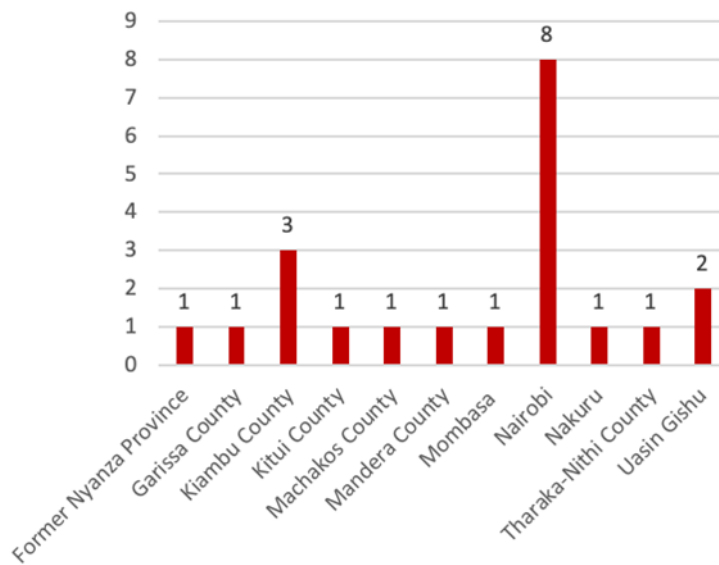


Fig. 6 Most referenced Kenyan counties



All locations were converted from state to county location, in accordance with the 2010 Constitution of Kenya. However, one dissertation involved the study of health centres across a number of counties in the former Nyanza Province, so for brevity this graph lists the location as 'Former Nyanza Province'.

Sudan: 12 studies, four of which were dissertations.

Fig. 7 Sudan paper focus

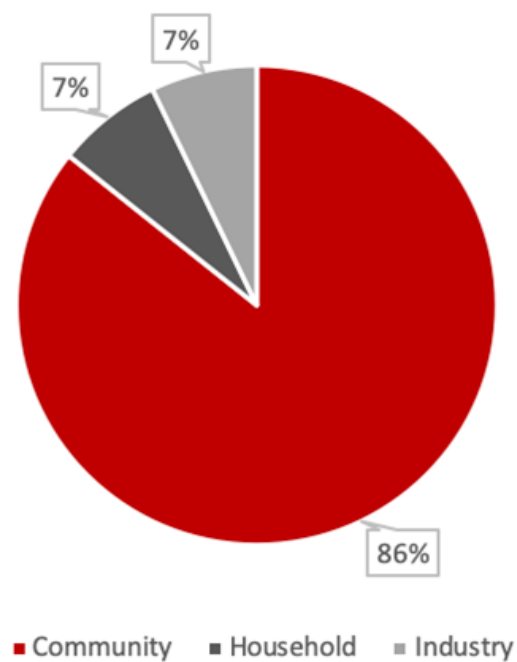
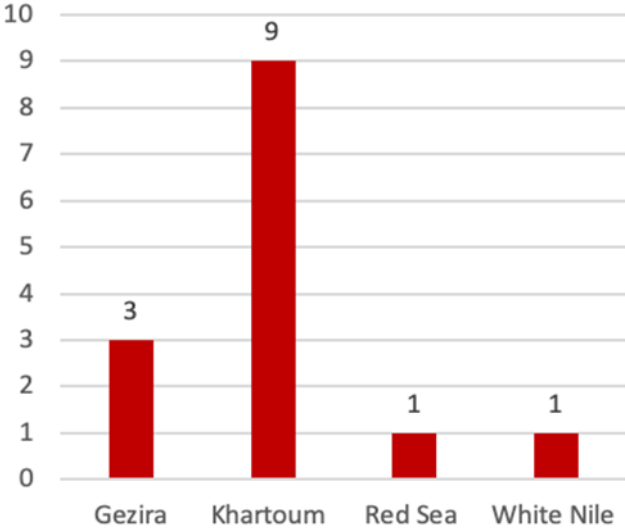


Fig. 8 Most referenced Sudanese states



Uganda: 15 studies, four of which were dissertations.

Fig. 9 Uganda paper focus

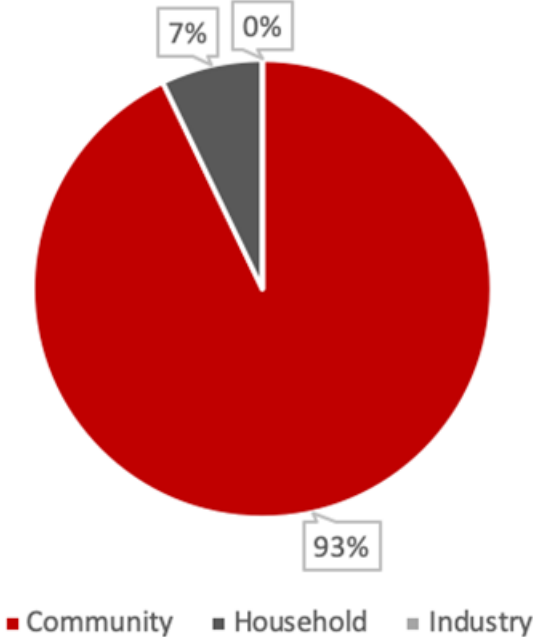
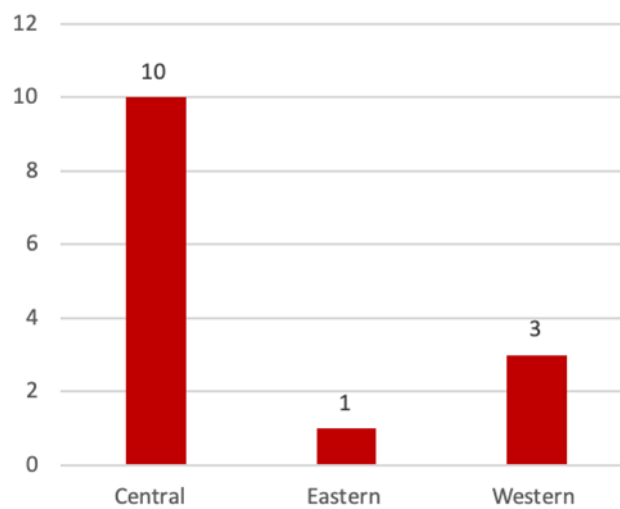


Fig. 10 Most referenced Ugandan regions



Unsurprisingly, most studies were completed in the region that houses the country’s capital. Ethiopia is the only exception; most studies were not conducted in the Oromia region, where Addis Ababa is, but rather in the Amhara region.

Only two papers involved industry-level disposal practices, one in Ethiopia (Wongiel et al., 2015) and the other in Sudan (Doro et al., 2012). Across the four countries, community-level studies were the most common, followed by household studies and industry-level studies.

Survey Results

There were 21 respondents; 14 were from Ethiopia, 6 from Uganda, 1 from Sudan, and none from Kenya. The majority (33%) of respondents work in pharmaceutical manufacturing. 14% work in private wholesale/retail pharmacies, 10% in public hospitals, 10% in third- or fourth-party logistics companies, 10% in NGOs, and 10% in pharmaceutical supply agencies. We also obtained respondents from National Health Insurance Funds and Public Health Institutes.

4. Case Studies

4.1 Ethiopia

National Legislation

Guidelines from the Food, Medicine and Health Care Administration and Control Authority of Ethiopia (2011) stipulate procedures for protecting public health and the environment from hazardous pharmaceutical waste. The guidelines state that “medicine that is unfit for use shall not be stored for more than six months” and that any disposal practice requires the attendance of an inspector. Certificates are issued following the disposal activity. Disposal sites must meet Environment Impact Assessment standards.

The guidelines also require the careful sorting of disposed medicines into dosage forms (solids, liquids, aerosol canisters), with special attention given to hazardous waste and controlled substances (FMHACA, 2011). Workers must wear adequate personal protective equipment (PPE) and disposed medicines must be recorded and registered. Once sorted, the waste must be kept in a room that is clearly marked as containing medicines waste. and labelled with ‘Expired medicines – Not for Sale’. The guidelines stipulate that health-care facilities, medicine manufacturers and suppliers, and disposal firms must follow these procedures.

Recall

The Ethiopian Food, Medicines, and Health Care Administration and Control Authority established a Traceability Office in 2011 to facilitate the tracking and tracing of pharmaceutical products throughout the Supply Chain. This was an effort to synchronise the approach for addressing counterfeit medicine and improve the efficiency of the Health Supply Chain. The system is meant to address effective recall of drugs and alert authorities to the expiry date of pharmaceuticals (Ethiopian Food and Drug Authority, n.d.).

Ethiopia has pharmacovigilance guidelines in place (FMHACA, 2014). According to these guidelines, authorities issue a recall, but the manufacturer is responsible for recalling and disposing of the recalled product; however, it is unclear whether there are specific guidelines for how this process is undertaken. There were 13 product recalls from 2019-2020, yet a study of pharmacovigilance systems in East African countries found the regulatory guidelines to be insufficient (Barry et al., 2020).

Incinerators

Incineration is one of the most popular methods for waste disposal, in part because it can significantly reduce the volume of waste. However, an Infection Control and Waste Management

Plan from the Ethiopian Ministry of Health (2019) recognises that toxic emissions from incinerators can be harmful for humans and the environment. These guidelines state that it is important to treat the flue gas of incinerators and include ambient air monitoring, in addition to developing strategies to mitigate the impact of incinerators, such as providing workers with PPE, improving incinerator infrastructure, maintaining incinerators, purchasing environmentally-friendly incinerators, and monitoring emissions (Ethiopian MOH, 2019: 46). In general, hazardous pharmaceutical or cytotoxic waste should either be incinerated at 1200°C minimum or encapsulated and buried at a safe distance from water sources (Ethiopian MOH, 2019: 81).

In Practice

Yazie et al. (2019) conducted a systematic literature review of health-care waste management in Ethiopia, finding that hazardous waste is ‘unacceptably high’ at health facilities and health-care waste is poorly managed. Their literature review yielded 17 studies and concluded that across health facilities in Ethiopia, there is a lack of proper waste segregation and lack of awareness on proper health-care waste management from facility staff. Furthermore, many facilities use low combustion incinerators and open burning or other open disposal processes to dispose of health-care waste.

The systematic review conducted for this study yielded 32 studies that fit the inclusion criteria. The majority of studies (22) took place at the community level, followed by the household level (9) and the industry level (1). Most studies took place in the Amhara region (13), followed by the Oromia region (9), the Harari and Southern regions (3 each), the Tigray region (2), and the Somali region (1). Ethiopia was the only country of the four case studies for which the majority of studies took place outside of the region that houses the capital, with the majority occurring in Amhara rather than Oromia.

Ethiopia was one of two countries with a corresponding industry-level study. Wongiel et al. (2018) examined the disposal practices of 55 medicines importers and factories in and around Addis Ababa. Of the sample size, 55% were not aware of the guidelines provided by EFMHCA (Wongiel et al., 2018). Of those surveyed, 46.3% landfill their waste and 62.7% use open-air burning, which is dangerous for the environment and public health, and 70% do not sort the waste (Wongiel et al., 2018). Wongiel et al. (2018: 437) concluded that the training of ‘personnel in industries, importers and regulatory authorities about safe disposal of pharmaceutical waste is urgent’.

22 papers focused on health-care waste disposal at the community level, reviewing the waste practices of HCFs, hospitals and pharmacies. The findings include:

Findings	Paper authors
Some facilities did not have guideline documents on HCW management.	Abebe et al., 2017; Azage and Kumie, 2010; Muluken et al., 2013; Yenesew, 2012.
Knowledge about HCWM guidelines, if they existed at the facility, was low.	Alemayhu et al., 2018; Debalkie and Kumie, 2017; Deress et al., 2018; Doylo et al.,

Findings	Paper authors
	2019; Gudeta and Assefa, 2020; Haylamichael et al., 2010; Hayleeyesus and Cherinate, 2016.
Inadequate segregation of waste in hospitals and health centres.	Abebe, 2017; Azage and Kumie, 2010; Debalkie and Kumie, 2017; Debere et al., 2013; Doylo et al., 2019; Haylamichael et al., 2010; Hayleeyesus and Cherinate, 2016; Meleko et al., 2018; Muluken et al., 2013; Sahiledengle, 2019; Sahiledengle et al., 2018; Tadesse and Kumie, 2014; Tesfahun et al., 2014; Yenesew, 2012.
Colour-coding was inadequate at many HCFs and hospitals.	Abebe et al., 2017; Debalkie and Kumie, 2017; Deress et al., 2018; Haylamichael et al., 2010; Muluken et al., 2013; Tadesse and Kumie, 2014.
Open burning of waste practised by HCFs.	Azage and Kumie, 2010; Debalkie and Kumie, 2017; Gudeta and Assefa, 2020; Muluken et al., 2013; Sahiledengle, 2019.
Inadequate use of or low-quality incinerators.	Abebe, 2017; Debalkie and Kumie, 2017; Debere et al., 2013; Derso et al., 2018; Haylamichael et al., 2010; Hayleeyesus and Cherinate, 2016; Sahiledengle et al., 2018; Tadesse and Kumie, 2014; Meleko et al., 2018.
A significant amount of unused or expired medicines at facilities, due in part to receiving medicines near expiration and inappropriate storage.	Ebrahim et al., 2019 and Gudeta and Assefa, 2020.

Recommendations from the studies:

Findings	Paper authors
A 'holistic approach' to improving the system, including collection, storage, treatment, transport and disposal.	Derso et al., 2018.
Increased training and activities to raise awareness of proper practices.	Abebe et al., 2017; Doylo et al., 2019; Hayleeyesus and Cherinate, 2016; Muluken et al., 2013; Sahiledengle, 2019; Tadesse and Kumie, 2014.
Stricter monitoring of health professionals.	Ebrahim et al., 2019; Muluken et al., 2013.
Improved legislation and enforcement mechanisms.	Haylamichael et al., 2010.
Better-constructed incinerators.	Tadesse and Kumie, 2014.

Eight studies were conducted at the household level, which involved surveying individuals in their homes or at health-care facilities. Findings include:

Findings	Paper authors
Over half of households surveyed had unused medicines at home.	Ayele and Mamu, 2018; Kahsay et al., 2020; Kassahun and Tesfaye, 2020.
Disposing of unused medicines by throwing them in the trash was the most common method of household disposal.	Atinafu et al., 2014; Ayele and Mamu, 2018; Kahsay et al., 2020.
Disposing of medicines by flushing them down the toilet was another common method.	Gelayee and Binega, 2017; Kassahun and Tesafye, 2020; Yimenu et al., 2020.
Burning unused medicines was the second or third most common disposal method.	Atinafu et al., 2014; Gelayee and Binega, 2017.

Recommendations include:

Findings	Paper authors
Public education on proper medicine disposal is necessary.	Atinafu et al., 2014; Yimenu et al., 2020.
Health-care workers should give advice on proper disposal and there should be stricter guidelines to ensure health-care workers educate patients.	Atinafu et al., 2014; Ayele and Mamu, 2018; Kassahun and Tesfaye, 2020.

Survey Results

The following results are from the 14 survey respondents who work in Ethiopia.

- All respondents except one agreed that Ethiopia has access to state-owned incinerators.
- 57% of respondents believed that the majority of pharmaceutical waste comes from expired donations. 21% believed waste resulted from pharmacies and 7% each believed it resulted from recalls, Supply Chain malpractice, or change in demand. Only Derso et al. (2018) dealt with medicines donations in the systematic literature review, thus, pharmaceutical donations and their disposal would be a worthwhile area for future research.
- Respondents disagreed on the most common method of pharmaceutical waste disposal at the industry level. The majority (36%) believed it to be burning, followed by 29% who believed it to be medium temperature incineration (>800°C) and 21% who believed it to be high temperature incineration (>1100°C). Only 7% of respondents believed landfilling was the most common method and 7% believed immobilisation/inertisation was most common. The majority concurred with the findings of the systematic literature review, which found that most hospitals use a facility to burn waste, although it may be a low-quality incinerator.
- The majority (71%) of respondents said that there were no efforts to train health-care workers in pharmaceutical waste disposal best practices. Only 7% believed there were efforts, and 21% were unsure. The respondent who believed there were training efforts said these efforts involved understanding ‘disposal guidelines’. This finding aligns with those of the systematic literature review in emphasizing the necessity to train health-care workers in proper waste management.
- 93% of respondents said there were no community engagement efforts that target households for safe training in pharmaceutical waste disposal, and one respondent was unsure. This also aligns with systematic literature review findings, highlighting that households are not supported when it comes to safe pharmaceutical waste disposal.
- 50% of respondents said Ethiopia has best practices in place for accepting pharmaceutical donations, while 50% said Ethiopia does not have best practices in place. Those who said there are best practices included rules about remaining shelf life before expiry. This finding echoes that of Wongiel et al. (2018), who found that about half of the industries in their

sample size were unaware of guidelines for pharmaceutical waste disposal, which suggests that guidelines for donation need to be implemented more strongly.

- 85% of respondents said safe pharmaceutical waste disposal is not enforced at the household level. 8% said it is enforced and 8% said they were unsure.

Conclusions

Collating the findings from the systematic literature review and survey, it appears that although Ethiopia's guidelines for pharmaceutical waste disposal are relatively comprehensive, they require stronger enforcement measures at each level of the Supply Chain. Industries are unaware of national guidelines and enforcement and regulation mechanisms could be stronger across all levels of the Supply Chain.

Regarding disposal methods, burning health-care waste is quite common at the facility level, although this is problematic given the low quality of incinerators and prevalence of open burning. While incineration is helpful for reducing waste, it is essential that incinerators operate at the standard required; otherwise, they emit toxic gases that are dangerous for public health. There was little mention of immobilisation in the literature and in the survey, which suggests that few industries or health-care facilities are immobilising their health-care waste. Immobilisation could be a good method for the Ethiopian industry to examine as a potential option because the WHO (2014) recommends it as one that is efficient, safe and relatively inexpensive.

Finally, it appears that there should be stronger training efforts for health-care workers, including those who work in hospitals and pharmacies, who can then educate patients about medicine disposal. Such an initiative would improve health-care waste management at the community level in areas such as waste segregation, and it would improve the disposal practices of households. It could be worthwhile to invest in pharmaceutical take-back programmes, meaning that pharmacies manage the drugs' disposal, rather than individuals who may throw these drugs in the garbage or flush them.

4.2 Kenya

National Legislation

The Kenyan national medicine regulatory authority, Pharmacy and Poisons Board (PPB), provides guidelines for the safe management of pharmaceutical waste, which should be adopted by

pharmaceutical manufacturers, distributors, and any staff attached to pharmaceutical waste disposal facilities (PPB, 2018). PPB couches the guidelines in environmental protection, but also references the importance of pharmaceutical waste disposal for public health, citing the administrative, economic, health and environmental impacts of pharmaceutical waste that is not disposed of properly. Kenya Medical Supplies Authority (KEMSA) receives pharmaceuticals as donations and through other procurement activities. The preferred strategy is to minimise pharmaceutical waste rather than dispose of it, and practices to minimise waste include checking expiry dates, using suppliers who accept short-dated stocks' return and FEFO (PPB, 2018).

The guidelines highlight the importance of segregating pharmaceutical waste, noting that it is best to keep the waste in its packaging to make segregating easier (PPB, 2018). They also recommend using brown rigid containers labelled in English or Kiswahili to identify the pharmaceutical waste, its weight, who generated the waste, and a warning statement. Waste transportation vehicles must be roadworthy and meet a set of criteria, including that they have a system to safely secure cargo and equipment in case of emergencies. Drivers must also be trained and carry consignment notes. Waste is quarantined separately from usable pharmaceuticals, and the quarantine storage should be cleaned regularly and clearly marked with hazard signs.

At the treatment facility, waste should be sorted and labelled according to dosage form or by active ingredient, with special attention given to controlled substances and cytotoxic medicines. The PPB guidelines give options for small quantities of waste, including: return to donor/manufacturer, encapsulate and landfill, inertise and store or bury in a landfill, chemically decompose, or discharge into a sewer (without dilution if the substance is an intravenous solution, with dilution if it contains vitamins and amino acids). The guidelines note that antibiotics and cytotoxic drugs should never be discharged into sewers or watercourses and cytotoxic drugs should never be landfilled. Pharmaceutical waste disposal should always be supervised by a PPB Inspector and it should be conducted at a National Environment Management Authority-approved pharmaceutical waste disposal facility. Supervision requires an application and a fee of KSh. 2,500 paid to PPB for a Certificate of Safe Disposal.

PPB details the incineration process and notes that a disadvantage of incineration is that it releases potentially harmful by-products into the atmosphere. However, waste requires no pre-treatment if it does not contain halogenated materials such as packaging, sealed ampoules or vials, or pharmaceuticals that are thermally stable in conditions below 1200°C (PPB, 2018). According to information from a KEMSA Quality Assurance Officer, KEMSA does not have its own incinerators, but hires a privately owned and government-approved incinerator through open national

tenders. Although WHO guidelines recommend incinerators operate at >1200°C, KEMSA guidelines include the possibility for pharmaceutical waste disposal in incinerators that operate at >800 °C. A review of Kenyan health-care waste management guidelines found that the guidelines did not promote the use of centralised incinerators enough and permit small-scale incineration, which should not be encouraged because of the negative environmental impact (Okweso, n.d.). The guidelines also detail encapsulation, noting that an advantage is that it reduces the risk that scavengers could encounter the pharmaceutical waste. Finally, the guidelines describe inertisation, highlighting the advantage that the process is relatively inexpensive and uses unsophisticated equipment (PPB, 2018).

Recall

The PPB provides ‘Guidelines for Product Recall or Withdrawal’ (PPB, 2006). These guidelines assert that the PPB will closely monitor the effectiveness of a company’s recall process to provide advice, and if the company’s actions are inadequate PPB can remove the product from the market. Although these guidelines detail the recall procedure, including classification of the product and a communication strategy, the guidelines say little about disposal. The only mention of disposal is: ‘A recall will be terminated when the PPB and the recalling company are in agreement that the noncompliant product has been removed and proper disposal or correction has been made’ (PPB, 2006: 7). However, a specific disposal process is not detailed in these guidelines.

In addition, PPB’s (2019) ‘Guidelines for Good Distribution Practices for Medical Products and Health Technologies’ reference recall procedures. Specifically, these guidelines add that warehousing areas must have a specific area for quarantine of faulty and recalled goods. The guidelines also state that the recall procedure should include a written account of the action that is set to take place.

In Practice

The systematic review for this paper produced 18 papers that fit the inclusion criteria, including seven dissertations which, though unpublished, still provide valuable insight. No studies dealt with industry-level waste disposal, 14 studied the community level, and four the household level.

14 studies were published at the community level, and key findings include:

Findings	Paper authors
The majority of respondents had good knowledge of waste management.	Maina, 2018; Maina et al., 2016; *Mugumura, 2015.
Although one study found that full adherence to guidelines was low.	Njue et al., 2015.
Some papers found that health-care workers had little information on or knowledge of policies and guidelines for HCWM.	Gitonga, 2017; *Mwania, 2019.
Less than half of respondents had been trained properly in health and safety, including disposal.	Gitonga, 2017; Njagi et al., 2012.
Inadequate waste segregation at HCFs.	*Kodiaga, 2007; Matan et al., 2018; *Mwania, 2019; Robert and Ananias, 2014.
Other studies found good knowledge and practice of waste segregation, specifically.	Maina, 2018; Maina et al., 2016; Njue et al., 2015.
Colour-coded bins existed, but they were used improperly.	Gitonga, 2017; Maina, 2018.
Disposal of expired drugs through the garbage or open dumping.	Abuga et al., 2019; Gitonga, 2017; *Mokua, 2013.
Low-quality or old incinerators constructed in dangerous locations.	*Kodiaga, 2007; Kungu et al., 2016; Matan et al., 2018; Njue et al., 2015.

Recommendations from the papers:

Findings	Paper authors
Enhanced enforcement of regulations	*Mugumura, 2015.

Enhanced practitioner training	Maina 2018; *Mugumura, 2015; *Mwania, 2019; *Wepukhulu, 2011.
Improved policies at hospitals	Gitonga, 2017.
Standardised incineration requirements	Njue et al., 2015.

Four studies were published at the household-level. Key findings include:

Findings	Paper authors
Low knowledge of disposal methods for hazardous waste but high awareness of health risks resulting from waste.	*Selin, 2013; Angi'enda; Bukachi, 2016; *Sheikh, 2018.
Little advice received from health-care professionals on disposal methods.	Angi'enda and Bukachi, 2016.
Throwing waste in garbage is common, as is open air burning and flushing waste.	Angi'enda and Bukachi, 2016; Orina et al. 2017; *Selin, 2013; *Sheikh, 2018.

Conclusions

Kenya is seen as the standard for sound pharmaceutical waste disposal (Information from KII), and it does have comprehensive guidelines and Standard Operating Procedures for pharmaceutical waste management. Yet, little research assesses disposal practices at the industry level, which constitutes a research gap that would be worthwhile to study in order to illuminate the extent of compliance at the industry level.

Studies seemed to diverge on the level of knowledge that health-care workers had regarding waste disposal policies and the practice of waste segregation, specifically. A number of studies highlighted the good knowledge that a majority of health-care workers seem to have. Yet, certain areas were still lacking, including the segregation of waste, which was due in part to inadequate equipment. This could be a funding issue and it would be important that facilities invest in the proper tools, such as

colour-coded bin bags, for waste segregation to occur. The divergence in findings could indicate that some areas of Kenya have strong waste disposal policies and practices, while others are lacking. It is important to target the areas where knowledge was found to be lacking in order to bring the entire country's disposal system to a high standard.

Many hospitals have their own private incinerator, but many incinerators are in sub-optimal condition or in an unsafe location. The PPB disposal guidelines could prioritise centralised, high-temperature incinerators, rather than small-scale incinerators that are dangerous for the environment and public safety.

In addition, there is little knowledge of safe pharmaceutical disposal practices at the household level. Pharmacists occupy an important position in communicating safe disposal practices to households and should be trained in educating patients on safe disposal in addition to practicing safe disposal on behalf of the pharmacies.

In summary, while the PPB guidelines are relatively comprehensive, compliance to the guidelines, especially at the community and household levels, is lacking. It is essential to institute training for community health workers, including pharmacists, nurses and waste handlers. Further, the National Environment Management Authority (2015) suggested that in addition to education, it is important to bulk up waste disposal infrastructure to support the implementation of policies. This includes supporting a higher standard for hospital incinerators or facilitating the transport of material to a higher-temperature, more centrally-operated incinerator. At the household level, pharmaceutical take-back programmes should be instituted with a clear disposal path for pharmacists.

4.3 Sudan

National Legislation

The national guidelines for health-care waste management in Sudan are based on WHO's 'Guidelines for Safe Disposal of Unwanted Pharmaceuticals' and match the WHO guidelines almost exactly. There are also regulations for pharmaceutical recalls and Sudan has a policy to reduce waste from expired medicines.

The 'Guidelines for Safe Disposal of Unwanted Pharmaceuticals' (NMPB, n.d.: 3) state that 'In general, unwanted or expired pharmaceuticals do not represent a serious threat to public health or

to the environment’, though the guidelines caution against incorrect disposal. The first recommended disposal method is to return pharmaceuticals to the donor or manufacturer; then, the guidelines give an overview of methods including landfilling, encapsulation/inertisation, sewer, burning in open container (which is not recommended), medium- and high-temperature incineration, and chemical decomposition (which is not recommended unless chemical experts are available). The guidelines also recommend sorting pharmaceuticals into categories by disposal method. While these guidelines provide an overview, they are not as comprehensive as those of other case-study countries, such as Ethiopia or Kenya.

Recalls

The National Medicines and Poisons Board (NMPB) provides guidelines for product recalls, removals and corrections, which detail that the recall of a product may be necessary for public and animal health. Recalls are usually highly publicised, and the guidelines provide example information to include in press statements for recalled goods (NMPB, n.d.). To recall a product, firms submit a form to NMPB with information such as the quantity to be recalled, how the product was distributed, how the product will be quarantined, institutions where the product has been distributed, and an estimation of the remaining quantity with customers or in warehouses and pharmacies (NMPB Recall of Medical Products, n.d.). Firms are responsible for the effective recall of their products, and they are liable for effectiveness checks to evaluate the quality of their recall. Recalled products should be labelled and quarantined until the relevant authorities determine how they should be disposed, depending on the reason for their recall. The recalling firm is responsible for compensating patients and customers for any harm incurred by the product (NMPB, n.d.). National Medical Supplies Fund (NMSF), the public medical supplies agency of Sudan, conducts a comprehensive assessment of the product recall. All recalled products are disposed according to the National Medicines and Poisons Board’s guidelines on ‘Disposal of Unwanted Pharmaceuticals’ (NMPB Recall of Medical Products, n.d.).

Policy to reduce waste from expired medicines

The 2014 National Medicines Policy calls for the development of guidelines to address the disposal of pharmaceuticals. NMSF has policies in place to balance stocking pharmaceuticals and reducing waste from expiration, including a forecasting system and quantification software to purchase adequate quantities of medicines. Typically, NMSF only accepts medicines to their Khartoum warehouses if the product has 2 years, or 75%, of its shelf life remaining. Rarely, NMSF will accept

items with shorter shelf lives if the supplier has provided a written statement that they will immediately take back any expired products and replace them with fresh stock.

NMSF takes a number of measures to ensure the reduction of expired medicines. The General Directorate of Distribution and General Directorate of Procurement and Contracting have regular meetings to review stock. The stock is also physically checked twice per year to ensure the actual inventory matches the computer inventory. The Department of Inventory Control monitors product expiration and submits quarterly reports on medicines due to expire. A Standing Committee meets weekly to 'take action' against expiry items. These actions include reducing the price of medicines with less than 9 months of their shelf life remaining, selling medicines with a 6-month remaining shelf life at a 50% discount, and free-of-charge distribution of products with a remaining shelf life of 3 months or less. Every January a committee meets to study the reasons for expiration of medicines and other health products for the past year, even if the proportion of expired products was between the acceptable range of 3-5%.

Incinerators

A report by the Ministry of Environment and Physical Development (2007: 66) claimed that 'there is no hazardous waste management and classification in the country', raising questions about whether hazardous and medical waste is being disposed of by open burning or if it is being dumped into landfills. The Shell Formulation Plant in Marinjan, Wad Medani, Gezira State, 'used to have an incinerator to get rid of the obsolete pesticides' (Ministry of Environment and Physical Development, 2007: 45). Incinerators are responsible for 0.02% of Persistent Organic Pollutants (POPs), whereas uncontrolled combustion processes account for 94.11% of POPs emissions. Indeed, a survey in Sudan showed that the most common method of pharmaceutical disposal for individuals is burning (Alnahas et al., 2020: 4). The Ministry of Environment and Physical Development (2007: 141) recommended prioritising incineration over chemically disinfecting hospital waste, noting that a number of hospitals in Sudan had signed two-year contracts for chemical treatment technology. This report also emphasised the importance of segregating pharmaceutical waste.

In Practice

A systematic review of the literature pertaining to Sudanese health-care waste disposal resulted in 14 papers, four of which were unpublished dissertations.

Only one paper involves pharmaceutical disposal at the industry level. Doro et al. (2012) randomly selected six NGOs working in Sudan to study donation practices. NMPB has published national guidelines for donations. However, the organisations selected do not have official donations guidelines. The study finds that 96% of donated drugs were labelled in a locally understood language, a stipulation in the WHO Best Practices for Medicines Donations. The guidelines also state that drugs should have at least one year of their shelf life remaining when they are received in the country. However, the study found that more than 50% of donated drugs would expire in less than a year.

12 studies dealt with community-level disposal practices, including studies of health workers in hospitals and health care facilities. Key findings across the studies include:

Findings	Paper authors
Lack of suitable HCWM policies in facilities.	Ahmed et al., 2014; Elya and Babiker, 2015; Hassan et al. 2018; *Idris, 2016; Saad, 2013.
Lack of awareness of policies by health-care professionals, including HCF staff and pharmacists.	Elnour et al., 2015; Eltayeb et al., 2017; Fedlel-Moula et al., 2009; Idris and Elmula, 2018.
While pathological waste was usually segregated, overall segregation is low.	Ahmed et al., 2014; Eltayeb et al., 2017; Elya and Babiker, 2015; Fedlel-Moula et al., 2009; Hassan et al., 2018; Idris and Elmula, 2018; *Nour, 2012; Saad, 2013.
Colour-coding was infrequent due to improper supplies, such as coloured bags.	*Ahmed, 2015; Ahmed et al., 2014; Hassan et al., 2018.
Low usage of incinerators, and those that existed seemed to be of low capacity.	*Ahmed, 2015; Ahmed et al., 2014; Elya and Babiker, 2015; Idris and Elmula, 2018; Saad 2013.
Low awareness of a pharmaceutical take-back programme and 87.2% of pharmacists surveyed said expiry is the biggest source of pharmaceutical waste.	Idris and Elmula, 2018.

Findings	Paper authors
Medium to high levels of knowledge about waste management, but many employees did not have official training.	*Ahmed, 2015; Ahmed et al., 2014; *Mohammed, 2012; *Nour, 2012.

Recommendations from papers:

Findings	Paper authors
Greater collaboration between hospitals and MOH to develop comprehensive disposal policies.	Ahmed et al., 2014; Elya and Babiker, 2015; Saad, 2013.
Allocate financial resources for facilities and training.	Ahmed et al., 2014; Hassan et al., 2018.
Educational sessions about pharmaceutical disposal for patients.	Hassan et al., 2018.

The literature review resulted in one study conducted at the household level (Yousif, 2002). This study found that out of 469 households studied, there is a high rate of storing drugs, though only 15% of those stored were expired. This study is not sufficient for drawing conclusions about Sudanese household disposal practices because it is dated and because the researchers did not survey households on disposal practices specifically. However, it is useful for noting that there is a high rate of storing drugs in households.

Survey Results

The following are results from the respondent who worked in Sudan for the National Health Insurance Fund. The respondent stated that:

- Sudan's incinerators are state-owned.
- Central Medical Stores are the biggest contributor to pharmaceutical waste.
- Medium temperature incineration (>800°C) is the most common method of disposal at the industry level.

- There are no efforts to train health-care workers in pharmaceutical waste disposal practices.
- There are no community engagement efforts to train households in safe disposal practices.
- Sudan developed guidelines for accepting pharmaceutical donations.
- Safe pharmaceutical waste disposal is not enforced at the household level.

Conclusions

First, it is essential to coordinate the legislation governing pharmaceutical waste disposal in Sudan. Various policies pertaining to pharmaceutical disposal exist, yet the survey and literature review both indicate that they are not always adhered to by NGOs (Doro et al., 2012). Further, the guidelines could be more comprehensive and specific to the context in Sudan.

Second, low-quality burning is a common disposal method, which is problematic for public and environmental health. Third, education efforts for both staff and patients on proper pharmaceutical disposal techniques would help reinforce these procedures.

In terms of research, it would be useful to increase the number of studies at the industry and household levels, as only one study of each level was available. Further, an increased number of studies in states other than Khartoum would also be useful, considering nine out of 15 studies took place in Khartoum.

4.4 Uganda

National Legislation

Uganda's National Drug Authority (NDA) is responsible for ensuring public and environmental health related to pharmaceutical waste disposal. Guidelines provided by NDA (n.d.) prioritise sorting and segregating the materials by form (e.g. tablets, syrups, etc.). NDA commonly uses ultra-high temperature incineration, inertisation then landfilling, and dilution then flushing into a protected soak pit or lagoon. NDA recommends seeking specialised advice for hazardous industrial chemicals or radioactive waste.

Disposing of pharmaceutical waste requires a letter to the NDA with a list detailing the items that must be disposed (NDA, n.d.). The NDA requires a fee for every kilogram of pharmaceutical waste, which is determined by the method of destruction used and the type of product that must be destroyed. After payment, the items are 'kept in the NDA "expired drugs store"', although it is unclear if these items are strictly quarantined from other pharmaceuticals. For cargo that is greater than 100 kilograms, the client must contact an NDA accredited service provider for destruction. An Inspector for Drugs will then supervise the safe disposal of the wastage. In these cases, NDA charges a fee per hour for supervision and safe disposal of the waste.

Recalls

NDA has published 'Guidelines for the Recall or Withdrawal of a Medical Product' (2017a). Under these guidelines, the Directorate of Inspectorate and Enforcement is responsible for supervision of the recall and/or withdrawal; however, the importer is responsible for carrying out the recall process and ensuring the process was effective. The importer must report when a recall is necessary to the NDA, including information such as the product name, total importer quantity, and details of distribution. The NDA will then make the final decision on whether a recall is necessary considering the health risks for patients, and the NDA will determine the recall strategy. The importer bears all costs associated with the recall (NDA, 2017a). Guidelines for Good Manufacturing Practice state that products that are rejected, recovered and returned should either be returned to the supplier or, when possible, reprocessed or destroyed (NDA, 2017b).

In Practice

The literature review resulted in 15 studies relating to pharmaceutical waste disposal, four of which are unpublished dissertations. None of the papers studied industry-level pharmaceutical waste disposal.

13 studies related to community-level disposal practices in hospitals and health-care facilities. Key findings across the studies include:

Findings	Paper authors
Ineffective or inefficient waste management policies.	Katusiime, 2018; Muhwezi et al., 2014.
Low awareness of disposal procedures.	Babirye et al., 2020; Kwikiriza et al., 2019.
Low segregation of waste, though high knowledge that waste should be segregated.	Akulume and Kiwanuka, 2016; Aliyu et al., 2017; Babirye et al., 2020; *Kasoma 2013; Katusiime, 2018; Kwikiriza et al., 2019; Mugambe et al., 2012; Muhwezi et al., 2014; *Obote 2014; Wafula et al., 2019.
Low use of colour-coded bins, though high knowledge that this system exists and should be used.	Akulume and Kiwanuka, 2016; Aliyu et al., 2017; Katusiime, 2018; Kwikiriza et al., 2019; Wafula et al., 2019.
Lack of or low quality of incinerators.	Aliyu et al., 2017; Muhwezi et al., 2014.
Open burning at some HCFs.	Aliyu et al., 2017; *Twesige, 2017; Wafula et al., 2019.
One study showed that 71% of pharmacists gave information to patients on disposal of medicines, but only 15% advised returning medicines to an HCF.	Dalahmeh et al., 2020.
Donated medicines were prone to expiry.	Nakyanzi et al., 2010.

Recommendations from papers:

Findings	Paper authors
Harmonise coordination among medicine wholesalers and clients.	Nakyanzi et al., 2010.
Stronger national disposal policy enforcement mechanisms.	Nakyanzi et al., 2010.

Two studies dealt with household-level disposal practices. Many households (between 35 and 68%) had unused drugs (Ocan et al., 2014; *Tusubira, 2017) and the majority of patients were not given information about medicine disposal (*Tusubira, 2017). Disposing of medicines in the trash or pit latrine were the most common practices (Ocan et al., 2014; Tusubira, 2017). Take-back programmes are not widely utilised (Ocan et al., 2014).

Survey Results

The following results are based on the six respondents who work in Uganda.

- All respondents agreed that Uganda has access to incinerators. 66% of respondents believed they are state-owned incinerators, while 33% believed they are owned by a third-party.
- The majority (67%) of respondents believed expired donations were the biggest contributor to pharmaceutical waste, while 17% believed pharmacies are the biggest contributor and 17% believed expired pharmaceuticals from public health facilities were the biggest contributor.
- 67% of respondents agreed that high-temperature incineration (>1100°C) is the most common method of pharmaceutical waste disposal, while 17% believed medium-temperature incineration (>800°C) was most common and 17% believed immobilisation/inertisation was the most common method.
- Respondents were divided over whether there are efforts to train health-care workers in pharmaceutical waste disposal best practices, with 33% saying yes, no, and unsure. Those who claimed there were training efforts said the efforts involve guidelines about disposal, waste segregation, and a documentation process.

- 83% of respondents said there are no community engagement efforts to train households in safe pharmaceutical disposal practices, and the remaining respondent was unsure.
- 67% of respondents stated that Uganda has best practices for pharmaceutical donations, including that all donations must be registered and abide by country standards and that there must be 3 months of remaining shelf life. 17% said there are no best practices and 17% were unsure.
- 100% of respondents agreed that safe pharmaceutical waste disposal is not enforced at the household level.

Conclusions

Three key takeaways emerge from comparing the literature review and survey responses. First, donations are believed to be a source of pharmaceutical waste, although there are guidelines in place for pharmaceutical donations. It would be useful for further research to explore how much pharmaceutical donations contribute to pharmaceutical waste in Uganda.

Second, HCF staff seemed to be knowledgeable about waste segregation, colour-coding and other HCW policies. However, adherence to policies was low, perhaps indicating that further training should be instituted. This could also indicate that facilities are not adequately equipped to ensure adherence to waste disposal policies. It is important to determine if HCFs have the resources they need to follow the disposal guidelines. In addition, it would be useful to increase education efforts about pharmaceutical waste disposal at the household level.

Third, although incinerators exist, they seem to be in poor condition, and it is concerning that open-pit burning is relatively common at HCFs. Incinerators should be brought up to standard and the process could be centralised to ensure standards are met.

5. Conclusion

Overall Survey Results

The following are relevant national-level findings from the survey:

- The majority of respondents in both Ethiopia and Uganda believe expired donations are the biggest source of pharmaceutical waste.
- The greatest percentage of respondents in Ethiopia believe burning is the most common disposal method, while in Uganda most respondents believed it was high-temperature incineration.
- Respondents did not generally believe there are efforts to train health-care workers in pharmaceutical disposal best practices, although the highest percentage (33%) of respondents in Uganda believed there are training efforts.
- All respondents except two, who were ‘unsure’, agree that there are no community engagement efforts that target households to teach safe pharmaceutical disposal practices.
- Most respondents believe there are guidelines in their country regarding pharmaceutical donations (57%).
- 90% of respondents said that safe pharmaceutical disposal is not enforced at the household level.

This study has explored the pharmaceutical waste disposal policies and practices in four African countries: Ethiopia, Kenya, Sudan and Uganda. The policies in place for pharmaceutical waste disposal in the case study countries are generally comprehensive and comply with WHO guidelines. This report has used a systematic literature review to show that although the policies exist, many are not enforced and do not require compliance at all levels of the Health Supply Chain.

We have seen that there is little compliance at the community level in locations such as health facilities, hospitals, and pharmacies. Yet, it is more difficult to assess whether pharmaceutical disposal is managed properly at the industry and household levels due to the lack of research on these areas. Only two studies out of the 79 gathered through this systematic literature review assessed disposal practices at the industry level, making disposal practices at the industry level an important area for future research.

Third, low-quality burning appears to be a common means of disposal at many HCFs. While high-temperature incineration is a recommended method for disposal by the WHO (2014), low-quality burning using incinerators that do not meet the required standards or reach adequate temperatures can be very dangerous for the environment and for public health. It will be important for

community-level disposal practices to develop long-term strategies other than incineration, and to consistently practice pharmaceutical waste minimisation.

In terms of the research produced, all four countries could benefit from a greater research focus on industry-level pharmaceutical disposal practices. At the country level, Ethiopia has a reasonable number of studies on health-care waste disposal, but Sudan and Uganda would benefit from more studies at the household level. Guidance on pharmaceutical waste disposal has developed alongside our knowledge of toxins and the environment over time, and it is important to engage with HCF staff and the community through education efforts to reinforce the fact that medicines can and should be returned to an HCF for proper disposal.

In summary, there are a number of areas regarding pharmaceutical waste disposal that require further research to understand how the disposal processes are functioning on-the-ground at the country level. Although a country may have regulations in place, such as the four studied in this report, these policies are not necessarily implemented. It is useful to assess how these studies are enforced at the industry, community and household levels in order to critically assess and ultimately improve the pharmaceutical waste disposal system.

Appendix A

KII Questions

1. Does the country use incinerators to dispose of health-care waste and pharmaceutical waste specifically? If not, what methods do they use?
2. What is the biggest contributor to pharmaceutical waste in the country?
3. Is one method of pharmaceutical waste disposal used more frequently than others within the country?
4. How closely do you feel national regulations for pharmaceutical waste disposal are adhered to at the industry, community and household levels?
5. How does the country engage with pharmaceutical donors? Specifically, does it institute agreements about disposal before products are shipped?
6. Are there education efforts for pharmacists and the general public for pharmaceutical disposal?

Appendix B

Survey Questions

1. Select your country

Country	Tick
Ethiopia	
Kenya	
Sudan	
Uganda	

2. Which health service category below identifies your organization?

	Tick
Private Hospital	

Public Hospital	
Pharmaceutical Manufacturing & Distribution Company	
Private Wholesale/Retail Pharmacy	
3PL/4PL Company	
Data Collection Company	
ICT Company	
Other (please specify)	

3. Does your country have access to incinerators that are used for pharmaceutical waste disposal?

	Tick
Yes, they are state-owned.	
Yes, they are owned by a third-party.	
No	
Unsure	

4. What is the biggest contributor to pharmaceutical waste in your country?

	Tick
Expired donations	
Recalls	
Pharmacies	
Over-prescription	
Other (please specify)	

5. What is the most common method of pharmaceutical disposal at the industry-level?

	Tick
Landfilling	
Immobilisation/inertisation	
Burning	
Medium-temperature incineration (>850°C)	
High-temperature incineration (>1200°C)	

Other (please specify)	
------------------------	--

6a. Are there efforts to train health-care workers in pharmaceutical waste disposal best practices?

	Tick
Yes	
No	
Unsure	

6b. If yes, please elaborate on what the training efforts for health-care workers involve.

.....

.....

7a. Are there community engagement efforts that target households for training in safe pharmaceutical waste disposal?

	Tick
Yes	
No	
Unsure	

7b. If yes, please elaborate on what the community engagement efforts involve.

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8. Does the country have best practices in place for accepting pharmaceutical donations?

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