Compliance with Good Distribution Practices and Antibiotic Stewardship in Health Care Institutions in Eastern Ethiopia

Study report
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Summary

Ethiopia is one of the Least Developed Countries by the United Nations which bear the major burden of antimicrobial resistance (AMR). Resistance to commonly used antibiotics is widespread and multidrug-resistant bacterial strains are highly prevalent, making bacterial infections a major cause of mortality. Overuse, misuse, and broad presence of falsified and substandard antibiotics are major drivers of AMR.

In their "Antimicrobial Resistance and Use Surveillance System (GLASS) report" of 2025 the WHO noted little to no use of antibiotics of the reserve group[1] in some low- and middle-income countries or areas, although they "are needed to treat infections caused by the most drug-resistant bacteria". Respondents from the health care institutions (HCIs) involved in our survey mentioned only one reserve antibiotic among the 17 most frequently used antibiotics. This may indicate this region to be an underserved area in this respect. To improve the chances that innovative reserve antibiotics are registered and made available in Ethiopia, the manufacturers must be confident that their quality and integrity are preserved during supply, storage and distribution, and their appropriate use (stewardship) is ensured.

The presented cross-sectional study elicits local health care professionals' (HCPs) relevant knowledge, practices, perceptions, and compliance with selected requirements set forth by the WHO guideline on "Good storage and distribution practices for medical products (GDP)" and objective 4 (stewardship) in the Ethiopian "Third One Health strategic plan on antimicrobial resistance, prevention, and containment 2021-2025". This report uses data collected from 509 HCPs working in four types of primary-, secondary- and tertiary-level HCIs in urban and rural areas of the Somali region of Ethiopia. The outcome informs opportunities for improvement and highlights strengths that may be leveraged to address them.

The findings revealed disparities in infrastructure, staff training and availability and compliance with quality assurance and stewardship standards in HCIs of different levels in urban and rural areas. Although unfortunate, these disparities create opportunities for better-educated and more experienced individuals from higher-level HCIs to mentor younger, less experienced individuals - and those from lower-level HCIs - in addressing identified weaknesses. The survey findings may be grouped as follows:

The geographical setting (urban, rural) implied unequal standards, extents of staff training, storage infrastructure and lab equipment, and availability of guidelines, with HCIs in rural areas consistently performing worse than HCIs in urban areas.

Low resources: Limited financial and adequately educated human resources imply high staff turnover, limited availability or awareness of standards and guidance and related training, weak supervision, and partially inappropriate infrastructure - all possible reasons for the relatively low abidance by standards and guidance: While the team approach to drug procurement may help to secure continued procurement operations, adherence to professional standards and patient safety may be at risk if team members without special education in pharmaceutical procurement may be unaware of the importance of licensed sources or the dangers of falsified medicines. Frequent power interruptions may impair stored products' quality. The reported antibiotic sourcing from private wholesalers and unlicensed sources, and requests to patients to purchase them independently, are attempts at coping with the frequently experienced unavailability of antibiotics. However, both practices are potentially compromising the patients' safety. A similar risk is involved by the frequently reported dispensing of partial doses or even expired drugs, and the low use of reserve antibiotics for the treatment of infections by multidrug-resistant pathogens.

Lack of advanced diagnostic infrastructure: Not more than 50% of respondents from general hospitals and the referral hospital confirmed availability of microbiology-based testing which is required to identify the bacteria causing particular infections. Therefore, empirical treatment choices prevail and de-escalation of empirical therapy and transition from intravenous to oral dosage forms are rarely practiced. This supports the assumption that watch antibiotics may be overused.

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[1] Refer to the explanation of the WHO classification of antibiotics by AWaRe groups in the Abbreviations chapter

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Abbreviations

Abbreviation	Explanation
ABS	Antibiotic stewardship (activities promoting appropriate use of antibiotics)
AMR	Antimicrobial resistance
ASP	Antibiotic stewardship program
AWaRe	AWaRe stands for Access, Watch, and Reserve[2]. It is an antibiotic classification system introduced in 2017 by WHO to provide guidance for appropriate use of antibiotics (stewardship).
EEML	Ethiopian Essential Medicines List
EFDA	Ethiopian Food & Drug Agency
EPSA	Ethiopian Pharmaceutical & Supply Agency
FEFO	First Expired, First Out
FMoH	Federal Ministry of Health
HCI	Health care institution
HCP	Health care professional
JJU	Jigjiga university
LDC	Least Developed Countries
LMIC	Low- and middle-income countries
RTA	Swiss Round Table on Antibiotics
Swiss TPH	Swiss Tropical and Public Health Institute
UniL	University of Lausanne

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[2] **Access** antibiotics are antibiotics with a narrow spectrum of activity, generally with less side-effects, a lower potential for the selection of antimicrobial resistance and of lower cost. They are recommended for the empiric treatment of most common infections and should be widely available

Watch antibiotics generally have a higher potential for the selection of antimicrobial resistance and are more commonly used in sicker patients in the hospital facility setting. Their use should be carefully monitored to avoid overuse.

Reserve antibiotics are last-resort antibiotics that should only be used to treat severe infections caused by multidrug-resistant pathogens (Zanichelli *et al.*, 2023)

Introduction

Antimicrobial-resistant bacteria pose a growing threat globally and especially in low-and-middle-income countries (LMIC), making it more difficult - and sometimes impossible - to effectively treat infectious diseases (Muhie, 2019). AMR is driven by several factors. The usage of antibiotics, and particularly their misuse and overuse are the main drivers of AMR (Erku *et al*., 2017). In LMICs the threat of AMR is amplified by poor sanitation, low vaccination rates and poor infection prevention and control practices. The quality, safety and effectiveness of drugs is a further concern considering the apparently widespread presence of deliberately falsified and substandard antibiotics (Cox *et al*. (2017).

The circulation of substandard antibacterial medicines near the Ethiopian borders to Sudan and Eritrea was documented (Denekew *et al*., 2024). Although their findings focus on a specific area, they point to a wider vulnerability in similar settings such as the Somali region in Ethiopia where this study was conducted and which shares a border of about 1,600 kilometers with Somalia and Somaliland. This is also reflected in a very low knowledge about AMR in the Adadle district of the Somali Region, especially among women (Muhummed A.M. *et al*., 2024). Furthermore, limited awareness and implementation of stewardship measures in hospitals in Northwestern Ethiopia were shown by Abejev *et al*.(2024).

When antibiotics lose their effectiveness, both new and existing infectious diseases can (re)emerge, potentially leading to increased morbidity, greater demands on healthcare resources, as well as premature mortality (Muhie, 2019).

Sub-Saharan Africa and Asia face a disproportionate burden of infectious diseases, compounded by inadequate regulatory infrastructure, non-prescription sales, falsified antibiotics, inappropriate prescription practices, and significant weaknesses in diagnostic testing and surveillance *(*Gebretekle *et al*., 2018).

In Ethiopia, resistance to commonly used antibiotics is widespread and multidrug-resistant bacterial strains are highly prevalent (Muhie, 2019), (Abejew, A.A, Fenta, T.G., Wubetu, G.Y., 2025). Consequently, bacterial infections are a major cause of mortality (Edessa *et al*., 2024).

Despite Ethiopia's early engagement in AMR prevention and control the government remains concerned about the current state of adoption of these measures (Ministry of Health *et al*., 2021). Their "Third One Health strategic plan on antimicrobial resistance, prevention, and containment 2021-2025" defines five strategic objectives, with objective 4 addressing stewardship: "Optimize the use of antimicrobials in human, animal and plant health care".

1 Method

1.1 Study design and population

At the suggestion of the Swiss Tropical and Public Health Institute (Swiss TPH) and thanks to its connections and infrastructure in the Somali region of Ethiopia, the Swiss Round Table on Antibiotics (RTA) in collaboration with the universities of Lausanne (UniL, Switzerland) and Jigjiga (JJU, Ethiopia) conducted a cross-sectional study in the 4th quarter 2024 and 1st quarter 2025 to elicit the knowledge, practices, and perceptions of HCPs relating to measures ensuring the quality, integrity and effectiveness of antibiotics, and stewardship in the Somali region of Eastern Ethiopia (Figures 1a and 1b).

The survey questionnaire was developed in two steps: In the first step dedicated to measures ensuring the quality, integrity and effectiveness of antibiotics, members of the RTA, including the project leader in Switzerland, defined selective questions about standards, infrastructure, tools and practices per the WHO guideline on "Good storage and distribution practices for medical products (GDP)" (WHO Team, 2020). In the second step, upon proposal by the designated local data collectors and the local project leader and post-doctoral fellow at UniL, the scope of the survey was extended to cover antibiotic stewardship (ABS). The questions cover important contributors of AMR and key interventions as stated for objective 4 (stewardship) in the Ethiopian "Third One Health strategic plan on antimicrobial resistance, prevention, and containment 2021-2025" (Ministry of Health *et al*., 2021). After conduct of an initial set of trial interviews and feedback from the interviewees the questionnaire was further refined to improve clarity and enhance its relevance to the surveyed institutions. This happened in close on-site collaboration between the data collectors and the two study leaders.

The scope extension allowed collection of integrated information about the knowledge, infrastructure, tools and practices of HCPs along the pathway from procurement and storage of antibiotics to antibiotic selection, prescription, and dispensing to patients.

We conducted 522 interviews in 10 HCIs, at the Ethiopian Pharmaceutical & Supply Agency (EPSA) and a government office. For this report only the data collected in the 10 HCI from 509 interviews was used. Of the 509 respondents 26% were female and 74% male. The following professions were represented: Nurses (46.7%, n = 236), pharmacists (29.7%, n = 151), medical doctors (10.2%, n= 52), midwives (8.8%, n= 45), public health specialists (3.1%, n = 16), and laboratory technicians (1.8%, n = 9).

The study was conducted across all levels of the health care system: primary (4 health centers/primary hospitals), secondary (4 general hospitals and one private health facility including a pharmacy), and tertiary care facilities (1 referral hospital). Data was collected from HCIs located in the two major towns, (383 interviewees, of which 323 in Jigjiga and 60 in Gode), and in rural areas (126 interviewees).

Figure 1a. Location of Ethiopia in the Horn of Africa

Figure 1b. Somali region in Eastern Ethiopia

1.2 Data collection and analysis

The questionnaire was set up in Open Data Kit (ODK), allowing direct sharing and monitoring of the responses during the interviews (Get ODK Inc, 2008). The questionnaire was structured to capture knowledge and experience specific to each profession and was administered by trained data collectors from JJU.

Prior to the study start approval was obtained from each involved HCI as well as from the JJU ethical commission (RERC/092/24).

The data collection was carried out by six experienced data collectors and staff holding master's degree at JJU. They received training from the two study leaders.

The study results reflect the interviewees' personal perceptions and self-declared work practices.

Data analyses were conducted by UniL in RStudio (RStudio Team, 2020).

2 Results

2.1 Compliance with Good storage and distribution practices for medical products (GDP)

2.1.1 Procurement responsibility and sources of supply

Across all HCI types, pharmacists were identified as the principal professionals responsible for procurement. Yet, the involvement of medical doctors and occasionally nurses, and midwives was also reported, and is wanted per procurement guidelines recommending a team-based approach.

Figure 2 shows that more than 80% of respondents from all types of HCIs, except general hospitals, identified private wholesalers as their main source of antibiotic supply. In contrast, only about 50% of respondents from all HCIs, except private health facilities, cited EPSA. EPSA is a public agency accountable to the Federal Ministry of Health (FMoH) "mandated at the national level to provide all public health facilities in a sustainable manner with affordable and reliable pharmaceuticals" (Boche *et al*., 2022). Responses from private health facilities suggested a clear preference for private and occasionally also unlicensed sources of supply and only a negligible extent of sourcing from EPSA. Even general and referral hospitals seem to use unlicensed sources occasionally.
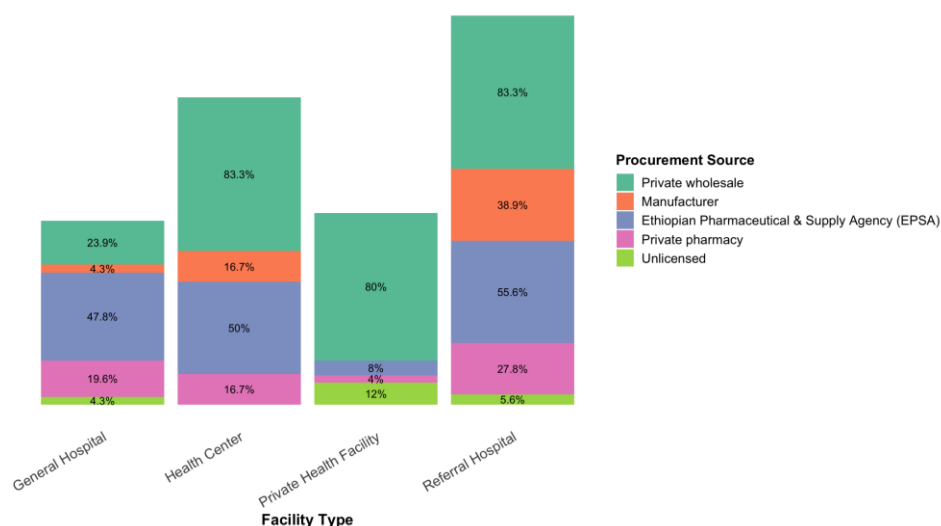

Figure 2 Reported sources of supply across different types of HCIs

2.1.2 Goods receipt checks

Figure 3 shows the extent of self-declared compliance with a list of seven goods receipt checking criteria across the four types of HCIs. The largest proportion of interviewees indicated checking received goods against the three criteria of expiry date, product quality, and reference to the purchase order. Generally, cleanliness and safety measures preventing unauthorized access to the freight in the delivery vans seem to get the least attention. Respondents from the referral hospital paid more equal attention to all seven check criteria than the respondents from the other types of HCI.
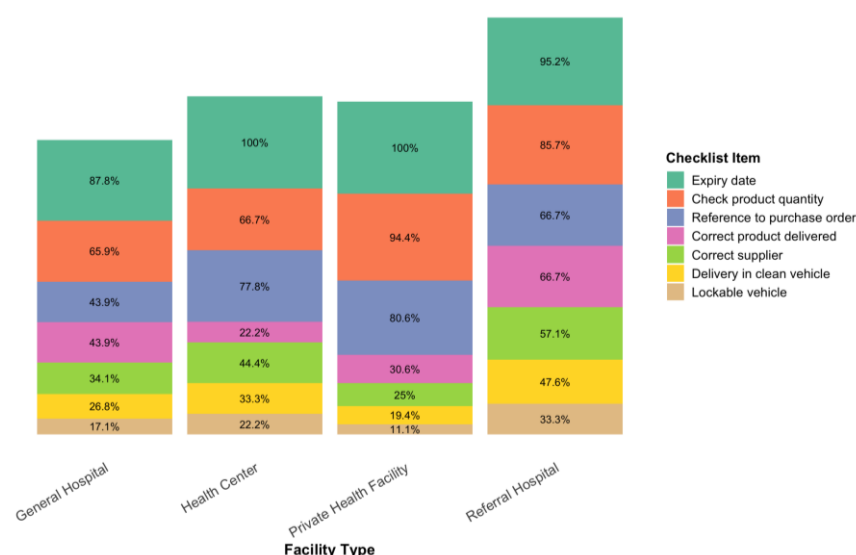
Figure 3 Goods receipt checking across different types of HCIs

Relatively high proportions of respondents from the referral hospital (57.1%) and health centers/primary hospitals (66.7%), but less than 30% of respondents from the general hospitals and private health facilities reported having specific procedures to detect falsified products upon receipt.

2.1.3   Inventory management and goods issue

Between 95% and 100% of respondents across all HCI types informed that written records are kept of received and issued antibiotics, and between 80% and 96% of respondents stated that the expiry dates of stored antibiotics are recorded.

Manual inventory systems were the most common tool to manage product stocks. Forty percent of the respondents from the referral hospital reported availability of electronic systems.

The availability of guidelines on the handling of expired products varied greatly across the four HCI types, with 84% of respondents from referral hospitals but only 48.7% from private health facilities, and 10% from health centers/primary hospitals reporting availability of such guidelines.

Across all types of HCIs goods issue was stated to largely follow the FEFO principle (First Expired, First Out).

2.1.4   Storage facilities

Concluding from the interviewees' responses access to storage facilities in all types of HCIs was not consistently controlled and storage areas were not regularly locked: "Controlled access" was confirmed by 68% and 69.8% of respondents from the referral and, respectively, the general hospitals, but only by 51.3% and, respectively, 40% of respondents from the private health facility and health centers/primary hospitals. "Locked storage area" was mentioned by 20% and 20.5% of respondents from the referral and the general hospitals, however by 41% and 50% of respondents from the private health facility and the health centers/primary hospitals. High 96% up to 100% of responses from the referral hospital, the private health facility and the health centers/primary hospitals, and somewhat lower 71.8% of respondents from general hospitals mentioned that damaged and returnable products are separated from the main storage area.

Frequent power interruptions were a common concern, with over half of the interviewees across all facility types, regardless of location in urban or rural areas, reporting such occurrences as "often". However, with 66.7% - 92.3% of respondents from the referral and general hospitals and the private health facility reporting availability of generators, the negative effects of power outages on product quality might at least be partially mitigated. Only 57.1% of respondents of the health centers/primary

hospitals reported availability of generators, which illustrates a less robust infrastructure in these primary level HCIs.

2.1.5   Training of storage staff

While almost all respondents from the referral hospital reported that storage staff had received relevant training, this was confirmed by only three quarters of respondents from general hospitals and private health facilities, and 50% of interviewees from health centers/primary hospitals.

2.1.6   Complaints handling

Delivery of damaged, wrong or expired products, or incorrect product quantity, were mentioned to give reason to complaints. For their handling 60% of the interviewees across all types of HCIs reported involving the person responsible for quality, while 45% declared to document the complaints. Forty percent of the respondents mentioned the involvement of the pharmacovigilance officer, and 20% reported to determine preventive measures. Notably, 10% of respondents stated to take no action in response to complaints. The responses were not mutually exclusive. Rather may several actions be taken cumulatively in the handling of a complaint.

2.2   Antibiotic Stewardship (ABS)

2.2.1   Awareness of Antimicrobial Resistance (AMR)

Figure 4 illustrates that a majority of respondents from all HCIs was aware of AMR as a global health concern, correctly identified it as resulting from microbes (here: bacteria) developing resistance to antibiotic treatment, and noticed AMR to present a challenge in their health facility. However, recognition of the specific drivers of AMR was more limited, with only 37% and lower rates of respondents correctly identifying over-the-counter antibiotic sales, inappropriate use, non-adherence to treatment, and antimicrobial use in animals as contributing factors.
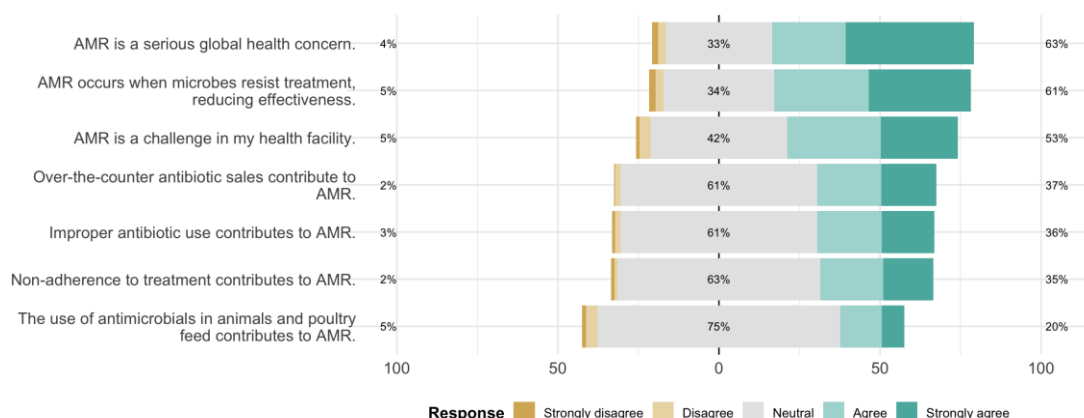

Figure 4   AMR awareness across HCIs

2.2.2 Antibiotic Stewardship Programs (ASPs)

The responses of HCPs working in urban and rural settings relating to ASPs differed markedly: About 28% of HCPs in urban, but only 11.5% in rural healthcare settings reported awareness of ASPs. A quarter of respondents from an urban setting confirmed the presence of a formal ASP for stewardship activities at their facility compared to 10.3% of their colleagues working in a rural setting.

Several demographic characteristics were significantly associated with greater awareness of AMR and ASPs: The level of education (medical doctors versus laboratory technicians), the number of years of professional experience, and age. Not surprisingly, working in a referral versus lower-level HCIs was also positively associated with greater awareness of AMR.

Resource disparities between rural and urban settings were particularly evident in the areas of funding and training: While over half of the urban interviewees (56.5%) reported the presence of a dedicated ASP budget, none of the rural interviewees did. Similarly, specialized training in ABS was reported by 60.9% of urban respondents but was absent among rural interviewees. A majority of respondents from HCIs in urban (51.0%) and rural areas (56.6%) informed that there were no AMR ambassadors in any ward of their facility.

2.2.3 Treatment guidelines and treatment decisions

The availability of local guidelines on treatment of infectious diseases varied notably across HCI types but overall was widespread. Forty-eight percent of respondents from general hospitals and 41.0% of respondents from the referral hospital reported availability of such guidelines. Professionals from health centers/primary hospitals (39.3%) seemed to be quite well equipped with guidelines whereas only 10% of professionals in private health facilities indicated availability of treatment guidelines. The availability of local treatment guidelines was slightly higher in urban (42.2%) than in rural areas (36.7%).

The reported application of measures tailoring the use of antibiotics during a treatment course did not substantially differ between urban and rural settings: De-escalation of empirical therapy was almost absent in both settings, and transition from intravenous to oral dosage forms was claimed to be practiced by about one third of respondents from both settings. The practice of dose optimisation was mentioned by a higher percentage of respondents from rural (45.8%) than from urban areas (29.6%).

2.2.4 Antibiotic prescription and dispensing to patients

Medical doctors were reported to be the main prescribers (mentioned by 63% of respondents), closely followed by pharmacists (55%) and, to lower degrees, nurses (15%) and health officers (9%).

Forty-three percent of respondents from general and 50% from the referral hospital mentioned availability of microbiology-based antibiotic testing in their institutions. Private health facilities and health centers/primary hospitals did not respond to this question.

Further responses suggested that dispensing of partial doses was more common than the dispensing of full product doses: The proportions of respondents of the referral hospital, the private health facility and the health centers/primary hospital reporting the dispensing of partial doses were twice as high as those reporting the dispensing of full doses. The disparity was even more pronounced in general hospitals where 63.2% of respondents reported dispensing of partial doses whereas 10.5% reported dispensing of full doses.

All interviewees from health centers/primary hospitals reported that they label the partial doses with the expiry date and product name whereas the respondents from the other types of HCIs seemed to handle the labeling less strictly.

2.2.5 Antibiotic unavailability

Interviewees from all types of HCIs frequently experienced unavailability of needed antibiotics, especially those from referral (55.8%) and general hospitals (53.1%) and from health centers/primary hospitals (52.4%), and less frequently the respondents from the private health facility (38.3%).

When antibiotics were not available, professionals overwhelmingly reported advising patients to look for alternatives on their own. The highest proportions of respondents mentioning application of this remedial strategy were noted for the private health facility (87%) and health centers/primary hospitals (81.8%). High proportions were also noted for the referral hospital (72%) and the general hospitals (55.0%). The use of alternative or even expired antibiotics was far less common. The highest percentages of respondents confirming the use of expired antibiotics were noted in general hospitals (12.4%) and private health facilities (8.3%).

2.2.6   Monitoring of antibiotic use

Monitoring of antibiotic use as a measure to prevent misuse was more often reported by respondents from the referral hospital (64.7%) and the private health facility (65%) than from general hospitals (40.7%) and health centers/primary hospitals (38.1%).

2.2.7   Antibiotic treatment options

With 55.0% of respondents reporting that they had "enough" treatment options private health facilities scored highest. The respondents from referral and general hospitals, and health centers/primary hospitals described the antibiotic options accessible by them as "limited" or "very limited." Generally, respondents from rural areas were more likely to report limited antibiotic treatment options than their colleagues in urban areas.

2.2.8   Types of antibiotics used in practice

The interviewees were asked to name the three antibiotics most often used in their HCI. Figure 5 summarises the interviewees' nominations across all types of HCIs. Except for cotrimoxazole all antibiotics listed in Figure 5 are included in the Ethiopian Essential Medicines List (EEML). The 7th edition of the EEML of October 2024 adopted the WHO AWaRe classification with modifications accommodating the national context. It includes 36 antibiotics classified as access (14), watch (15), or reserve (7).

Highest proportions of interviewees mentioned ceftriaxone as one of the three most used antibiotics in general hospitals (31.1%), the referral hospital (28.1%), and health centers/primary hospitals (27.0%). Ceftriaxone is available only as intravenous formulation and belongs to the watch group.

Amoxicillin, belonging to the access group, was mentioned by the second highest proportions of respondents mainly from lower-level health facilities: health centers/primary hospitals (20.1%) and private health facilities (19.8%).

Vancomycin, belonging to the watch group, was mentioned by 18.7% of respondents from referral hospitals and over 12% from general hospitals.
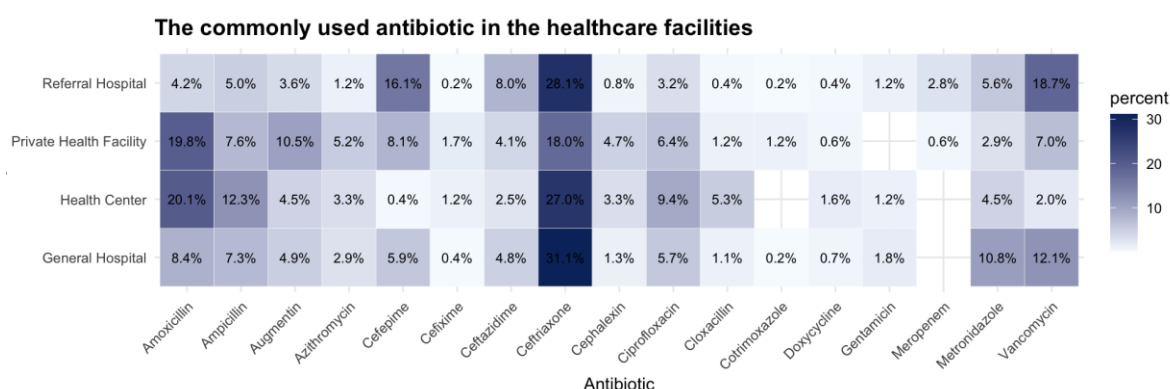

Figure 5 *Antibiotics most often used across different types of HCIs*

2.2.9   Public health emergencies

More than half (55.6%) of all respondents had experienced public health emergencies, highlighting Ethiopia's vulnerability to such crises.

A clear majority of 63% of respondents reported that their institutions have no plans for the prevention and handling of disasters and generally public health emergencies. Consequently, 60.7% reported that they did not communicate with relevant stakeholders about antibiotic supply chain planning.

3 Discussion

This study provided insights into the infrastructure and work practices subject to GDP and ABS requirements across the four types of HCIs surveyed in the Somali region of Eastern Ethiopia. Resource limitations appear to be important determinants of non-abidance by the relevant guidance and standards. Not surprisingly, the findings revealed disparities in the implementation of quality assurance and stewardship measures between institutions of different levels and by urban–rural location:

Disparities in infrastructure and work practices subject to GDP requirements became evident in different levels of stability of power supply and physical protection of the storage rooms, in manual versus electronic inventory management systems, the availability of guidelines (e.g. on the handling of expired products), and training of storage staff.

Disparities also became evident from the responses to questions about stewardship practices: While awareness of AMR was generally quite high the availability of budget support for ASPs, treatment guidelines and staff training were unevenly distributed and largely absent in lower-level facilities and generally in facilities located in rural areas.

The study outcomes highlight opportunities for improvement across all types of HCIs in urban and rural settings. They are described in some more detail in the sub-chapters 3.1 and 3.2, along with hints at possible remedial actions. The findings and suggested actions will be discussed with local stakeholders to jointly reflect on measures to address them.

3.1 Compliance with GDP

3.1.1 Procurement responsibilities and sources of supply

The prominent role of pharmacists in procurement is a positive indicator of professional specialization. The team-based approach foreseen by procurement guidelines may help to secure continued procurement operations in case of staff shortage. However, adherence to professional standards may be undermined if team members without special education in pharmaceutical procurement may be unaware of the importance of licensed sources or the dangers of falsified medicines. The dominant antibiotic sourcing from private wholesalers and occasionally from unlicensed suppliers reported by three of the four types of HCIs contradicts the FMoH's intention of pharmaceutical procurement to be made through EPSA to improve efficiency, reduce costs, and ensure quality (Boche *et al.*, 2022). Yet, one of the reasons for HCIs resorting to other sources of supply may be the frequently experienced shortages of supply which likely also affect EPSA's ability to fill all orders in full. Long distances to EPSA branches may further contribute to HCIs' opting for use of geographically closer private sector suppliers.

However, as Cox *et al.*, (2017) observed, "the large and growing private sector poses a particular problem, as in many LMICs its control by regulatory bodies is even more challenging than [the control of] the public sector."

To mitigate potential safety risks arising from professionals who may lack special education in pharmaceutical procurement, it is essential for the HCIs to facilitate basic training in professional procurement practices for all team members.

3.1.2 Goods receipt checks

The wide variation in response rates across the seven goods receipt checking criteria within each type of HCIs, as shown in Figure 3, suggests that goods receipt checklists may be absent or not generally enforced.

Given the high professionalization of the "falsification" industry the performance of effective checks for substandard and falsified products presents a significant challenge. This renders the procurement of antibiotics through trustworthy channels all the more important, particularly in view of the location of the surveyed HCIs in a border area and the high risk to patients' health and life implied by the use of falsified and substandard drugs.

Where checklists are lacking their introduction should be considered. Listing goods receipt checking in the job descriptions, training, and supervision are deemed appropriate measures to ensure more systematic and consistent performance of goods receipt checks.

3.1.3 Inventory management and goods issue

Record keeping of inventory movements and the products' expiry date seems to be a standard procedure in the surveyed HCIs. The widespread use of manual inventory management systems looks like a pragmatic solution given the frequent power outages, although potential efficiency gains and tracking capacity offered by electronic systems may be foregone.

The declining percentages of responses from the referral hospital to the health centers/primary hospitals regarding the availability of guidelines on the handling of expired products correspond with an increased risk to antibiotic quality and, potentially, patient safety.

Ensuring the availability and strict enforcement of guidelines on the correct disposal of expired products is essential, as the use of such products - often driven by shortage - poses significant health risks.

3.1.4 Storage facilities

Concluding from the interviewees' responses unauthorized access to stored goods did not appear to be adequately prevented, even in the best-scoring referral hospital.

The reasons for this shortcoming should be investigated to inform appropriate measures enhancing the level of physical protection of stored goods from unauthorized and illegal access.

3.1.5 Training of storage staff

The disparity of very high training levels of storage staff at the referral hospital and very low training levels of storage staff at health centers/primary hospitals illustrates a quality gap at the primary care level.

Exchange of best practices between HCIs in the surveyed area might be a pragmatic approach to generate more equitable levels of training and hence capacity across different types of HCIs and urban and rural settings, generally, and particularly to determine appropriate measures of storage protection and their consistent application.

3.1.6 Complaints handling

Similar to the wide variation in response rates across the seven goods receipt checking criteria, the responses regarding actions taken to handle complaints also lacked consistency.

This observation may highlight the necessity for standardized protocols and targeted capacity building to ensure uniform and effective complaint management throughout all levels of the health system. Again, there may be opportunities for more advanced HCIs to share their practices and experience with HCIs with a less developed quality management system.

3.2 Stewardship

The observation of disparities in knowledge and experience between urban and rural institutions in this study is consistent with outcomes of other studies showing that rural HCIs often face structural and resource limitations that hinder effective stewardship implementation (Cox *et al.*, 2017).

3.2.1 Awareness and measures to improve of AMR and ASPs

The limited understanding of the factors driving AMR presents a hurdle for the definition of targeted countermeasures.

However, the observed positive association of AMR and ASP awareness with demographic characteristics of the respondents may offer opportunities for better-educated and more experienced individuals from higher-level HCIs to act as mentors of younger, less experienced individuals and generally lower-level HCIs. Awareness and understanding of stewardship are also available at JJU, as demonstrated by the initiative of the designated data collectors to extend the study scope to cover stewardship.

Cox *et al.* (2017) recommend ASPs to first address low-hanging fruit, for example by creating greater awareness of the benefits achievable by converting intravenous to oral routes of antibiotic administration or the optimization of antibiotic use in surgical prophylaxis. The establishment of guidance and training on such measures may generate visible benefits in the short term. A collaborative process will promote the contextualization of ABS measures, their feasibility and acceptance in the mentored HCIs.

3.2.2 Treatment guidelines

The availability of guidelines on treatment of infectious diseases was not widespread and the disparity between urban and rural settings, albeit following the expected pattern, was not very pronounced. Only the private health facilities stood out with a very low proportion of 10% of respondents confirming availability of such guidelines. Cox *et al.* (2017) explain this observation by referring to "limited availability of locally applicable high-level evidence and little experience with evidence-based guideline development". Furthermore, in the past, guidelines may have been perceived as less useful when they were not sufficiently adapted to the local context.

Noteworthy to mention in this context that the 2024 update of the EEML was informed, among other, by the 2021 Standard Treatment Guideline for General Hospitals in Ethiopia. The relatively low percentage (48%) of respondents from general hospitals in the Somali region reporting the availability of treatment guidelines on infectious diseases may be attributed to a lack of awareness, insufficient training, or limited use of the guidelines - particularly if they might not have been adequately tailored to the local context.

Future follow-up on this study's findings should aim to clarify the underlying reasons for the limited availability or use of guidelines and define appropriate remedial measures.

3.2.3 Antibiotic prescription and dispensing

The high rates of respondents mentioning antibiotic prescriptions to be issued by pharmacists and, albeit to a lower extent, nurses and even health officers reflect a known and worrying pattern in LMICs as described by Cox *et al.* (2017). These health care workers have different educational backgrounds which do not necessarily qualify them for deciding on antibiotic treatment in individual patient situations.

This finding also corresponds with Cox *et al.* (2017) who cited a "widespread use of nonprescribed antibiotics that can be purchased over the counter" in many LMICs. Just like over-the-counter access to antibiotics their prescription by inadequately qualified persons presents a risk to patient safety and contributes to overuse and misuse of antibiotics, the main drivers of AMR. This may be the reason why Ethiopian law does not foresee professionals other than medical doctors to prescribe antibiotics.

The dispensing of partial doses in a resource-limited country like Ethiopia often responds to patients' inability to pay for full doses. However, partial doses may not allow patients to get the full benefit of the treatment and may contribute to rising rates of antimicrobial resistance.

Addressing these issues requires a multifaceted approach:

- Efforts should be undertaken, at least within HCIs, to ensure that only professionally qualified staff may prescribe antibiotics.
- HCPs should play a proactive role in educating patients about the importance of completing the full course of prescribed antibiotics and the risks associated with partial dosing.
- At the same time, regulatory bodies should strictly enforce policies that prohibit the sale of incomplete antibiotic regimens.
- Moreover, expanding access to health insurance schemes could alleviate the financial burden on patients, thereby improving access to essential medications and promoting adherence to dosing guidelines.

3.2.4   Antibiotic unavailability

The survey outcome informed about a widespread practice of HCIs asking patients to buy the antibiotics which the institutions were not able to procure. This practice comes with financial and health risks, especially when the patients turn to unlicensed providers, a likely scenario in a situation where the HCIs are not able to procure the required antibiotics nor any suitable replacement products.

Similar risks are incurred when HCIs dispense expired antibiotics to accommodate shortages. The WHO warns that poor-quality and expired antimicrobials can contribute to therapeutic failure and antimicrobial resistance (WHO Team, 2024). Even high-income countries are experiencing high and rising rates of stockouts for many medicinal products, particularly antibiotics.

There is no simple solution for this issue – and even less so in low-resource countries. However, it may be worthwhile discussing with the Ethiopian authorities the feasibility of maintaining safety stocks for essential medicines at national or regional level.

3.2.5   Antibiotic treatment options

The reported unequal access to treatment options across different types of HCIs contrasts with the objective declared by the EFDA for the EEML to provide the basis for "equitable healthcare to the population in line with defined policies, strategies, laws, standards, and guidelines".

A glance at Figure 2 in sub-chapter 2.1.1. might suggest that private health facilities fare "better" than other types of HCIs thanks to their strong cooperation with private wholesalers and non-negligible use of unlicensed sources of supply.

It may be worthwhile for the HCIs in the Somali region to consult with EFDA and EPSA about support in ensuring more equitable access - via legal procurement routes - to the antibiotics listed on the EEML.

3.2.6   Types of antibiotics used in practice

The high nomination rates of ceftriaxone, amoxicillin, and vancomycin among priority antibiotics do not necessarily reflect their actual usage quantities nor the proportion of use by AWaRe group.

However, the prominent mention of ceftriaxone, a broad-spectrum antibiotic, suggests a strong reliance on empirical treatment, even in higher-level HCIs which, as mentioned earlier, seems to be driven by the wide absence of microbiology-based testing infrastructure, also in first and second-level hospitals. The same reason is likely also responsible for the reluctance to change regimens during an ongoing treatment course. Although with 74.2% in 2022 the rate of access antibiotic use in Ethiopia is even higher than the threshold of 70% requested by the United Nations General Assembly (UNGA) in 2024 (Hailemariam, E..,

2025), there may still be room for a further increase of the access rate if de-escalation strategies and switch from intravenous to oral dosage forms could be applied more often.

Regarding reserve antibiotics, the recently published "WHO Antimicrobial Resistance and Use Surveillance System (GLASS) report" (WHO, 2025) noted little to no use of these medicines in some low- and middle-income countries, territories, or areas - although they "are needed to treat infections caused by the most drug-resistant bacteria". Given the high prevalence of multidrug-resistant bacterial strains in Ethiopia (Muhie, 2019) and the fact that only one reserve antibiotic, meropenem, appeared in Figure 5 with minimal nominations from the referral hospital and private health facilities, the Somali region of Ethiopia may qualify as an underserved area.

To get a more precise picture of the actual drug availability and use by the HCIs in the Somali region of Ethiopia more data will be required.

To improve the chances that innovative, often reserve-classified antibiotics are registered and made available in Ethiopia, their manufacturers need to be confident that the quality, integrity and effectiveness of these antibiotics are preserved during supply, storage and distribution, and their use is governed by strict stewardship.

3.2.7   Public health emergencies

Less than 40% of respondents were aware of plans for the prevention and handling of public health emergencies. This may be explained by the challenges which stakeholders in a low-resource country face to secure a minimum level of health care services even in normal times.

The proposed discussion with the Ethiopian authorities about a set-up of safety stocks for essential medicines at national or regional level in sub-chapter 3.2.4 may be held with a view not only on the maintenance of routine health service levels but also on health emergencies.

4 Conclusion

This study aimed to shed light on standards, infrastructure and work practices impacting the quality, integrity, and effectiveness of antibiotics, and stewardship, in the Somali region of Ethiopia.

The outcomes appear to confirm the government's concerns about the current state of adoption of the measures defined in the third edition of the "Antimicrobial Resistance Prevention and Containment Strategic Plan 2021-2025". This assessment is exemplified by the broad awareness of AMR observed, which contrasted with the limited understanding of its underlying drivers and the very low awareness of the existence of ASPs, and widespread lack of their funding.

On the positive side, the study revealed existing human capacities mainly in higher-level HCIs in urban areas which may be leveraged to mentor younger, less experienced individuals - and those from lower-level HCIs - in addressing identified weaknesses. The initiative taken by the designated data collectors at JJU, young master students, to expand the study scope to include stewardship not only demonstrated their strong understanding of the concept but also their motivation to support its practical implementation.

Such knowledge and motivation, if put into action, provide an excellent resource for further strengthening product quality, integrity and effectiveness, and stewardship in Ethiopia. Achievements in these areas are of paramount relevance to manufacturers of innovative antibiotics to get them registered and launched in Ethiopia.

To this end, we recommend that the findings of this study be discussed with the local stakeholders to jointly validate them and reflect on measures to mitigate the identified – and locally confirmed - weaknesses. In some areas more data is required to better understand the root causes of the findings and any relevant circumstances which may impact the choice of remedial actions.

Any progress made in terms of compliance with GDP guidance and stewardship requirements will be for the benefit of the Ethiopian people which is currently exposed to a significant and often fatal risk of AMR.

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