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RESEARCH ARTICLE

The market systems and supply chain of antimicrobial agents in Malawi

[version 1; peer review: 1 approved with reservations]

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Abstract

Background

A central pillar of the Global Action Plan on Antimicrobial Resistance (AMR) is to optimize use of antimicrobials. Whilst excessive use of antimicrobials drives AMR, scarcity has a negative impact on patients needing access to treatment for infectious diseases. Addressing this issue necessitates concerted efforts to enhance the antimicrobial supply chain. However, achieving tangible improvements requires a comprehensive understanding of the existing processes of antimicrobial supply. Notably, there exists a gap in the literature on the market dynamics and supply chain processes of antimicrobials in Malawi.

Methods

We used an exploratory qualitative approach to this study; data were collected through in-depth interview between March and June in 2021 in Blantyre, and findings triangulated at a workshop at the end. Purposive sampling methods were used to identify 17 study participants from both the public and private health sector. Data

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1. **Stephen Hinchliffe**, Geography University of Exeter, Exeter, UK

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analysis was done using thematic analysis in NVivo 11 software.

Results

Antimicrobials are largely imported into Malawi and consumers access antimicrobials through a mixture of public, private, and parallel supply chains. Formal antimicrobial supply chain actors comprise distributors which operate under obligations set by regulators while informal supply involves distribution of unregulated antimicrobial products. Regulation of distributors is compromised by human and financial resources constraints.

Conclusion

Shortcomings in the regulation of the antimicrobial supply chain in Malawi poses potential significant challenges for the optimal management of patients with infectious disease. This includes an inability to enforce regulation of the formal market leading to poor prescription practices and unnecessary antimicrobial usage. Addressing these issues is crucial for safeguarding public health and combating the spread of antimicrobial resistance. Further research should be done to investigate the extent of the problem posed by illegal antimicrobial routes and to develop interventions aimed at strengthening regulatory frameworks and health systems to improve patient access to antimicrobials.

Plain language summary
Antimicrobial agents are essential medicines used to treat infections, but in Malawi, accessing these drugs is challenging due to a complex and often poorly regulated supply chain. This study explores how antimicrobial medicines are supplied and accessed across the country. Interviews with key stakeholders showed that these medicines are primarily imported and distributed through three main supply chains: public, private, and informal. The public supply chain, though central to the government's efforts to provide essential medicines, is frequently affected by shortages. These gaps are often filled by private pharmacies and informal vendors, where regulations are weaker. This may introduce the risk for distribution and purchase of substandard or falsified antimicrobials within the market system. Furthermore, leakages from the public supply chain into private markets alter procurement and demand signals. The situation is escalated further by low public awareness about proper antimicrobial use and the pressure on healthcare providers to prescribe or dispense these medicines. This inadequately regulated complex interaction of the three supply chains, public and private actors, and consumer behavior may fuel the growing crisis of AMR in Malawi.

Keywords
Antimicrobial resistance, regulation, distribution, global action plan, World Health Organization, stock outs.

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Background

Inappropriate usage of antimicrobial agents in healthcare and agricultural sectors has been previously described to be among key drivers of emergence of antimicrobial resistance (AMR)[1]. The World Health Organization's (WHO) Global Action Plan (GAP) on AMR describes optimization of antimicrobial usage (AMU) as a priority in combating AMR[2]. The efforts towards optimizing AMU cannot progress in the absence of a sustainable and well-regulated antimicrobial supply system. Ensuring appropriate AMU is preceded by well-regulated drug supply in hospitals and approved pharmacies[3,4]. Efficiency in the supply chain processes of antimicrobials has a far-reaching impact on the success of AMU. This is because timing of administration of antimicrobials has a direct impact on patient care[5].

Previous research in Malawi has mainly focused on assessing access, availability and affordability of essential medicines as well as identifying that pharmaceutical agents are mainly supplied through the private sector, public sector, and non-governmental organizations (NGO)[6,7]. The public sector supply chain is managed through the Central Medical Stores Trust and supplies essential medicines to all public hospitals and other faith-based hospitals. The private sector includes all businesses that sell essential medicines for profit whereas NGO sector includes all organizations that procure and supply essential medicines to the public hospitals to support efforts of the public sector[8]. These are the formal processes through which people access essential medicines in Malawi.

Although there are several processes through which antimicrobial agents can be accessed in Malawi, there have been previously reports of frequent stock outs in public hospitals[9,10]. There is also evidence that people have access to antimicrobial agents beyond these formal supply chains[6,11].

Furthermore, studies have previously attributed limited access to antimicrobial agents to poor supply chain management and stock pilfering and stock outs[12,13]. These reported issues reflect how the supply chain, driven by the overall market environment, fills gaps through informal channels, responding to demand that exceeds formal supply. However, there are no previous studies that have mapped the processes within the supply chains, which is critical in identifying possible solutions. In this study, we explored the different routes through which antimicrobial agents from suppliers get to the consumers, and some of the perceived factors influencing antimicrobial purchases. We also analyzed the different barriers within the antimicrobial supply chain in Malawi.

Methods
Study design
An exploratory qualitative research approach was conducted among private and public sector pharmacists, clinicians and employees from Ministry of Health and regulatory institutions for distribution of medicines in Malawi from March 2021 to June 2021. The exploratory research design was considered appropriate since the area of the research is not clearly defined,

and the approach enabled us to gather descriptions and gain in-depth understanding of the supply chain and market system for antimicrobial agents in Malawi[14,15]. After the interviews we also conducted a stakeholders' workshop with individuals from institutions that emerged as playing a role in the antimicrobial supply chain to triangulate the findings. The workshop also aimed at disseminating preliminary results from the in-depth interviews and to get feedback on the same. This study has been reported following the consolidated criteria for reporting qualitative (COREQ) research guidelines (https://doi.org/10.5281/zenodo.14672981).

Research team and reflexivity
For consistency, all in-depth interviews were conducted by a female researcher, Effita Fifi Masoamphambe, MSc, the first author, who was a Master of Science Research Fellow at the Malawi-Liverpool-Wellcome Clinical Research Programme at the time of the study. During the study period, she was undergoing graduate training in an MSc program at Kamuzu University of Health Sciences. The stakeholder workshop presentations were organized and implemented by the first author alongside a male researcher, Raymond Pongolani, BSc, who was a Field Research Assistant for the qualitative research or social science arm of the "Drivers of Resistance in Uganda and Malawi" project at the time. Prior to the study's implementation, identified participants were contacted to establish rapport and to inform them about the study objectives. All participants consented before the research interviews and the stakeholder workshop. Participant information leaflets were distributed to facilitate this process.

No biases, assumptions, or prior interests about the interviewer or facilitators of the stakeholder workshop are known or reported here. The author used an interview guide with open-ended questions to ensure unbiased data collection, allowing participants to express their perspectives. The open-ended design reduced the risk of leading responses, and the interview guide was refined after piloting with initial interviews to address ambiguities and ensure it supported a thorough exploration of the topic. The stakeholder workshop was utilized for member checking and feedback on the results of the in-depth interviews, enhancing the robustness and credibility of the findings.

Setting
The study was conducted in the city of Blantyre, which is the principal commercial city located in the southern region of Malawi with an estimated population of about 844,161 as of 2021[16]. Health care services are accessed through a mixture of public and private hospitals[11]. There is one tertiary public hospital, and several community hospitals (which provide primary healthcare services), plus private hospitals and clinics within the urban setting were citizens access medication. People also access services through retail pharmacies, medicine stores and drug vendors that sell antimicrobials informally. Antibiotics can theoretically only be acquired over the counter in retail pharmacies and drug stores with a prescription from a medical professional, such as a doctor[17,18]. There are substantial commercial activities in Blantyre, including pharmaceutical wholesalers and

companies. Public sector offices and the pharmacy and medicines regulatory authority (PMRA - a regulatory body for medicines), are based in Lilongwe, so we interviewed some study participants from Lilongwe.

Sampling and recruitment of study participants

We purposively sampled 17 participants for our study, targeting individuals with key roles in the antimicrobial supply chain, including pharmacists, clinicians from both private and public health sectors, regulatory body personnel, and Ministry of Health representatives. Participants were chosen based on their roles, location, and relevant work experience to ensure comprehensive and insightful data collection. We specifically sought individuals with over 2 years of experience to ensure a thorough understanding of antimicrobial supply chain processes. Participants were contacted through email or phone calls. This purposive sampling approach allowed for specificity and enhanced information power, ensuring comprehensive data collection until saturation was reached[19–21]. Our sampling approach allowed for categorization and diversity to achieve an optimal representation from all relevant institutions in the supply chain. Additionally, we prioritized participants with substantial knowledge to maximize the concept of information power, even though the number of participants per sector was relatively small[19]. No participant dropped out of the study but only one potential participant we had reached out to from the private sector declined to participate because of time constraints on their end. The details of study participants can be found on Zenodo (https://doi.org/10.5281/zenodo.14672981).

Data collection

We conducted in-depth interviews with research participants between March 2021 to June 2021. In-depth interviews (IDIs) were conducted in English using an interview guide comprising open-ended questions. The specific study objectives served as a guide for the development of the interview guides. The guides were piloted with the initial two interviews to refine the interview guide, addressing any redundancies and any questions that seemed unclear. The data from the pilot interviews were included and used during data analysis because they offered important insights on the topic. Participants were approached via phone calls, emails, and face-to-face meetings, based on availability of their contacts. All interviews were administered by the first author, who had received prior training in qualitative data collection methods. Each interview session lasted between 30 minutes and 1 hour, and data was collected in audio format using a digital recorder. However, no repeat interviews were conducted during the study period. The interview guides can be accessed on Zenodo (https://doi.org/10.5281/zenodo.14672981).

There were no repeat interviews with any of the research participants. Instead, we made a presentation at a stakeholder workshop with study members included in the in-depth interview to disseminate findings and for member checking of the results from the in-depth interviews. Field notes were only recorded for the stakeholder workshop but not audios. The stakeholder workshop was a brief breakfast meeting lasting 3 hours. Transcripts were not returned to the participants due to time limitations and because it was extremely difficult to recruit participants from the said institutions. Instead, we presented all the preliminary results from the initial data collection we did using in-depth interviews.

Data management and analysis

Audio data were transcribed verbatim and securely stored in a OneDrive folder to maintain confidentiality. Data analysis was conducted on a password-protected computer accessible only to study investigators involved in the analysis. The audios were listened to multiple times to become familiar with the data before being transcribed into Microsoft Word documents. After several readings of the transcripts to identify patterns and meanings, codes were assigned to approximately half of the transcripts based on emerging impressions from the data. The initial codes were then applied to the remaining transcripts to complete the coding process. Any discrepancies or inconsistencies in coding were addressed through open discussion until a consensus was reached.

NVivo 11 software was used for the coding process (https://lumivero.com/product/nvivo/). NVivo is proprietary software, for open-source alternatives, consider using QualCoder (source code available from: https://github.com/ccbogel/QualCoder/releases/tag/3.5). Coding was done by the first author (E.F.M) and the fourth author, MacWellings Phiri (M.P). Any inconsistencies and disagreements were checked by an opinion from the second author (B.L) and then vetted by one of the senior authors (L.N.M). We do not provide a description of the coding tree here, and all the themes were derived from the data. Feedback on the findings was given at the stakeholder workshop.

Codes that were related or similar were grouped together to develop themes. Utilizing the supply chain processes described in the data, we adapted a market systems tool for pre-crisis market analysis to virtually represent the market system for antimicrobial agents in Malawi[22]. This involved a detailed examination of the transcripts to identify actors and processes involved in the supply chain of antimicrobial agents. Using thematic analysis, they were categorized into regulatory institutions, support services and infrastructure, and the actual supply chain actors handling antimicrobial products. Once agreed upon, these themes were mapped onto the market template to create a virtual representation of the antimicrobial market in Malawi.

Results

Characteristics of study participants

Of the 17 participants recruited into this study, 13 were males and 4 were females. 11 were in senior management positions in their organizations or business while 6 were from middle management. The participants' work experience in the pharmaceutical sector ranged from 2 to 36 years and private sector businesses that were recruited in this study have been running for 2 to 21 years.

The supply processes of antimicrobial agents from suppliers to markets in Malawi

Participants explained that there are three formal supply routes through which antimicrobial agents come to market in Malawi; the public sector, the private sector and the parallel supply chain which is entirely funded and managed by global health institutions (See Figure 1). Participants narrated that antimicrobial agents are largely imported into Malawi with only a few local pharmaceutical companies currently manufacturing antibiotics for local distribution. Participants further elaborated that antimicrobial drugs are manufactured and sourced from China, India, Kenya, South Africa, and Zimbabwe whereas most veterinary antimicrobials are imported from Zambia. There are a few distributors that source from European countries. We, the authors, declare that the figure below is original, created solely for this study, and no permissions or licensing are necessary.

The public sector is the main distributor for most antimicrobial agents as they are funded by government to provide for the public health facilities in Malawi. A notable exception is the Central Hospitals of Malawi, which recently started making independent purchases.

"Majority of the hospitals in Malawi, are supplied via the Central Medical Stores, now, the recent trend is that the central hospitals are allowed to basically buy, which is a very recent trend. But most antibiotics come into this country, via tender suppliers from the central medical stores". - Participant 1.

The participants explained that the private sector supply chain includes all actors that sell antimicrobial agents for profit. These actors are key in healthcare service delivery in Malawi as they complement the public sector in trying to meet demand. They also explained that in the private sector, the product moves from manufacturers, which are either local or international through wholesalers to an array of private retailers including pharmacies, clinics, drug stores, vet stores and grocery stores. This occurs through the regulatory framework in Malawi, some drug stores selling antimicrobial agents are not licensed to do so, and form part of the informal distribution chain, while the formal chain includes licensed retailers. Antimicrobials sold through the informal network are mostly imported, and the traders pass through the porous ports of entry into Malawi while some are stolen from either wholesalers or public health facilities.
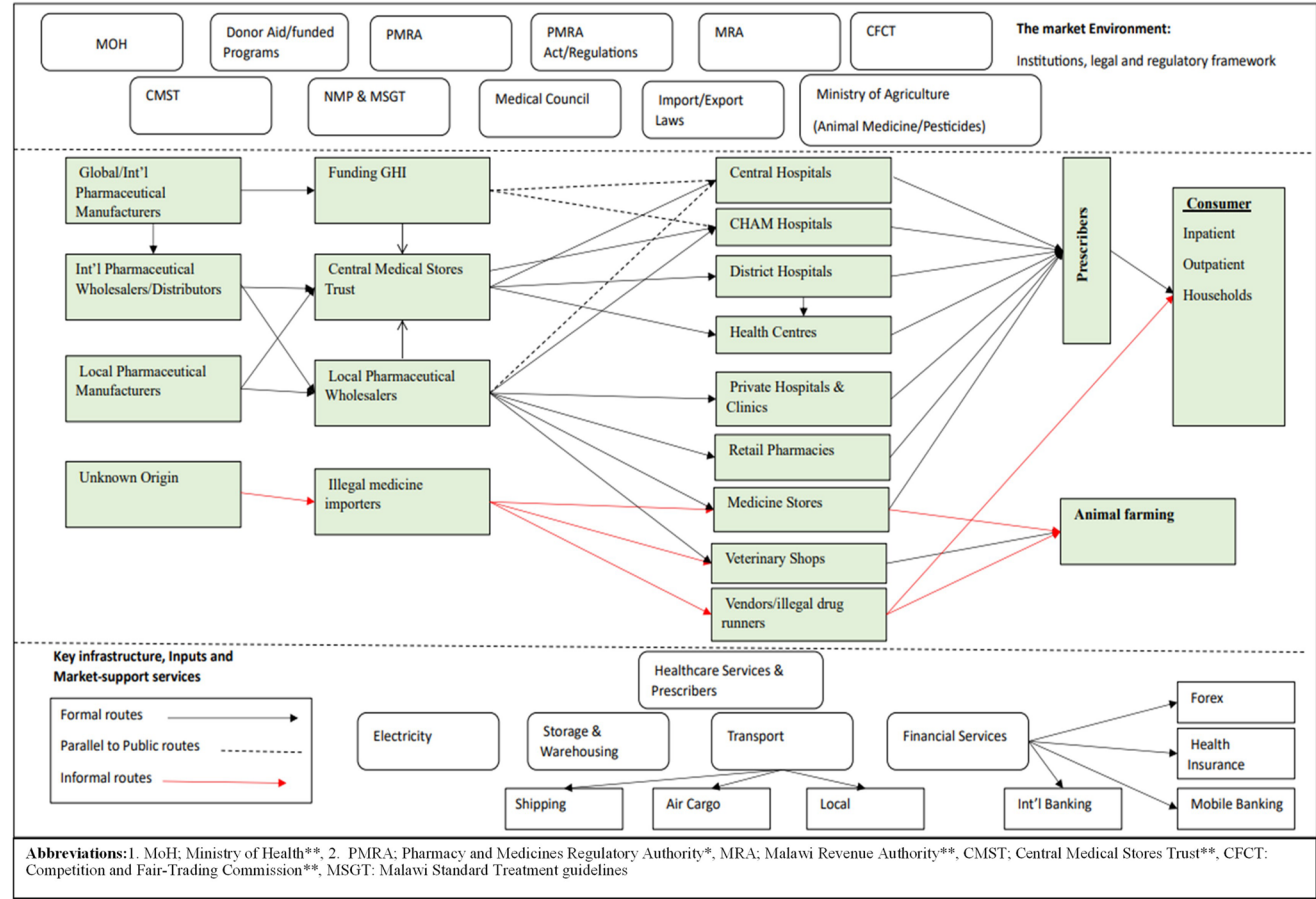

Figure 1. The established market system for antimicrobial agents in Malawi.

Participants stated that the parallel supply chain consists of distribution operations of antimicrobials from donor funded projects that are separate from those of CMST. The aim of this supply channel is to accelerate access to antimicrobial agents to address global health burdens such as Malaria, TB, and HIV/AIDS. To manage these disease-specific burdens, the government established dedicated projects that oversee the distribution of antimicrobials directly to public hospitals. However, the processes for procurement of antimicrobials are handled by funding organizations such as the Global Fund and not the government projects.

"Our role is limited to focusing on supply planning of the needs and submitting to a procurement agent of the global fund, which is the global drug facility based in Geneva. Once we submit our request to the global drug facilities all we can do is arrange for the items to be received, cleared, and distributed. As for procurement, our options are limited" –Participant 2

Drivers of trends in antimicrobial sales in the market systems

According to private sector pharmacists and clinicians, frequency and demand for antibiotics varies throughout the year due to seasonality, common knowledge and adjunct treatment, and range of usage to be the main factors behind the observed patterns.

Seasonality

Participants from the private sector, particularly the pharmacists and clinicians explained that they observe that certain infections that are common in specific seasons drive the demand for and distribution of certain antibiotics used to treat these infections. Seasonality which drives infection patterns also affects antibiotic demand and use.

"We have seasons whereby we have so many coughs and that would mean so many flu-related infections and diseases like pneumonia. Then that would mean that using a lot of amoxicillin and then there are times when the coughs have reduced, like during the festivities we use a lot of doxycycline, gentamicin because of sexually transmitted infections". – Participant 3

Common knowledge and adjunct treatment

Participants mentioned that there are antibiotics that are commonly dispersed because they are prescribed as concomitant treatment to some diseases like HIV/AIDS and other antimicrobial agents that people purchase because they are used to getting such prescriptions.

"There are some that are purchased more because of their adjunct treatments, like Cotrimoxazole because of the HIV treatment guidelines. Amoxil, Metronidazole, but these are antibiotics that are very popular mostly because in society people tell each other that if you have a cough aah take some Amoxil, if you have a running stomach take metronidazole." – Participant 4

Range of usage

Participants stated that certain antimicrobial agents are prescribed based on their broad range of action against various pathogens. The participants stated that most clinics lack access to point-of-care diagnostics or formal diagnostic microbiology laboratories to identify the aetiologic agent of the infection and therefore often prescribe broad-range antibiotics.

"I commonly give them the broad-spectrum antibiotics with a reason of course. We are looking at it like amoxicillin yeah, those ones cover the many antibiotics, I mean the microbials right. We are looking at the drug which can cure most of the bacteria, since we don't have a laboratory to isolate that organism". **–***Participant 5*

Barriers and challenges in the antimicrobial supply chain

Participants from both the private and public health sector highlighted barriers to supplying adequate quality and quantity of antimicrobial agents in a well-regulated fashion in Malawi. The challenges reported by the participants were categorized into regulatory challenges, access challenges, poor prescribing practices, and illegal trading of antimicrobial agents.

Regulatory challenges

Despite the many structures and strategies set to help effective regulation of the supply chain, there are challenges which were described as inadequate human resources, insufficient funding and poor coordination among the parties involved as regulators. The shortage of trained staff is on all levels of the required regulatory processes. The main regulator, which is PMRA, has a few employees to execute a huge workload.

"The law of the pharmacy act that I talked about, it strictly prohibits people from selling antimicrobials medicines, you must be an approved seller in an approved facility. Okay, and so aah government doesn't have enough enforcement Officers to do that" .- Participant 6

The problems of staff shortage were also described by a study participant from the Malawi Revenue Authority (MRA), which is responsible for inspecting medicine shipments that are imported into Malawi. Problems were compounded by the fact that the port officials lack technical expertise to judge imported antimicrobials versus the medicines listed on an actual issued importation permit. The participants stated this in an interview describing their inadequacy in terms of technical expertise to crosscheck a consignment.

"So, in the event where the officer cannot be able to tell, they are easily fooled and it is not even easy to classify, so you would find most of the medicaments (antimicrobials) they are just classified medicines". – Participant 7

Lack of funding is a common problem and is linked to limitations in human capacity within the public sector both in terms

of supply and regulations. The study participants described this problem as coming in the way of implementing their organizational activities. The PMRA, which is the main government regulatory body for medicines explained that funding problems affect their ability to conduct quality tests for antimicrobial products.

"The challenge we have is the procurement of standards for testing because if you are going to do a test you know, you must have standards you are testing against, they are quite expensive and so it is very likely that you do not do a proper test that you are supposed to do for the product." -Participant 8

Another emerging issue in regulation was poor coordination among the regulators. There is an overlap of responsibilities among some regulators and players. There is an overlap between the public sector and parallel supply chain, this affects the product distribution process.

"We usually encounter a situation whereby we have product AB; they have the same product in the supply chain now, these two products can have two different shelf life for example, maybe our shelf life here its shorter than the shelf life there. The moment the health facility gets product B from the supply chain, it means that my product A here will not move because they already have it through the supply chain, therefore, the shelf life for the product here will be affected". - participant 9 -

Access challenges
The participants also described barriers to access of antimicrobial agents which were grouped into scarcity of antibiotics and active pharmaceutical ingredients (API), forex scarcity and ineffective data management systems. Several participants attributed these access challenges for Malawi as the main drivers for poor access of antimicrobial product by the supply chain actors. API scarcity affects the availability of a product on the market and leads to low supply. This causes fluctuations in prices of the antimicrobial products and occasionally, unavailability of products locally.

"The API price doubled and basically the cost of the medicine went up, there were shortages and things like that, so yeah, you do see prices of these things increasing and decreasing on the regular basis." – Participant 1

Participants stated that forex is important because importation both of API for manufacturing and of antibiotics manufactured elsewhere requires foreign currency, the scarcity of it brings delays in product purchase. This consequently affects access to antimicrobial products by the retailers evidenced by one of the responses of the retail pharmacists.

"Yes, we do, very regularly, okay, because of forex availability in Malawi, that's a major issue and that sometimes it takes a long time to get goods into Malawi". –Participant 10

Another challenge that was raised by the participants was the ineffective data management processes experienced in the public and the parallel supply chain. This is because they use the pooled systems to consolidate the data from all public health facilities of the required antimicrobials. However, there have been times when the systems are fed volume requirements that are not representative of the actual need. The systems in different institutions that vet the processes are also different and this affect stock management in describing this challenge,

"In the supply chain what is critical is the data, the data must be smart. The data must be at least a true representation of what is on the ground. Whatever we have mentioned here, we will go into the system and it's either you will use the correct data or wrong data. When I say wrong data, I am looking at the requirements now, the quantification with wrong data, it means problems, it can either cause stock outs or overstocking of products which eventually lead to expiries". –participant 11

Prescription practices
This problem was described on two fronts, that there is a culture of self-prescription (self-medication) where patients walk into retail pharmacies to purchase antibiotics without an official prescription and this problem is consumer demand driven. This problem of self-prescription is frequently encountered in the private sector supply chain and is faced by pharmacists as they act as regulators at the end of the chain. Here they are faced with conflict of interests where they want to do the right thing by blocking a patient from buying antibiotics without prescription, but they also want to make sales.

"One of the challenges we face is balancing ethics and business. I may know that I'm not supposed to sell antibiotics without a prescription because eventually it will cause drug resistance, but the owner would want to make sales"- participant 12

A further challenge is "old" prescribing patterns where clinicians repeatedly prescribe the same antibiotics that they are very familiar with. This not only affects distribution patterns of antibiotics but also potentially risks development of AMR. The prescription patterns, representing "demand" upon the supply chain may contribute to determining the range of antimicrobials that are distributed in the supply chain. A study participant who owns a wholesale pharmacy observed the patterns of distribution of antibiotics and concluded that there is a system of prescribing due to familiarity with antibiotics.

"I do find in Malawi that there is a very- very bad, I would say it is bad, in my opinion it is bad, an outdated method of antibiotics prescribing, it is the old prescribing, they just stick to what they know". – participant 13

Unregulated trading
The barriers that were identified during discussion of unregulated trading of antimicrobial agents included informal supply routes, "leakages" during storage, illegal distributors, and

market pressures. Participants stated that another source of antimicrobials for distributors that are not legally mandated to sell antimicrobials is theft of the actual regulated ones in wholesales or public facilities. These unregulated traders create a competitive market for the regulated distributors.

"*I go to the wholesaler and then I order, and the prices are a bit higher, so because this is also a business, I need to put my mark up to make a little profit out of it so for those people that are selling as [informal] vendors, their prices are usually cheaper than us, so people would rather go to the [informal] vendors*". –participant 14

The participants, specifically from the regulatory institutions stated that there is trend of selling unregulated antimicrobial agents which are illegally imported into Malawi. This also forms a trail for informal distribution of antimicrobials.

"*There is smuggling that takes place in most of our porous border areas and not only using unchartered routes where the importation of these can happen but also through use of informal conveyances. Because these are actually commodities, perhaps that may not be imported in huge quantities you would find somebody can simply cross the border on a motor bike or cross the border on a bicycle*"- Participant 7

Discussion

This study was aimed at describing the supply chain processes for antimicrobial agents in Malawi. While our findings indicate that antimicrobial agents in Malawi are largely imported, with few exceptions for locally manufactured antibiotics, further research would be beneficial to conclusively establish the extent of local production versus importation. People access antimicrobial agents through public, private and parallel supply chains and informal channels such as local vendors and drug stores. These results align with those of a study aimed at exploring the impact of medicine supply chain on antimicrobial use where they described that medicines in Malawi are distributed through government, nongovernmental organization and private sector procurement agencies[12]. This structuring of the antimicrobial supply chain is helpful for resource-poor settings like Malawi where public sector health services struggle to keep pace with demand, several pathways for supply of antimicrobial proved alternatives for antibiotics access[23]. The government of Malawi is committed to ensuring supply of and access to essential medicines, however, there have been previous reports of significant stock outs[7,24–26].

Poor access to antimicrobial agents hinders timely treatment of infections, and in many circumstances narrows treatment options which may lead to development of AMR[1,12,27]. Having alternative pathways for access to antimicrobials is very important, however it creates the risk of incorrect usage of antimicrobial agents where there is inadequate regulation and/or diagnostic capacity. Our study highlights concern over a growing informal sector that creates an alternative pathway for accessing antimicrobial agents. The negative side to distribution of unregulated medicines will mean there is unnecessary supply of antimicrobials that may be created in the market system. This

may exacerbate the current trend of increasing AMR because consumer purchases are not regulated, and courses of antibiotics are dispensed based on what people can afford rather than what is necessary for successful treatment[18,28,29]. This route is also a route through which substandard and falsified medicines can be introduced to the system[30,31]. Unregulated trading therefore reflects a key deficiency in the current enforcement of the regulatory processes.

Our findings show that there are observed variations in demand and supply of antimicrobial agents which are attributed to seasonality of infections, adjunct treatment and peoples' common knowledge and experience of antibiotics. The clinicians also described their preference for prescribing broad-spectrum antibiotics particularly when there are no diagnostic tools and laboratory facilities. The findings of our study are consistent with a previous investigation into antibiotic usage in households in Blantyre, which reported a usage rate of 6.4%, particularly, broad-spectrum antibiotics were found to be the most frequently used[17]. The common practice for empirical prescription of broad-spectrum antibiotics in absence of diagnostic microbiology capacity are in line with previous reports from Malawi[32]. Empirical treatment with WHO "Access" antibiotics with narrower spectrum activity is perceived to have lower potential for AMR selection, but there is also a perception that these agents are less likely to work leading to greater usage of Watch and Reserve antibiotics[1,33]. Inadequate diagnostic tools and poor access to laboratory services therefore enhance empirical prescriptions of broad-spectrum antibiotic[34,35]. Of note, a point-of-care diagnostic device that can be used in primary health care to determine whether an infection requires antibiotics or not, is the "holy grail" of infectious disease diagnostics, however such a tool does not currently exist anywhere[36].

Our findings on challenges in the antimicrobial supply chain are consistent with those of an earlier study conducted in Malawi that identified human and financial resource limitations and a lack of stakeholder collaboration as the main barriers in the public procurement and supply of all essential medicines in Malawi[37]. The malaise in the regulation system as expressed in our study may imply inadequate resources to monitor both antimicrobial quality and the processes and actors involved in distribution of these antimicrobial agents. This may perpetuate distribution of poor-quality antimicrobials, bad antimicrobial distribution practices and in some cases illegal trading of antimicrobials. All these issues may consequently escalate the emergence of antimicrobial resistance to these antimicrobial agents[30,31].

In this study we did not have the capacity to engage with traders of antimicrobials from the informal sector, nor to explore illegal routes to market or interview vendors in the informal sector to establish where they source drugs. This meant we could not check the statements made by the other research participants. Further studies should explore the extent of the problem of illegal or informal distribution of antimicrobial agents and the roles these unregulated traders create a competitive market for the regulated distributors in Malawi.

Conclusion

The antimicrobial access processes highlighted in this study reflect a complex web of factors driving behaviors across the antibiotic market system. Antimicrobials are predominantly imported into Malawi are accessed through the formal private, public, and parallel supply chain and through the informal supply routes. The demand for the distribution of antimicrobial agents is influenced by seasonality, public knowledge about antimicrobials, and the range of infections they can treat. Furthermore, the study has established that inadequate enforcement of regulation, access challenges, unregulated trading and prescription practices are key barriers within Malawi's antimicrobial supply chain.

The regulatory environment, which has been designed primarily with the public supply chain in mind, does not reach the informal and even the formal private markets adequately. Leakages from the public supply chain into private markets further complicate the situation, disrupting the market's signals to procurement functions about demand. This has led to frequent but periodic shortages, often seasonally aggravated when certain diseases spike. Consumer awareness is low, and many medical professionals bow to pressures to prescribe or provide ill-suited antimicrobials.

This complex relationship between the three supply chains, public and private actors, is creating a dangerous cocktail of antimicrobial misuse which is fueling the AMR crisis. This points to serious public health risks, as unregulated antimicrobials, possibly of substandard quality, may become more accessible than those in the formal sector. Tackling these informal supply routes is essential for improving public health outcomes and reducing the spread of antimicrobial resistance. Increasing resources for strengthening regulatory processes would help improve the problem of informal supply of antimicrobial agents.

Ethics and consent

This study was approved on November 11, 2020, by the College of Medicine Research Ethics Committee (Protocol No. P.09/20/3137), the IRB of Kamuzu University of Health Sciences (formerly known as the University of Malawi, College of Medicine). We also sought permission to conduct this study from Blantyre City Council. Prior to each IDI, the participants were given an information sheet which comprised a summary of the study aims, risks, benefits, and the approach for confidentiality. All study participants could speak English, and they gave written informed consent in English as approved by the ethics committee. Data collection was done at the place the participant preferred and all of them opted to do the interviews at their workplace. The interview process was anonymized using participant IDs.

Data availability

Underlying data

The data includes sensitive information collected during in-depth interviews with key stakeholders, which are protected by ethical agreements and participant confidentiality. All data used in this study are not publicly available to protect the privacy and confidentiality of research participants. Data access can be requested from the corresponding author, and are subject to ethical approval and the signing of a Data Transfer Agreement which will be drafted in compliance with the Malawi Data Protection Act. The formal request should include a detailed research proposal and evidence of ethical approval from an IRB. The data associated with this study show a direct association of responses with specific institutions and individuals. Linking these responses to identifiable entities or individuals could have significant implications, including reputational risks, regulatory scrutiny, or unintended consequences for participants and their institutions.

Extended data

Zenodo: Supplementary files for a study: "The Supply Chain and Market Systems of Antimicrobial Agents in Malawi", https://doi.org/10.5281/zenodo.14672981[37]

This project contains the following extended data:

1. Background characteristics of study participants

-Includes a detailed description of the study participants which made our sampling framework.

2. Interview guide for distributors (public and private sector)

-A structured guide with open ended questions and probes used to conduct interviews with distributors across both public and private sectors.

3. Interview guide for regulators and the ministry of health

-An interview guide used to facilitate interviews with regulatory bodies and representatives from the Ministry of Health

The extended data are published on an open access repository and accessible on Zenodo.

Data are available under the terms of the Creative Commons Attribution 4.0 International license (CC-BY 4.0).

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Open Peer Review

Current Peer Review Status: ?

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Version 1

Reviewer Report 01 April 2025

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? **Stephen Hinchliffe**

Geography University of Exeter, Exeter, UK

A useful paper that opens up questions around the structural elements of antibiotic use in Blantyre, Malawi. By implication, this is important information and knowledge for many other LMIC settings and for future action plans. The paper demonstrates, through discussion with key actors in the purchasing, distribution and prescribing of antimicrobial pharmaceuticals, the significance of supply networks, interruptions to supply, ability to source, global supply chains and informal / illegal provision.

The paper is based on a series of interviews with key actors, who presumably can, by virtue of their position and experience, speak to and inform us about a wide body of knowledge. The approach is qualitative, allowing for depth as well as this breadth of insight to emerge from the research. Like all qualitative work, the paper should be judged not on the number of informants, but on the degree to which their depth of experience has been communicated and on the quality of the analysis of the material generated.

To this end, there are two areas of work that would improve the paper and its impact:

1. The paper is clear in terms of methodological steps, but there is very little here on analysis. Thematic analysis is mentioned, but the authors really need to say more about what this is and how it works. Braun and Clarke's work would be useful here (as they initiated the concept of thematic analysis). At the moment without this extension and considered use of the term, the paper reads as descriptive (this is what was said) rather than analytical (this is how and why it was said). A useful review of some of the issues in utilising thematic analysis is here https://www.sciencedirect.com/science/article/pii/S0167587723002258

A useful example here occurs when one of the participants starts to say that prescribing in Malawi is very very bad and outdated. What is going on here? - is this one moment when the NAP and its behaviourist assumptions inform the normative judgement of practices? How is this judgement made and by whom? Analysis needs to go a little further than description of an utterance.

2. There is now a wide body of social science work on AM use, stewardship and practice - it would be worth signalling how this work contributes to that field. Most importantly, the move away from awareness and behaviour, to markets, audits, regulation and imbalances of power are key to moving this issue on. It would be useful to mark how this paper adds to that body of work.

Some final small remarks:

1. 30 minutes is rather short in qualitative interview work - this may be a practical issue (time constraints for participants) but suggests that in some interviews, respondents were less forthcoming, or the structure of the research was too constrained. This might be worthy of comment. Likewise, more detail on the workshop might be helpful to other researchers.

2. In qualitative work, extracts from interviews / workshops etc are normally given greater context and where possible, a more useful identifier. So, for example, if possible Participant 1 might be re-named 'public servant/ hospital manager' etc - the point of qualitative work is interpretive depth, a lot of which is communicated through the context of the research. Good context/ identifiers also allow the reader to build up a narrative and characters in the plot that is being built.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Partly

Are sufficient details of methods and analysis provided to allow replication by others?
No

If applicable, is the statistical analysis and its interpretation appropriate?
Not applicable

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Social Science, qualitative methods, social theory, health and disease practices, One Health

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.