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CHALLENGES REGARDING THE PROVISION OF ANTIBIOTICS VIA THE INFORMAL SECTOR ACROSS LOW- AND MIDDLE-INCOME COUNTRIES AND POTENTIAL WAYS FORWARD

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Antimicrobial resistance (AMR) is a public health threat across the world in view of its impact on morbidity, mortality and costs[1-5]. AMR rates are highest in low- and middle-income countries (LMICs), including among children, driven by high levels of inappropriate dispensing and prescribing of antibiotics[6-11]. By 2050 unless addressed, it is envisaged that there will be 1·91 million deaths attributable to AMR, and 8·22 million deaths associated with AMR, with the greatest burden among African and Asian countries[12,13]. The estimate for sub-Saharan Africa is 4.1 million AMR-related deaths annually by 2050 unless urgent activities are undertaken[13].

Primary care is a critical sector to address among LMICs to reduce AMR as this sector accounts for upto 95% of total antibiotic consumption in humans[14]. Consequently, this is a key target area for initiatives to help improve future antibiotic use as there continues to be high rates of inappropriate dispensing of antibiotics without a prescription as well as high levels of poor antibiotic prescribing[9,15-18]. This includes appreciable utilisation of Watch antibiotics that have a greater potential for resistance development[6,10,19-23].

High levels of inappropriate prescribing of antibiotics in recent years among LMICs have been aided by continued issues with prescribers' limited knowledge concerning antibiotics, AMR and antimicrobial stewardship (AMS), alongside ongoing diagnostic uncertainty[9,24-26]. There also continues to be high levels of inappropriate dispensing of antibiotics without a prescription among LMICs due to limited changes to existing barriers and challenges[15,24].

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Barriers and challenges include long travel times, costs and waiting times to see healthcare professionals (HCPs) in primary healthcare clinics (PHCs), high co-payments for the visits and medicines, PHCs often out of stock of key antibiotics necessitating their purchasing from community pharmacies anyway, previous experiences with antibiotics including successfully treating self-limiting conditions, current infectious disease seen as minor, convenience of community pharmacies, and community pharmacy personnel may be the only HCPs available especially in more rural areas of LMICs[15,26-31]. Stock control and funding of antibiotics among PHCs are further challenged if there are sudden increases in their prices occur as recently seen in Nigeria[32-34], which resulted in more patients necessarily purchasing their medicines from community pharmacies and other sources to reduce costs.

High levels of inappropriate prescribing of antibiotics in LMICs are also driven by considerable patient pressures for HCPs to issue antibiotics even for self-limiting infections, with a similar experience in community pharmacies[24]. This pressure is exacerbated by often limited knowledge among patients regarding antibiotics, including whether they are effective or not for self-limiting viral infections, AMR and antimicrobial stewardship[24,26,35-37].

There have also been issues and challenges with the extent of substandard and falsified antibiotics among LMICs, which further exacerbates AMR[38-41], with the availability of these medicines likely to be greater in the informal versus formal sectors among LMICs[34,35,41]. Definitions of the informal sector are contained in Supplementary Table S1, with a lack of formal training and qualifications a common theme among informal providers (IPs) alongside cash payments for services provided including medicines[42-45].

Of equal concern is that the informal sector is a major provider of services and medicines in LMICs, including antibiotics[43,44,46-49], with antibiotics generally treated as another commodity further driving up AMR[30]. Khare et al. (2019) documented that 74% of all prescriptions issued by IPs in rural India contained antibiotics[50], and in Bangladesh 63% of antibiotic prescriptions issues in primary care are from IPs[51]. In their study, Tesema et al. (2025) documented that among children under 5 years of age with a cough or fever in sub-Saharan Africa taking antibiotics, on average 67.19% were from unqualified sources[52]. This ranged from 40.34% in Chad to 92.67% in Sao Tome[52]. The odds of being issued and taking antibiotics were also 1.23 times higher in rural compared with urban areas[52].Other researchers have estimated that 44% of antibiotics issued in primary care among LMICs come from informal sources[30,53]. In their study, Ingelbeen et al. (2022) found that antibiotic use was considerably higher in private clinics including IPs versus public clinics[48]. However, this is not always the case with Wildbret et al. (2023) documenting greater antibiotic use in the formal sector (56.2% of paediatric prescriptions) versus the informal sector (29.3%)[54]. In any event, a key issue among IPs is that the most affordable antibiotics have included ciprofloxacin and azithromycin, both Watch antibiotics[55].

These high rates of antibiotic use among IPs are enhanced by the fact that IPs can account for up to 90% of situations when patientsfirst contact providers whether informal or otherwise[45]. Das et al. (2022) in their study ascertained that 68% of healthcare providers in primary care in India were IPs[56,57]. Others have documented that IPs can account for up to 55% of all primary care providers in India, increasing up to 77% in Uganda, and close to 96% in rural Bangladesh[42,46]. This makes IPs an important stakeholder group among LMICs where these are present to reduce inappropriate antibiotic use in primary care.

Barriers and challenges resulting in the high use of IPs among LMICs include a lack of available trained HCPs especially in rural areas and urban slums, issues of affordability as antibiotics and other aspects of care can be cheaper in the informal sector with no co-payments for HCPs, and convenience. In addition, IPs can often provide a greater range of

antibiotics compared with PHCs[30,31,44,56,58-62]. Alongside this, IPs may be more empathetic towards patients than HCPs[63], can take delayed payments, and, as mentioned, are typically the first point of contact for patients in rural and undeserved areas[49,64].

Typically, there is inadequate knowledge of antibiotics, AMS and AMR among IPs causing considerable concern (Supplementary Table S2). Encouragingly, we are seeing increasing formalisation of this sector among some LMICs. In Nigeria, Patent and ProprietaryMedicine Vendors (PPMVs) are increasingly being recognised as important providers of healthcare in the country, and alongside retail pharmacies do obtain their licenses from the PharmacistsCouncil of Nigeria to practice[44,60]. In addition, the Pharmacist Council does conduct educational programs for existing PPMVs alongside inspections as well as the publishing of the Approved Patent Medicine List to guide prescribing[60]. These activities have resulted in PPMVs and the public being encouraged to reportitinerant drug sellers as well as unlicensed and non-compliant PPMVs to theregulatory bodies for potential fines and closure to improve future medicine use[44,60]. In Tanzania, the ADDO (accredited drugs dispensing outlets) program was a donor-initiated project launched in 2003 to improveaccess to, and use of, medicines in rural areas where there are currently a limited number of HCPs[65]. ADDOs can dispense some antibiotics with a prescription including amoxicillin, trimethoprim/sulfamethoxazole suspension, doxycycline and phenoxymethylpenicillin[65]. However, there are ongoing concerns with high and inappropriate levels of theselling of antibiotics without a prescription among ADDOs[65-67]. Over the counter medicine sellers in Ghana can also dispense cotrimoxazole without a prescription, with all other antibiotics requiring a prescription[68]. However, in practice, they also sell many antibiotics despite no prescription[69,70].

In South Africa, we know there are a number of spaza shops operating in Townships without formal licenses[71]. They sell everyday goods to millions of South Africans where there are issues of affordability and limited access to formal retail outlets[71]. However, there are ongoing moves towards their formalisation in view of ongoing concerns, and it is debatable whether they would be able to dispense antibiotics without a prescription as these medicines would need to come from wholesalers, with such activities illegal[71,72].

There are a number of activities that can be undertaken address current issues and challenges with the informal sector, including addressing high levels of inappropriate use of antibiotics. These build on existing suggestions to reduce the extent of substandard and falsified medicines among LMICs and include[34,35,41]. They include firstly addressing health coverage concerns especially in rural areas in LMICs.

- Potential ways forward include increasingthe number of community pharmacist and their activities to be able to treat and dispense key antimicrobials, including antibiotics, for certain conditions complementing ongoing activities across countries that have enhanced the activities of community pharmacists when treating patients with infectious diseases[16,73-75]. This will make community pharmacy more attractive especially in rural areas with a greater range of provided services, and build on the increasing recognition of their role in healthcare delivery following COVID 19[76-80]. This though may take time depending on existing pharmacist training programs within a country and their emphasis
- In the meantime, increase the number of trained community pharmacies working in health care, including those working in the public sector, dispensing medicines and providing advice and guidance to patients especially where there is currently unemployment among pharmacists as seen for instance in South Africa[81,82]. This is critical to improve the utilisation of antibiotics in the community in the future
- Alongside this, encourage task shifting where pertinent especially in the short versus medium or long term to redistribute certain activities to the informal sector alongside

increased training for IPs[50].This builds on the experience in Tanzania with an increase in the number of ADDOs, training programmes for IPs in India, and the development of PPMVs in Nigeria[42,50,60]. However, linking IPs to theformal healthcare system will requireclearly defined roles and responsibilities including for instance among Government personnel and PPMV associations in Nigeria[44,83]

Secondly improve the performance of community pharmacy personnel as well as IP personnel. This will be achieved by:

- Universities ensuring that trainee community pharmacists leave universities fully knowledgeable with the WHO AWaRe antibiotic guidance and system for classifying antibiotics to appreciably improve future antibiotic utilisation in LMICs given current concerns[24,35]
- Alongside this, Universities need to work closely with Pharmacy organizations across LMICs to encourage continual professional development and associated activities among practising community pharmacists and pharmacist assistants, as well as among IPs where pertinent, surrounding the WHO AWaRe antibiotic system and guidance [24,35]. This will reduce their reliance on pharmaceutical companies for advice and training on antibiotics[43,45,84]
- Undertake research regarding the influence of training of IPs to improve future antibiotic use[49,85].Adamu et al. (2020) found that PPMVs in Nigeria who had not received any training on antibiotic use and AMR were twice as likely to sell antibiotics to patients compared with those who had received training[86,87]. In view of the variable findings, Universities needto work more closely with pertinent organisations to review previous findings as a basis for improved targeted educational activities among IPs where pertinent, certainly in the short term, given theircurrent importance among across a range of LMICs in the management of infectious diseases.

Thirdly, reduce the prices of antibiotics among LMICs to improve their affordability in the public sector. Activities include:

- Prices of antibiotics can be appreciably reduced through initiatives such as encouraging international non-proprietary name (INN) prescribing[88,89], which has appreciably helped in other countries[88]. This is especially important among LMICs where there are currently a considerablenumber of branded generic antibiotics available for critical antibiotics, with each manufacturer lobbying governments to increase their prices whilst concurrently encouraging greater prescribing and dispensing of their branded genericsincluding among IPs for their sustainability[88,90-93].
- Reducing antibiotic prices among community pharmacies is critical in LMICs where available financesare a key issue to reduce the need and reliance on IPs, e.g., considerable switching to IPs occurred in Zimbabwe following their changing economic circumstances[16]

Fourthly, educating the public regarding antibiotics, AMR and antimicrobial stewardship through:

- There are currently major concerns regarding patients' knowledge of antibiotics, AMS and AMR across LMICs – resulting in considerable pressures on providers, including IPs, to prescribe and dispense antibiotics even for self-limiting infections such as coughs and colds (Supplementary Table 2)[24,35-37,43]

- Consequently, there is an urgent need for health authorities and others to educate patients regarding the appropriate use of antibiotics to reduce AMR. This can be via multiple channels including social media[24,35]
- Prescribers and dispensers can also play their role through educating patients and encouraging alternative solutions to antibiotics, which includes symptomatic relief initially for viral infections, building on the WHO AWaRE guidance[24,43,94-96]
- Educational campaigns must acknowledge the importance of language when HCPs and others talk with patients and about the optimal use of antibiotics to prevent AMR and its implications for them and their families; consequently, educational campaigns need to be targeted and specific including in local languages where pertinent [24,37,97]
- There is also a need to educate patients regarding the effectiveness of generics, i.e. their quality, and have been tested and approved by the Regulatory Authorities, given potential concerns with unbranded generics as a result of the extent of marketing by branded genericsby companies across LMICs (Supplementary Table 2)[91-93,98]. This has worked well across countries leading to high rates of voluntary INN prescribing and dispensing[88]

In conclusion, Governments in LMICs can undertake a range of actions to reduce their reliance on IPs through increasing the number of community pharmacists and their potential activities. In the meantime, upskill IPs to improve future antibiotic use. This though needs careful planning and subsequent monitoring to reverse increasing rates of AMR, and the implication, in line with United Nations' recent goals for AMR[99].

CONFLICT OF INTEREST

The authors declare they have no relevant conflicts of interest

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Supplementary Tables

Table S1 – Definitions of the Informal Sector

Study, author and year	Definition
Sudhinaraset et al, 2013[1]	• IPs have typically not received any formal training, and are generally not recognized by formal institutions - typically outside of formal regulations and registration within a country • IPs typically collect payment directly from patients for any medicines dispensed – usually undocumented and in cash • If professional affiliations exist – usually these are centred on business activities with minimal self-regulation
Liow et al., 2016[2]	Seen as unlicensed outlets
Khare et al, 2019[3]	• Have not received a formal degree in healthcare, including medicine, from any institution and are not registered as HCPs with any governing body • Some may have received some informal training; however, they are not certified by any formal institute and include unqualified doctors, spiritual healers and unqualified drug vendors
Nair et al., 2019[4]	IPs do not hold formal degrees and are untrained in allopathic medicine
Suy et al., 2019[5]	IPs have no qualifications or licensing recognised by local authorities
Matin et al. 2020[6]	• Unlicensed private pharmacies/ drug stores • Typically run by individuals without any formal training and may be working as insufficiently trained village doctors • Most frequently dispensed antibiotics from informal medicine providers include azithromycin, cefixime, ceftriaxone, ciprofloxacin and flucloxacillin
Nahar et al., 2020[7]	Without any health-related training who sell medicines including antibiotics, assist shop keepers or provide prescriptions (verbal or written) not endorsed by HCPs
Schäfermann et al., 2020[8]	Informal vendors do not include any Government Health or Church Health facilities, and are not Community Pharmacies
Gautham et al., 2021[9]	IPs refer to a wider range of actors, which can include unregistered pharmacies, itinerant drug sellers and traditional faith healers
Gautham et al., 2022[10]	• IPs typically function out of small clinics and shops or seen as itinerant and mobile • IPs typically charge a fee for their services, which includes medicines, e.g. antibiotics, and these are typically without any prescription
Das et al., 2022[11]	Informal providers have no formal healthcare training
Kumah 2022[12]	• Not recognized by a country's regulatory and legal framework, i.e. typically operate outside of regulations • Typically have little or no officially recognized training and receive undocumented payments • They may be part of professional associations which do not have certification or any regulatory authority and include drug sellers, untrained allopathic providers, traditional and faith healers and homeopaths
Rousham et al., 2023[13]	Typically operate without a license, and staff generally have minimal training regarding medicines
Wildbret et al., 2023[14]	Street vendor, friend/relative/neighbour or chemical shop
Das et al., 2024[15]	• Typically practice allopathic and non-allopathic medicine with

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Study, author and year	Definition
	minimal or no formal training • They include medicine sellers, traditional and faith healers, untrained allopathic providers and traditional medicine practitioners with a lack recognition within a country's regulatory and legal framework • Payment is typically received directly from patients and without documentation
Edessa et al., 2024[16]	• Are untrained personnel - but some work with the experience they gained from their families • Such sellers focus more on profit and do not generally follow drug dispensing regulations, they can include kiosks • Antibiotic are a key area as they can account for up to 60% of the medicines dispensed
Odii et al., 2024[17]	• Include a wide and diverse group of practitioners who provide a range of services for which they have no formal education or training • This includes patent medicine vendors, herbalists, traditional healers, and informal allopathic providers
Tandan et al., 2024[18]	• IPs encompasses a broad spectrum of groups including drug sellers, village doctors, medicine vendors, and traditional healers • Common attributes to define IPs include the absence of formal qualifications, operating outside the formal healthcare system, and lacking registration or affiliation with any regulatory body
Tesema et al 2025[19]	• Unqualified/ informal sources of antibiotics include churches, drug sellers, shops, traditional practitioners, and supermarkets

NB: HCPs = Healthcare Professionals; IPs = Informal providers

Table S2 – Extent of knowledge, attitudes practice concerning antibiotics, AMR and AMS among informal providers and sellers

Study, author and year	Definition
Khare et al, 2019[3]	• 74% of prescriptions from IPs included antibiotics, with antibiotics prescribed either singly or in combination with up to 5 antibiotics (mean of 1.4) • Fluoroquinolones were the most prescribed antibiotic (31%), followed by penicillin and third-generation cephalosporins (20%) • 27% of prescriptions were for a fever, out of which 87% were prescribed antibiotics, with 26% for upper respiratory tract infections of which 81% were prescribed antibiotics
Nair et al., 2019[4]	• Over 80% of IPs dispensed antibiotics some or all of the time to patients with colds or sore throats • IPs frequently disbursed 3-day courses of antibiotics rather than complete courses, and had little idea regarding gentamicin and its links to potential birth defects even though IPs frequently provided gentamicin • Many IPs relied on pharmaceutical companies for information regarding antibiotics
Suy et al., 2019[5]	• High proportion of use of antibiotics for patients with a cough as well as on patient demand
Matin et al., 2020[6]	• Antibiotics are sold based on health concerns/ visible symptoms, specific requests for an antibiotic and perceived

Study, author and year	Definition
	patient needs • IPs are worried that if they do not provide antibiotics according to the customer demand, they will leave go to another seller adversely affect their business • As a result, they often provide antibiotics for fevers, colds, coughs and acute watery diarrhoea, and regularly sell incomplete courses as patients often have limited financial capacity • A concern is that information regarding antibiotics is primarily from the pharmaceutical industry
Nahar et al., 2020[7]	• Antibiotics work against all kinds of diseases, ranging from viral to bacterial infections • Most unqualified providers had little clear idea about the different generations of antibiotics and the implications - To them, the more expensive the antibiotic, was the more powerful it was, with antibiotics they considered less effective referred to as half-antibiotics
Gautham et al., 2021[9]	• IPs typically believe antibiotics can cure most illnesses, and are seen as indispensable for primary care, with only 30% of IPs knowing that antibiotics cannot cure viral infections • IPs also typically believed antibiotics are a therapeutic necessity, and without dispensing them patients may not come back, with IPs representing a significant market for pharmaceutical companies (antibiotics are the most utilised medicines in primary care) • The choice and dosage of antibiotics is largely based on IPs' experiences of the effectiveness of different antibiotics for specific symptoms
Nizame et al., 2021[20]	Drug shop operators had no clear knowledge of the different generations of antibiotics available and for what diseases antibiotics are effective, both contributing to inappropriate antibiotic use
Tandan et al., 2024[18]	Inadequate knowledge and training, financial incentives, the influence of pharmaceutical representatives are significant contributors to inappropriate antibiotic use and AMR

NB: AMR = Antimicrobial Resistance; IPs = Informal providers, URTIs = Upper respiratory tract infections

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