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Current access, availability and use of antibiotics in primary care among key low- and middle-income countries and the policy implications

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REVIEW

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Current access, availability and use of antibiotics in primary care among key low- and middle-income countries and the policy implications

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ABSTRACT

Introduction: Antimicrobial resistance (AMR) poses a significant threat, particularly in low- and middle-income countries (LMICs), exacerbated by inappropriate antibiotic use, access to quality antibiotics and weak antimicrobial stewardship (AMS). There is a need to review current evidence on antibiotic use, access, and AMR, in primary care across key countries.

Areas covered: This narrative review analyzes publications from 2018 to 2024 regarding access, availability, and use of appropriate antibiotics.

Expert opinion: There were very few studies focussing on a lack of access to antibiotics in primary care. However, there was considerable evidence of high rates of inappropriate antibiotic use, including Watch antibiotics, typically for minor infections, across studied countries exacerbated by patient demand. The high costs of antibiotics in a number of LMICs impact on their use, resulting in short courses and sharing of antibiotics. This can contribute to AMR alongside the use of substandard and falsified antibiotics. Overall, limited implementation of national action plans, insufficient resources, and knowledge gaps affects sustainable development goals to provide routine access to safe, effective, and appropriate antibiotics.

Conclusions: There is a clear need to focus health policy on the optimal use of essential AWaRe antibiotics in primary care settings to reduce AMR in LMICs.

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Antibiotics; antimicrobial resistance; antimicrobial stewardship programmes; AWaRe classification; AWaRe guidance; dispensers; falsified medicines; health policy; patients; prescribers; quality indicators; shortages; utilization patterns

1. Introduction

Rising antimicrobial resistance (AMR) globally, especially among low- and middle-income countries (LMICs), continues to be a concern, increasing morbidity, mortality, and costs [1–5]. Whilst AMR is seen across all countries, AMR rates are disproportionately higher among LMICs [6–10]. Currently, LMICs account for an estimated 80% of approximately 10 million deaths annually attributable to AMR [11,12]. This situation is likely to worsen with the increasing use of antibiotics from the World Health Organization's (WHO) Watch list among LMICs, with resultant implications for increasing rates of multi-drug resistant bacteria [13–15].

Key areas of concern among LMICs include continued high levels of inappropriate prescribing of antibiotics, as well as their dispensing without a prescription, including among informal sellers, often for minor or self-limiting infections such as upper respiratory tract infections (URTIs) [9,10,13,16–22]. This is particularly important in primary care, including hospital outpatients, as this sector accounts for approximately 90% of the total antibiotic use in humans in LMICs [23], some of which will be substandard and falsified [24–28]. There are also continuing challenges with supply chains and shortages of medicines across LMICs, including essential antibiotics, which can impact on their routine availability and subsequently AMR [29–33]. Shortages are defined by the WHO as 'The supply of [approved and marketed] medicines, health products and vaccines identified as essential by the health system is considered to be insufficient to meet public health and patient needs' [33,34]. They can be broken down into short-term shortages, defined as the inability of a market authorization holder (MAH) to adequately supply a requested medicine, e.g. antibiotics, for a period of 3 months or less, or longer-term shortages, i.e. lasting longer than 3 months [35]. Challenges with forecasting, especially among public primary healthcare (PHC) facilities, can aggravate the situation among LMICs [35,36]. However, there are ongoing efforts to try and address challenges with shortages, which include improving stock control and forecasting systems in LMICs as well as possibly stockpiling antibiotics, building buffer stocks, and introducing novel payment systems [33,37–39]. Alongside this, enhancing manufacturing capabilities among LMICs as well as potentially increasing import fees [39–41]. Standardizing the dosing of antibiotics among LMICs, which can now be based on AWaRe guidance, as well as prioritizing the registration of essential antibiotics, would also enable local manufacturers to streamline their production processes and save costs [42–45].

Substandard medicines, including antibiotics, are also a concern across LMICs. Substandard medicines are defined as those that fail to meet agreed quality standards or specifications, or both, with falsified medicines also including those that fraudulently misrepresent their identity [46]. Both types of antimicrobials are associated with considerable morbidity, mortality, and economic consequences in LMICs in addition to adding to AMR [24,47–51]. Levels of substandard and falsified antibiotics have previously been estimated at 17.4% of the global supply of antibiotics, greatest in LMICs including among African countries [24,26–28,49,52–55]. Such rates may grow with substandard and falsified medicines becoming increasingly available online, enhanced by currently an unregulated e-pharmacy market across LMICs [52,56,57].

In their recent analysis, Asrade Mekonnen et al. (2024) estimated that the prevalence of substandard and falsified medicines in Africa was lower at 22.6%, with the average prevalence of unregistered medicines at 34.6%, with antibiotics (44.6%) accounting for most of these [52]. This was similar to rates of 28.5% of antimalarial medicines failing to comply with current standards in the 2011 WHO report among six African countries [58]. Tegegne et al. (2024) also documented similar rates [59]. However, this is not always the case among African countries [60–62].

Addressing substandard and falsified medicines, alongside improved access to quality medicines including antibiotics, is

Article highlights

- There are rising rates of antimicrobial resistance (AMR) across low- and middle-income countries (LMICs) exacerbated by high rates of inappropriate prescribing and dispensing of antibiotics alongside the availability of substandard and falsified antibiotics. Issues of affordability also impact on achieving SDG 3.8, i.e. on arrival at the point of care, patients should have access to safe and effective antibiotics meeting agreed quality standards in an affordable formulation.
- There are ongoing steps, especially in LMICs such as China, as well as across Africa, to limit the availability of substandard and falsified medicines; however, more actions are needed by the authorities across countries, including potential fines and joint activities among Regulatory authorities, to limit their availability. Appreciable improvements in supply chain management, including improved forecasting and electronic systems among dispensers, are urgently need to track current antibiotic usage patterns to limit possible shortages of essential antibiotics in primary care and improve their use.
- There were clear concerns across LMICs regarding the overuse of antibiotics, including those from the Watch list, for minor infections such as respiratory tract infections and mild diarrhoea. Antibiotic overuse is not helped by variable knowledge of all key stakeholders regarding antibiotics, AMR and antimicrobial stewardship (AMS), coupled with pressure from patients on both prescribers and dispensers expecting antibiotics for self-limiting indications.
- Often practice regarding the effectiveness and use of antibiotics differed appreciably from stated knowledge. Targeted comprehensive educational campaigns, especially based on the recommendations in the WHO AWaRe book, among all key stakeholder groups are needed to address the situation, helping towards attaining United Nations General Assembly goals of 70% use of Access antibiotics across sectors to reduce AMR. As a result, University curricula need to be updated for all student healthcare professionals going forward regarding the WHO AWaRe guidance and ASPs, as well as post-qualification through professional development activities.
- Practical suggestions going forward for improving education of all providers and receivers of antibiotics were noted and will be expanded upon in future studies.

important not only to help address rising AMR rates in LMICs but also as part of ongoing moves to attain universal healthcare and improve patient care [49,53,63]. Ongoing initiatives to reduce the prevalence of substandard and falsified medicines across LMICs include those by the WHO such as the 'Lomé Initiative' as well as countries pushing for an African Medicines Agency [59,64–68]. The later builds on the ongoing efforts by the East African community to harmonize the regulation and registration of medicines [69]. We are also seeing LMICs such as China make considerable progress in recent years to improve the quality of locally produced multiple-sourced medicines, including antibiotics, with appreciable penalties when counterfeit and substandard medicines are found [70–72].

Pharmacists' vigilance can also help with issues of falsified medicines [73]. Alongside this, improved patient access to quality antibiotics, especially among African countries, can reduce the market for falsified medicines [74]. However, there are currently concerns with the necessary financial and human resources, as well as infrastructures and stakeholder coordination, needed to fully address detection and prevention of substandard and falsified medicines among LMICs, alongside an urgent requirement to reduce the attractiveness of the market [65,74–76].

There are also continuing issues whether community pharmacists in LMICs have sufficient knowledge and skills to identify substandard and falsified medicines, as well as concerns that in times of shortages, community pharmacists may be tempted for financial reasons to dispense falsified medicines [77,78].

Overall, appropriate access to essential antibiotics is a clear challenge among a number of LMICs, potentially adding to mortality and costs [35,79,80]. The lack of access to key essential antibiotics also challenges the 2024 United Nation General Assembly (UN GA) target that 70% of all human use should be of Access antibiotics [36,81]. Access antibiotics as defined in the World Health Organization's (WHO) AWaRe (Access, Watch, and Reserve) classification [15,82]. Access to, and use of, appropriate antibiotics can be exacerbated by issues of affordability among patients in African and Asian countries, especially where there are high patient co-payment levels. Issues of affordability are demonstrated by the dispensing of only a few tablets of antibiotics where available funds are an issue, as well as using leftover antibiotics, including stored antibiotics and those from family members and friends, before visiting prescribers or dispensers with their associated costs [83–85]. These combined issues challenge LMICs to achieve Sustainable Development Goal (SDG) 3, particularly SDG 3.8, i.e. on arrival at the point of care, patients should have access to safe and effective antibiotics meeting agreed quality standards in an affordable formulation [33,35,86–89]. In addition, that any subsequent prescribing or dispensing of antibiotics is appropriate for the presenting infectious disease. This approach is a key component of countries achieving Universal Health Coverage as part of the UNGA AMR goals, including improving 'access to Access' antibiotics [36,81].

Critical issues to address among prescribers, alongside issues of access to essential antibiotics of an agreed standard, include excessive prescribing of antibiotics for self-limiting conditions such as coughs, colds, undifferentiated febrile fever, and other upper respiratory tract infections (URTIs) [18,21,90–92]. Inappropriate antibiotic prescribing practices among LMICs may well be influenced by pressure from patients, with their expectations for antibiotics to be prescribed for viral infections including URTIs as well as for acute diarrhea [90,93–95], enhanced by concerns with prescribers' limited knowledge of antibiotics and AMR [18,21,96–101]. Inappropriate antibiotic prescribing, including the overuse of broad-spectrum antibiotics, may also be exacerbated by only a limited number of microbiology laboratories being available among LMICs to fully understand local AMR patterns alongside a lack of routine monitoring of antibiotic use in practice [12,102–108].

There is also currently considerable inappropriate self-purchasing of antibiotics without a prescription among African and Asian countries adding to AMR [16,17,19]. Key factors behind self-purchasing include concerns with limited knowledge of antibiotics among dispensers and patients, lack of communication skills among dispensers, long waiting times to see healthcare professionals (HCPs) in primary care clinics, high patient co-payments, as well as often shortages of antibiotics in public clinics as a result of forecasting, lead time and resource issues [16,19,109,110]. Coupled with this, the convenience and

availability of community pharmacists and drug sellers, especially in rural areas in LMICs [16,17,19,111–114]. Having said this, community pharmacists can play a key public health role with improving antibiotic use in the community, building on their role during the recent COVID-19 pandemic, exemplified by some countries now allowing pharmacists to dispense certain antibiotics without a prescription [19,115–121]. Such activities are endorsed by pharmacists' growing involvement in Antimicrobial Stewardship Programmes (ASPs) in LMICs to improve future antibiotic use [19,120–123].

Encouragingly, the number of ASPs across all sectors in LMICs has been growing in recent years to improve future antibiotic use despite earlier concerns with available resources and personnel [6,97,105,124–134]. ASPs are also essential to help mitigate against shortages [135]. Challenges with ASPs still include issues with the dosing of antibiotics in practice as well as collecting antibiotic utilization data in real time in both primary care clinics and drug outlets [136,137]. Current Drug Laws may also need addressing in some LMICs if this does not include pertinent Access antibiotics to help with ASPs and achieve UNGA goals for AMR [81,138].

As a result of concerns with rising AMR rates and the consequences particularly across LMICs, there have been a number of regional and global initiatives in recent years to try and address this [5,139–141]. Global initiatives to reduce AMR include the WHO's Global Action Plan (GAP), as well as increased global surveillance of AMR, alongside comments, suggestions, and examples from the OECD and the World Bank [106,139,140,142–144]. As part of the WHO's initiatives with the EML, antibiotics were classified into their AWaRe groups, emphasizing reduced use of Watch and Reserve antibiotics where clinically appropriate due to their greater potential for selection of AMR [13,15,145]. In 2022, the WHO AWaRe antibiotic book was launched, providing guidance on the optimal use of antibiotics among 35 infections seen across care settings [44,45]. However, there are currently major challenges across LMICs with implementing NAPs due to issues and challenges with available personnel and resources [146–154].

Similarly, current challenges exist with national and local implementation of the guidance included in the WHO AWaRe book given the rising use of Watch antibiotics across LMICs [13,155–157]. This also needs urgent addressing to attain the 70% target for the use of Access antibiotics across care settings recently agreed in the UNGA for AMR in order to achieve their ambitious goals for reducing AMR [81]. There are though issues with routine access, availability, and affordability to essential antibiotics, especially those from the Access list across a number of LMICs, exacerbated in some situations by greater availability and profit from dispensing Watch antibiotics as well pressures on prescribers and dispensers to promote them [29–32,92,112,158–163].

Consequently, in view of rising AMR rates across LMICs, coupled with concerns with the development and equitable availability of antibiotics, especially among LMICs [164], there is a need to ascertain the current situation with respect to antibiotic patterns of use, and their drivers, as well as key issues surrounding access, availability and affordability of antibiotics, including substandard and falsified antibiotics, across LMICs. This includes the role of patients and parents exacerbating inappropriate prescribing and dispensing of antibiotics, as well as ASPs that have addressed the situation, to provide future direction [19,94,165–168]. Alongside this, the current situation regarding shortages of antibiotics in primary care among LMICs. This is because creating an antimicrobial market that ensures adequate access and affordability to essential antibiotics in primary care, alongside active stewardship, is key to fighting AMR [38]. This importance is reflected in the suggested activities of SECURE to improve the access, availability, and use of antibiotics in LMICs to reduce AMR [169]. Baraldi et al. (2024) recently described the economic and clinical consequences of four different types of antibiotic shortages and availability, i.e. short-term shortages, long-term shortages, de-registration of essential antibiotics, as well as lack of registration of essential antibiotics [35], and we wanted to build on this. In view of this, the aim of this review was to build on recent papers and publications in these areas [30,32,35,49,160,170,171], with the combined findings informing future practical activities for LMICs to help achieve SDG 3.8 for antibiotics.

2. Body of the paper

2.1. Materials and methods

2.1.1. Study design

A narrative review approach was undertaken for this study with the anticipation that this would provide a broader scope than a systematic review. Information contained within identified papers may be part of a wider paper, whose insight and findings may have been missed when undertaking a formal systematic review. This could include, for instance, knowledge regarding the extent of dispensing of antibiotics without a prescription contained within studies assessing community pharmacists' attitudes toward antibiotics, AMR and ASPs; alternatively, data on the availability of antibiotics in PHCs contained within a study principally assessing prescribing practices [92,114,172,173].

LMICs were chosen for this narrative review as AMR rates are disproportionately higher among these countries as opposed to high-income countries [6–10], with, as mentioned, LMICs currently accounting for an estimated 80% of approximately 10 million deaths annually attributable to AMR [11,12]. Within LMICS, critical African and Asian countries were chosen for this review as they currently face the greatest challenges with respect to rising AMR rates [2,6,9]. Challenges regarding AMR are exacerbated by concerns with access to UHC across LMICs, and include a lack of routinely available and affordable essential antibiotics, substantial use of Watch and Reserve as opposed to Access antibiotics, and appreciable availability of substandard and falsified antibiotics compared with high-income countries [2,7,13,31,52,86,174].

2.1.2. Data gathering and analysis

The narrative review builds on previously published systematic reviews assessing attitude and practices regarding antibiotics, ASPs and those surrounding access, availability, and shortages,

as well as the extent of substandard and falsified antibiotics, with a focus on primary care across Africa and Asia [32,52,112,171,175–179]. However, this narrative review includes more up-to-date findings as well as combining key issues surrounding antibiotic use, ASPs, availability, shortages, and falsified antibiotics, into one comprehensive review to provide future direction. We have adopted similar approaches in the past when suggesting activities to improve the care of patients in Africa and Asia with infectious diseases to minimize AMR [9,19,97,98,130,146,180,181].

Documented future suggestions will be based on the findings of the reviewed papers combined with the considerable experience of coauthors across LMICs that deal with these issues. This paper is part of a series of other narrative reviews undertaken by the coauthors across LMICs, especially African countries, regarding the management of infectious diseases [9,19,97,98,130,180–182].

Databases were searched for potential papers published between January 2018 and December 2024, including Google Scholar and PubMed/MEDLINE. Only papers cited in PubMed were included in the sourced papers as a measure of their quality, with no other analysis of their quality using scales such as the Newcastle Ottawa scale which the coauthors have used before [183–185]. This was because the principal aim of this paper is to comprehensively collate relevant information on these key areas associated with rising AMR rates across critical African and Asian countries to provide a basis for the suggested future activities. 2018 was chosen as the starting year for sourced papers for this narrative review as NAPs within countries were typically only launched from 2017 onwards following the WHO GAP in 2015, and recognizing that there were considerable initial and subsequent challenges with their implementation [139,146,151]. Choosing 2018 as a start year would also lead to the inclusion of studies during the COVID-19 years as patients across LMICs were often inappropriately treated with antibiotics despite COVID-19 being a viral infection [186–191].

High utilization of antibiotics to treat patients with COVID-19, despite limited evidence of bacterial co-infections or secondary infections, resulted in increasing concerns with rising AMR rates [157,186,192–196]. There were also concerns with potential shortages of antimicrobials during the first pandemic following misinformation and lockdown activities.

Primary care was selected as the focus for this narrative paper as opposed to hospital care since, as mentioned, primary care currently accounts for up to 90% of total antibiotic use in humans in LMICs [23]. Consequently, key stakeholder groups, including health authorities, across LMICs need to focus on improving antibiotic utilization in primary care to appreciably reduce AMR in the future, with the previous emphasis typically on hospital care across LMICs [130,182,197,198].

The Search terms included ambulatory care; primary care; antibiotics; antibiotic prescribing; access and availability of antibiotics; falsified and substandard medicines; primary health facilities; primary healthcare centers; community pharmacists; drug sellers; patients; antimicrobial stewardship; and antimicrobial stewardship programs among African and Asian countries. The references in accessed papers were also searched for potential additional references to include in the narrative review. The critical African countries included Cameroon, DRG Congo, Eritrea, Ethiopia, Ghana, Kenya, Nigeria, Malawi, South Africa, Tanzania, Uganda, Zambia, and Zimbabwe, with critical Asian countries including Bangladesh, China, India, Iraq, Nepal, Pakistan, Thailand, and Vietnam [2,3,6,13].

Sourced papers were subsequently divided into two Regions. Following this, into individual countries within the regions based on their World Bank economic status, e.g. low, low-middle and upper-middle-income countries [133,199]. This is because there could be differences in access, availability, extent of substandard and falsified medicines, as well as utilization patterns between income levels due to a number of issues, which include the extent of self-purchasing of antibiotics and affordability of care [19,52].

Key sourced information was further subdivided in each country into (i) prescribers including physicians and nurses; (ii) dispensers including pharmacists and drug sellers; (iii) Patients/public; (iv) access/availability/shortages and (v)

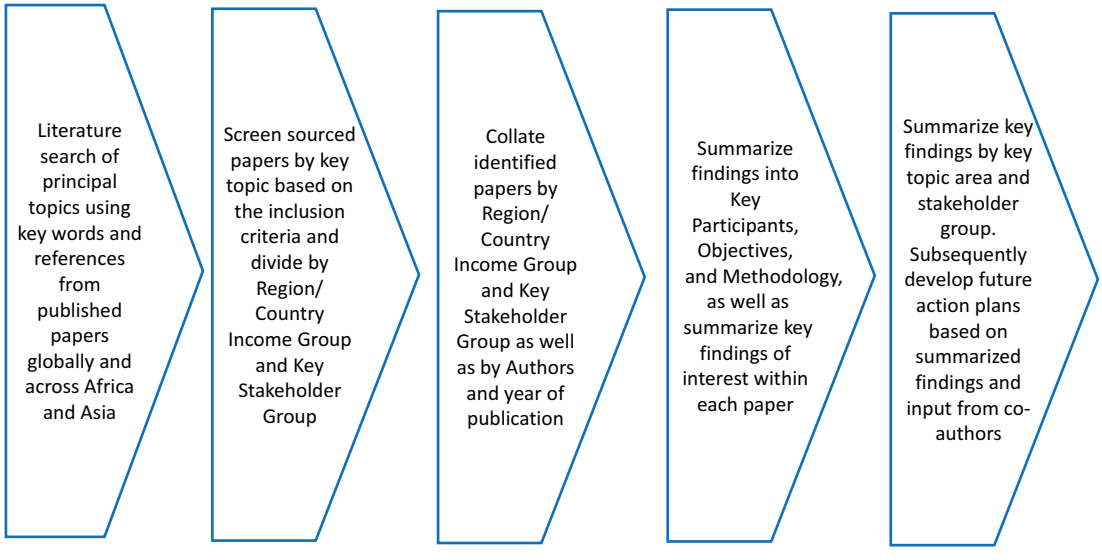

Figure 1. Summary of key activities.

falsified and substandard antibiotics (Figure 1). No attempt was made to document the total number of individual papers initially sourced as this was not a systematic review. In addition, using a deliberately inclusive approach, multiple authors and experts from different LMIC countries were involved with identifying possible papers from their country.

2.1.3. Inclusion and exclusion criteria

Only papers dealing with primary care, including hospital outpatients, and published from January 2018 to December 2024, were eligible for inclusion in this review. In addition, only papers in the English language were included in the Tables, which is similar to other reviews with English seen as the recognized international scientific language and increasingly used in peer-reviewed publications [200–202].

Exclusion criteria included studies which discussed antibiotic use and ASPs among hospital in-patients, papers among LMICs outside of the critical African and Asian countries, studies published before 2018, those dealing with animals/veterinary scientists and any papers not cited in PubMed (for inclusion in the Tables).

2.1.4. Synthesis of the findings

The data analysis and synthesis process followed a systematic approach. This included identifying, extracting, and organizing the relevant information from the included studies, which included incorporating information about the characteristics of each study and findings of interest. The results were subsequently summarized in a series of tables. The tables contained a summary of the objectives, methodology, number of participants (where pertinent), and key findings for each targeted group/information, i.e. Prescribers, Dispensers, Patients/Public, Access/Availability/Shortages and Substandard/Falsified information by Region (Africa or Asia) and country, including its economic status (Figure 1).

Where pertinent, details of the questionnaire design were also included in the tables, to add robustness to the findings, along with publication dates and author(s). The cited papers were listed in year sequence to assess whether there had been any changes in key issues such as appropriate utilization of antibiotics over time as well as access. Among African countries, this also included any changes since the WHO Lomé agreement to prioritize activities toward substandard and falsified medicines in 2020 [66].

The key findings were subsequently synthesized to provide a basis for subsequent recommendations. This includes any differences between perceived knowledge of antibiotics, AMR and AMS, among the key stakeholder groups versus actual practices alongside key issues regarding access and shortages of antibiotics as well as substandard/falsified antibiotics.

No attempt was made to combine the findings and produce summary statistics, apart from documenting the overall number of sourced papers. This was because of the anticipated heterogeneity of the sourced papers in terms of their methodology, objectives, and populations studied. However, key reported quantitative descriptive statistics, or measures of effect, have been summarized to help provide guidance. The consolidated themes were subsequently used to provide guidance to all key stakeholder groups regarding potential key activities to instigate to improve access, availability, affordability, and use of antibiotics in the future, as well as reduce the extent of falsified and substandard antibiotics where these still occur. As a result, help to reduce AMR. This also includes concerns with any current Drug Lists and their relevance now that the WHO AWaRe book has been published, as well as any regulatory issues [44,138,163].

2.1.5. Ethical consideration

Ethical approval was not needed for this review as this study did not involve direct contact with humans as noted in similar studies [9,16,97,98,146,180,181].

2.2. Results

The inclusive review process identified 426 sourced papers from across key African and Asian countries, with their content divided into various categories to meet the objectives of the study. The area of focus included issues of access, availability, affordability, and shortages of antibiotics, particularly among key African and Asian countries, coupled with issues and findings regarding substandard and falsified medicines. Subsequently, a synopsis of key findings regarding knowledge concerning antibiotics and AMR, as well as practices and their rationale, among the three key stakeholder groups, i.e. prescribers, which includes nurses in LMICs, dispensers, including those from the informal sectors, and patients/the public, were summarized among African and Asian countries.

The critical African countries included Cameroon, DRG Congo, Eritrea, Ethiopia, Ghana, Kenya, Nigeria, Malawi, South Africa, Tanzania, Uganda, Zambia, and Zimbabwe, and the critical Asian countries included Bangladesh, China, India, Iraq, Nepal, Pakistan, Thailand, and Vietnam.

In view of this, Tables 1 and 2, as well as Tables S1–S3 contain, a synopsis of published papers addressing key issues surrounding access, availability, usage, and affordability of antibiotics across Africa and Asia that impact on AMR and subsequent mortality. Future potential interventions by Governments and Health Authorities in both the short and long term are included in Table 3. The suggestions build on Tables 1 and 2 as well as Tables S1 to S3. Future guidance for all other key stakeholders including Prescribers, Dispensers, Patients/Public and Universities is included in Tables S4 onwards.

2.2.1. Access, availability, and shortages regarding antibiotics

There have been reported shortages of antibiotics among African and Asian countries, including amoxicillin and other critical Access antibiotics [203,204]. However, concerns with shortages and stocking issues tend to be greater among PHCs compared with community pharmacies and drug stores; this though does occur in community pharmacies in these countries [92,323].

Shortages when they occur are not helped by concerns with supply chain management issues, which include limited stock keeping and forecasting abilities, only a limited number of manufacturers for the APIs of essential antibiotics and concerns with the profitability of manufacturing older antibiotics

Table 1. Access, availability, and shortages of antibiotics principally across Africa and Asia.

Country, author and year	Refs	Objectives and study design	Summary of the findings
Global			
Tängdén et al. and Cohen et al.	[203,204]	• Commentary papers discussion shortages of older antibiotics generally as well as specifically amoxicillin across countries, their causes and potential ways forward	• Shortages of amoxicillin have been seen across countries including LMICs and high-income countries • Shortages of antibiotics typically enhanced by the cost of raw materials as well as low prices charged – exacerbated if anticipated volumes are low • Shortages of antibiotics need to be avoided as this potentially affects global security [36] • Proactive policies to address shortages include mapping current production and supply chains and improved stock management generally as well as collaboration between national regulatory agencies to improve the availability of effective/recommended antibiotics and progress joint procurement policies
Knowles et al.	[92]	• Appraise antibiotic availability among PHCs in 20 LMICs including Benin, DR Congo, Kenya, Malawi, Rwanda, Senegal, Sierra Leone, Tanzania, Uganda, Zambia and Zimbabwe in Africa as well as Bangladesh and Nepal in Asia – mainly among health centers (39.1% of the sample) • Obtained data on the availability of 27 antibiotics (19 Access, 7 Watch, 1 unclassified) among 13,561 health facilities	• Whilst no Access antibiotic was universally available, metronidazole and co-trimoxazole were the most widely available antibiotics – stocked in 89.5% of health facilities • Some Access antibiotics, i.e. ampicillin, cloxacillin, co-amoxiclav, tetracycline, cefalexin and clindamycin, were available in a median of 30.9% or fewer health facilities, • The most widely available antibiotic from the Watch group was erythromycin, which had a median overall availability of 65% • In total, 17 Access and Watch antibiotics were, on average, stocked by fewer than 50% of the surveyed facilities across the 20 surveyed LMICs, which needs addressing going forward
Do et al.	[205]	• Assess antibiotic access and use among six LMICs across Africa (Mozambique, Ghana, and South Africa) and Asia (Bangladesh, Vietnam, and Thailand) • Availability/Access in terms of DDDs supplied to surveyed population	• Drug stores were typically the most common source of antibiotics especially for mild infections, with self-medication with antibiotics common in Vietnam (55·2% of antibiotics dispensed), Bangladesh (45·7%), and Ghana (36·1%) – seen as time saving, more convenient and cheaper • Access antibiotics were predominantly dispensed in almost all sites ranging from 50·7% of DDDs in Vietnam, 71.4% in Ghana, 73.0% in Thailand, to 84·6% in South Africa • The exception was Bangladesh where Watch antibiotics accounted for 74·6% antibiotics dispensed • No Reserve-group antibiotics were dispensed at any of the study sites
Bhandari at al. and Pandey et al.	[32,170]	• Assess access to antibiotics as well as patterns and causes of shortages across countries • In addition, investigate the effect of shortages on health systems/patient outcomes as well as identify potential strategies for forecasting and managing shortages • Systematic/Narrative reviews	• Among shortages of antibiotics reported in published studies, 37% were from the Access group of antibiotics, 51% from the Watch group, and 11% from the Reserve group. • Antibiotics most affected by shortages included piperacillin-tazobactam (28% of cited studies) and penicillin G (20%) • The most common reasons identified for shortages included a lack of supply of APIs – especially where single-sourced manufacturers exist including within China and India [178] • Ways forward to address antibiotic shortages include enhancing their appropriate use, suggesting possible alternatives when the need arises, and introducing measures and initiatives including healthcare strengthening especially in LMICs to improve future forecasting/supply chains. In addition, exploring potential ways to instigate price adjustments where pertinent especially for older antibiotics – however already concerns with affordability of antibiotics in a number of LMICs and pricing policies can be complex

(*Continued*)

Table 1. (Continued).

Country, author and year	Refs	Objectives and study design	Summary of the findings
Sharland at el.	[30]	• Narrative review investigating antibiotic shortages and suggested next steps to address these • Recent amoxicillin shortage provides an exemplar	• Shortages of amoxicillin are a concern as the WHO now recommends amoxicillin (± clavulanate) as the first-choice antibiotic for adults and children in 10 of the 12 most common infections seen in primary care (WHO AWaRe guidance - [44,45]) • Shortages of amoxicillin not helped by being generally very low-priced with slim profits although very high-volume global sales and multiple suppliers -which threatens implementation of AWaRe guidance unless addressed • Strategic public investment in the supply side of antibiotics across LMICs – including those in Africa and Asia – would help to improve future access and supply of key antibiotics. This includes generic antibiotics of an acceptable quality to help with access/affordability issues [159]
African countries			
3 African countries - Lyus et al.	[43]	• Assess the proportion of essential as well as non-essential antimicrobials currently included in drug registers in Kenya, Tanzania and Uganda for prescribing • Classify all antimicrobials currently on the national drug registers and EMLs in these countries using the British National Formulary as well as the AWaRe classification	• In 2018, Kenya had 2105 registered antimicrobials, Tanzania had 1327 and Uganda 1563. Of these 64.3% were non-essential in Kenya, 53.2% in Tanzania and 51.1% in Uganda • Kenya had 160 antimicrobials on its EML with 20.7% currently not registered in the country, Tanzania 182 with 28.6% not registered in the country and Uganda 187 antimicrobials with 26.7% currently not registered in the country • Of essential antibiotics in the Access group, 14.3% were not registered in Kenya, 20.5% not registered in Tanzania, and 8.6% currently not registered in Uganda. Of essential antibiotics from the Watch group 25.0% were not registered in Kenya, 19.1% in Tanzania and 14.3% currently not registered in Uganda
East Africa - Loosli et al.	[112]	• Assess the provision/availability of widely used antimicrobials to ascertain whether major inadequacies exist in terms of their access as well as quality of antimicrobials • Provide future guidance based on the findings • Systematic review	• While the focus globally in recent years has been on reducing excessive antimicrobial use to reduce AMR – major constraints surrounding access as well as affordability to antibiotics shape patients' health-seeking decisions – leading to concerned practices potentially exacerbating AMR • Potential ways forward include optimizing the drug supply chain especially among public healthcare facilities, clear communication and education regarding national treatment guidance to optimize future antibiotic use and training of communication skills in Universities among HCPs and post-qualification especially where language can be an issue with words such as antibiotics and AMR [206]
East African Community - Ndomondo-Sigonda et al.	[69]	• Appraising the impact of the East African Community (EAC) medicines regulatory harmonization initiative concerning the capacity of national medicines regulatory agencies, with a special focus on the registration and inspection systems in these countries (to help with issues such as shortages of essential antibiotics and falsified medicines) • Exploratory mixed-method approach accessing data from 6 national medicines regulatory authorities (NMRAs) and the EAC Secretariat	• Legal frameworks and policies deliver a foundation for the effective regulation regarding the availability of medicines in the country • Collaboration and harmonization including joint dossier reviews and inspections of manufacturing sites, as well as reliance and cooperation among NMRAs are key factors to build trust and capacity among national authorities to benefit each country in the future • 5 out of 6 of the EAC Partner States currently have comprehensive medicines laws with autonomous national authorities. All NMRAs assessed have functional registration and good manufacturing practice inspection systems which are supported by regional harmonized guidelines with respect to registration, inspection, and quality management as well as information management systems with four of the national authorities attaining ISO 9001:2015 certification. This is important to enhance the quality of any locally produced antibiotics in East Africa to help reduce future shortages

(*Continued*)

Table 1. (Continued).

Country, author and year	Refs	Objectives and study design	Summary of the findings
3 East African countries – Baldeh et al.	[110]	• Assess for each therapeutic class, including antibiotics on the NEMLs of Kenya, Tanzania and Uganda, the number of essential medicines produced in each country • Appraise in each country the NEMLs alongside the NDRs to help identify local manufacturers as well as local medicines by their essential medicine status	• Currently 9 companies manufacture locally in Kenya, 4 in Tanzania and 6 in Uganda, with most local medicines non-essential, i.e. of the 946 locally produced medicines in Kenya, only 310 were seen as essential; of the 97 locally produced medicines in Tanzania only 39 were essential and of the 181 locally produced medicines in Uganda, only 100 were seen as essential • Many locally produced essential medicines were duplicate, with overall only a small proportion of essential medicines contained in each NEML produced locally – 21% (92 out of 430) in Kenya, 5% (24 out of 510) in Tanzania, and 10% (55 out of 526) in Uganda • The proportion of essential medicines registered were different across the countries. These ranged from 327 (76%) in Kenya, 269 (53%) in Tanzania, and 319 (60%) in Uganda • Overall, there is a need for authorities and others to continue auditing their NDRs and NEMLs regarding local production to inform regional and national local manufacturing strategies to help reduce shortages. Essential medicines should necessarily be prioritized for local production as well as drug registration to ensure any local production is aligned with local health needs to aid their supply
3 East African countries – Green et al.	[207]	• Review national drug registers in Kenya, Tanzania and Uganda with respect to NEMLs • Analyze highly registered products including a sub-analysis of registered antimicrobial medicines • Retrospective analysis regarding the registration of essential medicines and medicinal products contained within NDRs as of February 2018	• An appreciable proportion of essential medicines were currently not registered in these 3 countries: Kenya 28% (175/632), Tanzania 50% (400/797) or Uganda 40% (266/663) • Regarding registered products on their NDRs, more than half were seen a non- essential: Kenya 71% (4350/6151), Tanzania 64% (2278/3590) and Uganda 58% (2268/3896). When the 3 NDRs were brought together, there were a total of 42 medicines with over 50 registered products, accounting for 30% (4153/13637) of registered medicines, most non-essential • Overall, the lack of registration of essential medicines in a country is a barrier to their availability. The over-registration of medicines, especially non-essential medicines, does divert regulatory resources away from registering essential medicines and registering sometimes clinically sub-optimal medicines • The East African Community Medicines Registration Harmonization Project subsequently has the potential to improve access to key medicines across these countries, including antibiotics, if registration of essential medicines is prioritized going forward. As a result, there needs to be closer links between NEMLs, including antibiotics, and the registration of antibiotics away from non-essential antibiotics across countries to improve their availability [208]
7 African countries - Kamere et al.	[29]	• Assess the link between medicine supply chains and the use of antimicrobials among seven African countries: Kenya, Malawi, Nigeria, Sierra Leone, Tanzania Uganda and Zambia • In addition, appraise country medicine supply-system structures as well as global study reports to develop evidence-based strategies to improve the effectiveness and efficiency of current medicine supply chains to support AMS activities in the countries • Review paper	• Improved management of medical supply chains involves enhanced rational selection of antibiotics based on for instance the WHO AWaRe book now that it is published [44,45], as well as improved quantification, forecasting, stock management, storage, and distribution of antimicrobials • Important supply-chain considerations include the potential for pooled procurement networks to help ensure consistent pricing of quality-assured antimicrobials alongside improved resource utilization as well as information exchange among key stakeholders. • In addition, establish ASPs that include supply-chain management as an essential component. Until recently, ASPs were seen as difficult to introduce in LMICs due to resource and personnel issues [129]. However, this is changing with multiple ASPs now being introduced across Africa offering direction [209–211]

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Table 1. (Continued).

Country, author and year	Refs	Objectives and study design	Summary of the findings
Low-Income African countries*			
DRC Congo - Kakumba et al.	[212]	• Determine antibiotic dispensing patterns among HCPs • 400 medical prescriptions were collected from 80 drugstores • Prescribed antibiotics broken down by ATC class and AWaRe classification	• 75.2% of collected prescriptions from 80 medicine stores contained antibiotics • Of these, 54.5% contained one antibiotic, 38.9% two antibiotics, 5% three antibiotics and 1.6% four antibiotics. As a result, a total of 463 antibiotics were prescribed • Third generation cephalosporins were the most prescribed antibiotics (34.33%), followed by penicillins (17.17%) and macrolides (7.63%) • Overall, 43.2% of antibiotics prescribed were from the Watch group, 36.5% were from the Access group and 20.3% were from the not-recommended antibiotic group
Eritrea - Abdu et al.	[213]	• Appraise antibiotic prescribing practices and subsequent determinants among the elderly attending outpatients • 2680 prescriptions were analyzed among specialists, GPs and nurse prescribers	• The prevalence of antibiotic prescriptions among elderly outpatients was 35.8% - greatest among GPs and least among nurse practitioners • 53.7% of prescribed antibiotics were from the Access group, 32.1% were from the Watch group and none from the Reserve group. However, 14.1% of prescribed antibiotics did not fall into any of these three AWaRe classification categories • Overall, nurse practitioner prescribers were 40% less likely to prescribe an antibiotic than medical specialists and 51% less likely to prescribe a Watch antibiotic than specialists. Further efforts are need to reduce prescribing of Watch antibiotics
Ethiopia - Dereje et al.	[214]	• Appraise antibiotic prescribing practices and their potential determinants in community pharmacies • 1200 encounters were reviewed including 2354 individual medicines • Prescribers include physicians, health officers, nurses and midwives	• Among encounters – antibiotics were included in 467.8% of these, with antibiotics constituting 35.3% of all medicines prescribed • 55.3% of prescribed antibiotics were from the Access group, 43.1% from the Watch group and 1.7% from the Reserve group • Of concern is that prescriptions for antibiotics were 2.5 times more likely to be prescribed for patients under 18 years versus those 65 years or older, with men more likely to be prescribed antibiotics compared with women
Malawi - Limwado et al.	[215]	• Assess the prevalence of antibiotic self-medication and ABR knowledge among community members • Cross-sectional study including quantitative survey data collection methods and interviews • 531 household participants and 39 drug retailers were interviewed	• 71.2% of participants reported self-medicating in the past 6 months, with 69.5% of these participants self-medicating with antibiotics at least twice. Of concern is that 60% of patients preemptively asked for antibiotics, subsequently sold without a prescription • Amoxicillin (61.1%) and cotrimoxazole (29.6%) were the most utilized antibiotics, with 53.1% of participants reusing leftover antibiotics, and employed participants were significantly more likely to self-medicate than others. Of equal concern is that 57.7% of participants who self-medicated stopped their antibiotics when their symptoms improved • Common symptoms for self-medication included a cough (29.9%), and a sore throat (28.6%) as well as aches and pains (28.6%). The convenience of medicine retailers (31.5%) as well as confidence (26.7%) were the principal reasons for self-medication with antibiotics • Of concern was that awareness of ABR was low (16.1%) among participants, with 61.5% of drug retailers declining to reveal their source of antibiotics although 97.4% recognized it is illegal to sell antibiotics without a prescription

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Table 1. (Continued).

Country, author and year	Refs	Objectives and study design	Summary of the findings
Uganda – Rajab et al. and Ndagije et al.	[41,216]	• Initially appraise local production capacity in the country before and after the introduction of increased import verification fees – from 2% to 12% • 6 local pharmaceutical industries and 7 key informant interviews were included in this mixed method study • The cost and availability of selected essential medicines, including antibiotics, were subsequently assessed after the increase in verification fees among 328 wholesale and retail pharmacies combined with 7 key informant interviews	• Uganda had previously imported approximately 90% of the medicines it uses – with approximately 60% of these distributed via the private sector. Import fees were introduced to help promote local production and reduce lead times [110] • In subsequent studies, the availability of locally produced medicines was mainly low (45%); however, those for imported medicines still remained fairly high (74%). The most commonly available imported antibiotics included metronidazole 200 mg Tablets (88.1%), ciprofloxacin 500 mg (91.4%) and amoxicillin trihydrate 125 mg/5 ml (92.4%) • The increase in import fees led to a significant increase in prices for the lowest-priced local and imported medicines among 10 (23.8%) and 7 (15.9%) of the medicines respectively; however, median prices of imported medicines were still generally higher than locally produced medicines • Overall, the median unit prices of 28.6% of locally produced medicines, as well as 47.6% of imported medicines, were still higher than the international median unit prices. Consequently, there is a need for transparency and greater price controls in the private sector going forward – especially where affordability of antibiotics is an issue
Uganda - Igirikwayo et al.	[217]	• Assess antibiotic prescribing patterns along with associated factors among outpatients with RTIs • Abstraction from all patient records with a diagnosis of RTIs (1542 records after data cleaning) combined with an Interviewer-administered questionnaire among 30 drug prescribers (40% nurses) in relevant health facilities	• 79.8% of outpatients were prescribed antibiotics for their RTIs, including 93.3% for acute otitis media, 74.4% for URTIs, 71.4% for acute bronchitisand 8.13% for common colds • 86.6% of prescribed antibiotics were from the Access group – with amoxicillin accounting for 50.45% of all antibiotic prescriptions – and 13.4% were from the Watch group with azithromycin (4.56% of all antibiotics) and erythromycin (3.9%) the most prescribed. No antibiotics were prescribed from the Reserve group • Overall high rates of inappropriate prescribing (74.4% to 74.9%) when compared with European guidelines • Encouragingly prescribers who had access to Uganda STGs and Integrated Management of Childhood Illness guidelines were less likely to prescribe antibiotics. Prescribers who had not received training on appropriate antibiotic prescribing e were 3.55 times more likely to prescribe antibiotics
Zambia - Yamba et al.	[218]	• Appraise antibiotic prescribing patterns among 6 PHCs • Prescription pattern data obtained from pharmacies with identification and antimicrobial susceptibility determined by conventional methods	• Most prescribed antibiotics among PHCs were in the Access group (74%), with all PHC facilities adhering to the WHO AWaRe guidance of ≥ 60% of prescribed antibiotics being in the Access group • However, appreciable resistance to Access antibiotics - *E. coli* resistance to ampicillin ranged from 71% to 77% among patients and to co-trimoxazole resistance from 74% to 80%. *Enterococcal* resistance to tetracycline ranged between 59%–64% of isolates. MDR was highest in *E. coli* (75%) isolates with XDR highest among *enterococcal* isolates (97%) • Consequently, a need to critically evaluate current use of antibiotics to decrease AMR based on the AWaRe system and guidance
Low-Middle income African countries*			
Cameroon - Chem et al.	[219]	• Assess prescribing and predictors of antibiotic prescriptions among PHCs • Retrospective study analyzing 30,096 prescriptions combined with questionnaires supplied to 59 prescribers	• 36.7% of prescriptions contained an antibiotic, with a mean of 1.14 antibiotics prescribed per patient • The most prescribed antibiotic was amoxicillin – 29.9% of antibiotic prescriptions – followed by cotrimoxazole (19.09%) and metronidazole (15.59%) – with penicillins accounting for 45.82% of all antibiotics prescribed • 21.2% of antibiotics were prescribed for RTIs (most prevalent indication), 11.7% for uncomplicated malaria and 10.3% for gastroenteritis • Current misuse of antibiotics needs to be addressed going forward

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Table 1. (Continued).

Country, author and year	Refs	Objectives and study design	Summary of the findings
Ghana – Greene et al.	[220]	• Appraise the challenges dispensers of medicines face relating to antimicrobials (antibiotic and antimalarial medications) as well as identify opportunities for improving their AMS activities • 79 dispensaries were contacted and administered a structured questionnaire	• Key issues affecting AMS activities included strained interactions with customers and current the prohibitive costs of medications, with customers' purchasing decisions mainly based on the price of antimicrobials, i.e. patients typically started at the pharmacy closest to the hospital, inquired about prices, and subsequently visited adjacent medicine sellers until they found the lowest price • There were heightened emotions when patients were ill and self-diagnosed. There were also challenges when patients could not afford the antimicrobials prescribed or recommended – as well as concerns when dispensary personnel believe patients would not complete the full course – key issues to address going forward
Kenya - Gacheri et al.	[221]	• Assess patterns of antibiotic dispensing and use in the community during the recent COVID-19 pandemic • Interviews conducted with 243 pharmacies using a standardized and piloted questionnaire	• All pharmacies contacted reported selling one or more antibiotics to customers suspected of having COVID-19, with 81.5% reporting they prescribed an antibiotic without asking for a prescription • The four most commonly sold antibiotics to patients suspected on having COVID-19 were azithromycin (99.1%), co-amoxiclav (77%), cefuroxime (64.9%) and amoxicillin (approx. 50%) • This contrasts with the study of Opanga et al. (2021) where no pharmacy dispensed antibiotics to patients with COVID-19 – alternatively suggesting symptomatic relief [222]
Kenya – Sohaili et al.	[223]	• Appraise Kenya's AMR efforts regarding the implementation of policies to reduce AMR • A systematic scoping review collating and describing AMR activities	• As part of the review, there is a concern with the influx of counterfeit antibiotics into Kenya helping to drive up AMR alongside appreciable dispensing of antibiotics without a prescription • Both activities were exacerbated by informal pharmacies in Kenya – who currently account for approximately two thirds of the estimated 12,000 private pharmacies in Kenya. As a result, appreciably outnumbering certified branches
Nigeria – Obembe et al.	[224]	• Assess the dynamics of tariffs alongside tax policies on local drug pharmaceutical production – including the availability of essential medicines among vendors • Qualitative study involving 15 participants using a structured questionnaire	• The participants believed there was no significant shortage of essential medicines for the population in Nigeria because such demand pull creates business opportunities for drug importers • However, there are concerns with high levels of imported medicines, including antibiotics, into Nigeria – not helped by the current high cost of production of medicines in Nigeria exacerbated by current taxation levels, low patronage from the Government, lack of access to low interest funds and high costs of production – making it difficult for local manufacturers to compete favorably on price – with those of some locally manufactured equal or higher priced than those imported at the retail level
Tanzania - Ndaki et al.	[225]	• Assess antibiotic dispensing practices of providers of medicines – particularly the dispensing of antibiotics without a prescription • Cross-sectional study using mystery clients approaching 1148 accredited drugs dispensing outlets and community pharmacies across 3 regions asking directly for amoxicillin (and if asked for UTIs)	• 88.2% of outlets/community pharmacies dispensed amoxicillin without a prescription • Generally, most outlets were happy to sell amoxicillin on demand without asking questions, with the vast majority happy to sell a half course of amoxicillin on demand – Mwanza (98%), Kilimanjaro (98%) and Mbeya (99%) • There were significant variations among regions – accredited drug dispensing outlets in Mbeya and Kilimanjaro were more likely to dispense amoxicillin on demand than pharmacies – however, no difference was seen in Mwanza

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Table 1. (Continued).

Country, author and year	Refs	Objectives and study design	Summary of the findings
High-Middle Income African countries*			
South Africa - Alabi et al.	[226]	• Assess the appropriateness of the prescribing of antibiotics among GPs in the private sector • Analysis of 188,141 antibiotics prescribed for 174,889 patients • The appropriateness of antibiotic prescriptions were based on ICD-10 classification and whether an antibiotic is warranted	• Overall, 92.9% of patients surveyed were prescribed one antibiotic, with 7.1% prescribed two or more antibiotics • Penicillins were the most prescribed antibiotic (40.7% of all antibiotics prescribed) followed by macrolides (16.8%) and the cephalosporins (15.7%). Diseases of the respiratory system (J00–J99) accounting for 46.1% of all diagnoses • Of concern is that only 8.8% of all the prescriptions analyzed were seen as appropriate with only 32.0% seen as potentially appropriate. 45.4% were viewed as inappropriate and 13.8% could not be assessed due to a lack of specific codes/contained unlisted codes or contained unclear descriptions • In addition, only 57.7% of antibiotics were prescribed at the correct doses, 27.4% had wrong doses prescribed and 14.9% could not be assessed
Asian countries			
Low Income Asian Countries*			
Nepal - Koju et al.	[162]	• Determine promotional activities among pharmaceutical companies in medicine shops and community pharmacies combined with the affordability of selected antibiotics to patients on low wages • Cross-sectional study among 34 community pharmacies and medicine shops	• Popular promotional activities to enhance the sales of their branded antibiotics included brochures, financial bonus and free samples • A high number of promotional activities were associated with the top selling antibiotics, with amoxicillin having 42 promotional activities, azithromycin 29 activities and co-amoxiclav 17 promotional activities • However, among patients with URTIs, almost all of the most popular antibiotics were unaffordable for unskilled workers – typically they cost more than a day's wage
Nepal - Zheng et al.	[227]	• Determine healthcare-seeking patterns and households as well as sources of antibiotics for ARIs, fever and diarrhea among children among public and private clinics as well as pharmacies • 5457 children were included in the 2006 survey, 5054 in the 2011 survey and 4861 children in the 2016 survey.	• Antibiotic use among households in rural areas in Nepal increased over time. By 2016, antibiotic consumption for patients with ARIs and fever in rural areas surpassed that in urban regions, which is a concern • Increased antibiotic use was generally associated with higher levels of maternal education, particularly for fever • The percentage of children under 5 with only a cough receiving antibiotics increased from 7% in 2006 to 12% in 2011, and 75% of children who received antibiotics for diarrhea did not meet the recognized indication requirements • Overall, adherence to WHO-recommended antibiotics had decreased over time which needs to be addressed
Vietnam - Nguyen et al.	[228]	• Assess community-level utilization of antibiotics in rural Vietnam • Antibiotic purchasing data was collected via customer exit surveys from antibiotic suppliers in the community • 1342 out of 1404 encounters were for human use	• Antibiotics were purchased without prescription in 57.6% of cases • Antibiotics were dispensed for a number of infectious diseases including coughs (53.9% of encounters where an antibiotic was dispensed), sore throats (48.0% of encounters), fever (33.3% of encounters) and runny noses (28.2% of encounters) • Antibiotics from the Access group constituted 59.0% of all antibiotics dispensed with antibiotics from the Watch group constituting 39.3%. No antibiotics from the Reserve group were dispensed. However, 1.7% of antibiotics dispensed were not recommended • Factors associated with a higher likelihood of a Watch antibiotic being dispensed were a private pharmacy, a non-prescription sale or a child
Low-Middle Income Asian countries*			
Bangladesh - Orubu et al.	[229]	• Map antimicrobial supply chains in Bangladesh • This includes the number of antibiotic manufacturers and licensed antibiotics among humans in ambulatory care	• Overall, Bangladesh has a high local production capacity for antimicrobials (98%) – with138 unique, or individual, licensed antimicrobials/anti-infectives by INN currently available as 1,763 products in Bangladesh • The most common antibiotic classes available were the cephalosporins (44% of licensed antibiotics), followed by the penicillins (18%); quinolone/fluoroquinolones (15%) and macrolides (15%) • Of concern is that 54% of the top 10 licensed antimicrobials belonged to the Watch group, with only 39% in the Access group

(*Continued*)

Table 1. (Continued).

Country, author and year	Refs	Objectives and study design	Summary of the findings
Bangladesh - Islam et al.	[230]	• Appraise current antibiotic dispensing patterns in pharmacies according to the WHO AWaRe classification • Structured questionnaires among both drug sellers and patients purchasing antibiotics (with or without a prescription) • 128 drug sellers were surveyed alongside monitoring 2686 customers/patients	• Out of 2686 customers interviewed, 21.6% (580) had purchased antibiotics – 523 had purchased one, 52 had purchased two and 5 had purchased three courses of antibiotics (totaling 642 courses) • Watch antibiotics accounted for the majority of antibiotic courses dispensed by drug sellers at 53.6%, followed by those from the Access group – 36.4% - and Reserve group at 10.0% of antibiotics dispensed • 50.9% of antibiotics dispensed were purchased without a prescription, with dispensing of non-prescribed antibiotics higher in the Access group of antibiotics – 59.4% of all Access antibiotics dispensed – followed by those in the Watch Group – 46.5% of all Watch antibiotics dispensed, and Reserve group – 43.8%
India - Gautham et al.	[231]	• Appraise the extent of antibiotics stocked as well as their sales volumes, prices and mark-ups among informal providers • A cross-sectional survey was conducted among 291 informal providers using a structured questionnaire	• Among the 196 informal providers (IPs) surveyed that stocked antibiotics, 85% stated they stocked tablets, 74% stocked syrups/suspensions/drops and 18% stated they stocked injections • Among all informal providers surveyed, 42 antibiotic chemical entities were stocked including 278 branded generics from 74 manufacturers. The top five antibiotics that were stocked included co-amoxiclav – 52% of IPs, cefixime – 39% of IPs, amoxicillin –33% of IPs, azithromycin – 25% of IPs and ciprofloxacin – 21% of IPs • 71% of the IPs stocked an antibiotic from the Access group and 84% stocked an antibiotic from the Watch group, with median prices in line with government ceiling prices; however, there was substantial variation between the lowest and highest priced brands • The most affordable antibiotics among the top 5 tablet forms available were amoxicillin, azithromycin, cefixime and ciprofloxacin (US$ 0.8–1.9/course), and the most affordable antibiotics among the suspensions/syrups/drops were azithromycin and ofloxacin (US$ 1.7–4.5/course) – mostly from the Watch group of antibiotics
Pakistan – Gul et al.	[190]	• Appraise current antibiotic dispensing patterns post-COVID-19 due to concerns with excessive prescribing and dispensing of antibiotics from the Watch and Reserve groups during the pandemic • Cross-sectional study which collected dispensing data from 39 pharmacies as well as 53 drug stores	• 11,092 prescriptions were analyzed with 67.1% of patients dispensed at least one antimicrobial – 74.3% were antibiotics, 10.2% antifungals and 7.9% were anthelmintics. Overall, 33.2% of antimicrobials were supplied without a prescription • Respiratory infections (34.3%) and gastrointestinal (16.8%) infections were common indications for dispensed antibiotics, with 12% of antibiotics dispensed for the prevention/treatment of patients with COVID-19 • 59.2% antibiotics dispensed were from the Watch group followed by those from the Access (40.3%) and Reserve (0.5%) groups, with the most frequent antibiotics dispensed being ceftriaxone (18.4%) and amoxicillin (15.4%) • Among antibiotics dispensed for COVID-19, 68.3% were from the Watch group and 31.7% from the Access group

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Table 1. (Continued).

Country, author and year	Refs	Objectives and study design	Summary of the findings
Pakistan - Rafi et al.	[232]	• Record as well as compare the availability of essential antibiotics in the public vs. private sectors • 103 essential antibiotics were surveyed – comprising 51 from the Access group, 29 from the Watch group, 6 antibiotics from the Reserve group as well as17 anti-tuberculosis antimicrobials	• The mean percentage of on-spot availability of essential antibiotics was 23.76% ± 5.19 (14–25%) among public facilities and 59.20% ± 4.45 (54–66%) among private sector retail pharmacies • The overall percentage of essential antibiotics available varied significantly among public and private sector sampling sites. Overall, only 2.91% of surveyed essential antibiotics were available among all survey sites, with 30.9% of essential antibiotics not available at any survey site. • Unlike the Watch group where all were available at the surveyed sites apart from moxifloxacin, 11 antibiotics from the Access group were unavailable at any survey site. This may reflect the extensive number of branded generic Watch antibiotics currently available in Pakistan with the need for manufacturers to make a profit
Upper-Middle Asian Countries*			
China - Li et al.	[233]	• Assess prescription patterns and antibiotic usage trends in primary care institutions – especially following recent reforms • Retrospective analysis of antibiotic prescriptions among 25 PHCs	• 941,924 prescriptions were analysed, which showed a decreasing trend in both the rate and number of inappropriate antibiotic prescriptions from 2017 to 2022, which is encouraging following a number of reforms and initiatives in China [234] • Diseases of the respiratory system (70.7%) represented the most frequent symptom for the prescribing of antibiotics, with URTIs accounting for 52.0% of these. Penicillins were the most commonly prescribed antibiotics (64.4% of prescriptions) • 66.2% of prescriptions were seen as inappropriate, with physicians over 35 years, being an associate chief physician and having more than 11 years of experience seen as more likely to prescribe antibiotics inappropriately • Higher rates of inappropriate antibiotic prescribing were also seen among children aged five or younger vs. other ages

*World Bank Classification; ABR = Antibacterial Resistance; AMR: Antimicrobial Resistance; AMS: Antimicrobial Stewardship; AWaRe: Access, Watch, Reserve; EML = Essential Medicine List; FGDs = Focus Group Discussions; HCP = Healthcare Professional; HCW = Healthcare Worker; LMICs = Low- and Middle-Income Countries; NDRs = National Drug Registers; NEML: National Essential Medicine List; PHC = Primary Healthcare clinics; RTIs = Respiratory Tract Infections; STGs: Standard Treatment Guidelines; UTIs = Urinary Tract Infections; URTIs = Upper Respiratory Tract Infections.

Table 2. Substandard and falsified medicines especially antibiotics principally across Africa and Asia.

Country, Author and Year	Refs	Objectives and Study Design	Summary of the Findings
Global/LMICs			
Global – Tesfaye et al. and Ziavrou et al.	[235,236]	• Appraise potential trends regarding counterfeit medicines and their health impact before and during COVID-19 pandemic as their threat has appreciably increased • Narrative review of sourced papers	• In Africa, up to 60% of medicines are substandard, with the magnitude and the consequences of substandard/falsified medicines worsening during the pandemic [237] • The most counterfeited medicines relating to the management of patients with COVID-19 include antiviral medications, antibiotics, chloroquine, and painkillers – exacerbated by the closure of factories in the early stages of the pandemic making the APIs • Pharmaceutical companies can assist the situation in LMICs and reduce the extent of substandard/falsified medicines by making prices of authenticated medicines more affordable
Global - Feeney et al.	[238]	• Examining the global challenge of counterfeit and falsified medicines to provide a comprehensive understanding of the subject as well as explore potential solutions • Comprehensive search of pertinent databases as well as relevant publications including reports from international organizations	• Antibiotics accounting for 36% of all counterfeit medicines which had been seized by customs globally in 2014–2016. In a review conducted in 2015 among studies assessing counterfeit antibiotics, amoxicillin was reported in 29 countries, with counterfeit ampicillin reported in 17 countries, counterfeit tetracyclines in 11 countries, and counterfeit trimethoprim-sulfamethoxazole in 10 countries [239] • Pharmacists can play a crucial role with combating falsified and counterfeit medications; however, there can be issues of affordability with quality antibiotics that needs to be addressed especially in low-income countries • International collaborations are important for effective regulation and enforcement in order to address this global challenge as pharmaceutical supply chains seamlessly cross borders
LMICs – Alotaibi et al.	[240]	• Validate portable Fourier transform infrared (FT-IR) spectrometers to identify substandard antibiotics • 290 individual capsules of amoxicillin were analyzed from Ethiopia, DRC Congo Haiti, Ghana, India, Papua New Guinea and Sierra Leone	• 13 samples of amoxicillin were found to be substandard – with total APIs lying outside the acceptable range (90–110%) • Of these 13 samples – 4 were below 80% API • The FT-IR did reliably identify the outliers – and yielded results agreeing with established pharmacopoeia liquid chromatography methods • Consequently, this method may be suitable for LMICs where more sophisticated equipment is currently unavailable due to resource and other issues
LMICs – Ozawa et al.	[171]	• Perform a review of medicine quality by the amount of API across LMICs • Systematic review using PubMed, supplemented by the findings from previous reviews	• 130 studies were identified including 95,520 medicine samples from 130 studies. Based on the combined studies, 12.4% of the essential medicines that were tested were considered falsified or substandard • The majority of studies were from Africa or Asia • Antibiotics and antimalarials were the most examined therapeutic classes among the 130 studies
African Countries			
Southern African Development Community (SADC) – Kniazkov et al.	[65]	• The SADC region is subject to threats on health from the routine availability and subsequent use of substandard and falsified medicines • There is a need to map existing frameworks and mechanisms as well as current approaches to the prevention, detection and response to such medicines • Survey conducted among the National Medicines Regulatory Authorities (NMRAs) of the 16 Member States within the region, with 12 responding	• Only 3 of the 12 member states surveyed had included elements regarding the prevention, detection and the response to substandard and falsified medicines in their national medicine policies • However, regardless of the extent and status of policies, etc., legislation is in place to tackle these key issues among the majority of NMRAs in the Region • Enshrined in the legislation of 9 of the 12 NMRAs was the mandate for regular sampling, with 6 of the member states having both interagency and intra-agency co-ordination for responding to substandard and falsified medicines to help address concerns • Going forward, effective enforcement requires greater investment in resources in each member state, which includes infrastructure as well as stakeholder coordination and public outreach

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Table 2. (Continued).

Country, Author and Year	Refs	Objectives and Study Design	Summary of the Findings
Africa – Wada et al.	[49]	• Commentary paper to provide insights into the burden and impact as well as the threat of falsified and substandard medicines in Africa • Subsequently propose recommendations on potential ways forward	• Currently among LMICs, the African region also has the highest prevalence of poor-quality medicines – estimated at 18.7% prevalence rate [47,241] • The WHO stated that between 2013 and 2017, 42% of all falsified medicines reported to them were from Africa. Of concern as well is that 50% of medicines for sale on the internet were counterfeit • Currently, most African countries do have policies to support medicine regulation; however, of concern is that currently only 15% of African countries have a legal mandate to perform all core regulatory functions to reduce the prevalence of substandard and falsified medicines
Principally Africa – Pyzik et al.	[242]	• Comment paper seeking to tackle the threat of falsified and substandard medicines principally across Africa • Subsequently propose recommendations on potential ways forward	• The WHO currently estimates that at least 10% of medicines circulating in LMICs are either falsified or substandard, with > 75% of all substandard or falsified medicine alerts emanating from Africa • However, within Africa, detection rates for substandard and falsified medicines vary widely with reported prevalence rates ranging between 0.8–89% [243] • To help tackle the problem, 7 African leaders in 2020 placed substandard and falsified medicines on the highest political agenda through the Lomé Initiative. Such initiatives will be helped by the African Union countries in 2019 looking to create an African Medicines Agency • Alongside this, ongoing initiatives to secure the pharmaceutical supply – building on initiatives such as blockchain applications [244]
Francophone Sub-Saharan African countries – Mace et al.	[64]	• Document existing activities to detect, prevent and respond to falsified and substandard medicines in the Region/across Africa • Narrative review	Key activities included: • The Economic Community of West African States harmonising the requirements for marketing authorization in their respective countries as well as supporting regulatory strengthening based on the African Union Model Law in order to reduce the extent of substandard and falsified medicines [68] • Similar initiatives are also taking place across Africa including an African Medicines Agency and Medicines Regulation in Africa; however, similar concerns exist with these activities including political/financial commitment, appropriate organizational structures and concerns with legal and regulatory frameworks [67,245] • Benin, Burkina Faso, Guinea, Niger and Togo have ratified the Council of Europe Medicrime Convention Treaty as an example to other [246] • Ongoing activities among Universities in the Region to educate healthcare students of these key issues and challenges going forward
African countries - Asrade Mekonnen et al.	[52]	• Determine the prevalence of unlicensed, unregistered, substandard and falsified, medicines across Africa and associated factors • Undertake a Systematic Review and Meta-Analysis using the PRISMA methodology	• 27 studies were sourced for the review with 26 having good methodological quality • Of the 7508 medicine samples included within the sourced studies, 1639 failed at least one quality test and they were confirmed to be substandard or falsified medicines • From the sourced papers, the estimated prevalence of substandard or falsified medicines in Africa was 22.6%, and the average prevalence of unregistered medicines in the continent was 34.6%. Antibiotics accounted for the majority of substandard or falsified medicines across Africa at 44.6% with antimalarials accounting for 15.6% • The prevalence of substandard or falsified medicines across Africa was exacerbated by poor market regulatory permissions/registration coupled with high demand including antibiotics alongside poor importation standards
African countries - Sorato et al.	[74]	• Assess how improved access to medicines across Africa can reduce the presence and use of substandard and falsified medicines • Within this review assess the prevalence of substandard and falsified medicines in the continent	• The review included 71 papers • The review ascertained that the extent of falsified and substandard medicine, and their marketing, is highly variable across countries, e.g. their prevalence is estimated at between 20%–40% of medicines utilised in LMICs vs. approximately 1% in in high-income countries [247] • Africa is currently the destination for approximately 42% of global substandard and falsified medicine marketing/use [49]

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Table 2. (Continued).

Country, Author and Year	Refs	Objectives and Study Design	Summary of the Findings
East African Countries - Tegegne et al.	[59]	• Appraise the data that can help to quantify as well as provide the current prevalence of substandard and falsified antimicrobials among East African countries including Ethiopia, Eritrea, Kenya, Tanzania, Uganda, Zambia, and Zimbabwe • Systematic review focusing on papers published in scientific peer-reviewed Journals	• 15 studies that were sourced estimated the prevalence of antimicrobials that failed at least one quality test, with only 4 countries included – Ethiopia, Kenya, Rwanda and Tanzania • Overall, 22.6% of the antimicrobials included in the published papers failed at least quality measure – least for antibiotics at 17% and most for anthelmintics at 56% of the medicines analyzed • The API of the medicines was the most commonly examined quality control factor among the included studies
Low Income African countries*			
Democratic Republic of Congo (DRC) – Schäfermann et al.	[248]	• Assess the quality of 13 essential medicines in Cameroon and Democratic Republic of Congo • Essential medicines included predominantly antibiotics – amoxicillin, ciprofloxacin, doxycycline, metronidazole and trimethoprim • Samples of antibiotics and other medicines were collected from a range of drug sellers and analyzed according to the USP	• Overall, 502 medicine samples were collected from 26 sites in Cameroon and 34 in DR Congo including informal vendors • 0.6% of collected samples were identified as falsified medicines with all three sold by informal sellers • 8.5% of the collected samples failing USP specifications regarding their API content and 11.7% of the collected samples failed dissolution testing. There was a higher failure rate regarding medicines for non-communicable diseases (25.3%) compared with antibiotics (12.1%), with medicines from informal vendors having a higher out-of-specification rate (28.2%) than other drug outlet types (12.3%; P< 0.0001)
Ethiopia – Mekonen et al.	[249]	• There was a higher failure rate regarding medicines for non-communicable diseases (25.3%) compared with antibiotics (12.1%), with medicines from informal vendors having a higher out-of-specification rate (28.2%) than other drug outlet types (12.3%; $p < 0.0001$) • Determine community pharmacy professionals' KAP toward substandard and falsified medicines • 323 community pharmacists were surveyed using a structured questionnaire	• The most frequently mentioned class of medicines among surveyed pharmacy professionals with the highest risk of falsification were antibiotics (48.5%) and chronic disease medicines (35.6%), with metronidazole (31.4%) among the most frequently mentioned falsified medicines encountered. The main source of substandard and falsified medicines was India followed by China and Ethiopia • Whilst 81.7% of surveyed community pharmacists were aware of substandard and falsified medicines, only 31.7% could correctly define these terms • Overall, community pharmacists' knowledge and practice toward substandard and falsified medicines was seen as moderate, although an appreciable proportion of community pharmacists surveyed did have a positive attitude toward this subject • These findings contrasted with those of Abdunasir et al (2021) who found that an appreciable proportion of pharmacy professionals were unaware of the problems patients encounter with falsified medicines as well as potential methods to identify these medicines
Ethiopia – Anjulio et al., 2024 and Ahmed et al., 2024	[250,251]	• Assessing the quality of 4 commonly used antimicrobials as well as separately anti-malarial tablets • 54 samples of amoxicillin, co-amoxiclav, ciprofloxacin, and norfloxacin formulations were collected secretly from 43 facilities	• The quality evaluation detected no falsified medicines among the 54 samples • However, 14.3% of the 54 analyzed samples failed the Global Pharma Health Fund -Minilab screening test and 22.2% did not meet pharmacopoeial specifications • 56.3% of amoxicillin samples, 60% of co-amoxiclav samples, 20% of ciprofloxacin samples, and 54.5% of norfloxacin samples were not pharmaceutically equivalent with their respective comparators with respect to their dissolution profiles • This is different to the situation regarding treatments for malaria in the study of Ahmed et al. where only 25% of the 52 collected samples were registered with the Ethiopian Food and Drug Authority electronic regulatory/registration system. Alongside this, there was an appreciable prevalence of substandard anti-malarial medicines at 58.3% among the 52 collected samples

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Table 2. (Continued).

Country, Author and Year	Refs	Objectives and Study Design	Summary of the Findings
Malawi – Chiumia et al.	[252]	• Appraise the prevalence and factors associated with substandard and falsified medicines, which includes antibiotics • Cross-sectional study involving 23 faith-based, public and private healthcare facilities	• Out of 293 medicine samples that were collected, 14.3% were falsified or substandard including 19.2% of amoxicillin samples (5/26), 21.2% of ciprofloxacin samples (7/33) and 44.4% of flucloxacillin samples (4/9) • Antidiabetic and antimalarial medicines were of better quality compared with antibiotics ($p < 0.002$) • When the country of origin was stated, the prevalence of substandard and falsified medicines was 30% from Malawi (15/50), 33% from China (9/27), 26.7% from Kenya (4/15) and 6.6% from India (8/122)
Zambia – Chabalenge et al.	[253]	• Document the prevalence of recalls of substandard and falsified medical products • Through analyzing frequently recalled therapeutic categories and dosage forms alongside the country of the MAH/manufacturer • Descriptive cross-sectional review including 119 alerts	• Out of the 119 alerts, 69.7% were product recalls, with the number of recalls increasing in 2020 and 2021. The most recalled formulations were oral solid dosage forms (53%) • The majority (20.5%) of the recalled products were substandard disinfectants and antiseptics – attributed to their high demand during the COVID-19 pandemic • The principal reasons for product recalls (47.4% of the cases) were manufacturing and laboratory control issues – with most of the products recalled originating from India (38.6%) followed by Zambia – 25.3%. • Only one suspected falsified product was recalled between 2018 and 2021 • ZAMRA initiated 66 recalls among the 83 products recalled, with only 17 voluntarily recalled by foreign MAHs with no product recall initiated by local representatives of foreign MAHs or manufacturers
Lower-Middle Income African countries*			
Cameroon - Waffo Tchounga et al.	[254]	• Appraise the quality of 2 antibiotics in Cameroon • 150 samples of ciprofloxacin tablets and 142 samples of metronidazole tablets were collected from 76 licensed pharmacies as well as 75 informal vendors from 3 cities • 3 tests were carried out on each of the 150 samples using a mystery shopper approach	• 2 falsified samples (0.7%) were identified via visual inspection as a result of lack of information regarding the manufacturer, with 5 more samples (1.7%) seen as substandard as a result of flaws in the product • 4.5% of the samples subsequently failed the disintegration tests and a further 2.1% failed high-performance liquid chromatography assay testing as a result of insufficient API – although all samples contained some API • The overall prevalence of substandard and falsified medicines was 7.9% - greater among the informal sector (26.7%) versus the formal sector (2.6%) • Whilst the observed prevalence of substandard and falsified medicines was low, efforts are essential to continually monitor the market with ongoing concerns across Africa
Ghana – Opuni et al.	[255]	• Determine the quality of sampled medicines which included those for non-communicable diseases as well as antimicrobials including antibiotics in selected healthcare facilities as part of their participation in a digital pharmaceutical supply chain management system • Medicines assessed using a TruScan analyzer and GPHF-minilab	• Among the sampled medicines, approximately 75% were manufactured in Ghana and 16% were imported from India • The Ghana Food and Drugs Authority had registered 72% of the sampled medicines • 87% and 88% of the sampled medicines had passed the TruScan™ Raman and GPHF-minilab analysis respectively, with no significant difference between the two screening methods • Of the 21 collected samples, approximately 24% failed the pharmacopoeia test, which included azithromycin. Overall, when compared with the pharmacopoeia method, the performance of the TruScan™Raman analyzer and the GPHF-minilab technologies were 71% and 63%, respectively
Kenya – Irungu et al.	[256]	• Assess the quality of selected co-trimoxazole suspension brands that are currently marketed in Nairobi County • 106 samples of co-trimoxazole suspension were collected • Their API was evaluated against USP specifications	• The 106 samples were divided into 15 brands, which were primarily of local origin (86.7%) • On October 23, 2019, 6 of the 15 brands collected were no longer listed in the Pharmacy and Poisons Board retention register • Out of the 106 samples tested 70.6% and 86.8% were compliant with USP specifications for pH and API respectively, similar to the findings of Wafula et al., 2017 with different antibiotics [257], while 84.0% adhered to current labeling and packaging requirements

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Table 2. (Continued).

Country, Author and Year	Refs	Objectives and Study Design	Summary of the Findings
Nigeria - Maffioli et al.	[258]	• Review the extent of substandard and falsified medicines across countries especially LMICs as well as ongoing activities by the Nigerian National Agency for Food and Drug Administration and Control (NAFDAC) to reduce their prevalence • Test 246 medicine samples including antibiotics for their ingredients including APIs against current standards	• Since 2000, the Nigerian National Agency for Food and Drug Administration and Control (NAFDAC) has initiated a number of activities in order to reduce the prevalence of substandard and falsified medicines in the country • Activities include recommendations to the Government for changes in the law alongside stricter enforcement of registration guidelines/introduction of new guidelines to ensure that imported medicines are genuine, i.e. not falsified, coupled with the dismissal of corrupt NAFDAC personnel. Alongside this, destruction of current large quantities of falsified and expired products as well as raising public awareness regarding this key issue • In their study, 32% of sampled antibiotics (12/38) failed laboratory testing – principally due to a low API (83% – 10/12 samples). Similar findings (38.4% of antibiotic samples had ingredients outside of pharmacopeial limits) were seen in the study of Lawal et al. (2019) [259] • Investing in local manufacturing to improve the quality of available antibiotics is increasingly seen as cost beneficial [40]. However, there are concerns regarding the current commitment of the Nigerian Government to develop the pharmaceutical sector in the country [260], which includes addressing the current taxation environment [224]
Tanzania – Karungamye	[261]	• Estimating the extent of counterfeit and substandard drugs in Tanzania, and suggestions going forward • Review paper	• There have been historic estimates that up to 50% of medicines entering Tanzania are said to be falsified, i.e. fakes. Encouragingly, most people can spot these due to concerns and issues with their packaging, quality and labeling • This is continuing despite efforts by the Government to reduce the extent of substandard and falsified medicines • Potential ways forward to reduce their prevalence include mechanisms for recalling or confiscating antibiotics where there are concerns coupled with the suspension or termination of distributor licenses for allowing counterfeit medicines into the country
Tanzania - Mwalwisi et al.	[262]	• Appraise the quality of amoxicillin capsules, ceftriaxone for injection, and ciprofloxacin tablets imported into Tanzania to assess any differences in their quality depending on the country of European origin • All subject to quality control testing	• 31 brands, including 10 different brands of amoxicillin capsules, 9 different ceftriaxone sodium injections, and 12 different brands of ciprofloxacin tablets, were collected from the respected regions • Encouragingly, all the samples of the collected brands complied with the requirements as stated in their respective pharmacopoeial monographs
Upper-Middle Income African countries*			
South Africa - Lehmann et al.	[263]	• Determine the quality of medicines as well as pharmaceutical care in South Africa • Mystery customers collected 316 samples of medicines. Tablets containing amoxicillin alone or with clavulanic acid as well as analgesics including paracetamol were collected from both the formal and informal markets • In order to determine the extent of falsified, degraded or substandard medicines, visual inspections, uniformity of dosage units, and dissolution testing were conducted to pharmacopoeial quality standards	• Overall, no counterfeited medicines were identified among the 316 samples • However, merely 55.4% of the collected samples were able to fulfill all pharmacopoeial requirements regarding their quality • Most of the 139 samples (44.6%) which failed these requirements were unable to pass visual inspection due to inappropriate labeling and packaging • Several substandard medicines were also identified. Overall, 5.4% of the collected samples failed dissolution testing and 4.8% also failed the content uniformity test.

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Table 2. (Continued).

Country, Author and Year	Refs	Objectives and Study Design	Summary of the Findings
Asian Countries			
Low Income Asian countries*			
Nepal – Kafle et al.	[264]	• Appraise community pharmacists' perceived prevalence, awareness and attitudes toward counterfeit medicines • A cross-sectional study was undertaken using a structured questionnaire • 343 community pharmacists participated	• The perceived median prevalence of counterfeit medicines was 10.00%; however, of concern is that only a limited number of participants (2.3%) had clear knowledge of such practice • Encouragingly, 98.83% of participating community pharmacists stated they always check daily for the integrity of their drug suppliers and only use trusted drug distributors. In addition, 51.31% strongly disagreed and 40.52% disagreed with the statement 'Pharmacists decide to stock counterfeit medicines in their pharmacy since the quality is acceptable.' • 96.79% also believed that actions should be taken against community pharmacists dispensing counterfeit drugs with 94.75% believing that pharmacists who dispense counterfeit medicines are unprofessional; 338 (98.54%) stated that there should be strong laws against counterfeit medicine sales
Lower-Middle Income Asian countries*			
Bangladesh - Shohag et al.	[265]	• Assess the attributes regarding the quality of 22 commonly prescribed brands of ciprofloxacin 500 mg tablets collected among rural areas and cities • RP-HPLC along with UV-visible spectrophotometry and USP as well as British Pharmacopeia used for quality assessments	• 95.45% of the brands met Pharmacopoeia (BP) specified potency • 68.2% of the ciprofloxacin brands followed USP/NF dissolution test specifications. However, 31.8% of the ciprofloxacin brands failed to release 80% of the labeled amount of antibiotics within 30 minutes • Most of the ciprofloxacin brands prescribed followed the Weibull drug release kinetic model. However Fit factor analysis showed that 36.4% of the brands failed to comply with similar dissolution profiles to the reference ciprofloxacin • Encouragingly, minimum inhibitory concentrations assessed versus five bacterial strains showed good antimicrobial sensitivity among all ciprofloxacin brands tested
Upper-Middle Income Asian Countries			
Iraq - Al-Jumaili et al.	[266]	• Determine the extent of substandard and falsified medicines, which includes antibiotics at three levels. These include the Ministry of Health, community pharmacists and pharmaceutical company representatives • Exploratory mixed-method study	• Between 2016–2020, the Iraqi Pharmacovigilance Centre (IqPhvc) received 183 reports regarding substandard and falsified medicines from 25 international companies • The majority of the reports concerned substandard (parallel) medicines with 15.8% regarding falsified medicines • Based on surveys with pharmacists (590) – 72% stated they had not received any training regarding the identification of substandard and falsified medicines; however, 59.4% of surveyed pharmacists easily identified these. • Alongside this, approximately 75% of participating pharmacists stated they recognized genuine registered medicines through a number of means including their price stickers, costs, and packaging features; however, only 25.6% of pharmacists were willing to report substandard and falsified medicines

NB: *World Bank Classification; ABR = Antibacterial Resistance; AMR: Antimicrobial Resistance; API = Active Pharmaceutical Ingredient; MAH: marketing authorization holder; USP – U.S. Pharmacopeia.

Table 3. Potential interventions for Government/Health authority activities.

Short to Medium Term (1 to 5 years)	***A) Shortages*** • Activities to address possible shortages of antibiotics within countries can be divided into those to address short-term shortages (i.e. 3 months or less) as well as longer-term shortages (greater than 3 months and up to 5 years) [35] • Integrated within this are suggested activities to tackle antibiotic shortages within primary care clinics despite key antibiotics being available within the country *a) Short-term shortages* • Improve IT systems with local, regional and national health authorities to improve stock control and future forecasting for essential antibiotics especially in primary care – this will involve increased transparency and improved communication/training as well as the development of national risk management strategies [36,38,42,203,208,267,268]. • Seek ways to optimize procurement processes – which includes potentially rewarding improved delivery precision as well as evaluating the potential for longer term contracts/multiple contracts for the same antibiotic to reduce dependency on a single provider where pertinent. In addition, seek ways to enhance vendor transparency especially where shortages become a regular occurrence [42] • As part of this, reevaluate payment systems from health authorities to manufacturers and suppliers if concerns with payments are an issue behind limited stocks of essential antibiotics within public primary care clinics [29,36,268]. In addition, standardize dosing regiments for essential antibiotics based on the WHO AWaRe book guidance within countries and across regions to minimize the range of different antibiotic strengths needed to manufacture and keep in warehouses/PHC facilities to satisfy local demand • Improve early-warning systems between marketing authorization holders, importers, wholesalers and health authorities as part of the procurement process especially for primary care clinics [42] • Standardize pre-qualified supply mechanisms among suppliers to improve the availability of essential antibiotics [29], as well as prioritize the registration of essential antibiotics over non-essential antibiotics given concerns among LMICs [207,208] • Evaluate the possibilities of stockpiling and joint procurement of essential antibiotics within and across countries within the Region building on current experiences in a number of African countries as well as potentially diversify suppliers [33,36,203,204,268]. Alongside this, explore potential short term inter-change policies within the WHO AWaRe book guidance where necessary [29,44,45]. Developments such as the Africa Medical Supplies Platform should help in this regard [160] • Enhance the priority given to addressing antibiotic shortages within and across countries as well as improving resilience in the system especially where concerns are identified [178]. This will be helped by routinely implementing a data-driven approach to optimize antibiotic use across Africa and Asia to reduce AMR and improve patient outcomes [269] *b) Long-term shortages* • Explore the potential for encouraging local/regional production of essential antibiotics to minimize imports as well as shorten lead times [29,40,110]. However, locally produced antibiotics must meet agreed quality standards given and be affordable to optimize their use • Improve market attractiveness for essential antibiotics through improved education of all key stakeholders surrounding the guidance within the WHO AWaRe book as well as instigating quality targets based on the WHO AWaRe book [44,45,270]. In this way, optimize the use essential antibiotics at agreed doses to improve the attractiveness of these formulations and their potential profitability [42,271], recognizing that issues surrounding pricing and affordability of essential antibiotics is complex [38,42] • Streamline the registration processes especially for key essential generic antibiotics to continue to make the market attractive given current concerns with appreciable registration of non-essential medicines including antibiotics [207,208] – Pan African projects including the development of an African Medicines Agency will help in this regard [67]. As a result, focus Regulatory Authority activities on essential antibiotics and away from registering multiple brands of Watch antibiotics [231] • Further evaluate the potential for pooled procurement and stockpiling supplies [33,35,38], which can be achieved through initiatives such as the Africa Medical Supplies Platform [160], as well as appraising and investing in 'Just in Time' inventory management systems [271–273] • Continue to elevate the priority given to addressing antibiotic shortages within and across countries as well as improving resilience in the system [178] ***B) Substandard and Falsified Medicines*** • Reducing the availability of substandard and falsified antibiotics, especially essential antibiotics, should be routinely incorporated into NAPs to reduce AMR [24] • Potential activities include addressing concerns with current weak Regulatory Agencies across Africa and Asia where these occur through greater enforcement of current regulations [65]. The development of an African Medicines Agency and associated harmonization of regulations and approaches, building on the Lomé agreement, should help in this regard [49,67,68], as well as potentially evaluating blockchain applications [244] • Alongside this, toughen the laws and regulations against falsified medicines especially where these do not currently exist or are weak – building on the experiences in China [70,71]. In addition, toughen regulations surrounding locally produced API as well as multiple sourced antibiotics to make sure they comply with International standards, with re-registration and/or removal of licenses where concerns [24,52] • As part of this, continue to encourage research into cost-effective detection methods that can easily be implemented among African and Asian countries to continually assess the extent of substandard and falsified medicines [274–276] • Next steps could involve adapting case finding or risk-based sentinel surveillance to identify the extent of falsified or substandard antibiotics within a country [243], helped by encouragement of ongoing assessments of the value of different sampling and quality testing methods within LMICs. In addition, assess the potential for introducing track and trace systems for locally produced and imported medicines to help with the implementation of policies to reduce the extent of substandard and falsified medicines – building on experiences in Turkey [63,247,277] • Regulatory authorities, social media companies and Internet providers also need to instigate activities to reduce the extent of substandard and falsified medicines, especially antibiotics, readily available via the internet. This will require stronger regulations including legislation within countries where this is currently absent or weak [56,57,63,278] • Continue to explore ways to make the market for falsified medicines unattractive – including financial penalties for abuse as well as reducing affordability/improving access to quality antibiotics when dispensing/buying antibiotics [49,74,75], recognizing that appropriate pricing of antibiotics within countries given the many issues/stakeholders can be challenging, e.g. raising import fees may encourage local companies to raise their prices without price controls [216] • Seek to instigate pertinent educational activities among patients to aid their identification of substandard/falsified medicines where concerns with the help of patient organizations and others [279] • Routinely involve community pharmacists and drug store owners to identify falsified medicines and report these to the authorities. This may mean reevaluating the training of trainee community pharmacists in Universities as well as post-qualification regarding these issues [49,55,75,237]

(*Continued*)

Table 3. (Continued).

C) National Action Plans

- Governments and health authorities in their NAPs across LMICs need to focus on reducing inappropriate use of antibiotics in the primary healthcare setting in addition to tackling issues of falsified/substandard medicines as well as shortages when they arise to reduce AMR
- Activities will necessarily involve additional resources (technical/personnel and financial) to address current challenges including concerns with the knowledge and practice of key stakeholder groups (prescribers, dispensers and patients) currently translating into high levels of inappropriate prescribing and dispensing of antibiotics across Africa and Asia as well as ongoing concerns with substandard/falsified antibiotics. NAPs have been implemented across Africa and Asia; however, there are concerns with their rate of progress that needs to be addressed going forward including improved surveillance of antibiotic resistance patterns [146,149,150,280–282]
- This includes a focus on the integration of routine antibiotic surveillance into electronic healthcare systems such as DHIS2 and others as part of a primary care agenda [283], alongside potentially track and trace systems, and other mechanisms for antibiotics being prescribed in PHCs as well as dispensed among African and Asian countries, which will also help address any future issues regarding shortages of essential antibiotics in primary care [247,277]. Routine surveillance would include greater monitoring of prescribing and dispensing patterns against agreed AWaRe-based prescribing/quality indicators and quantity metrics [270,284]. Alongside this, Governments and Health Authority personnel in each country may need to refine existing indicators to ensure their relevance and enhance their use [270,285]
- Continue to encourage the routine use and standardization of primary care ASPs among prescribers and dispensers to improve future antibiotic use given ongoing concerns in practice.
- As part of this, continue to assess the cost-effectiveness of ASP interventions, as well as other policy initiatives including enhancing public awareness of falsified medicines and different monitoring systems, with the aid of academic institutions to help refine future strategies given often limited resources in LMICs [275,286,287]. This also includes the possible role of Artificial Intelligence/Machine Learning to improve future antibiotic use as part of ASPs [288–290]. In addition, potentially virtual reality initiatives [291]
- Explore additional activities to reduce the prices as well as costs to patients of multiple sourced essential antibiotics of agreed quality through encouraging INN (International Non-proprietary Name) prescribing [292–294]. However, this requires key stakeholder trust in the quality of available antibiotics alongside adequately addressing challenges that low prices of antibiotics may need to be balanced against manufacturers' requirement for a profit for their continued supply [30,295,296].
- Seek to pilot/introduce/expand educational campaigns among the public and patients to help attain NAP goals, aware of language and potential gender issues as well as challenges in accessing healthcare knowledge, and monitor their outcomes with the help of academic units, with the aim of providing future direction to all key stakeholder groups [167,176,297–299]. Implementing people-centered approaches and guidelines are increasingly needed to tackle AMR across Africa and wider [300]

D) Prescribers (Physicians and Nurses)

- Work with health authorities, managers and others within primary healthcare clinics to predict and monitor antibiotic use, with standardization of antibiotic use, including doses, enhanced by the availability of WHO AWaRe Book guidance [44,45]. Prescribers/managers within primary healthcare clinics also need to make administrators aware when lack of payment is holding up the supply of essential medicines in order that this can be rectified
- Continue to evaluate knowledge and actual practice of prescribers across Africa and Asia given current concerns regarding their use of antibiotics, especially Watch antibiotics, AMR, and ASPs in practice, as well as instigate pertinent additional educational activities where necessary through the help of Universities as part of CPD activities
- Encourage prescriber organizations among African and Asian countries to work with Governments/Health Authorities to refine local guidelines based on the WHO AWaRe book and local resistance patterns. As part of this, key organizations among African and Asian countries need to work closely with physicians and other prescribers to encourage them to regularly consult national/local guidelines concerning optimal treatment for patients where pertinent, including the WHO AWaRe book. This is because guideline adherence is increasingly seen as a key quality marker to be part of future ASPs to help with future forecasting/standardization of dosing [270,285,301]
- In view of this, where necessary, key organizations need to work with Governments/Health authorities to make guidelines easily accessible to prescribers – increasingly through simple, easy to use applications and other systems, necessary to help achieve UN GA goals for the use of Access antibiotics. This will require key organizations to work with National Governments and Health Authorities to improve electronic systems within countries to enhance real-time monitoring of prescribing practices against agreed quality indicators – increasingly based on the WHO AWaRe system [270]. However, cognizant not to overload prescribers with too many indicators to monitor – key prescriber organizations can help in this regard
- Work with prescribers and their organizations to reduce the influence of pharmaceutical company activities where pertinent through encouraging the use of the WHO AWaRe book when considering the prescribing of antibiotics with the aid of quality indictors [270,302,303], ASPs and other mechanisms – acknowledging that potential barriers may need addressing before AMS and ASP activities become normal practice among key LMICs

(*Continued*)

Table 3. (Continued).

	E) Dispensers (Community Pharmacists) • Work with Universities and Health Authorities to improve their identification of falsified/substandard medicines, and report these to the relevant health authorities when identified. As part of this, work with the authorities and others if track and trace systems are introduced • Work closely with health authorities, wholesalers and others to monitor the availability of essential antibiotics in primary care, as well as rapidly inform the authorities where concerns • Work with health authorities and suppliers to improve the monitoring of antibiotic dispensing generally in the community to improve forecasting/reduce the possibility of shortages. This can include the use of mobile technologies [19,304] • Continue researching the knowledge and practices of dispensers among African and Asian countries regarding antibiotics, AMR, and ASPs – especially given identified concerns in practice • Undertake post-graduate educational activities (CPD) where necessary through the help of Universities, including potential educational activities to dispel misinformation, which was problematic during the COVID-19 pandemic [305–308]. In view of this, Governments/Health Authorities in each country need to work with key pharmacy organizations to encourage dispensers to regularly consult national/local guidelines concerning optimal treatment for patients presenting with infectious diseases, increasingly including the WHO AWaRe book guidance, given current concerns • Where necessary, Governments/Health authorities need to work closely with pharmacy organization to make guidelines easily accessible to dispensers – again increasingly through simple, easy to use applications and other systems • Governments/Health Authorities also need to ensure that antibiotics that can be dispensed in community pharmacies are in line with the WHO AWaRe book recommendations especially where there are current concerns [138]. This includes any antibiotics that are part of potential quality indicators introduced in community pharmacies to improve future antibiotic dispensing ***F) Universities*** • Governments/Health Authorities need to work with Universities to ensure that current HCP curricula meet agreed standards. This increasingly includes education around identifying falsified/substandard medicines as well as making sure no HCP student leaves university without being fully aware and cognizant of the WHO AWaRe classification and the WHO AWaRe book guidance • University personnel also need to work with Governments/Health Authorities and others to continue to assess the cost-effectiveness of different systems to monitor the extent of substandard/falsified antibiotics in practice across African and Asian countries given current resource issues • Governments/Health Authorities also need to work closely with Universities to ensure that CPD activities are aimed at improving prescriber and dispenser knowledge of national/WHO AWaRe book guidelines so that they can give appropriate advice to patients when patients/guardians of children present with self-limiting conditions such as acute respiratory infections given expectations of antibiotics being prescribed/dispensed. Alongside this, instigate programmes to enhance dispenser communication skills with patients [309] • Governments/Health Authorities also need to work closely with Universities to monitor the knowledge and practice of all key stakeholders toward antibiotic use, AMR and AMS, and refine CPD and other activities where necessary • Governments/Health Authorities also need to work closely with Universities to research the outcomes of any national initiatives, including educational initiatives among patients and parents, and their associated cost-effectiveness, as well as guideline introduction/associated quality indicators, as part of academic activities to help refine future activities. This also includes the potential future role of Artificial Intelligence/Machine Learning activities to improve future antibiotic utilization as part of ASPs [288–290]. ***G) Patients/Patient Organisations*** • Patient organizations across LMICs need to work with Governments/Health Authorities and Universities to help patients identify substandard/falsified medicines in practice, as well as report these when found to the relevant authorities • Alongside this, patient organizations need to work with other key stakeholders including Governments/Health Authorities to improve existing communication and beliefs regarding the lack of effectiveness of antibiotics for viral infections, and that high levels of inappropriate use of antibiotics will increase AMR – building on successful campaigns among LMICs [310–316] • Patient organizations can also help Governments/Health Authorities understand key issues surrounding the terminology of antibiotics and AMR where pertinent, with these issues increasingly seen as crucial when health authorities and others are designing different educational initiatives and approaches for patients to enhance their chance of success [297,317–319] • Governments/Health Authorities also need to work closely with patient organizations where affordability of antibiotics is a problem as this can fuel the market for substandard/falsified medicines as well as enhance AMR. However, acknowledging that pricing of antibiotics is a complex issue • Alongside this, Governments/health Authorities need to work closely with patient organizations to explore new social media channels to effectively communicate with patients to address misinformation, which was problematic during the COVID-19 pandemic [180,305,320,321] • Alongside this, also explore virtual reality initiatives to increase awareness of antibiotics, including substandard/falsified antibiotics and AMR among the public [291] • Work with patient organizations to encourage people to become antibiotic guardians where such programs exist [322]
Longer Term	• Continue to invest in pertinent programs, including Pan-African initiatives as well as initiatives with the WHO, to guard against shortages of essential antibiotics in primary care as well as falsified/substandard antibiotics. The latter includes potential additional legislation to address any increase in the availability of substandard/falsified medicines via the internet • Regularly monitor antimicrobial utilization patterns, including the extent of any falsified/substandard antibiotics, across all sectors as part of agreed NAPs • Instigate where pertinent additional multiple strategies to improve antibiotic utilization based on the WHO AWaRe book guidance. This includes continuing to improve AMR surveillance as well as enhancing electronic monitoring systems where pertinent to collect utilization data in real time • Continue to refine international guidance and quality indicators where pertinent to make sure of their relevance/use. As a result, ensure any indicators remain current as well as avoiding overloading HCPs across locations • In addition, continue to research the cost-effectiveness of ASPs as well as educational activities among patients to help achieve UN GA goals, and refine where necessary • Continue to work with Universities to ensure adequate training of HCP as well as support for CPD and research activities

[29,32,92,170,203,267,324,325]. Shortages can also be hampered by a lack of prioritization of registering essential versus non-essential antibiotics alongside perceived over-registration of Watch antibiotics [43,110,207,229,230,232], as well as a lack of local production, which can lead to long supply chains [29,35].

Suggested ways forward include increasing local production alongside addressing concerns with incentives and minimizing production lines through encouraging greater adherence to international guidance such as the WHO AWaRe guidance given concerns with current prescribing and dispensing patterns across African and Asian countries [36,44,45,110,205]. Alongside this, harmonizing registration of essential antibiotics among countries close to each other within a region, researching possible joint procurement projects acknowledging the challenges, as well as improving forecasting capabilities [32,35,69,160,170,326].

Concerns with current prescribing and dispensing of antibiotics, impacting on forecasting and the potential for local production, are currently seen across a number of African and Asian countries. This includes 32.1% to 43.2% of antibiotic prescriptions being from the Watch group in DRC Congo, Eritrea, and Ethiopia [212–214], high rates of dispensing of azithromycin to patients with suspected COVID-19 in Kenya (99.1%) [221], 49.54% to 68.4% of antibiotic prescriptions being seen as irrational with STGs in Ethiopia and Uganda [327,328], and only 8.8% of all the prescriptions for antibiotics seen as appropriate in South Africa [226]. There were similar concerns among critical Asian countries. In Nepal, 75% of children who received antibiotics for diarrhea did not meet recognized indication requirements [227], and in China, only 18.3% of antibiotic prescriptions were appropriate [329], with 66.2% of prescriptions seen as inappropriate in another study [233]. Watch antibiotics constituted 39.3% to 73.5% of dispensed antibiotics in Bangladesh, Pakistan, and Vietnam [190,228,230,330,331].

Table 1 includes summaries of key issues regarding access, availability, and shortages principally among key African and Asian countries. The full list of sourced papers among the key African and Asian countries is contained in Table S1 (Supplementary Material).

2.2.2. Substandard and falsified antibiotics

There have been concerns with the extent of substandard and falsified medicines including antibiotics among African and Asian countries (Table 2), with the magnitude and the consequences worsening during the pandemic [237]. The considerable extent of falsified/substandard antibiotics out of all medicines surveyed was noted in the review of Feeney et al. (2024) to be up to 36% of all medicines analyzed [238], with other studies also showing similar findings [242,249,252]. This, though, is not always the case for antibiotics versus other medicines [59].

However, the prevalence of substandard and falsified medicines globally was lower at 13.6% in the review of Ozawa et al. (2018) [47], highest though in Africa at 18.7% among sampled medicines as well as Asia at 13.7%. Prevalence rates were similar at 12.4% of 95,520 essential medicines tested among 130 studies in their 2022 update [171]. A higher proportion of substandard and falsified medicines in Africa versus other continents is also seen in other studies [49]; however, detection rates can vary considerable among African countries [332]. This is an important area to address with estimates for the global economic impact of substandard and falsified medicines ranging from $10 billion to $200 billion [47].

From the published studies (Table 2), the prevalence rates of substandard and falsified medicines in recent years appeared lower in Asia [264,333–335]. In Africa, current high rates of substandard and falsified medicines are not helped by only a limited number of African countries having legal mandates to perform all the core regulatory functions to reduce the prevalence of these medicines [49]. However, this is beginning to change with initiatives such as the WHO Lomé initiative, as well as joint initiatives by the Regulatory Agencies across Africa (Table 2), building on current initiatives to harmonize regulatory activities as seen in East Africa (Table 1) [69,245,332]. Several African countries have also ratified the Council of Europe Medicrime Convention Treaty to help reduce the extent of falsified and substandard medicines as an example to other African countries [246], with the Nigerian National Agency for Food and Drug Administration and Control also initiating a number of activities to reduce the prevalence of substandard and falsified medicines in the country [258]. Such activities are welcomed to help address this critical issue, and associated reduction in AMR, with still an appreciable prevalence of falsified and substandard medicines in a number of African countries including Cameroon [242], DRC Congo [274] Ethiopia [250,336], Ghana [255], and Nigeria [258,337]. However, this is not always the case as seen for instance in Tanzania [62,262] and South Africa [263], providing direction to others. Overall, current estimates of poor quality medicines in Africa, which includes antibiotics, range on average from 18.7% to 22.6% of available medicines, with the greatest number seen with antibiotics [47,49,52,241]. Some studies though have reported higher rates in Africa up to 89% of available medicines [237,243,332], which needs to be urgently addressed going forward. A key target in the future will also be the considerable number of informal sellers across Africa, with typically higher rates of substandard and falsified medicines being dispensed than seen in community pharmacies [248,254,274].

Internet and other sources have also revealed that there are still considerable problems with substandard and falsified medicines in India leading to arrests [338–340], as well as in Pakistan [341–344]. However, the Regulating Agency in Pakistan appears to now be taking urgent steps to try and address this situation [345]. The Indian government has also formed a task force to tackle the problems with falsified medicines through, for instance, implementing unique identification numbers and a bar code on each medicine pack [63], although some problems persist [338].

There are also concerns in Vietnam with the extent of substandard and falsified antibiotics [346–348], which also needs addressing going forward alongside addressing concerns with the prescribing and dispensing of antibiotics in the country (Table 1 as well as Tables S1 to S3). We could not identify any studies from China published in PubMed in recent years documenting the extent of substandard and falsified medicines including antibiotics. This though may reflect recent toughening of the laws in China against counterfeit medicines, with appreciable penalties when these are

found [70,71]. However, we cannot say this with certainty without further research.

The appreciably lower rates of falsified and substandard antibiotics in high-income countries versus LMICs with their greater enforcement of current regulations provide direction to LMICs alongside ongoing activities in China [71,74].

Table 2 includes summaries of key issues regarding substandard and falsified medicines principally among key African and Asian countries. The full list of sourced papers among the key African and Asian countries is contained in Table S2.

2.2.3. Prescribers, dispensers, and patients

Tables S3–S5 contain summarized details regarding the knowledge and practice of Prescribers, Dispensers, and Patients/Public regarding antibiotics, AMR and AMS.

2.2.3.1. Prescribers.

High rates of inappropriate prescribing of antibiotics were seen among the studied African and Asian countries irrespective of income levels (Table S3). Antibiotics were often prescribed for self-limiting conditions, including acute respiratory infections in up to 96.2% of occasions [349], exacerbated by the lack of time that prescribers typically have with patients coupled with patient demands. Low rates of adherence to current guidelines are also a concern, potentially adding to AMR. This needs to be addressed with adherence to guidelines increasingly seen as an important marker of the quality of care, helping to reduce current high rates of the prescribing of Watch antibiotics across Africa and Asia where this occurs [9,91,130,212,270,301,350–352]. Where recorded, compliance rates with current guidelines varied among African countries, ranging from 11% up to 97% compliance [353,354]. However, improvements were seen following audits and feedback of prescription findings [354]. In one study in China, only 18.3% of antibiotic prescriptions were seen as appropriate [329], with high rates of inappropriate antibiotic prescribing also seen among children aged 0–5 years (78.5%) in another study [355].

Alongside this, high rates of prescribing of Watch antibiotics have also been seen in a number of Asian countries, against the recommendations in the WHO AWaRe guidance book [44,45,91,229,230,351]. Prescribing concerns were enhanced by limited knowledge regarding antibiotics, AMR and AMS among a number of prescribers in African and Asian countries. However, considerable variability was seen among prescribers across the countries.

Another key identified concern was that whilst in some African and Asian countries there was good knowledge of antibiotics and AMR among prescribers, this did not always translate into actual prescribing practices [68,356,357]. For instance, in Nigeria, 49.2% of prescribers had good knowledge of AMR; however, 75.7% admitted to prescribing antibiotics for sore throats [356].

The need for additional training regarding antibiotics, the AWaRe classification, AMR and AMS, was seen as a definite requirement among prescribers across Africa and Asia. This also included training surrounding current national STGs as well as the WHO AWaRe classification and WHO AWaRe book guidance where no current national STGs exist; alternatively, now seen as out-of-date [44,45]. This is important with cited studies showing that educational and other interventions surrounding STGs enhanced the appropriateness of future antibiotic prescribing [233,234,354,358]. In addition, more antibiotic utilization studies in LMICs are now recording usage based on the AWaRe classification as the forerunner to targeted ASPs [359]. However, there is a need to also strengthen antibiotic surveillance and reporting systems across LMICs to improve future prescribing [280].

2.2.3.2. Dispensers..

A similar picture was seen among dispensers (Table S4) and again irrespective of country income levels. There were typically high rates of dispensing of antibiotics without a prescription across the studied African and Asian counties, including up to 94% of patients. Alongside this, similar to prescribers across Africa and Asia, the dispensing of antibiotics without a prescription was typically for self-limiting conditions, which included acute respiratory infections alongside diarrhea. Identified concerns also included appreciable dispensing of antibiotics from the Watch group, which included up to 49.3% and 53.6% Watch antibiotics among patients visiting community pharmacists in Pakistan and Bangladesh, respectively, [230,331].

Alongside this, high rates of dispensing of antibiotics from the Reserve group among community pharmacies at 10% in Bangladesh and 19.0% in Pakistan [230,331]. Having said this, there was limited dispensing of antibiotics without a prescription for essentially viral infections, including patients with COVID-19 among community pharmacies linked to the University of Nairobi in Kenya [222,360].

The reasons for high rates of dispensing of antibiotics without a prescription were similar across Africa and Asia irrespective of World Bank income status. Reasons included high patient co-payments, concerns with available funds, convenience of pharmacies, ease of access of antibiotics in community pharmacies and drug stores and increasing pressure from patients [113,361–366].

Encouragingly, pharmacists with greater experience, and following educational activities, were generally less likely to sell antibiotics to patients or carers without a prescription [279,367]. However, similar to prescribers, whilst knowledge of antibiotics and AMR appeared reasonable among dispensers across Africa and Asia, this did not always translate into actual practice. Dispensers acknowledged issues of language surrounding the terminology for antibiotics and AMR as a potential barrier to reducing inappropriate dispensing alongside lack of knowledge [167,220,297,368,369]. This can be addressed now that the WHO AWaRe book guidance has been launched giving advice on the appropriate management of 35 common infectious diseases [44,45].

2.2.3.3. Patients/public..

There were similar concerns and issues to other key stakeholder groups among patients and the public across Africa and Asia with respect to their knowledge, attitude, and practice toward antibiotics and AMR (Table S3).

A number of studies demonstrated moderate-to-good patient knowledge and familiarity regarding terms such as antibiotics, AMR, and the problems associated with AMR [370–375]. For instance, in one study Nigeria, 76.6% of patients stated that

bacteria would become less resistant to antibiotics after prolonged use, and only 22.1% believed antibiotics can cure colds and sore throats faster [376], and in one study in Eritrea, 78.2% of participants correctly reported that ABR is an issue that needs addressing [377]. However, a number of knowledge concerns were identified among the critical African countries [378–381]. For instance in Tanzania in two studies, between 61.4% and 62.5% of participants believed sore throats could be treated with antibiotics [382,383], and in Malawi in one study, 92.4% of participants also believed antibiotics could stop a fever [384]. Similar findings were seen in studies in Eritrea, Ethiopia, Ghana, Nigeria, and Zambia [377,385–390].

Patients and the public among the studied African countries also commented on the appreciable self-purchasing of antibiotics, typically for self-limiting conditions including coughs, colds, and fever (Table S3). High rates were driven by the ease of the access and availability of antibiotics in community pharmacies and drug stores, previous experiences, condition seen as minor, costs, locations, e.g. rural area, as well as a desire for quick relief for their infectious diseases [191,385,391–394]. Documented rates of self-purchasing of antibiotics among patients ranged from 23.6% in Kenya [395], to 47% to 81.4% in Cameroon [374,396], and 26% to 86.5% in Nigeria [397,398].

There were again considerable differences between stated knowledge and actual practices among patients and the public among critical Asian countries [399]. For instance in Pakistan, 61.7% of participants in one study had good knowledge regarding antibiotics and AMR and the fact that antibiotics kill bacteria [94]. However, the majority of participants believed antibiotics can treat viral infections and that all types of infection can be cured with the help of antibiotics [94]. Having said this, among patients in critical Asian countries, there were encouraging signs [400–402]. For instance in China in one study, 83.5% of participants believed antibiotics were unnecessary for common colds, and in another, 70.2% believed that the overuse of antibiotics increases ABR, similar to other studies in China as well as Vietnam [403–406].

However there were also concerns that need addressing to reduce inappropriate antibiotic use [83,167,399,407,408]. For instance, in one study in Nepal, 84.6% of participants reported they sometimes prefer an antibiotic when they have a cough or sore throat [399], and in another, participants typically demonstrated a low level of knowledge concerning AMR [407]. Similarly in China, 91.6% of participants in one study thought antibiotics can control and treat viral infections [409,410], with 81.3% of participants in another admitted to using antibiotics to treat their acute respiratory infections [409]. Similar findings were also seen in studies in Bangladesh, India, and Vietnam, as well as other studies in Nepal [401,411–414].

Again, self-purchasing of antibiotics was common among patients in the key Asian countries [415,416]. These ranged from 33.4% to 59% in Pakistan [417,418], and between 50.9% and 80.9% in studies in Bangladesh, including high rates of dispensing of antibiotics from the Watch list [230,419]. The top three infectious diseases for self-medication with antibiotics in Bangladesh were coughs, colds, and a fever [420]. In China, rates of self-purchasing of antibiotics among patients were also a concern ranging up to 92.1% of patients, depending on the population and location [403,406,409,421–428].

Overall, patients' and parents' beliefs regarding the effectiveness of antibiotics across a range of self-limiting infectious diseases are a major issue to address going forward as they have resulted in appreciable pressure on both prescribers and dispensers to prescribe/issue antibiotics in situations where they are not needed and could cause harm (Table S3). Generally though, there was a better attitude toward antibiotics among more educated patients.

Positively, education initiatives among African and Asian countries improved patients' knowledge regarding antibiotics and their potential use in practice [310,311,368,429]. In their study, Otieku et al. (2023) found that participants exposed to an educational intervention appreciably increased their knowledge base and were significantly more likely to recommend restrictive access to antibiotics [429]. However, there can be challenges with undertaking educational campaigns among patients [430,431]. This includes patients' actual understanding of the terminology concerning key issues including antibiotics and AMR [432]. This can be a problem, especially among dispensers, when educating patients, or their care givers, regarding these crucial issues when recommending treatments for infectious diseases [167,297,368,369]. It is critical that health authorities and others are aware of these critical issues when designing educational and other initiatives for patients [297,317,318]. Health authorities also need to be aware that any intervention, or targetted educational program, among patients, caregivers, or the public, must include a range of stakeholders to ensure these initiatives are appropriate for their health system and cultural context [433].

2.2.4. Discussion and next steps

We belive this to be the most comprehensive narrative synthesis to date exploring key aspects of primary care antibiotic use across Africa and Asia as a basis for future recommendations. This includes critical issues surrounding access, availability, affordability, shortages, and the use of antibiotics alongside the possible reasons for current utilization patterns. The wide range of priorities and activities identified in the reviewed papers (Tables 1 and 2, S1 to S5) have been broken down into different key stakeholder groups. These include Governments/Health Authorities, Prescribers (Physicians/Nurses), Dispensers (principally Community Pharmacists), Universities (as educators of prescribers and dispensers as well as undertaking important research) and the Public/Patients. We are aware that dispensers also include the informal sector in many LMICs, e.g. Bangladesh, Cameroon, Malawi, and Zimbabwe, where there are concerns with issues of substandard and falsified medicines as well as particularly dispensing practices. However, in this paper, we will just deal with activities with community pharmacies and discuss key implications and activities regarding the informal sector in future publications.

There were very few papers that identified a systematic lack of access to antibiotics in the LMIC primary care setting. Short-term stock outs were identified and clear concerns around affordability, but there was a notable lack of evidence regarding short-term shortages or longer-term access to appropriate antibiotics in primary care (Table 1) [92]. It should be noted, though, that the countries selected for this review were not the most impoverished or in conflict zones. However, there are few studies to date in this area. There was a clear recognized need to improve supply

chain logistics, forecasting and financing to ensure key antibiotics recommended in the WHO AWaRe book are routinely available to prescribe to patients. These issues and suggestions are captured in Table 3 along with other evidence-based suggestions and initiatives for a sustainable reduction with respect to inappropriate antibiotic use across LMICs [434].

There remain concerns around the availability of falsified and substandard antibiotics. Joint working across continents, illustrated by the 'Lomé Initiative', as well as moves to develop a Pan-African Medicines Agency, should help in this regard, and provide guidance to other continents [59,64–68]. Vigilance among community pharmacists can also help with addressing issues of falsified medicines [73]. However, this may require additional education from Universities where student and community pharmacists may currently have limited knowledge regarding identifying substandard and falsified medicines, as well as addressing where pertinent any temptation among community pharmacists to dispense falsified medicines for short-term financial gain [77,78].

There were similar findings among African and Asian countries with respect to knowledge and usage patterns regarding antibiotics, AMR and AMS (Tables S3 to S5). As a result, just the suggested activities for Government/Health Authorities are documented here (Table 3). Those for the other key stakeholders, i.e. prescribers, dispensers, Universities, and patients, are included in the Supplementary Material (Tables S6–S9).

Across each stakeholder group among the included African and Asian countries, there was a clear identified need to improve knowledge regarding the optimal use of antibiotics and AMR, with self-reported knowledge about these issues typically different from actual practices across all country income levels. Knowledge gaps were exacerbated by a perceived lack of post-graduate education or training on optimal prescribing or dispensing of antibiotics among relevant stakeholder groups. This includes a need for training surrounding the WHO AWaRe system and prescribing guidance in the WHO AWaRe book [44,45], leading into potential ASPs. This is important as currently there is no detailed WHO guidance on undertaking ASPs in the primary care setting.

The review noted a clear opportunity for Governments and Health Authorities across Africa and Asia to enhance routinely collected healthcare data to monitor prescribing and dispensing practices, as well as collect data on the extent of substandard and falsified medicines (Table 3). Although this will require financial resources given the current extent of paper-based systems among African and Asian countries, such activities can build on systems such as DHIS2, which was developed for these continents in addition to the WHO GLASS initiative [283,434].

Improving IT systems will help Governments and Health Authorities when working with key Pharmacy organizations to reduce inappropriate dispensing of antibiotics, especially those from the Watch and Reserve groups. In time, we also monitor dispensing of antibiotics by indication to help reduce their dispensing especially for self-limiting conditions as noted in the WHO AWaRe Book guidance. A clear outcome of Table 3 is that Governments and Health Authorities should engage more effectively with patients to address current issues and concerns such as misconceptions regarding the effectiveness of antibiotics for viral infections. This though will need closer working with patient organizations and other similar bodies to explore potential social media channels to more effectively communicate with patients in concepts and languages they understand. These activities can build on social media experiences arising from the COVID-19 pandemic, including vaccinations, where appreciable concerns were identified [305,435, 436–438].

We are aware that there are many limitations to this study. It was not practically possible, given the number of studies identified, to report data across all LMICs, even those among all African and Asian countries. Consequently, we just concentrated on critical African and Asian countries. However, all major stakeholders involved in the day-to-day prescribing and dispensing of antibiotics were included alongside patients, parents, and the public. A formal systematic review was also not possible given the wide variety of methodologies used in the included papers. However, the generalizability of these studies was possible given the similarity of the key findings among all stakeholder groups and countries across Africa and Asia.

This review was also conducted during the preparations as well as during the UNGA-AMR in 2024 [81]. The major commitment of the UN GA that 70% of all antibiotics used in humans should be Access antibiotics has added to the urgency of the key findings certainly with respect to ensuring optimal access, affordability, and availability of Access antibiotics across locations and countries. There is a clear need for major training across all key stakeholders regarding optimal antibiotic use building on the WHO AWaRe book and guidance, which could be addressed by a standard program with national and regional modules. This should be practical and affordable with a small number of globally relevant educational training programs. We will be taking this further in future studies.

3. Conclusions

This comprehensive review, working with multiple key stakeholders across multiple LMICs, has identified significant knowledge gaps as well as potential interventions. Very few studies could be identified that assess the current barriers to access of antibiotics in the primary healthcare setting across LMICs. This includes a lack of evidence for short-term stock outs of essential antibiotics or of longer-term failure in the availability of antibiotics at a facility level. A clear barrier to more detailed and formal assessments of the 'antibiotic access gap' is the absence of agreed minimum access standards for essential antibiotics, doses, and formulations that should always be available in every primary healthcare facility in LMICs.

The review has identified clear concerns with the overuse of antibiotics for minor infections, particularly oral Watch antibiotics for respiratory tract infections and multiple antibiotics for mild diarrhea. Practical suggestions for improving the education of all providers and receivers of antibiotics based on the AWaRe classification and guidance have been noted and will be expanded upon in future studies. The continued concerns with sub-standard and falsified medicines as well as practical next steps have also been reviewed, although more recent data suggest that some improvements in this area have been made. However, the affordability of essential antibiotics remains a major concern across a number of studied countries, particularly with current major constraints on healthcare and out-of-pocket finances. This needs to be tackled going forward.

We are aware that this review was not able to develop a more formal prioritization exercise to estimate the relative impact of the multiple policy options listed here. We acknowledge that a more formal process of evidence-based priority setting to improve the use of antibiotics in primary care globally would help inform the planned review of the AMR Global Action Plan going forward. However, this was not the objective of this narrative review.

4. Expert opinion

There are appreciable concerns with rising rates of AMR across LMICs increasing morbidity, mortality, and costs. Co-ordinated activities are needed to ensure appropriate use of antibiotics, alongside the ready availability and affordability of quality antibiotics in primary care clinics, to reduce AMR whilst attaining SDG 3.8, i.e. on arrival at the point of care, patients should have access to safe and effective antibiotics meeting agreed quality standards in an affordable formulation.

There is continued availability of substandard and falsified medicines across LMICs, including African and Asian countries, which needs to be addressed going forward to reduce AMR. Countries such as China have shown the way forward by increasing quality standards for multiple sourced medicines within the country coupled with fines for manufacturers when falsified antibiotics are detected. Ongoing initiatives such as the Lomé initiative in Africa, coupled with the development of a Pan-African Medicine Agency, should help in the future to reduce the prevalence of falisfied and substandard antibiotics in Africa alongside making the falsified antibiotic market unattractive through improved local production and addressing issues of affordability. However, this is complex as such issues have to be balanced against concerns with profiability for manufacturers if prices are too low.

Access to appropriate antibiotics in public clinics can also be a challenge in a number of LMICs. Improved supply chain management, which includes making sure suppliers are paid for their antibiotics alongside instigating electronic systems to improve forecasting and determining usage patterns in dispensaries as well as primary care clinics, can help address this. Increases in the local production of antibiotics can also decrease lead times, which alongside making sure registration of essential antibiotics is prioritized over non-essential antibiotics, can also help with the availability of essential antibiotics in LMICs.

A key concern going forward is the current high rates of inappropriate prescribing and dispensing of antibiotics in primary care among LMICs, particularly oral Watch antibiotics for essentially minor infections. Minor infections include acute respiratory tract infections alongside mild diarrhea. High rates of inappropriate prescribing of antibiotics were often despite professed knowledge of antibiotics, AMR and AMS among all key stakeholder groups, i.e. demonstrating a disassociate between stated knowledge and actual practice when it comes to prescribing, dispensing, or consuming antibiotics. The availability of the AWaRe classification and guidance across 35 infections, including where antibiotics may not be the appropriate first choice, provides a robust foundation going forward to improve future antibiotic use. This is important with the United Nations General Assembly recently setting a target of 70% use of Access antibiotics across sectors to reduce AMR. As a result, it is increasingly likely to see SPs being introduced with quality indicators based on the AWaRe system and guidance to meet UN GA targets.

Education for healthcare professionals starts in University and continues post-qualification. Consequently, Universities need to ensure that their healthcare students leave their Universities with comprehensive knowledge of the AWaRe system, AMR, and ASPs, ready to help improve antibiotic use post qualification and subsequently through continual professional development activities. This includes ensuring that healthcare students understand the importance of good communication with patients, especially where terms such as antibiotics and AMR may not exist in the local language. Patient organizations can help here.

Patient organizations, together with academic personnel, also need to develop targeted educational campaigns given concerns with patients' knowledge of antibiotics and AMR across LMICs, coupled with their considerable influence on prescribers and dispensers to provide antibiotics for often minor self-limiting infections. Alongside this, academic personnel can also help with assessing the cost-effectiveness of targeted interventions to guide health authorities in the future.

These combined activities can help health authorities going forward to reach their AMR goals outlined in their NAP. A key first step will be prioritizing resources to where they are most needed. This is likely to initially include instigating multiple measures to enhance the appropriate use of antibiotics given current concerns.

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Declaration of interest

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