Magnitude of non-prescribed antibiotic dispensing in Ethiopia: a multicentre simulated client study with a focus on non-urban towns

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Objectives: Non-prescription dispensing of antibiotics significantly contributes to widespread antibiotic misuse, which in turn hastens the occurrence of antibiotic resistance. It is believed to be common in Ethiopia despite prescription-only regulations. We aimed to quantify non-prescription dispensing of antibiotics in community drug retail outlets (CDROs) with a focus on non-urban towns in the Amhara region of Ethiopia.

Methods: A multicentre simulated client (SC) study was conducted to measure the non-prescription provision of antibiotics in 225 consenting CDROs. Each CDRO was visited twice by two trained SCs, one to present pre-prepared clinical case scenarios and the other to directly request specific antibiotics. Descriptive statistical analysis was performed to report the findings.

Results: The study had 450 interactions across the two visits. Non-prescribed antibiotics were obtained in 198 (88%) of the 225 clinical case scenarios-based visits and in 205 (91%) of the 225 direct antibiotic request visits. Most of the supply was at the first level of demand: 84% of the 198 clinical case scenario visits and 95% of the 205 direct antibiotic request visits. CDRO staff requested further information about the patient or the case in 40% of the clinical case scenarios-based visits and 30% of the direct antibiotic request visits.

Conclusions: It was possible to obtain antibiotics without prescription from a high proportion of CDROs, both in clinical scenario-based and direct antibiotic request interactions. Multifaceted interventions including stringent regulatory enforcement, frequent CDRO practice surveillance, CDRO staff training and community health education are needed with greater emphasis on rural areas.

Introduction

Antibiotic resistance (ABR) is a threat to public health globally, resulting in longer hospital stays, higher medical costs and increased mortality.1 ABR is fuelled by increased inappropriate use of antimicrobials.2 Self-medication with antibiotics, mainly sourced from community drug retail outlets (CDROs), is a common practice in low- and middle-income countries (LMICs) and is usually inappropriate.3 CDROs are conveniently located for clients and play a pivotal role in providing access to medications.5 The provision of non-prescribed antibiotics by CDROs is reported to occur in high-income countries and LMICs but for different reasons.4,5

Despite Ethiopia’s prescription-only antibiotics sales regulation, a previous study reported that non-prescribed antibiotics were obtained from CDROs in the capital city to treat symptoms suggestive of viral origin.6 CDRO practices in Ethiopia are believed to differ between urban and rural areas and 78% of the Ethiopian population lives in rural areas.7 Hence, evidence about the extent of the practice in rural areas will be important to inform the response.

Potential reporting or observer biases mean that surveys or direct observation may not be the optimal approach to assessing non-prescription supply of antibiotics. The most robust approach is a simulated client (SC) study.8 This study used an SC approach to assess the magnitude of the non-prescription antibiotic supply by CDROs in the Amhara region, Ethiopia with a focus on non-urban towns.

Methods

Study design and setting

We used the SC method in a cross-sectional sample of CDROs selected from the two largest divisions in the Amhara region, Ethiopia: Gondar and Gojjam.9 CDROs include pharmacies, drugstores and rural drug vendors (Table S1, available as Supplementary data at JAC Online).

Except for Gondar and Bahir Dar cities, all available CDROs in Gondar and CDROs from Gojjam in towns near Gondar were invited to participate.
in SC visits during an earlier survey. Of the 270 survey participants, 231 (86%) consented in writing to a later visit by SCs at an unspecified time. The visits occurred around 3 months later.

Thirty-six towns were divided into three groups targeting 77 CDROs in each group. The three clinical case/antibiotic scenarios were randomly allocated to each of the three groups of towns by lottery; one scenario/antibiotic to one group. The scenarios were acute childhood upper respiratory tract infection (URTI)/amoxicillin (77 CDROs), acute childhood diarrhoea/co-trimoxazole (76 CDROs, one closed) and adult urinary tract infection (UTI)/ciprofloxacin (72 CDROs, five closed).

Case scenarios and CDRO visits

The clinical case scenarios and data collection instrument were designed based on published literature. The simulated case scenarios were acute childhood diarrhoea, acute childhood URTI and adult UTI for clinical scenarios and three specific antibiotics with substituents for direct antibiotic requests (Table 52). These scenarios were chosen because they are the most common disease symptoms and requested antibiotics associated with antibiotic misuse in sub-Saharan Africa including Ethiopia.

Eight postgraduate pharmacy students or pharmacy graduates, all male, from the University of Gondar were SCs. Each visit was performed by a pair of SCs, with one portraying the clinical case and the other capturing the interaction. Two visits were undertaken, with the clinical case scenario visit always preceding the direct antibiotic request visit. The researcher (S.A.B.) and the field supervisor rigorously trained the SCs on the case scenarios and visits (see Supplementary methods).

The SCs used three sequential levels of demand until an antibiotic was either dispensed or refused: (i) a request for medication to alleviate the symptoms; (ii) a request for a stronger medication than offered; and (iii) a request for an antibiotic if one was still not provided. On the following day, a different pair of SCs asked for the pre-specified antibiotic and if not available, they asked for the substitute antibiotic.

Ethics

The study was approved by the University of Queensland Human Research Ethics Committee (approval number 2020002195), Australia and the University of Gondar Institutional Ethical Review Board, Ethiopia (approval number V/P/RCS/05/4/12/2020).

Results

Most (78%) of the CDROs (n=225) visited were drug stores (Table 1).

Non-prescribed antibiotics were obtained from 198/225 CDROs (88%) for the three simulated clinical cases: 73/76 (96%) for acute childhood diarrhoea; 70/77 (91%) for acute childhood URTI; and 55/72 (76%) for adult UTI. Of those who dispensed antibiotics, 84% provided the antibiotic at the first, 15% at the second, and one staff member dispensed at the third level of demand. The reasons for not dispensing were that the client needed to visit a clinic (17/27 CDROs), that they required a prescription (7/27 CDROs) or that an alternative non-antibiotic remedy was recommended (3/27 CDROs). The commonest antibiotics dispensed were amoxicillin (54/70; 77%) for acute childhood URTI, co-trimoxazole (59/73; 81%) for acute childhood diarrhoea and ciprofloxacin (26/55; 47%) for adult UTI (Figure 1).

Antibiotics were dispensed after direct request by 205/225 CDROs (91%): 73/77 (95%) requests for amoxicillin or amoxicillin/clavulanic acid; 74/76 (97%) requests for co-trimoxazole or metronidazole; and 58/72 (81%) requests for ciprofloxacin or norfloxacin. The first requested antibiotic was provided in 194/205 (95%) of the visits. The reasons for not dispensing were that the client needed to visit a clinic (13/20 CDROs), that they required a prescription (6/20 CDROs) or that an alternative non-antibiotic remedy was recommended (1/20).

CDRO staff asked for further information about the patient or the case in 91/225 (40%) of the clinical case scenario visits, and in only 67/225 (30%) of the direct antibiotic requests visits (see Supplementary results).

Discussion

To our knowledge, this study is the first multicentre study to examine antibiotic dispensing behaviour using a SC model with a focus on CDROs in rural towns of Ethiopia. Despite Ethiopia’s prescription-only antibiotic dispensing regulation, we found that 88% of the clinical case scenario visits and 91% of the direct antibiotic request visits resulted in non-prescribed antibiotic dispensing. Our earlier survey of 270 CDROs, including all the CDROs in this study, reported that only 58% of participants ever dispensed non-prescribed antibiotics. This may reflect social desirability bias, and points to the importance of SC studies.

We found higher rates of non-prescription antibiotics dispensing than similar studies in other LMICs and higher than pooled estimates globally (62%) and in Sub-Saharan Africa (69%). This may be because of less strict regulation of antibiotic dispensing and CDROs’ high profit interest. Client demand for antibiotics has been also reported to influence dispensing behaviour. However, the majority of CDROs in our study dispensed antibiotics before the SC’s insistence.

There is no indication of antibiotics for acute viral infections. Antibiotic treatment for UTI is usually appropriate, and in some countries, pharmacy dispensing of antibiotics for specific
There could be a potential to effectively train and allow licensed pharmacists in Ethiopia to treat simple common conditions having clear symptoms and/or signs with antibiotics at least in rural areas to facilitate quick and appropriate antibiotic access. Our study found that the non-prescription sale of antibiotics is greater in rural areas compared with a study conducted in the capital city of Ethiopia. The sale of non-prescribed antibiotics may be more common in rural areas because of insufficient or inaccessible healthcare facilities, and that CDROs in rural areas may be inspected less frequently by regulatory officials. Rural–urban differences in non-prescribed antibiotic dispensing have also been noted elsewhere.

The CDRO staff in our study favoured broad-spectrum antibiotics. The inappropriate use of broad-spectrum antibiotics is associated with a greater risk of antimicrobial resistance. For instance, *Escherichia coli* cause the majority of acute UTIs, and fluoroquinolones are the first-line antibiotic treatment of UTI in Ethiopia. Yet, recent evidence in Ethiopia showed that 26% of *E. coli* isolates were resistant to ciprofloxacin, 21% to norfloxacin and 85% to moxifloxacin. The non-prescribed use of fluoroquinolones may partly explain the development of resistance.

A high proportion of CDROs did not ask appropriate questions prior to dispensing. For example, fluoroquinolones were given for UTI cases to SCs who were seeking antibiotics for women of childbearing age with no knowledge about their pregnancy status.

Our findings suggest the need for immediate and sustained measures to address this issue. These could include stricter enforcement of regulations that restrict antibiotics to prescription-only use, imposing heavier penalties for those who contravene the rules, and enhancing regular CDRO supervision. This has been found to be effective elsewhere. Enhancing the availability, affordability and quality of non-CDRO healthcare services may reduce the inappropriate dispensing. Regular CDRO staff and public education about rational antibiotic use or provision may also be beneficial.

**Strengths and limitations**

While the study was conducted rigorously, there were limitations. The SC approach records data based on specific case scenarios and it may not be possible to extrapolate to other conditions. CDRO staff dispensing behaviour may have changed due to an expectation of being observed after previously giving consent for SC visits. As our sample was purposely chosen, our findings may not be generalizable to the entire Amhara region.

**Conclusions**

Despite Ethiopia’s antibiotic prescription-only access regulation, it was possible to obtain antibiotics without prescription from a high proportion of CDROs. Antibiotics with a high potential of inducing resistance were dispensed without prescription. Our study highlights the need for an integrated multifaceted approach to stewardship of antibiotic use in CDRO settings with an emphasis on rural areas.
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Transparency declarations
None to declare.

Author contributions
S.A.B., L.H. and L.S. conceptualized and designed the research study. S.A.B. analysed the data and wrote the first draft of the manuscript. L.H. and L.S. contributed to all drafts of the manuscript and its final version, and supervised the research process. All authors read, revised and approved the final manuscript.

Supplementary data
Tables S1 and S2, Supplementary methods and Supplementary results are available as Supplementary data at JAC Online.

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