International Journal of Innovation and Applied Studies
ISSN 2028-9324 Vol. 34 No. 4 Nov. 2021, pp. 769-778

http://www.ijias.issr-journals.org/

Dispensing antibiotics for children in the City of Goma, DRC: A cross-sectional survey

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ABSTRACT: *Background:* Global action plans to tackle antimicrobial resistance include implementation of antimicrobial stewardship, but little is known about the dispensing practices of antibiotics of community pharmacists in low and middle-income countries. In this study, we aim to assess the dispensing of antibiotics for paediatric use in pharmacies in the City of Goma, capital of North Kivu province.
Method: Between June and December 2017, we performed a cross-sectional questionnaire-based survey with pharmacy managers about antibiotic dispensing to the paediatric population.
Result: Among a total of 225 pharmacies identified, 84% were managed by nurses. 70% of pharmacy managers had absolved secondary school. Only 10% of pharmacies were owned by pharmacists or physicians. 76% of antibiotics for children were prescribed after families asking for them and only 21% after a recommendation from the pharmacy manager. Amoxicillin/clavulanic acid was the most commonly dispensed antibiotic - 78% cases. 81% of pharmacy managers had no supervision by a pharmacist from the pharmacy division. There was no significant difference in requiring or not between a physician prescription to deliver antibiotics in children and the qualifications of pharmacy managers (P=0. 28), their level of school education (P=0.42).
Conclusion: Our findings suggest that there is a lack of regulation and consistency in the approach to dispensing antibiotics in children. A policy is needed to regulate the dispensing of antibiotics along with education and training to reduce the risk of antibiotic resistance.

KEYWORDS: Antibiotics, Issue, Pharmacies, City of Goma.

1 INTRODUCTION

Self-medication with antibiotics contribute to the development of multiresistant bacteria [1,2]. Between 2000 and 2010, the global use of antibiotics per person has significantly increased; this rise is more marked in low resource countries [3]. This is a major challenge for public health globally because of the slowing in the development of new antimicrobials [2, 4]. There is a lack of data and published studies from Africa about the level of resistance related to uncontrolled use of antibiotics [1]. In Nigeria [5, 6] and Sudan [6, 7], data concerning antibiotic self-medication are worrying.

In the Democratic Republic of Congo (DRC), few studies on this subject have been carried out. The recent global analysis of antibiotic use [3] highlights the lack of data from the Democratic Republic of Congo, amongst other countries that do not have data on antibiotic consumption. In addition to that, childhood mortality (104‰), mainly due to infections, is one of the highest in the world [8]. In the North Kivu province, a preliminary survey on the therapeutic itinerary in the city of Goma revealed that more than half of patients (51%) make their own care decisions, by purchasing medicines in pharmacies or on the street without a prescription [9].

No official data are available on the actual issuing and dispensing of medicines in Goma pharmacies, especially the number and location of pharmacies in the city. We also do not have information on the professional qualification of pharmacy managers, their level of school education and ability to dispense antibiotics without physicians' prescription. In the context of development of multi resistant bacteria worldwide, the aim of this study was to analyse antibiotic dispensing for paediatric use in pharmacies in the city of Goma. We analysed the conditions and approaches for dispensing antibiotics to children that could impact on unsuitable and incorrect use of antibiotics in this population. We were interested on the impact of factors such as school level of education and qualifications of the pharmacy manager, their confidence regarding the quality or efficacy of the antibiotic issued, and the minimum cost for dispensing

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antibiotics on the regimen of antibiotic delivered (compliance with antibiotics dispensing by physicians' prescription, the duration of antibiotics treatment).We were also interested on the level of supervision of the pharmacy by the Provincial Pharmacy Division authority.

2 METHODS

2.1 STUDY DESIGN AND SETTING

This is a questionnaire-based, cross-sectional survey on antibiotic dispensing for children in Goma pharmacies. Goma city, capital of North Kivu province, in the East of the Democratic Republic of Congo (DRC) is located just at the foot of Mount Nyiragongo, an active volcano whose last eruption in 2002 destroyed two-thirds of the city. More than 20 years of civil war in the region left Goma amongst the poorest in Africa with a population of approximately one million inhabitants.

2.2 RESPONDENTS

Our study's population was pharmacy manager's including pharmacists, nurses, pharmacy assistants and other professions such as teachers, who dispense antibiotics in pharmacies.

2.3 IDENTIFICATION OF PHARMACIES

The approach chosen was an exhaustive survey of all pharmacies in the city of Goma.

A six-month period was chosen between 01/06/2017 and 31/12/2017. We covered on foot the different streets of the eleven accessible quarters of Goma city and proceeded with a systematic and in-depth examination, quarter by quarter, of all pharmacies open in these quarters. Six districts located in the city's suburbs were not included in this study, as security conditions were not guaranteed.

2.4 DATA COLLECTION

2.4.1 DESIGN OF THE QUESTIONNAIRE

This survey used a questionnaire modelled on previously published studies [10], taking in account local considerations and the paediatric context. The questionnaire was validated by the research team and pre-tested in five pharmacy managers who were not included in the study. We used the same questionnaire to interview each pharmacy manager during the study period and asked about qualifications and education of the pharmacy manager the pharmacy owner's profession; reason for opening the pharmacy (profit, unemployed, professional in training or manager's field of expertise); pharmacy supervision by a professional and qualified pharmacist; why antibiotics were dispensed i.e. physicians' prescription, manager's recommendation, or client's request), and the most commonly dispensed antibiotic (Figure 1).

2.4.2 INTERVIEW STRUCTURE

In each pharmacy, we proceeded with an initial unannounced phase that consisted of carefully observing the dispense of antibiotics. During the second phase, one of the investigators (BTE) carried out the structured interview with the aim to reduce the risk of a low response rate. Consent was obtained to carry out the interview, which lasted 25 to 30 minutes.

2.4.3 VARIABLES

2.4.3.1 DEPENDANT VARIABLE

The dispensing of antibiotics to children was analysed according to the different factors as qualifications and education of pharmacy manager, the reason for opening pharmacy, pharmacy supervision by a professional and qualified pharmacist; why antibiotics were dispensed, the most commonly dispensed.

2.4.3.2 INDEPENDENTS VARIABLES

This category includes the above variables grouped as follows:

The first group assessed the qualifications (Nurse, pharmacy assistant, pharmacist) and the level of school education of pharmacy manager (primary, secondary, advanced, university) and different category of pharmacies owners (Traders, nurses, pharmacists, physicians).

The second group explored the reason for opening pharmacy, regulation and consistency in the approach to dispensing antibiotics in children.

The third group looked at the dispensing mode of antibiotics in particular: why the antibiotics was dispensed, the most commonly dispensed antibiotic and the minimum coast for which a course of antibiotic is dispensed.

2.4.4 DATA AND STATISTICAL ANALYSES

Data were anonymized, encoded, and analysed with the software package SPSS statistics version 23. Proportions were compared with the Pearson Chi 2 Test or exact Fisher test. Odd ratio (OR) were calculated considering the category of variables having the lowest relative frequency. For quantitative variables, means and/or medians were compared with the ANOVA or Mann-Whitney tests. The threshold for statistical significance was 0.05. Quarters of Goma city were mapped using the software package Adobe Photoshop CS 3, version 10.

2.5 ETHICAL CONSIDERATIONS

The study was approved by Université Libre des Pays des Grands Lacs (ULPGL) ethics committee (Ref/N°: 001/CE/ULPGL/MK/2019) in accordance with Helsinki Declaration principles. The participants were initially briefed about the study and informed consent was obtained before completing the survey form. Personal data were anonymized. No participant was under the age of 16 years and confidentiality was assured to all participants.

3 RESULTS

There were 225 pharmacies in eleven quarters included in our study (Table 1, Figure1).

No pharmacy manager refused to be interviewed.

Table 1. Pharmacies in the City of Goma during 2017 in relation to quarter and number of inhabitants

Inventoried Quarters in Goma	Pharmacies' number/ Quarter	Total population/Quarter	Inhabitants per Pharmacy
Mapendo	36	35783	994
Mikeno	35	34446	984
Katindo/Himbi *	34	89115	2621
Virunga	32	21671	677
Kyeshero	32	119240	3726
Katoyi	21	115376	5494
Mabanga/Kasika *	16	179396	11212
Murara	13	37863	2912
Le Volcan	6	16949	2824
Subtotal	225	651865	2897
Quarters without -information			
Kayembe	-	28229	
Bujovu	-	43988	
Majengo	-	20135	
Ndosho	-	80254	
Lac vert	-	24781	
Mugunga	-	20669	
Total		974832	

**Katindo and Himbi as well as Mabanga and Kasika were combined*

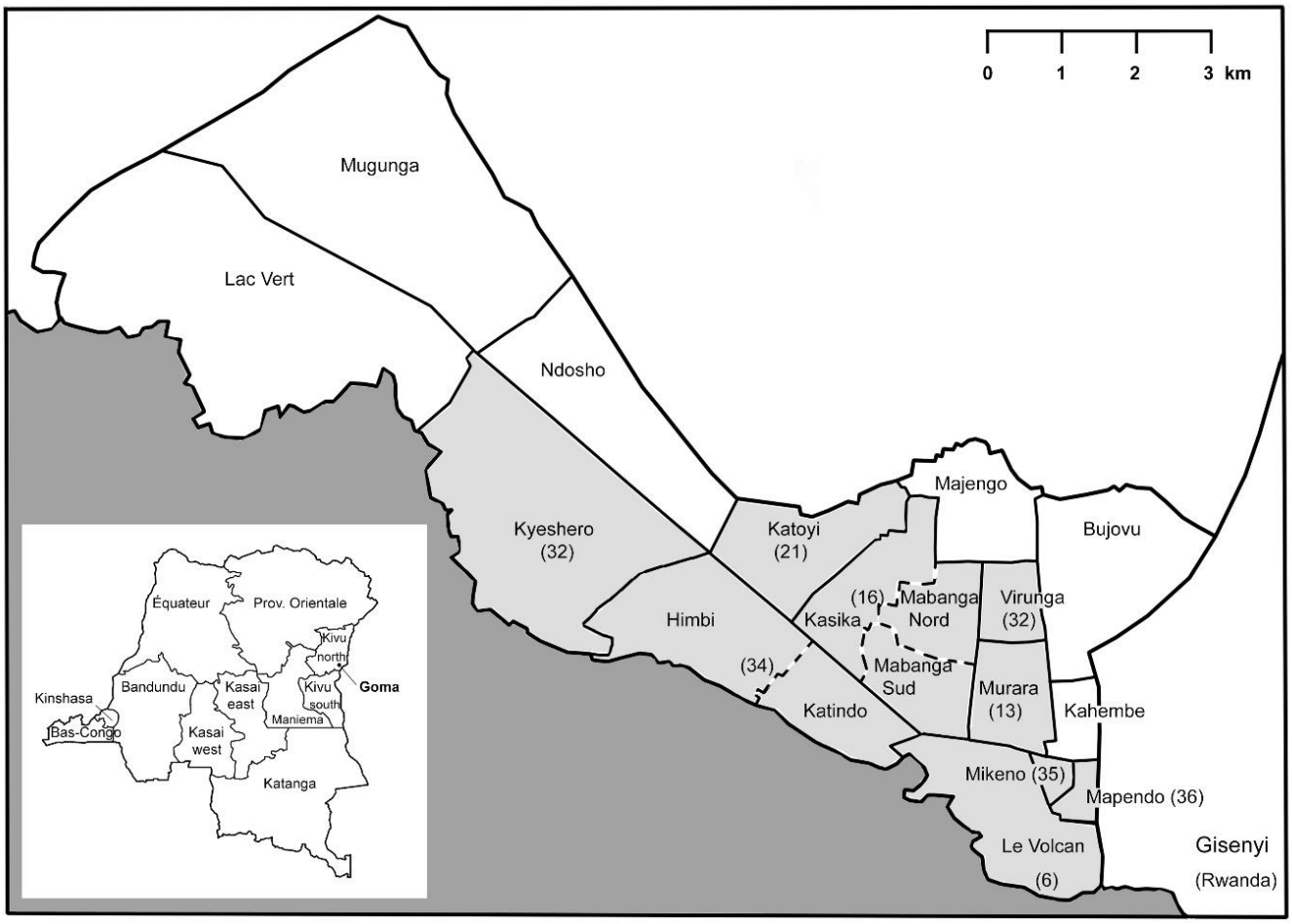

Fig. 1. Location and number of 225 pharmacies in eleven districts of Goma, DRC. White: Districts without information due to civil war

Our study shows that most pharmacies in Goma were managed by nurses, who had a secondary level of school education, and that pharmacy owners were mainly traders and nurses in equal proportion (Table 2).

Table 2. Professional qualification of staff /Pharmacies manager in 225 pharmacies during 2017 in the City of Goma

Expressed parameters	%
Qualification of pharmacy managers n=225	
Nurses	83.1
Pharmacy Assistants	16.4
Pharmacists	0.4
Level of school education of pharmacy managers n=225	
Primary	3.1
Secondary	68.9
Advanced	27.6
University	0.4
Pharmacy owners n=225	
Traders	44.9
Nurses	44.4
Physicians	7,1
Pharmacists	3,6
Dispensing mode of antibiotics n=225	
Exclusively on Physicians' prescription	11.6
On advice of the pharmacy manager	21.8
On simple request by the client	66.7
Reason for opening the pharmacy n=225	
For profit	94.7
Unemployed	2.7
Field of expertise (Nurses -Physicians-pharmacist)	2.7
Supervision/ Pharmacist from the Provincial Pharmacy Division n=225	
No	81.3
Yes	18.7
Most requested antibiotics n=225	
Amoxicillin /Amoxicillin Ac	77.8
Cotrimoxazol	7.6
Norfoxacin +Metronidazol	7.6
Azytromycin	7.1
Confidence of pharmacies managers about the quality/efficacy of dispensed antibiotics n=225	
No	96.4
Yes	3.6
Lowest cost to dispense antibiotic n=225	
< One US dollar	72.4
≥ One US dollar	27.6

In 81% of interviews, pharmacy managers indicated no professional supervision by a qualified pharmacist from the Provincial Pharmacy Division. Almost everyone reported they were uncertain as to the quality and efficacy of all the antibiotics dispensed to their clients. For the same antibiotic, the choice of presentation form was impacted by the client's financial means rather than by prescription or medical evaluation Responses from pharmacy managers (Table 2) showed that in more than three quarters of pharmacies, antibiotics could be dispensed on simple request by the client or on the advice of the pharmacy manager, and worryingly in only a minority of pharmacies, antibiotics for paediatric use were dispensed with a physicians' prescription. In over 75% pharmacies, the most commonly requested antibiotic was amoxicillin with or without clavulanic acid (Table2). Antibiotics could be issued for a minimum cost of less than one US dollar (equivalent to 1600 Congolese francs) in approximately three quarters of pharmacies.

There was no significant difference in the requirement or not to dispense antibiotics to children according to the qualification of pharmacy manager (P=0.28), their level of school education (P=0.42); type of pharmacy owners (P=0.33). The only significant association (P=0.01) was that expensive antibiotics were dispensed by physicians' prescription more frequently than cheap antibiotics (Table 3).

Table 3. Factors associated with readiness to dispense antibiotics for children on physicians' prescription (Fisher's test)

Factors	% with physicians' prescription	(OR and 95% CI	P
Qualification of pharmacy managers			
Nurses- pharmacy Assistants - Others (n=216)	11.1	1	
Pharmacists-Physicians n= (9)	22.2	2.00 (0.56-7.19)	0.28
Level of school education of pharmacy managers			
Primary - Secondary (n=162)	10.5	1	
Advanced- university (n=63)	14.3	1.36 (0.64-2.89)	0.42
Pharmacies' owners			
Pharmacists-Physicians-Nurses (n= 124)	9.70	1	
Traders (n=101)	13.9	1.43 (0.69-2.96)	0.33
Lowest cost to deliver antibiotics			
< One US dollar (n= 163)	8.0	1	
≥ One US dollar (n = 62)	21.0	2.63 (1.29 -5.35)	0.006

4 DISCUSSION

The aim of our study was to analyse the dispensing of antibiotics in children by pharmacies in the city of Goma. The survey aimed to determine factors that might have an impact on incorrect use of antibiotics. Our results show a variable number of pharmacies per inhabitant in the 11 quarters. This difference is mainly due to different commercial activities, and the location of large hospitals in some quarters. Socio-economic or cultural factors might also play a part [10]. Our study revealed that the majority of Goma pharmacies were owned by nurses whose level of school education was secondary. In DRC, A2 training, corresponding to the level of secondary technical training, is administered in Medical Technical Institutes while A1 training, corresponding to higher education nurses, is administered in Superior Institutes of Medical Techniques [11]. The National College of Pharmacists registered 1184 pharmacists in 2015 in the whole country [12]. Many pharmacies are run by nurses rather than pharmacists and this may be due to a higher number of trained nurses compared to pharmacists [13]. This could also account for deficits observed in the application of regulations concerning dispensing of medicines, including antibiotics [13].

In more than three quarters of pharmacies, our survey revealed that the readiness to issue antibiotics to children was based on a simple client request without physicians' prescription. Difficult socio-economic conditions for a poor population and absent health insurance might account for this approach of the community that procures medicines, including antibiotics directly in pharmacies without medical evaluation which would add an extra cost [9, 13, 18]. This might also lead to incomplete courses of antibiotics being dispensed due to patients being unable to afford a complete treatment course.

The characteristics of pharmacies operating in the city of Goma, and the mode of antibiotic dispensing is similar to that described in other low resource countries such as Tanzania [14], Uganda [15], Ivory Coast [16], Nigeria [17], Haiti [18], Yemen [19] or Vietnam [20]. In these countries, several common factors leading to widespread dispensing of antibiotics have been described: lack of qualified and trained pharmacists, absence of strict pharmaceutical sector regulations and poverty meaning populations self-medicate from any available /illegal market. A study in the north-east of Uganda [15], has reported that in addition to poverty, prolonged waiting times in hospitals and long distances to care centres were identified as factors predictive of self-medication. This observation also suggests a low level of knowledge in low resources countries concerning antibiotics using. This situation is in contrast to the current one of developed countries [21, 22, 23 26]. There was a low level of control of pharmacies by the Provincial Pharmacy Division (DPP) despite a legal framework that imposes compliance with pharmacy good practice requirements [27]. This is found in many low resource countries in West Africa [28], and sub Saharan Africa such as Namibia [29].

Amoxicillin/amoxicillin-clavulanic acid was shown to be the most commonly issued antibiotic in more than three quarters of pharmacies. In Africa, this antibiotic is accessible to more than 75% of people in both a public or private pharmacy [30]. This is the same pattern elsewhere with a Ugandan study describing its use by self-medication in 23% of cases [15].

Data on the level of resistance in our region to amoxicillin/clavulanic acid are worrying. This has been studied on enterobacteria, in urinary tract isolates and has been found to be 16% in Bukavu, in South Kivu, a province close to Goma [31], 59% in Rwanda [32] and 70% in Tanzania [33], respectively. Amoxicillin/clavulanic acid is used as a broad-spectrum antibiotic and is easily accessible and thus widely dispensed according to the results of our study. This is a major bacterial resistance target to be investigated in the region of Goma.

Our study did not reveal a statistically significant difference between the level of education or qualification of the pharmacy manager and the readiness to distribute antibiotics without a medical prescription. This supports previous studies that showed that antibiotics remain freely accessible even without medical prescriptions in low resource country pharmacies [14-17].

The strength of our study was to generate for the first time information on the quality of dispensing antibiotics in pharmacies in our region. It is limited by possible subjectivity of information obtained during the interview. Our results advocate with the health authority for stricter pharmaceutical regulation of "drug shops". We recommend that the pharmacies be grouped by axis or district, according to WHO standards, under the responsibility of a pharmacist recognised by the Order of Pharmacists and supervised by the Provincial Division of Pharmacy.

5 CONCLUSIONS

Antibiotic dispensing conditions in Goma pharmacies largely escape medical control. There is a lack of pharmacists, and nurses are the main managers of pharmacies. Antibiotics are broadly dispensed without physicians' prescription and there is a lack of pharmacy authority's control. The situation risks the emergence of multi-resistant bacteria. It will not improve until DRC has a strict regulation policy for the dispensing of antibiotics and a suitable training system that actually meets the healthcare needs of its population.

ACKNOWLEDGMENTS

The authors thank Cath HARRISON for proof reading and editing the manuscript; Thierry WALRAVENS and Kathy MELLOR for helping with the literature review; and Genevieve DEGEMINE for translation support.

AUTHORS' CONTRIBUTIONS

Conceived the questionnaire and designed the study, BTE, MN and BB. Performed the survey: BTE, MN and BB. Analyzed the data: BTE, MN and BB. Wrote the paper BTE, MN, OV and BB

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ANNEX 1.

SURVEY / INTERVIEW WITHIN THE PHARMACIES OF GOMA FROM 06/01/2017 TO 12/31/2017

1. What is your qualification?
   - Nurse
   - Pharmacist
   - Physician
   - Pharmacy assistant
   - Other (specify)
2. What is your level of education?
   - Primary
   - Secondary
   - Advanced
   - University.
3. What is your usual dispensing mode of antibiotics?
   - On customer's request
   - Exclusively on physician's prescription
   - When customer asking your advice
4. Are you confident in the quality/efficacy of the dispensed antibiotics?
   - Yes
   - No
5. Who is the pharmacy's owner?
   - Pharmacist
   - Physician
   - Nurse
   - Trader
6. Is your pharmacy supervised by a qualified pharmacist from the Provincial Pharmacy Division?
   - Yes
   - No
7. In which quarter is located your pharmacy?
   - Virunga
   - kyeshero
   - Mikeno
   - Mapendo
   - Katindo
   - Himbi
   - Katoyi
   - Mabanga
   - Le Volcan
   - Murara
8. Which are the most requested antibiotics within your pharmacy?
   - Cotrimoxazol
   - Amoxicillin
   - Metronidazol
   - Tetracyclin
   - Cefixime
   - Erytromycine
   - Ampicilline

- Norfloxacine + flagyl
- Azytromycin
- Chloramphenicol
- Cloxacilline

9. Why do you open your pharmacy?

- Because of unemployment
- For profit
- Because of your field of expertise (Nurse-Pharmacist-Pharmacy assistant-Physician)

10. What is the lowest cost to dispense antibiotics? (1 US dollar =1800 Congolese Francs) ?

- Less than 1 US dollar
- More or equal to 1 US dollar