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Retail drug shops market in Uganda incentives, effect on health care system, and implications for child health

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UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

Thesis for Doctoral degree (Ph.D.) 2020

Retail Drug Shops Market In Uganda

Incentives, effect on health care system, and implications for child health



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University of the Witwatersrand, Johannesburg, South Africa

Retail Drug Shops Market In Uganda:

Incentives, effect on health care system, and implications for child health

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Thesis submitted to the School of Public Health, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in fulfilment of the requirements for the degree of Doctor of Philosophy

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Johannesburg, June, 2021

Thesis Material

This thesis consists of the original papers listed below. For three papers, the candidate is first author, while for the fourth paper, the candidate shares the first authorship with another researcher with whom they shared studentship on the AXEX Research Project. All published and submitted manuscripts are appended on this thesis. Each publication or manuscript is formatted in the style and guidelines of individual journals to which they were submitted. The papers are referred to by their Roman numerals across this thesis.

I. **Mayora C**, Kitutu FE, Kandala NB, Ekirapa-Kiracho E, Peterson SS, Wamani H. (2018) *Private retail drug shops: what they are, how they operate, and implications for health care delivery in rural Uganda*. *BMC Health Serv. Res*, 18:532

Candidate's role: The candidate participated in conceptualization of the study, development of study tools, and collection and analysis of data. The candidate wrote the first draft as well as the subsequent drafts of the manuscript following reviews by co-authors, as well as finalizing the paper for submission. The candidate is also the corresponding author for the paper.

II. **Mayora C**, Kitutu FE, Ekirapa-Kiracho E, Peterson SS, Wamani H, Kandala NB. *For altruism or private gain? Analysing the incentives associated with the retail drug shops market in rural Uganda* (**Manuscript for re-submission to BMJ-Global Health: bmjgh-2020-003883**).

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IV. **Freddy Eric Kitutu, Mayora C**, Johansson EW, Peterson S, Wamani H, Bigdeli M, Shroff ZC. (2017) *Health system effects of implementing integrated community case management (iCCM) intervention in private retail drug shops in South Western Uganda: a qualitative study*. *BMJ Global Health*, 2

Candidate's role: Candidate participated in development of tools, conducting interviews, modification of topic guides during data collection, and discussions of emerging issues. The Candidate further participated in reading the transcripts and development of initial codes, and discussions and consensus on agreed codes, themes, and categories. The candidate also contributed to data analysis, interpretation, writing and review of the final manuscript for submission, as well as response to peer review comments.

Related Papers

The papers listed below were published within the same project as the thesis. Although they do not make a direct contribution, they are related and relevant to this thesis.

I. Johansson EW, Kitutu FE, **Mayora C**, Awor P, Peterson SS, Wamani H, Hildenwall H. (2016): It could be viral but you don't know, you have not diagnosed it: health worker challenges in managing non-malaria paediatric fevers in the low transmission area of Mbarara District, Uganda. *Malar J*, 15:197

II. Kitutu FE, Kalyango JN, **Mayora C**, Selling KE, Peterson S, Wamani H. (2017) Integrated community case management by drug sellers influences appropriate treatment of paediatric febrile illness in South Western Uganda: a quasi-experimental study. *Malaria Journal*, 16:425

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Abstract

Introduction.

The under-five mortality rate in Uganda has drastically declined to 55 deaths per 1,000 live births as of 2018 compared to 175 deaths per 1,000 live births in 1990, although it is still high. Febrile conditions – malaria, pneumonia, and diarrhoea – account for the largest burden of these deaths, yet these conditions are preventable. The Sustainable Development Goals (SDG 3.2) target reducing under-five mortality to 25 deaths per 1,000 live births by 2030. Achieving the SDG target requires more effort in expanding access to and utilization of essential and quality health care for children more especially in regions such as Sub-Saharan Africa (SSA) where the burden is still high. In many low-and-middle-income countries, including Uganda, private retail drug shops play a crucial role in providing access to essential care for children and hence can contribute to reducing under-five mortality. There are already discussions on how to implement hitherto public sector interventions, into the retail drug shop in order to expand the benefits of these interventions. In Uganda, for example, there are studies that have shown that drug shops can implement Integrated Community Case Management of childhood illnesses (iCCM) intervention, and also provide a range of health care services, including, family planning. Furthermore, there are studies that have demonstrated that retail drug shops can use rapid diagnostic technologies to improve quality of care, among others. Given that iCCM in Uganda is implemented through the public sector and community health workers (CHWs), it presents a missed opportunity for many children who bypass CHWS and use retail drug shops as their first (and sometimes main) point of contact with the health system. While there is now focus on working with the retail drug shop to implement such interventions as iCCM, the retail health market is not yet comprehensively understood – in terms of market characteristics and the incentive structure – factors that partly influence retail health market operations and performance. Makerere University School of Public Health (MakSPH) together with partners implemented an intervention study aimed at introducing a modified iCCM at the private retail drug shops in rural areas of Mbarara and Bushenyi districts, in South Western Uganda, between 2013 and 2015. The aim of the intervention was to determine the feasibility and effect of iCCM on the quality, appropriateness of care, and rational use of medicines in registered private retail drug shops. This Ph.D. study was nested on the main intervention study (AXEX study). The Ph.D. study specifically aimed to characterize the retail drug shop market, associated incentives, and determine the effect of an iCCM intervention on availability and affordability of paediatric febrile illness care in the private sector registered drug shops in rural South-Western Uganda, in order to contribute to improved access and utilization of appropriate care and child survival.

Methods.

Four sub-studies (I – IV) constituting this Ph.D. thesis were conducted using cross-sectional quantitative design (sub-study 1), cross-sectional mixed methods design (sub-study II), quasi-experimental design (sub-study III), and exploratory qualitative process evaluation design (sub-study IV).

S**ub-study I** aimed to describe the operational characteristics of the private retail drug shop market in rural South Western Uganda. In this sub-study, we surveyed 74 registered private retail drug shops where we interviewed drug shop attendants using a structured questionnaire. In addition, we

conducted 428 exit interviews with care-seekers who had sought care for under-five children at the drug shop during the study period. Descriptive analysis was conducted with means, medians, and proportions reported. The outcomes of interest included; training and skills of drug sellers, common childhood illnesses reported, the common medicines stocked and stocking decisions, prescription and dispensing decisions, use of diagnostics, drug shop operational environment, and type of clients served.

Sub-study II aimed to analyse the incentives and motivations of private retail drug shop providers in rural South Western Uganda. To achieve this, a survey of 74 drug shops in both districts was conducted at baseline, with an additional detailed investigation done on a sub-sample of 20 drug shops using structured questionnaires with close-ended and open-ended items. In addition, we included four (4) in-depth interviews with government officials in the two study districts. The qualitative interviews supplemented the quantitative data. We conducted a descriptive analysis and reported the outcomes in terms of means, medians, and proportions as appropriate as possible. The qualitative information from the open-ended section of the structured questionnaire was manually analysed following deductive manifest and content analysis. The four key informant interviews were also analysed following a process that involved reading the transcripts several times, coding and generating themes, using thematic content analysis. The quotable quotations from the qualitative analysis supplemented quantitative results where necessary. The main outcomes of focus in sub-study II included; motivations for start-up, incentives for drug shop operation, sales volumes, price mark-ups, profitability, and regulatory oversight, among others.

S**ub-study III** aimed to determine the effect of implementing an integrated Community Case Management (iCCM) intervention at private retail drug shops on availability and affordability of paediatric febrile care provided at retail drug shops in rural South Western Uganda. This sub-study utilized data from a survey of 74 drug shops (Intervention=40, Comparison=34) conducted before the intervention and 48 drug shops (Intervention=32, Comparison=16) after the intervention. Supplementary data was extracted from 428 care-seeker interviews (Intervention=212, Comparison=216) and 553 exit interviews (Intervention=285, Comparison=268) conducted before and after the intervention respectively. Supplementary qualitative data were collected from 18 focus Group Discussions with caretakers of under-five children, 8 Focus Group Discussions with Village Health Teams, 47 in-depth interviews with drug sellers, and 19 in-depth interviews with government officials. The WHO/HAI standardized methodology of assessing the availability and affordability of medicines was used. We conducted a difference Difference-in-difference (DiD) analysis to ascertain the effect of the intervention on the availability and affordability of iCCM recommended medicines. In addition, we conducted a manifest and content analysis of qualitative, and the qualitative findings reinforced the quantitative findings. The main outcome measures were the proportion of outlets reporting availability of selected medicines; affordability of treatment regimens after comparing treatment costs with day's wage rates of lowest paid government worker; and the proportion of care-seekers reporting affordability of treatment regimens. We also reported the views and opinions of care-seekers, caregivers, and VHTs, about the effect of the intervention on availability and affordability, among others.

Sub-study IV aimed to describe and analyse the AXEX iCCM intervention, how it was implemented at the drug shops, and the dynamics, and processes through which the observed effects were produced. This sub-study was qualitative in nature and adopted a process evaluation design approach. Qualitative data were generated through key informants with district health officials and health workers, drug

shop attendants, and FGDs with caregivers and VHTs. Deductive manifest and content analysis were used and a health markets framework proposed by Bloom and colleagues was adopted to guide the analysis. The main outcomes of focus were Perceptions and behaviours of stakeholders, effect on intervention on health system components, and factors that influenced intervention implementation.

Summary Results:

From S**ub-study 1,** it was found that most drug shops were operated by individuals with health-related training mainly midwifery, nursing, clinical medicine, and to some extent pharmacy assistants. Relatedly, the physical environment within which most drug shops operate is consistent with recommended standards and guidelines. The most commonly stocked medicines by drug shops were paracetamol, quinine, cough syrup, ORS/Zinc, Septrin (co-trimoxazole), and ACTs. Our study also found that prescription and dispensing decisions and practices were largely influenced by market factors, including client demand, client preferences, client finances, and profitability.

In **sub-study II,** it was found that retail drug shop start-ups were mainly motivated by the need to make a profit, although there were additional social benefits that accrued to drug shop operators, including the need to contribute to the community. Indeed, drug sellers enjoy social recognition and expanded social networks, and these social considerations partly influenced drug seller practices. It was also found that drug prices varied significantly across outlets with mark-up prices ranging between 43% and over 100%. It was estimated that drug shops make more than 90% per month after offsetting operational expenses. Finally, the retail health market regulatory system within the study area was found to be largely poorly streamlined and weak in capacity and under-resourced, and certain regulatory actions often resulted in perverse incentives to the operations of the retail market.

In **sub-study III,** we found that overall; implementing an iCCM intervention increased the availability of iCCM recommended medicines for paediatric febrile conditions at the retail drug shops. A higher proportion of surveyed retail drug shop outlets reported a higher availability of medicines for paediatric febrile conditions in the intervention district compared to the comparison district, after implementing the intervention. Besides, a higher proportion of care-seekers in the intervention district reported that drug prices and costs of treatment were lower and within their ability to pay, compared to care-seekers in the comparison district, after the implementation of the intervention. Further analysis done for the intervention district shows that the intervention increased the affordability of medicines. The cost of treatment courses (doses) was lower and required less of the daily wage incomes after the intervention compared to before the intervention.

Our sub**-study IV** found that retail health markets constitute various actors and stakeholders, including community health workers, government health workers in health facilities (centers), district health officials, Ministry of Health officials, NDA, drug sellers and owners, care seekers, and the community leadership. These actors operate and interact in a dynamic system with rules, beliefs, and incentives that influence the nature and quality of interactions and ultimately goods and services provided. Each of the actors appreciated and benefited from implementing iCCM at the retail drug shop. For example, the district health team, the NDA, and MOH appreciated the partnership and collaboration with the project team in monitoring and supervision, which resulted in an improved relationship with drug sellers and improved quality of services. The drug sellers appreciated the training and capacity building, the free RDTs and subsidized supplies, the improved trust that resulted in providing better quality services, as well as better sales and client retention. The care-seekers and the community

appreciated the quality of care received and the efficacy of the medicines. Finally, the intervention implementation demonstrated that private market-based interventions generate spillover effects to the broader health system beyond the targeted actors and these effects can be both intended and or unintended. For example, if services were improved at drug shops, there would be a shift from the formal health service providers to the retail drug shops, which could also have positive and negative results.

Conclusions

1. Most registered shops surveyed operated in environments that generally meet the minimum National Drug Authority (NDA) guidelines, and most drug shops are operated by drug sellers with health-related training. The decisions about what medicines to stock or dispense (prescribe) were largely influenced by among other factors; demand and preferences of clients or care-seekers; amount of finances that clients present with at the drug shop; and profitability objective.
2. While the need to earn profit was a significant motivator for retail drug shops, there are additional social benefits that accrue to drug shop operators including social recognition, expanded social networks, and a positive feeling of contribution to the community. In some circumstances, the social motivations generate intrinsic pressure that stimulates positive provider behaviour and action.
3. The regulatory system and framework for the retail drug shop market exist, and all key players appreciate the role and benefit of regulation. However, the system is weak, under-resourced, and not well structured to carry out its regulatory mandate. There were reported constraints to licensing, monitoring, and supervision, and in some cases, regulatory actions tended to stimulate perverse incentives to compliance.
4. Implementing iCCM at retail drug shops improved availability and affordability of treatment for uncomplicated malaria, pneumonia symptoms, and non-bloody diarrhoea for under-five children in a relatively low malaria transmission setting of South Western Uganda.
5. Identifying and implementing an appropriate package of market-based incentives and consumer empowerment actions can improve retail market practices and assure better health care provision as well as protect the public against negative practices that are detrimental to public and population health in a pluralistic health system.
6. Retail drug shops are part of a complex health system with multiple components and actors whose actions are influenced by multiple factors. The success of the AXEX intervention owes itself to the multi-component nature of the intervention which enabled the inclusion of different intervention packages each targeted at different actors and having different effects but all contributing to the objective of improving health care service delivery within the retail health market.

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Abbreviations

A2L	Access to Life
ACT	Artemisinin-based combination therapy
AL	Artemether – lumefantrine
AMFm	Affordable Medicines Facility – Malaria
AXEX	Access Excess Intervention Study
CHW	Community Health Worker
DADI	District Assistant Drug inspector
GOU	Government of Uganda
HAI	Health Access International
HBMF	Home based management of fevers
HSDP	Health Sector Development Plan
iCCM	integrated Community Case Management
IMCI	Integrated Management of Childhood Illnesses
IRP	International Reference Price
ITNs	Insecticide treated nets
LIC	Low-income country
LMIC	Low- and middle-income country
MakSPH	Makerere University School of Public Health
MDG	Millennium Development Goals
MOH	Ministry of Health
MOPS	Ministry of Public Service
MPR	Median Price Ratio
mRDT	Malaria Rapid diagnostic test
MRS	Medicines Retail Sector
MSH	Management Sciences for Health
NDA	National Drug Authority
NGO	Non-Government Organisation
NHP	National Health Policy
ORS	Oral Rehydration Salts/Solution
PFP	Private for Profit
PMVs	Patient Medicine Vendors
PNFP	Private-not-for-Profit

PPPH Public Private Partnership for health

RBM Roll Back Malaria

SDG Sustainable Development Goals

UBOS Uganda Bureau of Statistics

UCMB Uganda Catholic Medical Bureau

UDHS Uganda Demographic and Health Survey

UHC Universal Health Coverage

UMMB Uganda Moslem Medical Bureau

UNICEF United Nationals Children Fund

UNICEF United Nations Children Education Fund

UPMB Uganda Protestant Medical Bureau

USD United States Dollars

VHT Village Health Teams

WHO World Health Organization

Operational definitions

Febrile illnesses: Children present with fevers in these conditions. Other than malaria, they could be a result of cough, inflammations, colds, diarrhea, and pneumonia, among others. In this study, the term febrile illnesses refer to malaria, pneumonia, and diarrhea.

Incentives: These are defined as both monetary and non-monetary motivations upon which agents or actors make their decisions [1]. In this study, incentives refer to factors that attract or limit actors to participate in the retail drug shop business. The key considerations in this study are – the objective of drug shop start-up, price mark-ups, sales volumes and profitability, and regulatory environment, among others

Treatment Practice: Actions that provider or drug shop attendants take when managing childhood fevers. These include diagnostic decisions, prescriptions, and referral decisions, provision of health education advice, and use of medicines procured, among others.

Appropriate treatment: Medicines and dosages recommended for specific febrile conditions with appropriate guidance on usage provided to the caretaker according to existing guidelines.

Retail health market: This is an environment where small itinerant, owner-run shops or stores, which are sometimes located in communities and small urban centers where people live, provide health care. Individuals with specific health care needs interact with the providers and receive solutions for their health care needs. In the Ugandan context, retail health markets comprise drug shops and small retail pharmacies (both formal and informal) that are expected to sell over-the-counter prescription medicines. Experience, however, shows that they do not stick to regulation and more often than not, sell unauthorized medicines and a wide range of non-medical products for purposes of diversifying their business operations.

Retail Drug shop: These small shops or outlets sell a limited set of over-the-counter medicines on a retail basis. In Uganda, establishing a retail drug shop follows a successful application and vetting by the Uganda National Drug Authority (NDA). Retail drug shops are at the lower end of the health system sometimes operating without qualified staff and professional pharmacists or medical personnel.

Affordability: This reflects the clients' ability and willingness to pay for the service or treatment course that is required to treat a particular reported illness based on the standard of care or recommended course. Affordability is measured by the amount of money required to pay for a treatment course from the daily wage of the lowest-paid unskilled government worker [2]. If the amount of money that is required to purchase a treatment dose (regimen) is more than a day's wage, the treatment regimen or dose product is considered unaffordable.

Availability: Medicines availability refers to the proportion of surveyed drug shops that has a particular medicine of interest on the day of the survey irrespective of the formulation and quantity of medicine.

Preface

I encountered an experience in my community in Kasese District, Western Uganda, which illuminated the importance of retail drug shops in the provision of health services to communities. Sometime in 1998, a young lady that I studied primary school together could not register for Ordinary level (Ugandan Certificate of Education) examinations after failing to pay the required registration fees. At this point, she could not proceed with her education prospects and decided to opt for a "business" for her survival. The 'business' option was to open a small retail drug shop at the local small trading center, as owner, and attendant, with no basic training in pharmacy or medicines management. The drug shop and owner gained prominence in the area to the extent that at some point she added a 'clinic arm' and even started admitting patients for a day or two.

After studying and starting work at Makerere University School of Public Health, in 2013, I went back home to Kasese and attended a church service at my community church. During the church service, an announcement was made to congregants that '*Betty drug shop'* had procured 'new medicines' and an appeal was made to people to take advantage of the 'new medicines' at this facility. As an opinion leader in my church, I wanted to stand up and rebut the announcement on account that both the facility and the owner (who doubled as the attendant) were not registered and accredited to operate such a facility. I wondered why the church was offering a platform for an illegal entity to advertise unaccredited services to a larger audience. I held on to my views, until the end of the church service when I reached out to the individual who made the announcement and who coincidentally happened to be an area councillor in the Town Council. On inquiry, he told me how it is not possible to close down the facility because it emerged out of people's demand and the community itself had sustained the drug shop. He further said, 'the community perceives the attendant as one with good luck because everybody who gets drugs from the drug shop is healed'. He intimated to me that any forces against this drug shop and 'clinic' would fail because it has "saved" the community.

This experience demonstrated to me the place that retail drug shops occupy within community health systems, how the community holds them dear because the community highly relies on them for their health care needs. I noted that the social forces are in favour of the existence of drug shops, and for any regulation to succeed, the community would have to be part of the regulatory system. The existence of drug shops within communities is largely related, in many ways, to a constrained health care delivery system with limited capacity to provide the much-needed health services across all communities and more so for rural and hard-to-reach communities. An opportunity presented when I was invited to be part of the drug shop (AXEX) intervention study team. To me, this was a great opportunity to learn more about retail health markets in Uganda, how they are structured, what motivates their establishment and operations, and how drug shops could be turned into safer platforms for the delivery of quality health services to the communities, rather than being dismissive of them.

This research does not question whether or not retail drug shops need to be allowed to operate or whether they are necessary in Uganda's health care system. Rather, the thesis adds to the knowledge about the structure and characteristics of the retail drugs shops, what motivates their establishment and operations, and what considerations need to be recognized when designing feasible interventions and/or strategies aimed at improving drug shop practices to assure the provision of good quality and safe medications for the benefit of public health.

Thesis overview and structure

This is a PhD by publication and therefore the thesis comprises two parts. The first part is an integrating narrative that provides a synthesis and discussion of methodology and key findings. The second part includes the research papers (Appended) written as part of the material for this PhD thesis. The thesis comprises four related sub-studies. The first sub-study focused on characterizing the private retail drug shop and its operations in rural South Western Uganda (**Published paper I**). The second sub-study analysed the incentive structure as well as motivations for retail drug shop 'businesses' and the implications for access to paediatric medicines and services within the medicines retail sector (**Manuscript paper II)**. The third sub-study assessed the effect of implementing integrated Community Case Management (iCCM) at the retail drug shop on the availability and affordability of iCCM-recommended paediatric medicines (**Manuscript paper III**). The fourth sub-study explored the stakeholders' views and opinions on the AXEX intervention and the mechanisms through which the intended and unintended effects were achieved (**Published paper IV**).

Integrating narrative

The integrating narrative is composed of four chapters. **Chapter 1 – the introduction chapter** consists of six sections. The **introduction section** contextualizes the focus of the PhD study within the global discourse looking at child health within the framework of the global agenda for Sustainable Development Goals (SDGs) and particularly Universal Health Coverage (UHC). The section specifically brings to the discussion the progress so far made across regions but also recognizes that additional work needs to be done if countries are to achieve the SDG targets by 2030. The **second section**, which is the background, situates the study within the local Ugandan context by highlighting the burden of disease and related causes. It also demonstrates the benefits of expanding effective interventions such as iCCM into the private sector to optimize their advantage for a bigger population that access health care through the private sector. This section, therefore, provides an entry point to the AXEX intervention study – one of many pilot studies – aimed at testing how effective iCCM can be implemented within the private sector beyond the traditional public sector system with its inherent challenges. **Section 3** provides the rationale for the study – identifying the programmatic and policy significance and contribution of the study to the ongoing discourse of expanding access to quality care and accelerating progress towards achievement of UHC. **Sections 4 and 5** present the objectives of the study. Finally, **section 6** provides the conceptual framework that guided and helped in bringing together the different aspects of the study.

Chapter 2 is an extensive review of the literature relevant to this study. In this chapter, five different categories of literature that are relevant to this thesis are reviewed. The first category of literature focuses on the nexus between the private sector in health and the current UHC debate; and the second category reviews the burden and causes of under-five mortality. In the third category, the retail markets as commonplace for treatment and care of under-five children in vulnerable settings is explored. The fourth category explores two major theories, one, on health markets and the other on incentives and how they influence agent behaviour, which eventually influences how particular markets operate. The final category of literature summarises the various methods and approaches that have been applied in studying retail markets across various settings, the strengths and limitations of each, and what is applicable for the specific study objectives.

Chapter 3 synthesizes the methods used in the different sub-studies that comprise this thesis. The chapter presents the study setting, the overall AXEX study design, and the different designs adopted for the sub-studies, intervention design and package, sample size determination, and sample

selection. The chapter also presents the data collection process and the data management and analysis approaches. The detailed methodology applied for each of the specific sub-studies is extensively described in the specific papers (and manuscripts) appended to this thesis.

Chapter 4 synthesizes the main findings and highlights from the four sub-studies in light of the PhD study objectives. The detailed results are presented in the individual papers and manuscripts appended.

Chapter 5 presents the discussion and conclusion from this research. The cross-cutting issues arising from this work, how they link with the literature and similar studies that have been done elsewhere, are all presented in this chapter. In addition, the contribution of this research to the broader knowledge base on the place of retail health markets in health service delivery and achieving the SDGs in low-income countries (LICs) is presented. Finally, the methodological considerations including study limitations, conclusions, and potential implications for policy and programming and areas of further research are presented.

CHAPTER 1: INTRODUCTION

1.1 Introduction

Globally, many countries have committed to and are pursuing the Sustainable Development Goals (SDGs) agenda, following the end of the Millennium Development Goals (MGDs) in 2015. Sustainable Development Goal 3 (SDG3) is concerned with *ensuring healthy lives and promoting wellbeing for all at all ages*. Within this goal, SDG 3.2 aims at ending *preventable deaths of newborns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1000 live births and under-5 mortality to at least as low as 25 per 1000 live births[3]*. Relatedly, SDG 3.8 is about achieving Universal Health Coverage (UHC), whose principles entail *every individual having access to good quality health services that they need without suffering any financial catastrophe* [4]. There is a global recognition that to accelerate progress towards achieving UHC especially in LICs, adequate investments in strengthening health systems are necessary. However, these investments should not only be focused on the public sector but also bring on board non-state actors to complement government efforts [5, 6]. This view has emerged out of the realization that non-state actors do not only contribute an important role in the delivery of health care services, but also possess unique capacities and opportunities that should be harnessed to advance the SDG and UHC agendas. This discussion, however, must not be oblivious to the intrinsic challenges that come with engaging the private sector, and therefore stakeholders must explore better mechanisms of engaging the private sector in health without compromising the public good. This thesis aims to shed more light on the contribution of the private retail market to improving access to good quality and effective health care services particularly for children in a rural setting of South-Western Uganda, to reduce child mortality and achieve SDG3.2.

1.2 Background

Globally, under-five mortality is still high. For example, an estimated 5.3 million children under the age of five years died in 2018 alone, with almost half of the deaths occurring in Sub-Saharan Africa (SSA)[7]. A significant reduction in the deaths, however, has been recorded over time. For example, between 1990 and 2019, global U5MR declined by 59% to 38 deaths per 1000 live births, although the SSA average is still high at 76 per 1,000 live births[7]. The SDG 3.2 target aims at reducing U5MR to 25 per 1000 live births by 2030. This implies that additional effort and investments are required for countries to realize this target.

Uganda managed to surpass the Millennium Development Goal 4 target of 62 deaths per 1,000 live births and attained 55 per 1,000 live births by 2015. As of 2018, U5MR in Uganda had further declined to 46.4 deaths per 1,000 live births[7]. This number is still high, and a lot of effort is needed if the target of 25 per 1,000 is to be attained by 2030. Unless strategic, effective, and targeted interventions aimed at reducing U5MR are implemented, Uganda and other SSA countries may not achieve the SDG target related to U5MR.

Limited access to essential health services, more so, for the vulnerable and hard-to-reach communities in many low-income countries, is a major challenge in addressing U5MR. Health worker shortages, limited health facilities, poorly stocked facilities, and the high price or cost of accessing care, among others, contribute to this challenge [8]. The private sector has emerged as an alternative or complementary provider to the public sector in expanding access to care to vulnerable and hard-to-

reach populations. Retail health markets have particularly been identified as an innovative approach to expanding access to health services in many low-income settings[9, 10] [11-13]. In SSA for example, a sizable number of people prefer to seek care from retail drug shops and drug vendors especially for common childhood illnesses [12]. In Uganda, between 40% and 70% of sick children seek care from the retail drug shops, and approximately 50% of the essential medicines including antibiotics and malaria medicines are delivered through retail drug shops, private clinics, and retail pharmacies [14-16]. It is commonly the poor and low socioeconomic groups and geographically disadvantaged communities that utilize retail drug shops[17].

Preference for the medicines retail sector (MRS) is often attributed to easy accessibility, flexibility in operating hours, convenience, responsiveness to client demands, and low costs of services, provision of credit facilities, among other factors [16, 18-20]. Across many settings, the medicines retail sector (MRS) have demonstrable potential to improve access to and utilization of a range of health services and products [9, 16, 21, 22]. Even where cheaper alternatives for health care exist, for example with community health workers (CHWs), care seekers often bypass them for retail drug shops[12].

However, several violations of standards have been reported, including the sale of ineffective medicines in inappropriate dosages, stocking expired medicines, dispensing unauthorized medicines including antibiotics, among others [9, 13, 23, 24]. These practices culminate into costs to individuals and society as a whole, and are largely related to the current global challenge of antimicrobial resistance [23, 25, 26]. Indeed, in the recent past, there has been a lot of debate on the potential benefit of engaging the informal health market to expand access to quality health services, while recognizing the potential dangers and creating mechanisms of addressing them[10] [27]. Some of the noted adverse practices have been linked to or motivated by a combination of objectives for which drug shops are established and operated, and the existing market incentives[28]. It has been argued that some drug shops have been influenced by the market environment especially the high levels of competition and therefore to survive amidst such competition, they are forced to maximize profits which tends to influence how they operate [20, 29]. Thus, in circumstances where providers need to earn a profit, they face conflicting decisions on how to retain their clientele. In most cases, they decide to serve clients who wish to purchase only half of the recommended dose of medicine because of affordability constraints, otherwise, they risk losing the clients as they try to adhere to prescription standards by only selling complete doses of drugs [30]. The Accredited Drug Dispensing Outlets (ADDO) program in Tanzania reported that the pursuit for profits generated perverse incentives for positive action which harms the quality of care provided by drug shop outlets[28].

Many effective and tested interventions that address under-five mortality are being implemented in many settings, albeit through the public sector. This presents missed opportunities to reach the many households that seek care through the private sector. There are, however, attempts to expand to the private sector. In 2010, Uganda launched the WHO-recommended iCCM for paediatric febrile illnesses. The iCCM intervention is implemented through the public sector and CHWs, hence it misses on a significant number of children who bypass CHWs and rely mainly on private retail drug shops to access care.

In 2012, a pilot study introduced iCCM at retail drug shops in two high malaria prevalence districts in Eastern Uganda. The findings of this study demonstrated that it was feasible and effective to implement iCCM through the private retail drug shops [16]. This study noted that given that drug shops exist across communities and generally enjoy community trust, they could be harnessed to

deliver effective child survival interventions such as ICCM. Indeed, in other settings, retail drug shops have been appreciated as avenues that offer an opportunity to increase access to essential care especially for care-seekers who are unable to access care from existing public sector services for one reason or another[27] [10, 31]. However, a comprehensive understanding of the retail health market under which retail drug shops operate is necessary. This information is essential not only for the understanding of how best retail providers could be engaged but also for the design of feasible and effective interventions that improve and expand access to care provided by the retail drug shops.

1.3 Rationale for the research

Sustainable Development Goal 3 (SDG 3.2) aims to reduce under-five mortality to 25 deaths per 1000 live births by 2030. Expanding access to feasible and effective interventions is key to achieving this target. Uganda has recorded remarkable progress in reducing U5MR to 46.4 deaths per 1,000 live births (2018), but accelerated progress is still required to achieve the SDG target of 25 per 1000 live births. The high U5MR has been linked to a combination of factors, including limited access to timely care, high costs of care especially for poorly served hard-to-reach, and geographically disadvantaged settings[32] [33]. Expanding access to timely, less costly, safe and high-quality care is critical in reducing the high U5MR.

Given that a sizeable amount of health care in LICs is provided through the private sector and more particularly the retail providers, the private sector offers an important opportunity to expand access to safe, quality, and effective care for children, hence contributing to reducing U5MR[34]. There are, however, also reports that many drug sellers do not have adequate qualifications, knowledge, and capacity to provide appropriate treatments, some drug shops stock and dispense substandard, counterfeit, or even expired drugs, among other rule violations [16, 23, 35]. These violations create social costs, undermine the quality of care, and generate risks to the health of individuals who seek care [23, 25]. The violations and practices have partly been attributed to among others; pressures from the demand side (clients), the need to maintain legitimacy and trust of their clientele, the quest to optimize revenues and profitability to maintain a market presence, and a weak, ineffective or even non-existent regulatory capacity [26, 36].

In 2010, Uganda launched the iCCM strategy for malaria, pneumonia, and diarrhea [37]. The iCCM strategy has largely been implemented through the public health sector and CHWs. However, there are already attempts to scale up iCCM into the private retail sector in Uganda following some pilots that have already demonstrated positive results [16, 38]. To ensure successful implementation of interventions in the retail drug shops, it is critical that information must be generated on, among others, the structure of retail drug shops, their characteristics, motivations for the establishment and operational incentives, and how these may influence provider practices [5, 6, 39-41]. Without this information, it may be rather difficult to design and successfully implement feasible and effective interventions in the private retail sector. Similarly, in the case of the iCCM strategy, it may be arduous to project how providers will interact with the iCCM intervention and the likely effect of that interaction on the availability and affordability of paediatric care. This PhD study, thus, aimed to characterize retail drug shop providers, explore the incentive structure under which they operate, and determined the effect of an iCCM intervention at retail drug shops on the availability and affordability of paediatric febrile care.

1.4 Research aim

The thesis aimed to characterize the retail drug shops market and its associated incentives and determine the effect of an iCCM intervention on the availability and affordability of paediatric febrile illness care in the private sector registered drug shops in rural South-Western Uganda. This would contribute to identifying, designing, and implementing interventions and strategies to accelerate progress towards achieving SDG 3.2 particularly reducing under-five mortality by 2030.

1.5 Research specific objectives

1) To describe operational characteristics of the private retail drug shop market in rural South Western Uganda.

1) To analyse incentives and motivations of private retail drug shop providers in rural South Western Uganda.

1) To determine the effect of implementing an integrated Community Case Management intervention at private retail drug shops on availability and affordability of paediatric febrile care provided at retail drug shops in rural South Western Uganda.

2) To describe and analyse the AXEX iCCM intervention, how it was implemented at the drug shops, and the dynamics, and processes through which the observed effects were produced.

1.6 Conceptual Framework

This study adopted and modified a framework for understanding the determinants of market outcomes and normative consequences of private health provider sales, initially proposed by Conteh & Hanson [42]. The framework was later used with modifications in studying markets for malaria medicines by Goodman [43] and Patouillard [44]. The framework is grounded in the Structure-Conduct-Performance (SCP) paradigm theory of industrial organizations argued in the initial works of J.S. Baine in the 1950s[45]. According to the SCP paradigm, the structure of a particular market will determine the behaviour of the agents that operate within that market, and this in turn has a significant influence on the performance or output of that particular market [45]. This paradigm implies that changing the structure and characteristics of the market will alter the conduct of the players and ultimately affect market performance. If the market structure is competitive, for example, it will shape the way firms structure their operations and this will influence the performance of firms and consequently the entire industry. In this paradigm, the concept of 'structure' connotes a degree of market competition, size and number of buyers and sellers, the extent of integration, and the broader operational environment, including the regulatory framework [46]. 'Conduct' involves the actions of individual market agents and the rationale for the actions. These actions may include: determining prices at which to sell products, decisions and choices around what products to sell and in what quantities, products to stock, sales promotion strategies, among others [47]. Finally, market performance, according to this paradigm, is reflected in the quantity and quality of products and services offered, mark-ups, revenues, and profitability, among others [45]. Patouillard, in a modified framework, underscored the concept of context – the broader environment in which markets operate, and how this context shapes market dynamics and interactions of actors and the ultimate outcomes[44]. This context could be socio-economic, health system, or other implemented programs aimed at improving the operations of the market towards certain desired outcomes.

The first modification I made to the framework, therefore, was to introduce an AXEX iCCM intervention in the 'context' space. I did this because the intervention aimed at altering the functioning of the retail drug shop market and hence the outcomes, and the focus of this thesis, was to assess the influence of this intervention on market outcomes, through the influence of the intervention on market structure and agent behaviour and practices (demand and supply). The second modification introduced in our framework was to map the market outcomes for the AXEX intervention study and generally express them in public health terms such as appropriateness of care, perceived quality of care, availability of care, and affordability of care. The last modification to the framework was a move beyond intermediate outcomes of the AXEX intervention and mapping them to a long-term impact, which is to contribute to improved child health and reduced under-five mortality rate.

While the market ordinarily entails both the demand and supply side, this research majorly focused on analysing the supply side, except for a few demand-side characteristics such as preference and beliefs, income status, and product and provider information, among others. These factors were closely linked to and enabled a more in-depth understanding of the supply side. An additional motivation for this decision was related to feasibility and logistical concerns for the study.

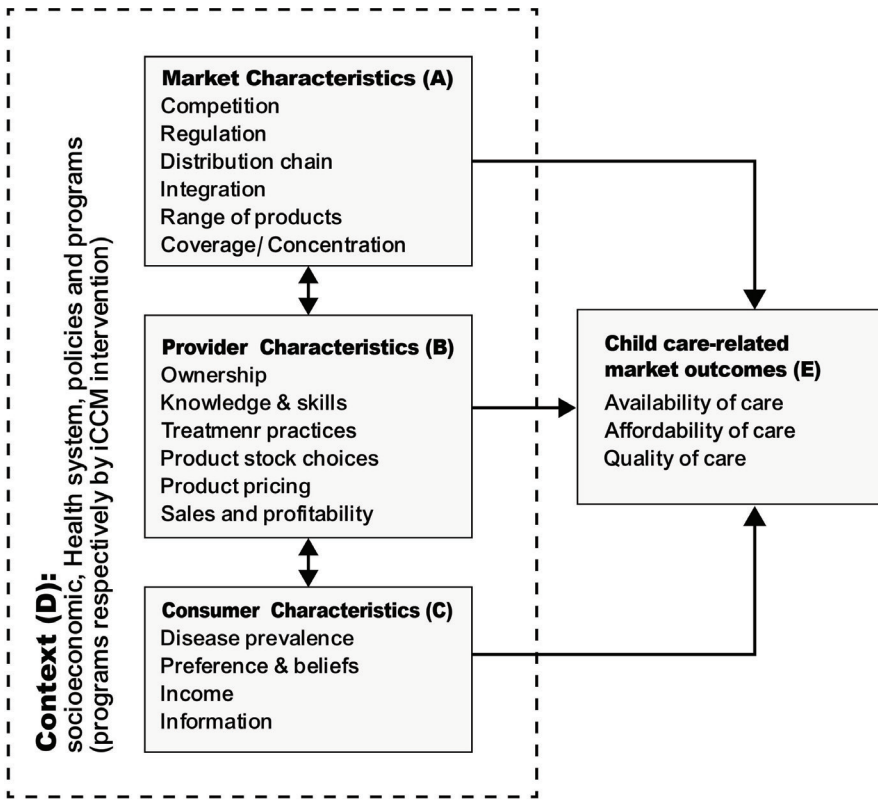


Figure 1. 1: A Modified conceptual framework showing the effect of iCCM on retail drug shops market performance. Adapted from Patouillard[44]

At the center of the conceptual framework is the market with both supply and demand components and an illustration of the interactions between and within the components. The nature of intermediate

outcomes that the market generates depends on the structure of the market, provider, and consumer characteristics (sub-study I & II), as well as motivations, and incentive structure of the market players which influence their interactions and practices (sub-study II). It is, however, important to note that these interactions and the resultant outcomes must be situated and understood within the broader context in which the market agents operate. Any changes in the context or the specific components of the contextual environment will likely change the interactions (conduct) and functioning of the market and consequently alter market outcomes. In this case, the market outcomes of focus are availability and affordability of paediatric febrile care (sub-study III). Although some elements of input, structure, and process quality were studied at baseline – including training and skills of providers (attendants), operational environment of drug shop outlets, and existence of as well as adherence to treatment protocols and guidelines, the effect of AXEX intervention on perceived quality was only comprehensively investigated in one of the papers arising from the AXEX intervention work [48]. . It is also is important, however, to note that the changes in the contextual environment and how the agents respond may generate predictable but also unpredictable effects beyond a specific targeted component of the health care system. It is therefore essential to map the intervention implementation process and illuminate how these observable and unobservable effects come about (sub-study IV).

CHAPTER 2: LITERATURE REVIEW

This chapter reviews the literature within the context of this research. The literature review was guided by the current global discussion and how this research fits in the conceptual framework that focuses on the retail health care market and approaches to studying and analysing private health care markets. Five different categories of literature that are relevant to this thesis were reviewed. The first category of literature focused on the burden and causes of under-five mortality and efforts aimed at addressing this burden. The second category explores the nexus between the private sector in health and the current SDGs and UHC discourse. The third category explores the retail health markets as commonplace for treatment and care of childhood conditions, especially in vulnerable settings. In the fourth category, two major theories of market behaviour – the market theory and the incentive theory, and how they influence the market operations are reviewed. The fifth and final category of literature summarises the various methods and approaches that have been applied in studying markets, including data collection and analysis approaches and their strengths and limitations. In the final section of this chapter, gaps in the reviewed literature are identified, and an entry point for the study is established.

2.1 The burden, causes, and efforts to address under-five mortality

2.1.1 The global burden and causes of under-five mortality

There has been global progress in reducing under-five child mortality compared to the1990 levels. In the year 2018, the under-five mortality rate reduced to 5.3 million compared to 12.5 million recorded in 1990 [7]. In terms of the numbers, there were few recorded deaths of under-five children (15,000) in 2018 compared to 1990 (34,000). This is a reduction of 59% from the 1990 figures, from 93 deaths per 1,000 live births to 39 deaths per 1,000 live births in the year 2018. Despite this global progress, regional disparities exist, with SSA being the most affected, with 78 deaths per 1,000 live births recorded, which is way beyond the global average of 39 per 1,000 for 2018[7]. The Sub-Saharan African region alone contributed 52% of the global under-five deaths in 2018, with children from low socioeconomic settings being the most affected[49] [50]. Under-five mortality is largely caused by preventable conditions such as pneumonia (15%) diarrhoea (8%) and malaria (5%), accounting for about 33% of the global under-five mortality[7]. Unless countries implement and expand access to proven and effective interventions, such as the promotion of breastfeeding, use of insecticide-treated nets, Intermittent Preventive Therapy (IPT), use of oral rehydration solution (ORS) and Zinc, vaccination, use of ACTs, community case management, among others, many countries may struggle to achieve the SDG 3.2 by the year 2030[51].

2.1.2 The burden and causes of under-five mortality in Uganda

Uganda has recorded considerable progress in addressing the high burden of under-five mortality, although more effort is still needed. Uganda recorded an U5MR of 64 deaths per 1,000 live births in 2015 [52] and a further reduction to 46.4 deaths per 1,000 live births in 2018[7]. This is commendable progress although more effort is needed to achieve the SDG target of 25 deaths per 1,000 by 2030. The burden of U5MR in Uganda continues to be dominated by pneumonia (15.6%), diarrhoea (8.4%), malaria (5.1%), and neonatal sepsis (7%). The 2017 hospital data in Uganda, shows that malaria (14%), other neonatal conditions (12%), pneumonia (10%), prematurity (11%), septicemia (7%), among others, are the leading causes of under-five deaths[53]. Profiling the cause-of-death is significant for identifying and prioritizing effective interventions. Studies attribute these deaths to,

among others; lack of timely symptom recognition and access to critical care, as well as poor quality of care ([54, 55]. These challenges are associated with longer distances to formal health service providers, low household socioeconomic status, and unavailability and poor quality of services and supplies at health facilities [56, 57]. Improving access to effective, and affordable care is an important step in reducing under-five mortality [58].

2.1.3 Global and national efforts to address under-five mortality

There have been efforts aimed at addressing the high U5MR both at the global and national levels, with some commitments made. At the global level, the following efforts are notable:

The Millennium Development Goals (MDGs) contained concrete commitments under the MDG 4 for countries to reduce child mortality by 75% of their 1990 levels by 2015[59].

Committing to Child Survival: A promise renewed. This was an initiative aimed at accelerating countries' progress towards achieving the MDG targets related to child survival. In this initiative, more than 200 countries came together and made recommitments to reduce under-five mortality to 20 deaths per 1000 live births by 2035[60].

Every New-born Action Plan" (ENAP). The ENAP initiative was launched in 2014 as a roadmap to identify and implement evidence-based strategic actions to end preventable newborn mortality and stillbirths. The ENAP initiative provided for specific action plans and strategies that would be implemented to achieve an agreed target of 10 deaths (or less) per 1,000 neonatal live births by the year 2035. Up to 197 countries endorsed the initiative at the 67th World Health Assembly[61].

The global Vaccines Action Plan 2011-2020 (GVAP). This was an initiative borne out of a recognition that vaccination was the most cost-effective approach to reduce child mortality, yet access to vaccines and vaccination programs remained a challenge across many countries[62]. The World Health Assembly in 2012, endorsed a plan to expand coverage and access to vaccines under the Global Vaccine Action Plan (GVAP). The GVAP provided a framework to reduce child deaths by 2020 through enhanced and more equitable access to existing vaccines for all[62]. A more disease-specific initiative to address the burden of pneumonia and diarrhoea was also launched - the Integrated Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea (GAPPD). This initiative spearheaded by WHO and UNICEF, with a target of reducing deaths from pneumonia to fewer than 3 children per 1000 live births, and from diarrhea to less than 1 in 1000 by 2025, using a multi-sectoral action approach[63].

Affordable Medicines Facility malaria (AMFm). This was an initiative of the Global Fund launched to expand access to and utilization of ACTs through the private sector. This was expected to be achieved through negotiating price reductions with manufacturers, a buyer subsidy through a co-payment system at the upstream of the ACT supply chain, and support to interventions that promote appropriate ACT use[64].

2.1.4 Evolution of child survival interventions

Interventions to address the high U5MR have evolved over time in many countries. In this section, I have highlighted significant timelines:

The integrated management of childhood illnesses (IMCI) strategy was launched in 1996. The IMCI strategy aimed at integrating existing strategies of disease prevention, early detection, and promotion of family and community health. These were expected to be achieved through training

and capacity building for health workers in addition to health system strengthening. Recognizing that it would be complex to reach households with a community-based intervention, Community Health Workers (CHWs) were brought on board and trained to implement the intervention within their communities[65].

The Home Based Management of Fever (HBMF) strategy. In 2004, the WHO recommended the implementation of the Home Based Management of Fever (HBMF) strategy. Under the HBMF, CHWs in several African countries were provided with antimalarials for distribution within their communities. CHWs acted as the first points of contact for sick children and offered first aid and other advice to caretakers before any referral to formal health facilities would be initiated. This HBMF was a success story in countries like Kenya, Uganda, the Gambia, Ethiopia, among others, where noticeable improvements in access to timely health care were recorded [66-68].

Community Case Management (CCM) Strategy. The CCM strategy was launched following a recognition that CHWs were a critical resource within communities that could be capitalized on to expand access to health care within the communities. The CCM strategy aimed to improve treatment-seeking behaviour for children within communities. The CCM strategy was a complementary strategy to the facility-based care that was expected to expand the capacity of the health system to provide much-needed health services to children with poor access to health facilities, but particularly focusing on conditions that account for most child deaths[69]. Under the CCM strategy, CHWs were trained to classify sick children based on a symptom-based algorithm that had been adopted from the IMCI guidelines. They would then provide medicines for common childhood conditions. The CHWs also acted as a link between the community and the health facilities. Indeed, CHWs were effective especially for areas that had inadequately trained health workers [70, 71]. The main challenge with the existing community-based strategies, however, was how to manage children with other conditions besides malaria, or even other childhood conditions that presented as malaria, yet were not (overlapping symptoms). This meant that a new strategy had to be developed to facilitate the integrated management of childhood conditions.

The Integrated Community Case Management (iCCM) Strategy. Following successful pilots, the WHO and UNICEF recommended the iCCM strategy to address the challenge of overlapping symptoms across childhood illnesses[72]. The iCCM strategy recommended an integrated management approach to treating childhood fevers at the community level. Under this strategy, the CHWs not only identified but also assessed children for common conditions – malaria, pneumonia, and diarrhoea, and provided appropriate medicines as recommended. The CHWs also referred any severe cases to health facilities for proper management. Within the iCCM strategy, the WHO also recommends parasitological confirmation of malaria before any ACTs were provided[73]. The details of iCCM in Uganda are in provided section 2.15.

2.1.5 The Integrated Community Case Management (iCCM) Strategy in Uganda

In Uganda, the iCCM policy, was launched in 2010, and as of 2015, the iCCM strategy had been rolled-out in about 64 out of 112 districts with support from development partners such as UNICEF, Clinton Health Access (HAI), and Global Fund. The iCCM policy is implemented through volunteer community health workers[74]. Community health workers are a cadre of lay health workers selected from communities and provide services within their communities. The CHWs are trained in symptom recognition and illness classification by applying simple algorithms, Rapid Diagnostic Tests (RDTs) for malaria, and respiratory count timers for pneumonia. After diagnosis, CHWs provide

appropriate medicines (Amoxicillin, ACTs, ORS for diarrhea, Zinc, pre-referral rectal artesunate) for malaria pneumonia, diarrhea, and other childhood illnesses[74]. Under the iCCM strategy, CHWs are provided with kits containing pre-packaged medicines, commodities, and diagnostic tools. CHWs, are generally charged with mobilization of communities to demand, support, and utilize the intervention; identification, assessment, and treatment of children in communities, counselling their caretakers and immediate referral of severe cases; identification of new-borns and assessing them for danger signs and referrals where necessary, collection of data on the intervention indicators, monitoring and reporting to health facilities within catchment areas, and peer to peer supervision. These roles are part of the broader roles of VHTs in delivering preventive health services such as health education, community mobilization, immunization, distribution of mosquito nets, among others. For all these activities, VHTs are not remunerated although the VHT policy recommends a minimum compensation of UGX 10,000 (about USD2.5) per month but paid on a quarterly basis[75]. It is important to note that VHTs and CHWs are used interchangeably because they are largely the same cadre of community-level volunteers. Within the iCCM implementing districts, there are implementation challenges that have been reported, which relate to, among others, limited resources, limited supervision, and a weak and unreliable commodity supply chain, and this has a negative effect on the anticipated benefits of iCCM [76]. Experiences also indicate that the performance and acceptability of CHWs under iCCM have been mixed. There are reports that CHWs are less motivated and have heavy workloads which undermine their capacity to deliver good quality services and this jeopardizes the sustainability of the iCCM policy[77, 78]. Other reports indicate that CHWs have performed well under their circumstances and with additional training and support supervision, CHWs would successfully implement iCCM [79, 80]. In the next section, I show from the literature that the private sector and more particularly the retail drug shops are an important network that can complement the efforts of the CHWs in delivering iCCM and similar interventions. The section starts by exploring the place of the private sector in the SDG and UHC agenda discourse, and later, the role of the private sector and more specifically the medicines retail sector in expanding access to and utilization of effective interventions such as iCCM.

2.2 Private Sector, Health Service Delivery, and Universal Health Coverage

2.2.1 The Private Sector and Universal Health Coverage

Many countries have committed to achieving Universal Health Coverage (UHC) by the year 2030. UHC is contained in the SDGs specifically SDG3.8. UHC implies that everyone is able to access health services of good quality without suffering financial hardship as a result[81]. UHC has been framed along the three coverages: expanding service coverage, expanding population coverage, and expanding financial coverage. Achieving this global agenda requires collaboration and partnerships across various players; including civil society, communities, and the private sector, among others[82, 83].

Many LICs have pluralistic health systems where the state and non-state actors work in a complementary framework to provide health care services. In fact, the role and participation of the private sector in the direct provision of health services have been expanding in many countries, has plugged the gaps in public provision, and therefore it would be unwise to ignore the private sector in the UHC discourse [5]. Non-state actors possess unique capacities and opportunities that must be harnessed to advance the UHC agenda[84]. This discussion, however, must not be oblivious to the intrinsic challenges that come with engaging the private sector, and hence the need to explore better

mechanisms of engagement. Harnessing private sector involvement requires deliberate policy and institutional reforms at the country level, including regulatory and financial tools, established public-private partnership frameworks, and a robust monitoring and coordination mechanism[5, 82].

2.2.2 Understanding the private sector in health

Many countries operate pluralistic health systems where health service delivery happens through the public sector and the private sector. The private sector includes a combination of health care providers that are not under the control of the government [85]. Going by this definition, the private sector includes individual private-for-profit facilities (PFP), the private-not-for profit (PNFP), and other non-government owned health care providers. The private sector also includes the 'retail sub sector' whose characteristics and composition vary across settings. It includes informal health providers such as drug vendors, private medicine distributors, drug shops or drug stores, pharmacies, market stalls, grocery stores, mobile vendors, kiosks, and traditional healers[86]. The private sector in LMICs is heterogeneous but largely consists of independent practitioners, with some being registered, and others not registered. They include large privately owned hospitals (private for-profit and private-not-for profit) providing specialized services, big insurance companies, private clinics, pharmacies, itinerant medicine sellers or vendors, and retail drug shops operating at the bottom and sometimes managed and operated by less qualified personnel[87, 88]. While there is a sense of coordination within the PNFP sub-sector, this is not the case with the PFPs and the more informal health providers where most of the players may not be known and often work outside the formal regulatory structures [89, 90].

2.2.3. Health care service delivery in Uganda (and study area)

Uganda operates a mixed health care system, where health services in both districts are provided through public health facilities, private not for profit facilities (PNFPs), private for-profit providers (PFPs), pharmacies, retail drug shops, and sometimes Traditional and Complementary Medicine Providers (TCMPs)[91]. Health service delivery in Uganda is decentralized, in which case the mandate to deliver health services falls under each district local government, in addition to planning and prioritization for service delivery[92, 93]. However, the overall governance and leadership of the health sector are directly under the Ministry of Health – whose role is to provide governance, policy direction, monitoring and supervision, and resource mobilization. The MOH is also directly responsible for regional and national referral facilities and Centers of Excellence. The health service delivery system is tiered, with community health workers or village health teams (VHTs) operating at the community level and engaged in providing preventive services, and the ministry of health on top with governance, policy, and supervisory functions. Figure 3.1, shows an elaborate structure of Uganda's health care referral system represented by a pyramid that incorporates both private and public provision of health services. It is important to note, however, that the Ministry of Health has a mandate over the private health providers – including accrediting and licensing their operations and assigning them a level of care based on what services they provide.

Under the decentralization policy, each district is a health care system *per se*. Each district has a District Health Team (DHT) that is charged with the responsibility of ensuring the district health system is functional and delivers on its mandate. The District Health Officer as the overseer of a district health system heads the DHT. The DHT includes the District Assistants Drugs Inspector (DADI), an officer who represents the NDA within each district. The role of the DADI is to, among others; grant licenses to drug shops after an elaborate vetting and approval process and fulfillment of

requirements as specified in the NDA policy guidelines[94].

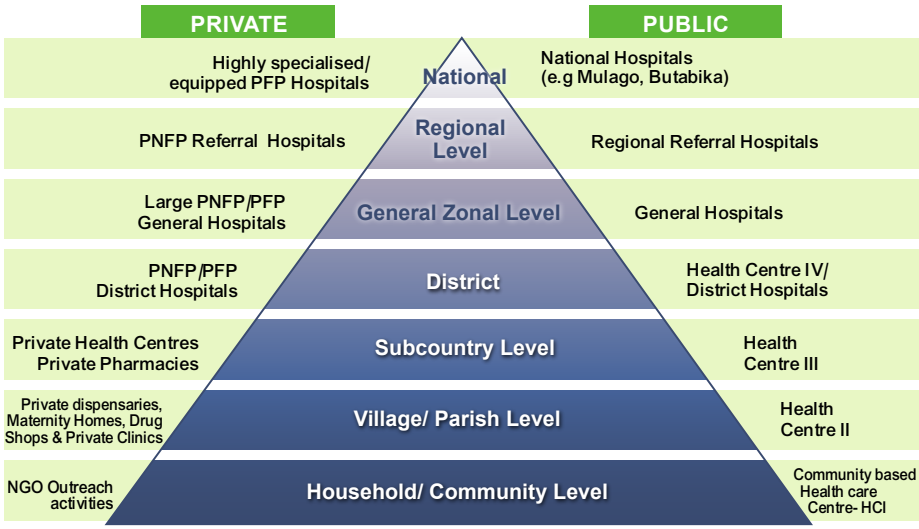


Figure 2.1: Uganda's Health System Referral Pyramid[95]

2.2.4. The private sector in health in Uganda

Uganda has a mixed or pluralistic health system where health care services are delivered through both the public and the private sectors. The public sector provides health services through a decentralized framework, where local governments have a mandate to plan and provide health services to the population within their areas of service[96]. In Uganda, the private sector is very diverse. Generally, the private sector in Uganda is, classified into the Private-not-for profit (PNFP) sub-sector and the private-for profit (PFP) sub-sector. The Private-not-for-profit (PNFP) sub-sector includes the mission and faith-based health facilities under the umbrella of Uganda Protestant Medical Bureau (UPMB), Uganda Catholic Medical Bureau (UCMB), Uganda Muslim Medical Bureau (UMMB), and Uganda Orthodox Medical Bureau (UOMB). There are, however, other facilities run by Non-Governmental Organizations (NGOs) that also provide services[95, 97]. Available data shows that about 85% of PNFP facilities are located in rural and hard-to-reach areas [98]. A health facility inventory assessment conducted by the Ministry of Health (MOH) in 2012, showed that the public sector owned 55% of health facilities, PNFP was 17% and the PFP was 28%, and between 35-40% of health services were delivered through the PNFP subsector [91, 98, 99].

The Private-for-profit (PFP) subsector has been defined to include clinics, high-end hospitals, pharmacies, individual medicine providers, and retail drug shops, and private medicine vendors (PMVs). Retail drug shops generally operate in both urban and rural areas, although their presence is largely in rural areas that are geographically and economically disadvantaged. Within the PFP subsector, are also Traditional and Complementary Medicine Practitioners (TCMP). It has been noted, however, that the PFP subsector in Uganda is not well regulated and this has adverse implications for the broader public health goals. Owing to the heterogeneous nature of the private sector actors, a one-size-fits-all policy framework may not necessarily be effective, and hence the need to identify and implement actor-specific policy prescriptions. To facilitate public-private sector engagement, the government developed the National Policy on Public-Private Partnership in Health (PPPH) in

2012[100]. The policy provides a general framework for how the public and private sectors should work together. The policy contains the general principles that are expected to guide the relationship. These include an emphasis on complementarity to minimize duplication; joint policy formulation and planning, service provision and orientation, transparency and accountability without compromising autonomy, self-regulation, and effective private sector representation at different decision-making organs, and issues of equity among others[100].

2.2.5 Medicines retail sector and health service delivery

2.2.5.1 The retail sector and its role in health service delivery in LMICs

The retail sector and particularly the retail drug shops play an important role in the provision of health care services especially in the low and middle-income countries (LMICs). In many LMICs, the medicines retail market constitutes a varied spectrum of informal providers, quite often providing health services without necessarily formal training, and sometimes evading a weak regulatory infrastructure [101]. Informal health providers bridge the gap where formal health care providers may not exist or where public sector provision is weak. While retail providers exist in both urban and rural settings, they are proliferated in rural settings where access to public health facilities is constrained by long distances, limited or even lack of a well-functioning public health system – characterized by limited health workers, and drug stock-outs – and household poverty[15, 16, 102]. In SSA, for example, a sizable number of people prefer to seek care from retail drug shops and drug vendors especially for common childhood illnesses[12, 102]. Retail drug shops are the first points of call for most febrile children before reporting to public facilities [87, 103, 104]. Studies have noted that a sizable amount of antimalarials and antibiotics are procured through the retail sector market [90, 105, 106]. Evidence also suggests that it is often the poor and the lower socioeconomic groups that seek care from retail providers[88]. Informal providers are preferred for various reasons, including flexibility in working hours, easy accessibility, flexible payment methods, and a high degree of community trust[89]. Working with the retail sector is no longer optional, rather it is a reality, and hence governments should identify a framework to positively work with the retail sector while limiting the adverse behaviour of the players and the likely market failure.

2.2.5.2 Retail health markets and regulation

Retail health markets have undoubtedly expanded services to communities that were hitherto constrained. However, there are also considerable concerns that have been noticed which relate to rule violations, selling poor quality products and services, and sometimes providing under-dosages or over-dosages medicines [9, 23, 90]. These rule violations generate individual as well as social costs, including antimicrobial resistance, increased health care access costs that culminate into catastrophic health expenditures, or even deaths due to inappropriate treatments [23, 25, 26]. Addressing these substandard practices through existing regulatory frameworks in many settings has proved very elusive and has generated suboptimal results[13, 90]. Bloom and colleagues noted that while the expansion of private health markets had enabled vulnerable communities to access hitherto hard-to-access health services, the capacity to regulate them was very limited[107, 108]. It is important to clearly define these market relationships and institutional arrangements within which they operate to design interventions that would improve their performance.

2.2.5.3 Retail drug shop providers in Uganda

The Uganda MOH recognizes the contribution that drug shops make in the delivery of health services and categorizes them as private for-profit (PFP) entities [109]. Drug shops are small medicine shops

that commonly sell drugs or medicines, which can be prescribed over-the counter. Drug shops sell medical supplies and services, but sometimes sell other market products beyond just medical supplies. Although drug shops have a very significant presence both in urban and rural areas, they are more prominent in rural areas where access to public health facilities is often constrained. In Uganda, drug shops are regulated by the National Drug Authority (NDA) under the NDA Act of 1993 and the Drugs Shops Licensing Guidelines of 2015 [94, 110]. It is a requirement that before being allowed to operate, a drug shop must be registered and granted an operational license upon fulfilling the requirements specified in the law, including an inspected and accredited operational environment, payment of certain fees, among others. It is, however, not uncommon to find drug shops operating illegally without operational licenses[23, 111].

In Uganda, drug shops are classified as 'B' and 'C' classifications. Class C drug shops are only allowed to sell 'over-the-counter drugs while class B, in addition to over-the-counter drugs, can stock and sell antibiotics[94, 112]. Unlike pharmacies where the use of trained personnel is mandatory, there is no clear regulation on the level of training and qualifications for drug shop attendants. It is therefore not uncommon to find untrained staff working in drug shops in addition to stocking un-recommended drugs. The monitoring and supervision system that would easily identify and address these irregularities is limited in capacity and resources, monitoring and supervision are irregular and generally ineffective [23, 113, 114]. In Uganda, between 40 and 70% of sick children seek care from retail drug shops. Retail drug shops are the first points of call for most febrile children before reporting to public facilities [16, 104, 115]. A sizable amount of antimalarials in Uganda are supplied through the retail sector market [15, 116]. Retail providers can thus relieve pressure off an overburdened and resource-constrained health system like Uganda.

2.2.5.4 Challenges of health service delivery within the medicines retail sector

While retail health markets are critical in delivering health services, particularly for underserved communities, concerns have overtime been raised about the poor quality of services they provide. For example, there are studies that have reported that many drug sellers were not qualified to operate drug shops. Other reports have noted that some drug sellers possess limited knowledge and skills to not only appropriately identify illnesses but also offer appropriate treatment. In some cases, drug shops have been reported to stock and dispense substandard and sometimes expired medicines[16, 117]. These poor practices have been partly attributed to pressures from the demand side (clients), the need to maintain legitimacy and trust of their clientele, the quest for revenues and profitability, the need to maintain a market presence, and a weak and ineffective regulatory framework [13, 23, 90]. Additional investigation into factors that influence retail market practices in Uganda would add to the existing body of knowledge to facilitate the design of feasible interventions that would improve retail sector practices and ultimately the quality of care.

2.2.5.5 Improving health service delivery within the medicines retail sector

Strategies to improve service delivery within the retail health sector have been varied across different settings. However, most of these interventions and strategies have generally focused on training and capacity building, policy development and regulation, stimulating demand for services through community mobilization, reducing prices of products through subsidy arrangements, and strong monitoring and supervision[118]. In a recent 2016 Lancet series, these approaches have generally been summarized into four levels: prohibit, constrain, encourage, and purchase[6]. The constraining approach includes establishing regulatory controls at all levels - upstream and downstream at

community, self or peer-to-peer regulation, consumer-based regulation, and accountability, among others to ensure adherence to rules and standards[119, 120]. The prohibition approach has involved a complete stop of some or all adverse practices of providers. In Uganda, for example, the NDA impounds unauthorized medicines found at drug shops not recommended to sell them such as antibiotics found at class C drug shops. Sometimes, however, prohibition may not have much success, rather, it encourages more illicit provisions and drives exchanges underground, hence generating some form of 'black marketing'[121, 122]. The 'encourage' approach involves providing support to private providers to improve their practice. Most interventions at this level have included training and capacity building and creating an enabling environment for better practice[118]. Others include social marketing, social franchising, quality improvement approaches, and provision of price subsidies along the supply chain in order to reduce consumer exploitation in the name of recouping high profits [123] [124, 125]. Experience from the Global Fund's AMFm ACT subsidy program in eight countries was successful at reducing prices and increasing access to ACTs through the private sector [126]. Subsidization, however, may not be a panacea to reduced prices and increased affordability as economic theory would suggest [127, 128]. The final level is 'contracting' where the government contracts the private sector to provide particular services to the people. Individuals can then access these services using either vouchers or some form of criteria. While this has not been applied extensively in the medicines retail market, there is a real opportunity to do so, given the strategic location of these retail providers, and the level of community trust they have. Services such as family planning, nutrition for children, health education, among others, can be provided at drug shops.

It is, however, important to note that these interventions have varied impacts and this may largely depend on the design of the intervention but also the setting where it is implemented [118]. In addition, some approaches may work in one setting and may not work in another, alternatively, an approach may not work in isolation, rather in combination [111, 125, 129]. Relatedly, a range of factors that must be investigated and considered may influence uptake of interventions by targeted providers. For example, *Wafula and Goodman* reported that while it was possible to improve knowledge and practices of pharmacies and drug shops to handle a number of diseases, the profit incentive appeared to have a strong bearing on the success of interventions [130]. In fact, they recommended further investigations on evaluating the cost-effectiveness and sustainability of such interventions. Identifying and implementing an appropriate and feasible strategy within the private sector and specifically, the informal sector requires additional evidence on the structure, characteristics, and incentive structure that exist within this retail health sector [6, 34, 39, 107, 119].

2.3 Understanding health care markets

2.3.1 Market theory in the context of health care services

From economics theory, the concept of a market implies a situation or mechanism that facilitates interactions between providers or producers and consumers or buyers of goods and or services. A health care market is thus an arrangement where various agents that are relevant to a particular health care problem interact to determine the supply and demand for a product or service that addresses that particular health problem. In market theory, agents have intrinsic objectives, for example, consumers aim to maximize utility from goods and services purchased, while producers aim at maximizing profits through adjusting demand and supply goals in response to market signals – such as price, quality, and quantity [131]. However, health care markets are unique, and therefore

some of the tools used for resource allocation in ordinary markets, prices, for example, may not necessarily be effective within health care markets. Health care markets are generally characterized by uncertainty, externalities, and asymmetric information, among other characteristics, and hence efficiency and optimality may be somewhat complex to achieve [42, 131, 132]. The nature and structural characteristics of a market have an impact on the interactions and transactions between the various agents within that particular market – including the types and nature of products and services provided the exchange and negotiation systems, and the regulatory architecture necessary. Demand and supply for products and services may not conform to the standard economic theory under such circumstances and the market may not achieve an efficient outcome. For example, in markets that are characterized by information asymmetry, supplier-induced demand (otherwise called provider moral hazard) is quite common, where providers use their superior knowledge and positions to influence (induce) consumers to unnecessarily demand particular products and services. Demand inducement has been recorded within private health care practice in the developed world and fewer investigations of this phenomenon have been conducted in low-income countries including Uganda. What is true, however, is that informal provider practice is influenced by, among other factors, the need to earn profits or revenues to cover operational costs and sustain businesses[133, 134]. Interventions should be designed in such a way that they recognize how incentives could influence the implementation and outcomes of the intervention. Depending on how an intervention is designed, it could generate even more distortions and suboptimal outcomes [135]. A careful and deliberate investigation and understanding of the market is necessary to ensure feasible and effective interventions.

2.3.2 Methods of studying retail health markets

Different studies have used different approaches for studying and analysing retail sector markets in various contexts. Each of the applied approaches has strengths and limitations that need to be considered when deciding which approach to use under what circumstances. Relatedly, some methods will be more suitable than others depending on what market variable is under investigation or which market agent is being studied [42]. In their review of methods for studying private sector supply of public health products, Conteh & Hanson summarised the methods used as follows: 1) surveys that use structured, semi-structured, or unstructured data collection tools, 2) in-depth interviews using structured or semi-structured interview guides, allowing for exploration of a wide range of typical issues, 3) direct observation of sales and practices, using observation checklists; and 4) record reviews. Additional methods that have been used include: 5) retail audits; 6) distribution surveys; 7) point of purchase surveys; 8) focus group discussions (FGDs); and 9) use of diaries and record-keeping; among others. They concluded that some methods may be more or less suited for informal markets than formal markets, and so understanding the context within which a study is conducted can facilitate appropriate methodological choices [42].

2.3.3 Identifying providers for inclusion in a market study

To identify providers for inclusion in market analysis, different methods have been suggested in the literature. One approach has been the use of provider registration data or official records or lists of outlets. Lists of providers will normally be accessed from the regulators [136-138]. The outlets on the official list may be classified based on specific products and services they are required or accredited to provide. This approach may, however, only allow access to registered providers. Yet, given the weak regulatory capacities in many settings, many providers elude regulatory systems and may continue to operate unhindered. There are also providers who may prefer to formalize their operations but

are sometimes constrained by the elaborate process of securing registration which may be beyond the providers' control. There could also be providers on the official register, who may have exited the market for one reason or another and it takes time for the official register to be updated. Leaving out unregistered providers may leave out critical information that would help shape the decisions and policy proposals likely to emerge from a particular study. These limitations, however, can be circumvented by using lists that have either been developed by previous studies or market research agencies, which lists tend to be relatively reliable and more updated than official rolls[139, 140].

The second approach to identify providers is the use of key informant interviews. Interviews can be conducted with different individuals operating at different levels and segments of the market, as either policymakers, supervisors, coordinators of national or regional programs, or local leadership within a particular area. These different officials are able to identify the number of providers that operate within their areas of jurisdiction or authority [141, 142]. This approach may, however, be limited by the fact that if key informants are not appropriately selected, one could easily miss out on certain providers that would have been included, because these may be operating further away from where the interviewee may be actively operating. It is therefore essential that key informants should include local respondents such as community leaders, local council leaders, CHWs, among others, to overcome this challenge [143].

Other studies have identified providers, using a census involving the use of Geographical Positioning System (GPS) locator, use of sales receipts, household surveys to ask households where they often accessed health care services, and interviews with the providers themselves especially high-end outlets where the lower outlets procure their stocks [136, 143-145]. Each of these approaches has strengths and limitations that must be put into consideration when selecting an appropriate approach to operationalize for a particular study.

2.3.4 Sampling providers for inclusion in market studies

From the review of literature, we identified various methods that have been used by various studies in sampling providers or outlets for inclusion in studies or surveys. The methods have been utilized depending on respective study contexts. Some studies have used convenient sampling either based on the purpose for which the study is being conducted, or geographical location, and logistical considerations [136]. However, this approach is limited by challenges related to the limited generalizability of findings. Other studies have applied random sampling [146], although this method, too, has an inherent limitation, particularly in circumstances where study units are not necessarily homogeneous. The other approach used is the stratification approach - where providers are stratified based on several considerations - including geography, level, type of service provided, the position of provider within the supply chain, among others[137, 143, 147].

2.3.5 Identifying products and services in market studies

Different methods are applied to study products that are provided at different market outlets. These include the use of official product lists which include only products that are officially sold at the outlets [139]. There are, however, circumstances where some products are sold at the outlets even when they are not recommended, and therefore using official product lists may leave out important product information. Other studies have used outlet surveys and analysed products displayed on the shelf [143]. Other methods used, include; the use of mystery shoppers (unobtrusive observers) – who are disguised clients with the main objective of understanding what exactly happens at the outlet and whether the outlet adheres to the standard accreditation and or prescription guidelines [42]; and the

use of client exit interviews to understand the products and services that clients have been provided with and their level of satisfaction with the provisions.

2.3.6 Estimating retail sales and profitability

There are majorly four methods that have been used in estimating and valuing sales volumes during market analysis studies: (a) Review of records. This involves the researcher looking into periodic sales and stocks of selected outlets and using the available data to project sales volumes for a month or a year. The challenge with this approach is the poor quality and unreliability of records and in some cases complete inexistence of these records. (b) Interviews with providers – in this method, providers or outlet attendants are asked to estimate sales for a previous recent week or period that one can easily recall, and those estimates are used to extrapolate sales for a specific period [148]. (c) Retail audits – in this method, providers or outlets are surveyed at regular intervals and during each visit, the stock of a selected product is recorded. Then any additional procurements in between the survey times is recorded as well. If there are no procurements done, then the difference between the stocks for the different intervals is recorded upon which an inference can be made as to the sales within that period [149]. (d) Exit interviews – in this method, clients of a particular outlet are interviewed as they exit the outlet to ascertain what products they have been prescribed and probably how much they have been charged [150].

Each of these methods has positive aspects as well as challenges and limitations in using them. The challenges may range from issues of the availability, quality, and reliability of records, the extent to which providers are willing to offer full disclosure and this is sometimes related to regulatory fears (for example, the fear that records could be used for taxation purposes), and estimation and valuation issues to ascertain projections. It is therefore recommended that researchers select an approach that minimizes these challenges and optimizes the accuracy of the estimates.

2.4 Emerging issues from the literature review

It is evident from the literature that the private sector generally plays an important role in health care delivery. The informal providers are particularly significant in providing medical care and drugs especially to the poor in many LMIC settings. The private sector possesses unique capabilities and opportunities that need to be harnessed to expand health service provision. Working with the private sector to advance the UHC Goal for LMICs may no longer be an option. The private actors should not be seen as mutually exclusive actors, rather as playing complementary roles to the government. It is important, however, that policies and interventions are designed to improve private sector delivery of health care services and address the incessant concerns of low quality, illicit practices, rent-seeking, profit motive that often undermine public safety, among others. To design interventions that might respond appropriately, the starting point must be to recognize the heterogeneous nature of the players, their objectives, operational structure, and incentives that influence the private health care market.

Methodological Choices

In terms of methodological choices used in the study;

a) We applied official NDA lists of registered and licensed drug shops to enroll outlets into the study. All registered and licensed drug shops were invited to participate upon meeting set criteria, including selling human drugs, located in the rural areas of the study area, among

others.

a) For a detailed study and analysis of the incentive structure of the retail drug shops, a sub-sample of drug shops was selected from the main list of study drug shops. The sub-sample constituted drug shops that had been used for client exit interviews from the main sample.

To estimate costs, sales volumes, and profitability, providers or drug sellers were interviewed about operations for the week preceding the study to avoid recall bias. Interviewing providers or attendants was a better approach because of the challenges of obtaining proper records of business operations at the drug shops. A study in Mukono District, Central Uganda, noted that the majority of private providers did not have patient registers and stock cards which made it difficult to assess track and assess their performance and product utilization [151].

To ascertain medicines availability, we observed medicines that were available on the shelves. This approach was also supplemented by interviewing the attendant to ascertain quantities and sometimes expiry information.

A more detailed description of the methodological choices used in this work, has been presented in the methodology chapter.

CHAPTER 3: METHODS

3.1 Introduction

This chapter describes the overarching mixed-methods approach that was used for this study to characterize the retail drug shop market and assess the effect of intervening in that market on availability and affordability of care for paediatric febrile illnesses, as well as the wider health system effects [152]. The mixed-methods approach provided an opportunity for different methods to complement each other in understanding the multiple dimensions and perspectives that would otherwise not be possible using one particular approach [153]. The mixed-methods approach was applied in the entire process from data collection, analysis, and reporting of findings. This chapter describes the study setting, study design, the intervention package, study population, sample size determination, sample selection, data collection, data management and analysis approach, and the ethical considerations. The rationale for applying particular methodological approaches over others and their limitations, are also presented.

3.2 Summary of methods

The sub-studies that constitute this thesis were generally done in a mixed-methods approach, except for **sub-study I**, which was quantitative-only. The methods used in the sub-studies that constitute this thesis are summarised in Table 3.1

Table 3.1: Summary of methods used in the studies

Sub-study	Design	Sample & Data collection method	Analysis & outcome
Private retail drug shops: what they are, how they operate, and implications for health care delivery in rural Uganda	Cross-sectional study design implemented to collect quantitative data at baseline	Baseline survey of 74 retail drug sellers, and 428 client exit interviews in both study arms. Structured questionnaire used for data collection	**Analysis**: Descriptive analysis with reported means, medians, and proportions. **Outcomes**: training and skills of attendants, prescriptive practices, decision making, store conditions, type of clients served, etc. others
For altruism or private benefit? Analysing the incentives associated with the retail drug shop market in rural Uganda	Cross-sectional study design implemented to collect quantitative and qualitative data from both districts at baseline	Survey of 74 drug shops in both arms at baseline. Detailed investigation of a sub-sample of 20 drug shops, using Structured questionnaires with close-ended and open-ended items. Additional 4 in depth interviews with government officials	**Analysis:** Descriptive analysis of medians, means and proportions (for quantitative data) Deductive manifest and content analysis of qualitative data (for open-ended qualitative items) **Outcomes:** Motivations for start-up, incentives for operation, sales volumes, price mark-ups, profitability, regulatory capacities

Increased Availability and Affordability of paediatric fever medicines at private retail drug shops with integrated management of malaria pneumonia and diarrhea. A Quasi-Experimental Study in South-Western Uganda	Mixed methods pre and post intervention design in both intervention and comparison arms	**Quantitative data:** Drug shop survey to ascertain availability of medicines. A total of 74 drug shops at baseline (Intervention=40, Comparison=34) and 48 drug shops at end-line (Intervention=32, Comparison=16). Care-seeker exit interviews Before intervention 428 (Intervention=212, Comparison=216) and after the intervention 553(Intervention=285, Comparison=268). **Qualitative data** -FGD with caretakers of under-five children (n=18) and VHTs (n=8) -IDIs with drug sellers (n=47) and Government officials (n=19)	Analysis of percentage differences in proportions of outlets reporting availability of medicines and applying a chi-square test to determine significance of the differences Analysis of difference in affordability of medicines at baseline and end-line (Intervention-only district) Difference-in-difference (DiD) analysis for care-seekers reported perceptions on affordability Manifest and content analysis of qualitative data **Outcome:** Proportion of outlets reporting availability of selected medicines Proportion of care-seekers reporting affordability of medicines Views and opinions about effect of intervention on availability and affordability
Health system effects of implementing the iCCM intervention in private retail drug shops in South Western Uganda; a qualitative study	Exploratory qualitative process evaluation design implemented to collect data in intervention district, at baseline, midline and end-line	FGDs with caretakers of under-five children (n=18), and VHTs (n=8). In-depth interviews with drug sellers (n=47) and Government Officials (n=19)	Deductive manifest and content analysis of perceptions and behaviours. Outcome: Perceptions and behaviours of stakeholders, and effect of intervention on health system components.

3.2 Study setting, population, and context

3.2.1 Study setting

The study was conducted in the rural areas of Mbarara and Bushenyi districts located in South Western Uganda, between 2013 and 2015. As of 2014, the estimated population of Mbarara and Bushenyi districts was 500,930 and 235,621 respectively[154]. Malaria parasite prevalence in the South Western region is estimated to be between 4% and 9.3%, which is relatively low compared to the national average prevalence of 19%[155, 156]. The South-western region of Uganda is a low malaria-endemic region compared to other regions of Uganda. The AXEX intervention study follows a successful study of integrating ICCM into retail drug shops in high malaria-endemic settings. Implementing the AXEX intervention study in a low malaria-endemic setting was, therefore, to try and investigate whether applying iCCM guidelines would: a) result in low fever cases being classified as malaria cases, and therefore, limit the prescription of anti-malarial ACTs, or b) would conflict with the known profit-maximising objective of drug shops and ultimately lead to non-adherence to the guidelines as a way of maintaining profits. In the two districts, most of the formal health care providers or facilities are located in urban or peri-urban areas, leaving the rural settings with access constraints. Given the socioeconomic and geographical challenges in accessing health care services from health facilities, drug shops provide an opportunity to fill the gap by bringing health care services closer to the people within communities.

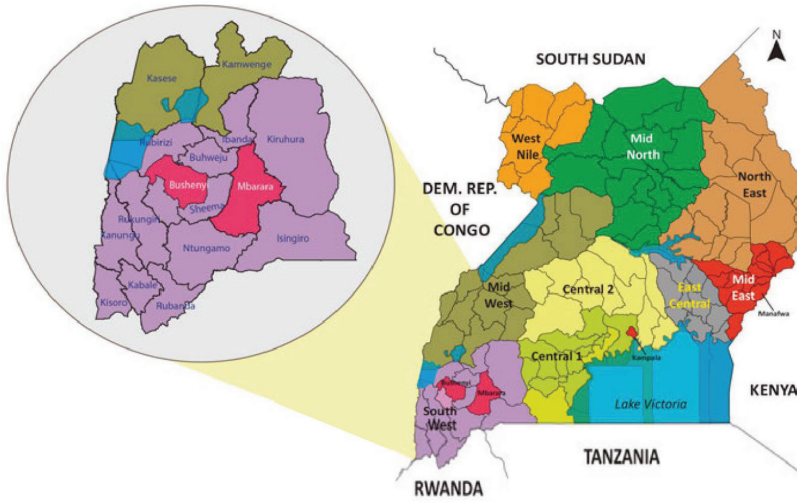


Figure 3.1: Map of Uganda showing Mbarara and Bushenyi districts (study districts) in South Western Uganda

3.2.2 Study Context

Integrated Community Case Management (iCCM) is one of the proven effective interventions that can reduce the under-five mortality rate. WHO and UNICEF following the challenge of over-lapping symptoms for malaria, pneumonia, and diarrhoea fevers among Children (72) recommended iCCM. Uganda launched the iCCM policy in 2010 and it is implemented through CHWs within the context of the VHT strategy [37, 74]. However, iCCM through the public sector does not benefit a significant number of children who bypass CHWs and access care at private retail drug shops that are not involved in iCCM implementation.

A pilot to introduce iCCM at the registered retail drug shop was conducted in Kaliro district, Eastern Uganda, a high malaria endemic area [16]. In this pilot, an iCCM package introduced to the retail drug shop included: (a) introduction and provision of diagnostics (mRDTs), and respiratory count timers for pneumonia); (b) and the provision of subsidized pre-packaged socially marketed drugs for malaria, pneumonia, and diarrhea for the under-five children at the private retail drug shops. In addition, the pilot study (c) trained drug shop attendants; (d) provided treatment algorithms; (e) provided monitoring and support supervision; and (f) conducted community mobilization and sensitization. Results from this pilot showed an increase in the appropriate treatment for febrile children, an increased access to good quality lifesaving drugs and diagnostics, enhanced skills for drug shop attendants, and a reported increase in drug sales [16].

It is against this background that a second pilot – a continuation of the proof of concept - was conducted in South Western Uganda, a low malaria transmission area. This second pilot coded named *"ACCESS and EXCESS, EQUITY and INFORMATION: Point of Care Diagnostics and Pre-packaged Subsidized Drugs for Integrated Fever Management for Malaria, Pneumonia and Diarrhea in Children at PRIVATE SECTOR Drug Shops in Uganda"* (AXEX project), was conducted between 2013 and 2015 in the rural areas of Mbarara and Bushenyi district, in South Western Uganda. It is this AXEX intervention study (project) on which this PhD study was nested.

The AXEX intervention study generally aimed at testing whether findings of the first pilot can be replicated in a low malaria-endemic setting. The AXEX intervention study specifically aimed to 1) determine the effect of the intervention on quality of assessment and rational use of drugs in registered private drug shops, 2) evaluate access to appropriate treatment and financial burden of the intervention across socioeconomic groups from a community perspective; and 3) measure the incremental costs/savings of the intervention compared to presumptive treatment. In addition, the AXEX intervention aimed to 4) extract information from private-sector treatment registry books and feeding it into the local Health Management Information System, local and national health managers; and 5) explore the attitudes and perceptions of various stakeholders towards the intervention in order to understand the wider health systems effects and implications for scale-up and sustainability.

3.2.3 Study population

The AXEX intervention study was implemented among selected registered retail drug shops. The study population included drug sellers, CHWs involved in community health, and caregivers in households with children under the age of five years. In addition, the study also included caregivers who sought care for children under the age of five at the drug shop during the study period and government officials who are involved in the management of the district health system.

3.3 Design, Sampling, and data collection

3.3.1 The AXEX Intervention Study Design

The AXEX intervention study was a quasi-experimental design with a pre-intervention and post-intervention evaluation. Two study districts were selected, with one (Mbarara) as the intervention arm and the other (Bushenyi) as the comparison arm. The AXEX intervention study was conducted among registered retail drug shops in the study areas. The intervention study was implemented between May 2013 and September 2015, in collaboration with the district health teams (DHTs) in the two study districts. Baseline data were collected in both intervention and comparison arm and compared with end-line data collected in intervention and compassion arms.

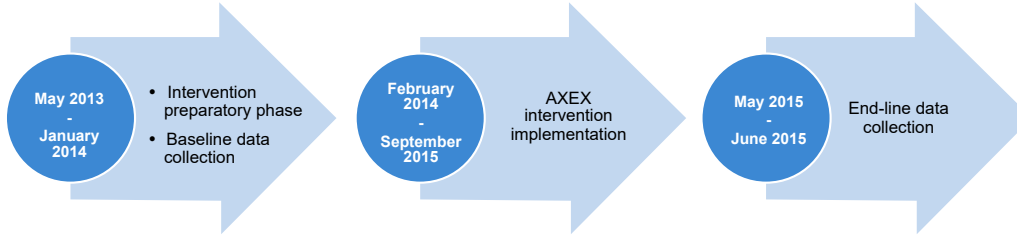


Figure 3.2: Critical timelines for the AXEX intervention study

3.3.2 The Intervention package

The AXEX intervention study adapted the UNICEF/WHO iCCM package to suit the context and logistical capacities. The details of the intervention package are provided in Box 1

Box 1. The AXEX Intervention package for participating retail drug shops

Box 1: The AXEX Intervention components (Adapted from Kitutu et al. 2017)[157]

1. **Supply mechanism for medicines and diagnostics**. The project identified pharmaceutical wholesalers that were close to the study area and supplied them with medicines at subsidized prices. These wholesale pharmacies were expected to sell these medicines at a subsidised price to the participating drug shops in the intervention arm. The medicines were pre-packed, color-coded and price-tagged. Drug sellers presented *special study medicine order forms* to pharmaceutical wholesalers for re-supply. Medicines were single-dose packed, color-coded for age, and provided to drug shops at subsidized prices. In addition, the intervention drug shops were supplied free of charge, with malaria rapid diagnostic tests (mRDTs), respiratory rate counters for pneumonia testing, iCCM treatment algorithms, and patient registers.
2. **Training of drug sellers.** Using the MOH curriculum for the integrated community case management of paediatric febrile illnesses, drug sellers were trained for five days using in-class lectures and hands-on practical methods. The training covered case detection and classification according to simple clinical signs and/or diagnostic testing of three febrile child illnesses of acute respiratory illness (ARI), malaria and diarrheal diseases, identifying danger signs and symptom, transmission, prevention, diagnostic testing, and identifying populations at risk of pneumonia, malaria, and diarrhea. Additionally, drug sellers were trained on filling in patient registries, referral, managing drug supplies, counselling care-seekers, adverse reaction monitoring, and patient follow-up for outcomes.
3. **Support supervision and use of drug shop patient registry.** Field visits were conducted monthly for every drug shop, by the field supervisor, other project staff, and district health team in the intervention drug shops. The drug shops maintained a standard ICCM registry in triplicate copies where they recorded children seen, their symptoms (fever or history of fever, cough, fast or difficult breathing), the diagnostic test done, the test results, the treatment given, and follow up action taken, respectively. These copies of filled iCCM register pages were retrieved from each study drug shop monthly. The supervisors also discussed with drug sellers any new information and areas of improvement after checking the filled registers.
4. **Information, education, and communication (IEC).** Intervention drug shops were branded with A2L (access to life) posters, and the communities were notified about the services the branded drug shops offered. Additional community sensitization campaigns using the MoH child health and malaria messages were delivered through monthly radio talk shows by study and district staff and radio announcements. In addition, Community Health Workers attended sensitization workshops organized by study and district staff. In these forums, the discussions and messaging focused on management of febrile illnesses among children, the importance of diagnostic testing and adherence to treatment, and what to do if symptoms of the sick child persist, referral procedures, and more generally the implementation of iCCM at the drug shops. The CHWs later delivered these messages to households with U5 children by word-of-mouth within their communities.

Comparison district package

The comparison district continued with the existing practice of selling subsidized ACTs only, relying on previous training

3.3.3 Thesis Design

3.3.3.1 Mixed-methods Design

This thesis is based on a concurrent mixed-methods approach. Under this approach, the sub-studies that constitute this thesis applied quantitative and qualitative methods of data collection and analysis concurrently [153]. The mixed-methods approach was used because of the diversity of research questions that needed to be addressed by more than a single standalone methodology. The mixed-methods approach did not only enable triangulation across the methods but also allowed the methods to complement each other which enhanced the degree of robustness and reliability of findings [152, 158, 159].

3.3.3.2 Cross-Sectional design

Sub-studies I & II adopted cross-sectional study designs in order to extensively describe, characterize and explore phenomenon at a particular point when we conducted the study. The major strength of a cross-sectional design is its ability to embrace varied methods for data collection and analysis and allow for triangulation of data and results [159]. There are, however, concerns about the validity and rigor of cross-sectional study designs and these concerns arise from the fact that cross-sectional designs do not allow for a comprehensive description of the phenomenon. In addition, it has been argued that cross-sectional designs offer limited legroom for considering counterfactuals in describing and explaining phenomena in addition to allowing embedded author biases [160]. However, these limitations were addressed by adequately describing the data collection and analysis methods and process, triangulation, and ensuring that personal biases and opinions are kept as much as humanly possible out of the research process[161, 162].

3.3.3.3 Quasi-experimental design

Sub-study III was based on a quasi-experimental design approach adopted by the AXEX intervention study, to specifically assess the effect of the intervention on the availability and affordability of iCCM recommended care for paediatric febrile illnesses provided by drug shops. The AXEX intervention study, to which this PhD was nested, was designed as a quasi-experimental study design with non-randomization of districts and study participants. Data were also collected before and after the intervention in both intervention and comparison districts. In the experimental or treatment arm, an intervention is implemented, while in the comparison arm, it's "business as usual" or routine practice, or the 'standard of care'. Quasi-experimental designs are very useful in demonstrating the effect of an intervention on a particular outcome of interest [163]. The AXEX intervention evaluation was done using the before and after measurement in both the intervention and the comparison arms.

3.3.3.4 Process Evaluation design

Sub-study IV employed a process evaluation design that involved assessing how the iCCM intervention was implemented and received by the stakeholders including drug sellers, caregivers of children, VHTs, and government officials[164, 165]. A process evaluation design is useful in enabling researchers to identify or explore alternative explanations to observable effects of interventions which may partly be found in understanding the context within which interventions or programs are implemented [166]. Process evaluation helps to explore mechanisms through which programs realise certain outcomes and how those mechanisms and pathways are shaped by context. Process evaluation is therefore an important design whose results can appropriately offer guidance into the implications of the research for policy and practice [166]. We adopted a process evaluation design to facilitate the eliciting of the facilitators and barriers for the success of the intervention components,

and the wider intended and unintended health system effects of implementing ICCM at the private retail drug shop. Process evaluation data (information) were elicited through FGDs with caregivers and VHTs, IDIs with drug sellers, and KIIs with government officials.

3.3.4 Sampling and data collection

3.3.4.1 Drug seller survey

Sub-study I: A drug shop survey targeting drug sellers was conducted among registered and licensed retail drug shops in both study districts before and after the intervention. The drug shop survey utilized a self-reporting structured questionnaire administered to the drug shop attendants by the study team. The drug shop survey data were utilized in **sub-studies I, II** and **III**. Sub-studies **I & II,** utilised drug shop survey data collected from 74 drug shops (Mbarara District=40, Bushenyi District=34) before the intervention. All registered and operational retail drug shops in the two study districts were invited to participate in the study. A list of all eligible drug shops was obtained from the District Assistant Drug Inspector (DADI) offices in the two participating districts. Initially, a total of 217 retail drug shops were assessed based on an eligibility criterion. The eligibility or inclusion criteria included: drug shop is located in a rural area in the study district; drug shop is registered and licensed; drug shop is operational during the study period; drug shop is dealing in human drugs; and drug shop attendant's willingness to participate in the study. From the main sample of 74 drug shops, a sub-sample of 20 drug shops was selected for an in-depth investigation of the objectives for drug shop start-up, pricing and mark-ups, sales volumes and profitability, and the benefits of operating drug shops. The selected sub-sample of 20 drug shops were those that had been selected to conduct care-seeker exit interviews as explained in **section 3.2.4.2**. The structured questionnaire administered to the drug shop sub-sample had both closed-ended and open-ended questions. The open-ended questions elicited the qualitative perspectives, but also, sought to further understand the context of the quantitative responses and this was helpful in augmenting the quantitative data.

After the intervention implementation, an end-line drug shop survey was conducted where a total of 48 drug shops were included in the drug shop survey with 32 drug shops in the intervention district (Mbarara) and 16 in the comparison district (Bushenyi). The number of enrolled drug shops reduced because of unforeseen circumstances including dropout, incomplete data, as well as unavailable during the period of data collection. The data from the baseline and end-line drug shop survey was utilized for sub-study **III** of this thesis.

3.3.4.2 Care-seeker exit interviews

This involved interviews with care-seekers who had visited the drug shop to purchase medicines for children under the age of five years during the period of data collection (before intervention implementation and after the intervention implementation). Care-seeker exit interviews were conducted in both study districts. Care-seeker or client interviews are useful in assessing provider practice and quality of care provided in relation to recommended practices and guidelines. Given that exit interviews are conducted immediately after the client is served, it is assumed that an exit interview would address the likely recall bias that would occur if a survey was conducted retrospectively. In this study, care-seeker interviews collected information about care-seeker characteristics, practices of the drug seller who attended to the care-seeker - including diagnosis, prescription, and treatment practices, appropriateness and quality of medicines purchased, perceptions about prices and affordability of medicines, and costs of illness. In addition, the care-seeker exit interviews also

elicited care-seeker decisions around the drug shop use, nature of child illness, onset of illness, and time taken to make a decision to seek care, among others. Data collected through the care-seeker exit interviews were utilized for sub-studies **I, II,** and **III** of this thesis.

The sample size for exit interviews was estimated using the formula for cluster sampling proposed by Bennett and colleagues [167]. A drug shop represented a cluster because each drug shop serves clients from a particular defined cluster area or defined community. The number of clusters (drug shops) to conduct the exit interviews was calculated by the following formula:

$$C = \frac{\rho(1-\rho)D}{S^2 b} \qquad \text{Where} \qquad D = 1 + (b-1)\rho$$

Where C=Number of clusters/ drug shops, p= the assumed proportion of pneumonia children correctly managed by retail drug shops (15%) (pneumonia is among the high burden paediatric febrile conditions which the study was targeting), D=design effect= 1.5 (expected homogeneity of proportions between-clusters as compared to within-clusters), S=Standard error, and b= the expected number of responses per cluster of 26). CI = the width of the desired confidence interval, often expressed as a percentage of P. We used ρ=0.05, b=26, p=0.15, CI=0.06, and standard error to fall within 5% level of significance, then within-cluster variance (s) =0.025 [16, 157].

Based on the formula and assumptions provided, a total of 24 clusters (12 clusters per study arm) were estimated. However, due to unforeseen circumstances including cluster performance, baseline data were collected from 12 clusters in the Mbarara district (later the intervention arm) and only 10 clusters in Bushenyi district (the comparison arm) were used. An average of 20 exit interviews was conducted at each selected cluster, with a total of 428 care-seeker exit interviews conducted at baseline (intervention arm=212, Comparison arm=216). After the intervention, a total of 553 care-seeker exit interviews were conducted (intervention arm=285, Comparison arm= 268). The end-line care-seeker exit interviews were conducted at those drug shops where baseline exit interviews had been conducted. Only care-seekers who had come to seek treatment for a child below five years were enrolled in the study, as long as they consented to participate.

The care-seeker exit interviews were conducted immediately after the care-seeker exited the drug shop, using a self-reporting structured questionnaire. The interviews were conducted by trained research assistants who were stationed at the drug shop during the data collection period every day from 09.00 – 19.00 (usually business hours), Monday to Saturday until the required target sample for that cluster (drug shop) had been met. The research assistants enrolled care-seekers as and when they exited the drug shop.

3.3.4.3 In-depth interviews

In-depth interviews are an important method of eliciting the views and opinions of respondents about a particular phenomenon with which they are associated. In-depth interviews help to generate information from a broader spectrum of knowledgeable and experienced people – leaders and professionals at all levels. In-depth interview respondents are knowledgeable people with a deeper understanding of the subject matter from varied perspectives [168, 169]. In-depth interviews have also been credited for their interview environment that ensures a high level of privacy and hence the respondent can provide detailed responses without having to worry about confidentiality [170]. This is because the interview environment is ample enough to allow for a candid interaction between the interviewer and the respondent.

In our study, respondents for IDIs were purposely selected from the DHT members or officials in charge of the district health system, some selected health facility managers where many sick children from the retail drug shops are commonly referred, and the drug sellers. Before the intervention, a total of 15 and 4 IDIs were conducted with drug sellers and government officials. During midline evaluation, 19 and 10 IDIs were conducted with drug sellers and government officials, and after the intervention, a total of 13 and 5 IDIs were conducted with drug sellers and government officials respectively (a total of 47 and 19 IDIs for drug sellers and government officials respectively for the entire AXEX intervention study). The number of interviews conducted across each category of respondents was determined by topical saturation [171, 172]. In-depth interview information was utilized for sub-studies **II, III** & **IV**. In-depth interviews explored issues of incentives and motivation for drug sellers, monitoring, supervision, and regulatory environment, availability of recommended medicines, views and opinions about the implementation of the intervention components and effect of the AXEX intervention on drug shop operations as well as on the broader health system. The IDIs were conducted in English since the respondents all understood the English language. In-depth interviews were guided by open-ended topic guides (semi-structured) that were structured along the areas of inquiry proposed by the study and each interview took between 30-45 minutes.

3.3.4.4 Focus Group Discussions

Focus Group Discussions (FDGs) is a common qualitative data collection method used especially to generate wider or broader views and perspectives from the participants [173]. Each FGD normally consists of between 7 to 10 participants purposely selected based on common characteristics relevant to the subject matter [174, 175]. FGDs requires an environment that allows all participants to express their opinions without fear or feeling of inferiority or marginalization [175]. FGDs are expected to be interactive, but the FGD moderator should ensure deeper interrogation and follow up on submissions to ensure the reasons behind a particular response are elicited [174]. The moderator must ensure complete control of the discussions and ensure a balanced participation of all members [173]. In this thesis, FGDs were conducted among VHTs (CHWs) and caretakers of under-five children to elicit experiences about using retail drug shops, the availability and affordability of care. FGDs also helped to explore opinions about the different components of the intervention, facilitators as well as barriers to the successful implementation of the AXEX intervention, and what was required to be done to improve health care delivery within their communities. FGD participants were selected from communities within the locality of the drug shop, and the area local leaders supported the selection of participants. The FGD data was used in sub-studies **III & IV**. Before the intervention, 6 FGDs were conducted with caretakers of under-five children, and 6 FGDs with VHTs/CHWs. At midline, 7 FGDs were conducted with caretakers. After the intervention, 5 FGDs and 2 FGDs were conducted with caretakers and VHTs respectively. The number of FGDs conducted was determined by topical saturation [171]. A trained qualitative researcher facilitated FGDs and a note-taker guided by open-ended topical guides structured along the objective areas of the study. FGDs were conducted in Runyankole, the local dominant dialect, and audio recorded. FGDs had between 6-12 participants and were conducted at convenient venues, especially sub-county headquarters, health centers, and at schools within that particular community. FGDs took between 30-45 minutes.

3.4. Data Quality Control

Data for the AXEX intervention – to which this PhD study is nested, were collected by research assistants who were university graduates with Bachelor degrees in information technology, social

sciences, education, nursing, and statistics, among others. These research assistants were recruited from within the study area because the study exercise targeted those who could speak both English and the local language. Working with research assistants from the study area was important in facilitating easy use of the tools in a local context, better data collection, and later the transcription process. After selection, the research assistants were trained for two days. The training focused on general instructions and procedures of data collection; including administering consent, various interview techniques and skills, probing, among others. Questions in the tools were discussed during the training and harmonization of English words to local terms across all trainees, and discussions on procedures were conducted. Role-plays and practical exercises were conducted amongst the trainees during the training to ensure comprehension. After the training, a pilot test was conducted using a neighbouring community (not part of the study area), and feedback was incorporated appropriately. Throughout the data collection process, I participated in field activities, including supervision of data collection, daily debriefs, and feedback meetings with the data collection team where emerging issues in data collection were discussed and plans for the next day data collection agreed upon. I also participated in conducting in-depth interviews for the government officials, among others. At the end of every day of data collection, all filled questionnaires were checked for completeness.

3.5. Data management

Baseline quantitative data was collected using paper-based tools or questionnaires and later entered into EPIDATA V.3.1 software (http://www.epidata. dk) fitted with a range of checks. All data entry was monitored and supervised by my colleague, *Freddy Kitutu,* and myself (both PhD students on the AXEX study). After the intervention, however, quantitative data was collected by the use of Open-Data-Kit (ODK) and routinely sent to the server. This data was later downloaded into STATA v.13.1 (StataCorp 2013) for additional cleaning before analysis. To ensure minimal data entry errors and guarantee good quality data for data that was not collected using ODK, two independent data entry clerks were recruited and trained on data entry procedures. Thereafter, the trained data clerks double entered the baseline data into the software, under the supervision of the study coordination team.

FGDs were conducted in the local language (Runyankole), while the IDIs were conducted in English because the respondents comprehended English language. All qualitative interviews were audio-recorded, later transcribed, and simultaneously translated directly into the English language by an experienced qualitative researcher who was conversant with both Runyankole and English languages. The transcriber was not part of the data collection team to avoid any biases that could have been introduced during the transcription if it was conducted by members of the study team [171]. Field notes taken during the interviews supplemented audio-recorded transcripts. Transcripts were double-checked and cleaned by my colleague and myself (PhD candidates) prior to analysis.

3.6. Data Analysis

3.6.1. Characterizing private retail drug shops in rural western Uganda (paper I)

This sub-study adopted first-level analysis and generated means and proportions of variables of interest, including profiling drug sellers and care-seekers who utilize the services of drug shops, prescription practices, retail drug shop operational environments, commonly reported symptoms, services provided at drug shops, and treatment appropriateness. In addition, this sub-study considered medicine stocks at the drug shop and identified the major factors that influence stocking, dispensing, and demand decisions. To determine appropriate treatment, we compared the medicines provided

to clients in relation to the symptoms that were reported to the drug seller and checking whether prescribed or dispensed treatment was consistent with the national and WHO guidelines on the rational use of medicines[176]. During the exit interviews, care-seekers were asked questions about what had happened at the drug shop during their interaction with the drug seller, in addition to physically checking the medicines that had been provided. The drug shop operational environment was assessed based on the National Drug Authority (NDA) guidelines for licensing and accreditation of drug shops [177]. We compared the outcome variables of interest across the two study arms (districts) using chi-square tests (chi Exact) under 5% significance level, to ascertain if there were any significant differences between the outcomes in the two arms. Any variable difference with a p-value of < 0.05 was considered statistically significant, implying that the outcome of that specific variable was statistically different for the two study districts.

3.6.2. Incentives associated with retail drug shop markets in rural Uganda (paper II)

The variables for investigation in this sub-study were based on the Structure-*Conduct Performance (SCP)* paradigm of industrial organizations [45]. According to the SCP paradigm, the structure (S) of the market greatly influences the conduct or behaviour (C) of the market agents or actors, and this, in turn, influences the performance (P) or output from that market. The SCP paradigm, therefore, argues that observable behaviour of actors, in this case, drug sellers, regulators, and care-seekers is largely influenced by how the retail market is structured in terms of nature of market and level of competition, incentives such as level of profitability, costs of operations, and nature, design, and effectiveness of the regulatory framework among others. In this sub-study, motivations for drug shop start-up, sales volumes, price mark-ups, operational costs, level of profitability, and regulation, were the variables considered. This analysis was motivated by the longstanding perception that drug shops are purely business motivated focused on private benefits and making profits at the expense of exploiting their clients and compromising public health.

For quantitative analysis, **sub-study II** adopted first-level descriptive analysis and generated means, medians, and proportions of the targeted outcome variables. For example, the objectives for drug shop start-ups, and benefits derived from operating retail drug shops were identified by estimating the proportion of drug sellers that reported a particular factor over the number of drug sellers who responded to that particular question of inquiry. Median values of operational costs, sales volumes, price-mark-ups, and level of profitability, were also calculated, based on a typical calendar month, using data elicited through the self-reporting questionnaire.

To estimate the price-mark-ups, a list of childhood medicines commonly stocked and dispensed by the drug shops was identified. For each medicine, the drug seller was asked to provide the purchase price. The purchase or procurement price was the price at which a particular medicine was procured from a wholesale pharmacy or whatever procurement outlet they commonly use. Drug sellers were also asked about the selling price, the price at which clients accessed the medicine from the retail drug shop. From this data, the median procurement and selling prices were calculated and from these, the median price mark-ups were derived for each selected medicine.

To calculate sales volumes and profitability, drug sellers were asked to estimate sales quantities for the selected medicines sold in a typical week with reference to the week preceding the survey in order to limit likely recall bias. Median quantities were then derived and purchase costs, as well as revenue, were estimated using the median purchase and selling prices. The product procurement (purchase) costs were added to the drug shop operational costs to derive the total costs. The total

costs were subtracted from the total revenue from the sales to derive weekly gross profits that were then projected onto a typical month to arrive at monthly growth profits. This analysis was conducted in an excel spreadsheet.

Qualitative information obtained from the open-ended section of the self-report questionnaire was analysed manually using content analysis and meaningful quotations were extracted, and used to emphasise or supplement the quantitative findings. The SCP framework and its domains guided the analysis. Additional qualitative information was generated from the four IDIs conducted with government officials (baseline) that had been transcribed and cleaned. The four IDIs were carefully read multiple times by I (PhD candidate) and my colleague (Freddy Kitutu) and were separately coded using software (OpenCode Software V.4.03) applying content and thematic analysis approach[178-180]. While most of the themes generated from the IDIs were applied in paper IV (health system effects of the intervention), specific applicable content relevant to the quantitative themes being explored in sub-study II (paper II) were extracted, manually processed, and applied as supplementary information to reinforce but also contextualize the quantitative findings[181].

3.6.3. Intervention effect on availability and affordability of paediatric treatment (Paper III)

The focus of this sub-study was to assess the effect of integrated management of malaria pneumonia and diarrhea at the retail drug shop on the *availability* and *affordability* of paediatric fever medicines at private retail drug shops.

Availability: Medicine availability is defined as the degree of fit between existing medicines and the demand for them [182]. In this sub-study, medicine availability was defined by the proportion of drug shops that had a particular medicine in stock on the day of the survey irrespective of the quantity, form, or pack-size in stock. According to the WHO recommendation on medicine availability, medicine is considered highly available if availability is more than 80% while it is considered to have low availability if it is less than 30% [183]. The effect of the intervention on the availability of iCCM-recommended medicines was estimated by comparing the proportion of outlets that reported having a particular medicine in both intervention and comparison districts before and after the intervention and estimating the percentage change in the proportion of outlets reporting availability after the intervention compared to before the intervention. The Chi-Square test was used to compare the percentage difference in reported availability between intervention and comparison district and any difference with $p<0.005$ was deemed significant. We only considered the iCCM recommended medicines for the three febrile conditions - uncomplicated malaria, pneumonia symptoms, and non-bloody diarrhoea - and the medicines considered in this case were ACTs (AL), Amoxicillin, Zinc Sulphate, and Oral Rehydration Salts (ORS). Two additional products – metronidazole and quinine – were added to this analysis because they were found to be common medicines dispensed by drug shops during the baseline survey and we needed to ascertain changes in their stocking patterns after the introduction of iCCM, given that they were not part of the recommended iCCM medicines.

Medicine prices: During care-seeker exit interviews, care-seekers were asked about the medicines they had purchased and the prices at which each medicine was purchased and from this, the median purchase price for each medicine was calculated. Only exit interviews conducted in the intervention district before and after the intervention were considered. The effect of the intervention on affordability was analysed for the intervention district only. Medicine prices were recorded in Ugandan currency and converted into United States dollars using the average exchange rates for 2013 for baseline data (1 USD = 2,763 UGX) and 2015 for end-line (1 USD = 3,226.5 UGX) to facilitate comparability(Uganda

Bureau of Statistics (UBOS), 2016 #538). The local median prices are recorded per unit of medicine (per tablet/capsule/ sachet). These local prices were used to calculate the median price ratios (MPRs) by dividing the local median price by the international reference prices (IRPs) extracted from the Management Sciences for Health (MSH) International Medicines Price Indicator Guide for 2013 and 2015[184]. An MPR is useful in comparing local prices with prices in other countries and observing whether local prices are higher in a particular country compared to other countries depending on an MPR threshold adopted. Different studies adopt different thresholds but for this study, we adopted the threshold of MPR<=2.5 for the private sector [183, 185]. In this case where MPR<=2.5, it means the local prices are almost the same as prices in other countries and vice versa.

Estimating the cost of treatment regimens: The course of treatment or treatment regimen for a particular febrile condition was determined based on the Uganda iCCM guidelines and WHO recommendation on the rational use of medicines [2, 183, 186]. Based on the guidelines, treatment regimens or combination of medicines, their different recommended strengths and number of days required to complete a recommended dose for each of the conditions - uncomplicated malaria, pneumonia symptoms, and non-bloody diarrhoea - were determined. These treatment courses or dosages were subjected to the local median prices per unit of medicine as initially determined and this generated the cost of each treatment course (Table 4.4).

Estimating wages to pay for treatment: The WHO/HAI standard methodology recommends that an estimate is done to ascertain the number of days required to pay for that standard course of treatment or treatment dose based on the daily income of the lowest-paid unskilled government worker[2, 186]. The Uganda public service salary structure was used to identify the lowest-paid unskilled public servant and how much they earned per month and the equivalent of a day's pay. Given that the study data were collected between 2013 and 2015, the public service salary structures for 2013 and 2015 did not differ significantly in salaries paid to public servants. Based on this fact, the salary structure for the financial year 2015/16 was used [187]. For purposes of reporting and standardization, the payments were converted to United States dollar values, using the official average exchange rate for the year 2015(Uganda Bureau of Statistics (UBOS) & ICF, 2016 #750).

Determining affordability: The concept of affordability reflects the clients' ability and willingness to pay for the service or treatment course that is required to treat a particular reported illness based on the standard of care or recommended course [182, 188, 189]. To determine the affordability of care, we compared the cost of a treatment course with the daily wage for the lowest-paid unskilled government worker. If the treatment course (dose) required for a particular illness cost more than a day's wage for the lowest-paid public servant, that treatment was considered unaffordable[2, 186].

Effect of iCCM intervention on the affordability of care: The effect of the AXEX intervention on affordability was determined by comparing affordability of care before the intervention and affordability of care after the intervention, in the intervention district only. This was done only in the intervention district because of data quality challenges for the comparison district. Additional analysis of the effect of the intervention on affordability was further conducted using care-seeker perceptions on affordability captured in care-seeker exit interviews in both intervention and comparison districts before and after the intervention. Three dimensions were used to capture perceptions: 1) whether care-seekers were able to afford the drugs prescribed; 2) care-seekers rating of prices in relation to ability to pay, and 3) care-seekers ability to meet the costs related to the illness.

A Difference-in-Difference (DiD) approach [190] was then used to determine the effect of the

intervention on each of the three dimensions by comparing the proportions of responses to these dimensions before and after and for intervention and comparison districts. Difference-in-Difference (DiD) analysis has been used in Quasi-Experimental study designs to determine the attributable effect of the intervention on the variable or outcome of interest [190, 191]. The DiD technique helps to 'detrend' the effects that may likely emerge from unobservable factors or other likely influences on the results other than the implemented intervention. By the time of conducting the intervention study, the iCCM strategy was already a national policy expected to be implemented countrywide, although a handful of districts had already started the implementation. While the study districts had not yet implemented the iCCM programme, there was a real possibility that the influence from districts that had already implemented the program could 'contaminate' the results.

The DiD technique helped to 'de-trend' the effects by 'weeding' off the confounding and other influences on the results other than the implemented intervention, and this guaranteed the robustness of the 'claimed' effect without much worry about confounding, 'neighbourhood' or 'spillover' effect[190]. The DiD technique was applied on care-seeker exit interviews that elicited the perceptions and ratings of care-seekers about the medicine prices in relation to their ability to pay, which responses were then used to determine the effect of the AXEX iCCM intervention on affordability of iCCM recommended paediatric care.

The DiD model was used by fitting the mixed effects regression model where proportions were modelled as proportions with robust standard errors to get an absolute difference, respective confidence intervals, and associated probability values. The model as follows:

Model: $Y= \beta0 + \beta1*[Time] + \beta2*[Study\ Arm] + \beta3*[Time*\ Study\ Arm] + \beta4*[Covariates]$

Among the assumption we assessed for the DiD estimation were: 1) that the allocation of intervention was not determined by outcome; 2) that the composition of intervention and comparison groups is stable for a repeated cross-sectional design; and 3) that there are no spillover effects. However, the assumption that without the intervention, the changes in outcome in both intervention and comparison groups was expected to be the same, was not tested.

The care-seekers were randomly selected at both baseline and end-line, and this was based on the assumption that care-seekers at both points, who were interviewed (bassline and end-line), had generally homogenous characteristics. The results are reported in sub-study **III** of this thesis.

Qualitative analysis on availability and affordability of medicines: A further analysis of qualitative data from the drug seller interviews (IDIs) and FGDs with VHTs and care-seekers was conducted. Transcripts were read by CM and FEK and separately coded in OpenCode Software V.4.03 (University of Umea, Sweden) using the content and thematic analysis approach [178, 179]. Using pre-defined areas extracted from the health markets framework [192], units were drawn up and applied to generate an initial coding scheme. Preliminary codes were refined and agreed upon by the two reviewers and later refined to formulate the final codes. Only themes related to the availability and affordability were relevantly applied in this paper to supplement and reinforce quantitative analysis, but also provide additional perspectives on the affordability of care provided at retail drug shops in the study area [181].

3.6.4. Health system effects, stakeholder views and opinions about the iCCM intervention

This sub-study adopted the process evaluation design to explore the views and opinions from various stakeholders about the intervention implementation process and factors that could have facilitated or hindered the success of the intervention. In this qualitative sub-study, the effects of implementing iCCM at the drug shop on the wider health system were also explored. A health market framework proposed by Bloom et al.[192] was used to examine the effects of the intervention, using the health markets and health systems lens[193]. Transcripts from the interviews were analysed to identify health system effects associated with the intervention. All interviews were audio-recorded and then later transcribed, cleaned, and checked for accuracy. The transcripts were read multiple times and separately coded the transcripts in Open- Code Software V.4.03 (University of Umeà, Sweden) (ICT services & Systems Development). Content and thematic analysis approaches were applied to generate and extract meaningful and relevant units that eventually culminated into preliminary codes based on the health markets framework and systems thinking[193, 194]. The preliminary codes were compared between the two reviewers and final codes refined into final categories that reflected the views and opinions of stakeholders in the various elements of the intervention. The analysis focused on identifying the views and opinions of stakeholders about the implementation of the different intervention components, factors that could have facilitated or impeded successful implementation, and the effects of the intervention. An additional focus was to reflect on the experiences, roles, and operations of the different stakeholders, and how that interplay influenced the functioning and outcomes of retail health markets, perceptions, opinions, attitudes, and behaviour during the implementation of the AXEX intervention. It also included their experiences and interface with the regulatory system, issues of the efficacy of medicines, drug shop linkage to the formal health system, provider incentives, among others.

3.7. Ethical Considerations

The data used in studies that constitute this thesis was part of a larger research project entitled "ACCESS and EXCESS, EQUITY and INFORMATION: Point of Care Diagnostics and Pre-packaged Subsidized Drugs for Integrated Fever Management for Malaria, Pneumonia and Diarrhoea in Children at PRIVATE SECTOR Drug Shops in Uganda", otherwise code-named AXEX. Makerere University School of Public Health, Uganda, implemented the AXEX research project with funding support from World Health Organization's Alliance for Health Policy and Systems Research (WHO-AHPSR). Ethical approval for the AXEX research project was obtained from the World Health Organization (RPC553), the Uganda National Council for Science and Technology (HS1385). Additional approval was received from the Makerere University School of Public Health's Higher Degrees and Research Ethics Committee (IRB00011353). The University of Witwatersrand, Johannesburg South Africa, registered the PhD Candidate. In that case, the University of Witwatersrand Human Research Ethics Committee (#M151016) granted approval for the PhD protocol. Further permission was obtained from Mbarara and Bushenyi district local governments to conduct the studies as well as the implementation of the intervention in the drug shops. For all study participants, written informed consent was obtained. Further permission to audio-record the interviews was obtained from the respondents before any audio recording was conducted. The audio recordings were later transcribed to transform the data into a usable format. Participants' confidentiality was maintained throughout the process of research including recruitment of respondents, data collection, data management, analysis, and dissemination of findings through various platforms. Specifically, all data was stored in secure and protected spaces

with limited access. The potential ethical risks from the study included: the possibility of drug sellers being unable to provide appropriate and recommended care for under-five children, especially given that RDT technology was new to most drug shops in the private sector. In addition, there was a risk that study participants (caretakers) might access substandard products and services at the drug shops especially in light of the perennial accusations of poor quality services at the drug shops. Finally, there was an apparent ethical risk of perceiving the study (intervention) as promoting the private drug shops at the expense of the public health facilities. This was especially in light of social franchising at the expense of public health facilities, yet there are existential concerns about the poor quality of care at drug shops. These potential risks were, however, mitigated through comprehensive 5-day training of drug sellers from drug shops included in the intervention accompanied by practical role-plays, and visits to public health facilities to understand the real practice of appropriate care. Furthermore, the research study employed a field supervisor with Pharmacy training, who worked together with the district health office to conduct regular monitoring and support supervision visits to drug shops throughout the research study period. To avoid a perception of promoting private drug shops at the expense of the public facilities, communities through their local leaders, public messages, and VHTs were informed that a similar iCCM package was available at the public health facilities and with the VHTs.

CHAPTER 4: SUMMARY OF KEY FINDINGS

4.1. Introduction

This chapter highlights the key findings of the sub-studies that constitute this thesis. The detailed results are presented in the respective papers and manuscripts appended on this thesis.

4.2. Characterizing the retail drug shop market in rural South-Western Uganda (sub-study 1)

This sub-study aimed at describing the operational characteristics of the private retail drug shop market in rural South Western Uganda. Specifically, the sub-study described the characteristics, operational environment, and practices of private retail drug shops in managing febrile conditions among under-five children in rural South-Western Uganda.

4.2.1. Characterising drug shops and services provided care-seekers

Following the profiling of drug sellers or operators, it was found that some drug shops are attended to by owners, while others use hired personnel as drug sellers or attendants. In Mbarara district 10/40 (25%) and Bushenyi district 22/34 (64.7%) of drug shops were operated by owners. In terms of cadre or qualifications, nurses or midwives operated most drug shops. Other cadres included clinical officers, nursing assistants, laboratory technicians, and pharmacists.

Table 4.1: Operational environment and other services provided by retail drug shops

	Mbarara District (n=40)	Bushenyi District (n=34)	
Variables at baseline (n=74)	**Number of drug shops (%)**	**Number of drug shops (%)**	**Pvalue**
Who attends to the drug shop?			
Owner	10 (25.6)	22 (64.7)	0.00*
Highest level of training for attendant interviewed			
Clinical Officer	8 (20.0)	5 (14.7)	0.73
Nurse/Midwife	26 (60.0)	20 (58.8)	
Others*	8 (720.0)	9 (26.4)	
Monthly salary earnings for drug shop attendant interviewed			
USD 9 – USD 44	24 (80.0)	34 (100.0)	0.00*
USD 45 – USD 88	16 (20.0)	0 (0.00)	
Drug shop environment/ conditions			
There exists a ceiling to control room temperature	40 (100.0)	28 (82.3)	0.00*
There are windows that can control aeration	29 (72.5)	15 (44.1)	0.01*
No direct sunlight to area for keeping medicines	40 (100.0)	33 (97.0)	0.27
Medicine store free from moisture from leaks	37 (92.5)	27 (79.4)	0.10
Premises can be secured to prevent theft	38 (95.0)	32 (94.1)	0.86
Other services provided by drug shops			
Immunization Services	0 (0.0)	4 (11.7)	0.02*
Vitamin A supplementation	31 (77.5)	23 (67.6)	0.34
Deworming	4 (10.0)	5 (14.7)	0.53
Reporting adverse drug reactions	18 (45.0)	12 (35.2)	0.39
Presence of treatment guidelines			
Uganda Clinical Guidelines	16 (40.0)	22 (64.7)	0.03*
iCCM Guidelines	6 (15.00	9 (26.4)	0.22
Malaria treatment algorithms/charts	17 (42.5)	15 (44.1)	0.88
Pneumonia treatment algorithms /charts	2 (5.0)	5 (14.4)	0.15
Diarrhea treatment algorithms/charts	12 (30.0)	15 (44.12	0.20
Other products traded at drug shops			
Soft drinks	4 (10.0)	1 (2.9)	0.22
Toiletries	4 (10.0)	2 (5.8)	0.51
Household goods	1 (2.5)	0 (0.0)	0.35
Mobile phone airtime	3 (7.5)	1 (2.94	0.38
Cosmetics	1 (2.5)	0 (0.0)	0.35
Food items	0 (0.0)	2 (5.8)	0.12

P-values are derived from chi-square exact, and ae comparing the indicators across the two study districts. Any p-value less than 0.05 (p<0.05) implies that the difference in the measured indicator between the two study districts is statistically significant.

In terms of the operational environment, the National Drug Authority (NDA) sets standards for the suitability of premises for drug shops to operate in. For example, it is a requirement that; premises must be protected against adverse weather conditions, have sufficient space and ventilation, as well as floors and walls made of washable material [177]. This study found that most drug shops surveyed adhered to the expected standards - including secure storage spaces for medicines, ceilings, and floored rooms, and most rooms were secure from direct sunlight and moisture. In terms of products and services offered this study reported that some drug shops offered products and services beyond just medicines or drugs. For example, a number of drug shops sold vitamin A supplementation, cosmetic products, soft drinks, mobile phone credit cards (airtime), etc. (Table 4.1). When asked about this phenomenon, some drug sellers reported that this was a way of diversifying their revenue, to meet costs of operation without necessarily depending on only one source, which may be affected by seasonal dynamics.

4.2.2. Care-seekers' characteristics

In terms of care-seeker characteristics, the study found that drug shops were commonly utilized by mainly clients with ordinary level (28% in Mbarara compared to 35% in Bushenyi), and primary level education (58.5% in Mbarara compared to 50.5% in Bushenyi). Relatedly, most care-seekers at drug shops were the self-employed (43.8% in Mbarara compared to 40.4% in Bushenyi, and housewives (11.9% in Mbarara compared to 24.6% in Bushenyi), among other categories (Paper 1 in appendix).

4.2.3. Common childhood illness symptoms reported at drug shops

Across both the intervention and comparison district (baseline), the common illness symptoms in children that were reported at drug shops; included cough (66%), fever (56%), diarrhea (27%), and rapid or difficult breathing (20%) (Figure 4.1).

4.2.4. Common illnesses/symptoms reported at the drug shops (baseline data)

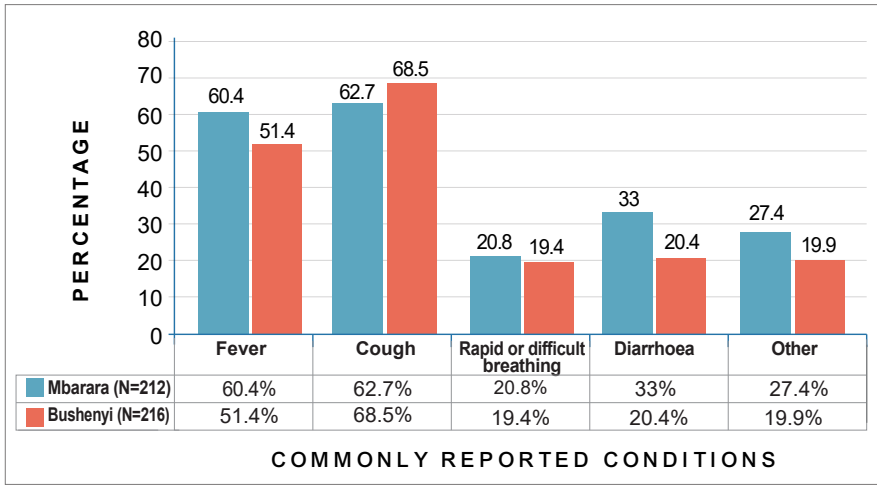


Figure 4.1: Proportion of U5 children who presented with different symptoms at drug shop at baseline (as reported from care-seeker exit interviews)

Across both the intervention and comparison district (baseline), the common signs and symptoms reported at drug shops were: cough (66%), fever (56%), diarrhea (27%), and rapid or difficult breathing (20%).

4.2.5. Stocking and prescription decisions

The study found that the common medicines stocked in drug shops included paracetamol, cough syrup, amoxicillin dry syrup, Quinine, ORS/Zinc, and ACTs. The decisions over which medicines to stock were majorly influenced by client demand (70%), Ministry of Health recommendations (54%), the most profitable medicines (26%), seasonal and disease patterns (30%). Relatedly, the drug sellers' decisions on which drugs or medicines to dispense to a particular care-seeker were informed by prescriptions that clients sometimes came with (47%), amount of money that client came with (30%), and client preferences for particular medicines (12%). In cases where clients did not have enough money to purchase a recommended drug, 69% of outlets reported providing credit given that most care-seekers are regular clients who are often known to the drug sellers, 27% reported that they referred clients elsewhere, and 18% reportedly provided cheaper alternative drugs to the client.

4.3. Incentives and motivations for the retail drug shop market in rural Uganda (Sub-study II).

This sub-study aimed at analysing the incentives and motivations of private retail drug shop providers in rural South-Western Uganda. Specifically, the sub-study focused on motivations or reasons for drug shop establishment, benefits or incentives that accrue from drug shop operations, operational costs, sales volumes and profitability, and the regulatory environment within which the drug shop market operates in rural South-Western Uganda.

4.3.1. Motivations and benefits from drug shop start-up

Based on a sub-sample of 20 drug shops, the main reasons that were provided for why drug shops are established included; the need to provide a service to the community, generation of income to sustain owners and their families, and employment creation in the context of high levels of unemployment. Additionally, some drug shops were established to provide an opportunity for a family member who has completed a health-related training to gain skills as they continue to search for better job placements that suit their academic qualifications.

> *"...the drug shop acts as employment for my daughter, but in addition to the drug shop, when clients are not coming, she sometimes works on those that come for mobile money services and this adds to the income that helps to pay rent and other utilities"* ***[Drug shop owner]***

Indeed, 90% of respondents indicate that drug shops were a source of income. Beyond the profit motive, however, drug shops provide the operators with social recognition, social capital, and networks within communities, and giving drug sellers experience in dealing and handling different people.

4.3.2. Estimated operational costs, sales, and profitability

From the results, it was noted, that drug shops mainly incur costs on rent, payment for workers or drug sellers, utilities such as water and electricity, transport costs to procure drugs from wholesale pharmacies, and license fees, which are paid on an annual basis. The median operational cost spent by a drug shop was estimated to be US$71.4 per month. Based on the monthly quantities of sales reported for selected medicines and median procurement (purchase) and selling prices, we estimated profitability. The total cost per month (cost of stock + operational costs) was estimated to be US$ 1,203, which is compared to the monthly estimated median revenue (estimated over the same quantities or doses of medicines), as US$2,263. The estimates showed that in a typical one-

month period, a drug shop earns in profits an equivalent of US$1,060. This is only an estimate from selected medicines although the range of medicines and services sold is broader than what is used in generating the estimate. It is, therefore, reasonable to assert that this estimate is conservative.

4.3.3. Estimating price mark-ups

Based on the reported purchase and selling prices of the selected medicines, we estimated the price mark-ups. The results show that the estimated price mark-ups varied across outlets, medicines, and dosages, but generally ranged between 43% and sometimes went beyond 100%. The lowest median mark-ups (43%) were recorded on ACTs and the highest was on multivitamins (86%), septrin (co-trimoxazole) syrup (100%), and paracetamol (100%). The observed variations in median mark-ups were attributed to varying purchase prices at the wholesale pharmacies, transportation costs, and the need to cover transaction costs and business sustainability.

4.3.4. Stakeholders' views and opinions about drug shop market operations

Table 4. 2: Stakeholder views and opinions about drug shops and their operations

Theme	Details	Example
Licensing and accreditation	Most drug sellers appreciate the role of licensing and accreditation but decry the complexities, inconveniences, high costs, and delays in the process. The regulators were also concerned that drug shop owners sometimes used unscrupulous methods to circumvent the rules, requirements and procedures of obtaining accreditation	*"...it takes a long time to get the license because there is a lot of back and forth where you have to go to the district health offices almost every week and this is very costly and inconveniencing…"* **[Drug shop operator]** *"...one thing is, some of these drug shops are owned by non-medical personnel who just want business. What they do is, when it is licensing season, they send qualified people to come and pick the forms and apply and get the license. As soon as the shop is licensed, the qualified person disappears and the shops are left in the hands of the spouse and some other untrained people to manage the medicines. And you know what this means for quality of service*s" **[Government official]**
Monitoring and supervision	Some drug sellers noted that supervision is concentrated in urban areas because urban-based drug shops have resources to "appreciate" the supervisors on every supervision visit they make. Further, supervisors are vindictive rather than supportive, and sometimes extortionary. They are concerned with closure of shops should they find small mistakes rather than guiding on how to do better. The supervisors, however, decry the limited resources to facilitate supervision, but also find challenges within communities where local people do not want a drug shop to be closed because they believe it is their only source of health services.	"*...these officials are sometimes corrupt and extort a lot money from us. In case they close your shop or sometimes they carry your drugs and to recover them you have to pay a higher price***" [Drug shop operator]** *"...we have even problems closing illegal drug shops. You go to close the illegal drug shop, the community leader comes, and everybody comes and at times confronts us. So, any drug shop regardless of its licensing state is valued in the community. They feel it is really what treats them and saves them from all those long distances…"* **[Government official]**
Streamlining drug shop operations	Drug sellers opined that supervisors should conduct regular sensitization forums to provide information to drug sellers on new practices and new medicines. In addition, there was a need to streamline the licensing, accreditation and regulatory system. The regulators recommend on-job training of drug sellers through re-fresher courses, in addition to providing additional resources for monitoring and supervision.	*"...there is a legal framework which provides for a number of things that need to be in place for accreditation and operation of drug shops, but the issue is implementation. If you go to visit them now, you will find them with the licenses. But the acquisition of these licenses, the process that they went through to receive these licenses is the one that is found wanting and needs to be revised"* **[Government official].**

4.4. Effect of the iCCM intervention on availability and affordability of paediatric medicines (Sub-study III).

This sub-study aimed at determining the effect of implementing an iCCM intervention on the availability and affordability of iCCM recommended medicines for paediatric febrile care provided at retail drug shops in rural South Western Uganda.

4.4.1. Effect of intervention on availability of paediatric medicines at retail drug shops

Table 4.3 and **Figure 4.2** shows the availability of key selected paediatric medicines at the time of the survey at drug shops in the intervention and comparison districts before and after the intervention. Our analysis focused on medicines that are recommended for febrile conditions under the iCCM policy. We however added quinine and metronidazole that were found during the baseline survey as common medicines prescribed, and so we were interested in understanding whether they were affected by the ICCM policy recommendations. Comparing across the study districts and at baseline, we found that 65% compared to 67% of outlets in the intervention and comparison districts respectively reported availability of ACTs. After the intervention, however, the intervention district reported a relatively higher availability of ACTs (68.8%) compared to 37.5% for the comparison district. Relatedly, only 27.5% of outlets in the intervention district compared to 35.3% in the comparison had reported availability of amoxicillin before the intervention. However, after the intervention, amoxicillin was reportedly available at 68.8% and 37.5% of the intervention and comparison districts respectively.

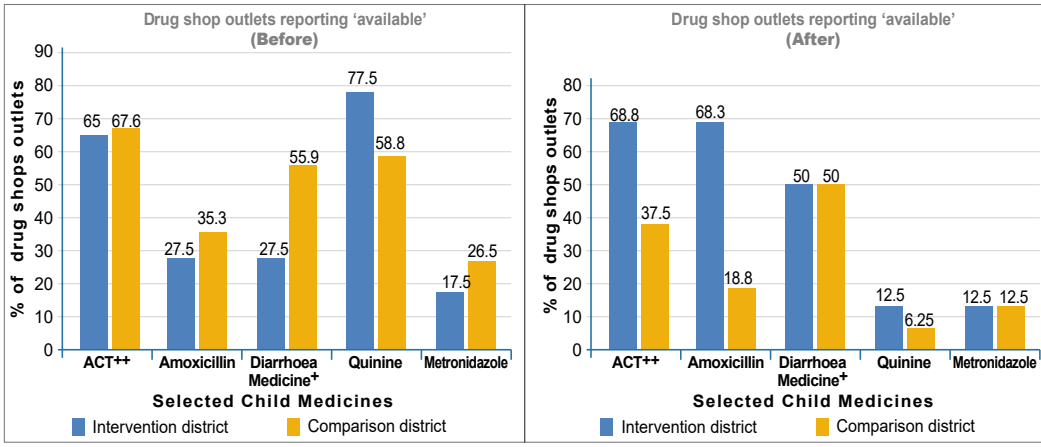


Figure 4.2: Comparing intervention effects on availability of medicines across space and time

It is also worth noting that the study reported an observed change in availability of diarrhoea treatment (ORS, ORS/Zinc) particularly for the intervention district from 27.5% of outlets reporting availability before the intervention to 50% who reported availability after the intervention. There was also a significant reduction in the availability of quinine in the intervention district from 77.5% before the intervention to 12.5% after the intervention. This result may be attributable to the fact that quinine was generally the predominant medicine that drug shops prescribed for fevers among children before the intervention although this was no longer included in the essential medicines to prescribe under iCCM. This may perhaps account for the significant reduction in its availability given that its demand or market had significantly been undermined by the iCCM policy, and more so for outlets that were implementing the iCCM intervention. Another critical point to note about medicine availability is that no striking differences in medicine availability were observed between the two districts before

and after the intervention, except for ACTs (chi2=4.2857, P<0.038) and Amoxicillin (chi2=10.6852, P<0.0001) (Table 4.3).

Table 4. 3: Availability of selected paediatric medicines before and after the intervention

		Before			After		
		Intervention	**Comparison**	**Chi2(Pr)**	**Intervention**	**Comparison**	**Chi2 (Pr)**
ACTs[++]	Yes	26/40 (65.0%)	23/34 (67.6%)	0.0576	22/32 (68.8%)	6/16 (37.5%)	4.2857 (0.038)*
	No	14/40 (35.0%)	11/34 (32.4%)	(0.810)	10/32 (31.3%)	10/16 (62.5%)	
Amoxicillin	Yes	11/40 (27.5%)	12/34 (35.3%)	0.5212	22/32 (68.3)	3/16 (18.8%)	10.6852 (0.001)*
	No	29/40 (72.5%)	22/34 (64.7%)	(0.470)	10/32 (31.3%)	13/16 (81.2%)	
Diarrhea Medicine[+]	Yes	27/40 (27.5%)	19/34 (55.9%)	1.0546	16/32 (50.0%)	8/16 (50.0%)	0.0000 (1.0000)
	No	13/40 (32.5%)	15/34 (44.1%)	(0.304)	16/32 (50.0%)	8/16 (50.0%)	
Quinine	Yes	31/40 (77.5%)	20/34 (58.8%)	2.9927	4/32 (12.5%)	1/16 (6.25%)	0.4465 (0.504)
	No	9/40 (22.5%)	14/34 (41.2%)	(0.084)	28/32 (87.5%)	15/16 (93.8%)	
Metronidazole	Yes	7/40 (17.5%)	9/34 (26.5%)	0.8727	2/32 (12.5%)	2/16 (12.5%)	0.5455 (0.460)
	No	33/40 (82.5%)	25/34 (73.5%)	(0.350)	30/32 (93.8%)	14/16 (87.5%)	

Drug sellers' opinion about what facilitated the availability of medicines

Improving the medicines supply chain can significantly increase the availability of medicines for childhood illnesses. The AXEX study team was able to identify wholesale pharmacies within the study area where the study medicines were accessed. This reduced the distances, inconvenience, and costs of procuring medicines by the retail drug shops. In some cases, the study supervisor – a trained pharmacist – moved with some medicines during supervision and so it was easy to procure the medicine from the supervisor if a drug shop required additional stocks. This system was created to ensure a regular supply of the study medicines. Indeed, some respondents noted that the system that had been created by the study team to ensure a regular supply of study medicines to the participating outlets worked well and this led to an increased availability of medicines.

> *"It has been easy for me because they were supplying them to us. 'C' would bring them for us but at times she would not have the drug that you want and then you find that it would not be easy to get them sooner. It has been easy to get the drugs because I do not incur transport costs so when she brings I pick what I know will push me on till she brings the next batch."* ***(Drug shop operator _IDI_3).***

4.4.2. Effect of iCCM intervention on the affordability of paediatric medicines at retail drug shops

Medicine prices

The median prices for medicines under consideration were estimated per unit (per tablet or per sachet, whichever the case) using data from care-seeker exit interviews and converted to United States dollars (US$). There was an overall reduction in local median prices for medicines after the intervention compared to before the intervention in the intervention district. For example, ACT 20/120mg DT prices reduced from US Cents 11.0 to US Cents 8.0 per tablet. Relatedly, prices for amoxicillin 200 mg DT reduced from US Cents per 11.0 to US Cents 6.0 per tablet (Table 4.5). There was also an

overall observed reduction in the median price ratios (MPR) for the medicines under consideration after the intervention compared to before the intervention. Significant reductions in MPR were recorded for ACT 20/120 mg DT from 1.17 before the intervention to 0.49 after the intervention and for amoxicillin 200mg DT from 7.28 before the intervention to 2.46 after the intervention (Table 4.4).

Table 4.4: Median prices for different medicines (Prices in US Cents per unit (cap/tab, g, sachet)

	Before Intervention		**After Intervention**	
Medicine name (including strength and dosage form)	**MSH Price (2013)**	**Median price (MPR)**	**MSH Price (2015)**	**Median price (MPR)**
Arthemether/Lumefantrine 20/120mg DT.	9.42	11.0 (1.17)	16.22	8.0 (0.49)
Amoxicillin 125mg DT	1.51	11.0 (7.28)	2.03	5.0 (2.46)
Zinc Sulfate 20mg DT	2.46	11.0 (4.47)	1.41	6.0 (4.26)
Oral Rehydration Solution 500ml (Sachet)	6.54	18.0 (2.75)	5.55	15.0 (2.70)

Average exchange rate 1 USD =UGX 2765 (2013), and 1 USD =UGX 3,226.5 (2015)

ACT 20/120mg DT had the lowest MPR after the intervention compared to other child medicines such as amoxicillin and oral rehydration salts (ORS). For ACTs, MPR was less than the threshold both before and after the intervention compared to amoxicillin, Zinc, and ORS who's MPR was slightly above the threshold. This means that local prices for ACTs were relatively similar to their IRPs. The MPRs for the rest of medicines were slightly above the threshold, implying that their local prices were higher compared to their corresponding IRPs.

Affordability of iCCM recommended standard treatment regimens

According to the 2015/16 Uganda Ministry of Public Service Salary structure, the lowest paid public servant in Uganda is an *Office Attendant.* In the financial year 2015/2016, an *Office Attendant* earned a monthly gross salary of Uganda Shillings 187,660, an equivalent of US$ 58.2 based on the 2015 average exchange of US$1=UGX 3,226.5 (UBOS 2016). This monthly wage payment is equivalent of a daily minimum wage of UGX 6,255 (194.0 US. Cents). Table 4.5 shows the cost of treatment regimens for the selected health conditions. From Table 4.5, generally, all treatments were affordable both before the intervention and after the intervention because they required less than one day's wage for the lowest-paid unskilled government worker, except for two treatments both for pneumonia symptoms for age 2-11 months (1.13 days' wage) and 12-59 months (1.70 days' wage) that were costly before the intervention. We also observe that on the whole, after the intervention, all standard treatments cost less than one day's wage (ranging between 0.25 days' wages and 0.77 days' wages) compared to affordability before the intervention (ranging between 0.34 days' wages and 1.70 days' wages). It was noteworthy that amoxicillin for treating pneumonia symptoms in children of all ages had the largest effect in terms of increased affordability. Relatedly, ACT for treating uncomplicated malaria was most affordable both before (0.34 days' wages) and after (0.25 days' wages) the intervention.

Table 4. 5: Cost and affordability of recommended treatment regimens (United States Cents)

Febrile condition	Appropriate/ recommended medicines	Strength [mg/tbl./ cps.]	Dosage Regimen[tbl. or cps./day	Treatment Duration	No. of tbl/cps/ treat course	Total cost of treatment course	Number of days' wages required	Total cost/ treatment course	Number of days' wages required
Uncomplicated Malaria (+RDT)	Artemether/ lumefantrine	20/120 mg DT	6 Tabs in yellow pack (4-35 months)	1 tab twice daily for 3 days	6 Tabs	(11.0*6) =66.0 cents	(66.0/194.0) =0.34 days	(8.0*6) =48.0 cents	(48.0/194.0) =0.25 days
			12 tabs in blue pack (36-59 months)	2 tabs twice daily for 3 days	12 Tabs	(11.0*12) =132.0 cents	(132.0/194.0) =0.68 days	(8.0*12) =96.0 cents	(96.0/194.0) =0.49 days
Pneumonia symptoms (confirmed by respiratory time counter)	Amoxicillin DT	125mg	20 tabs in pink pack (2-11 months)	2 tabs twice daily for 5 days	20 Tabs	(11.0*20) =220.0 cents	(220.0/194.0) =1.13 days	(5.0*20) =100.0 cents	(100.0/194.0) =0.52 days
			30 tabs in green pack (12 – 59 months)	3 tabs twice daily for 5 days	30 Tabs	(11.0*30) =330.0 cents	(330.0/194.0) =1.70 days	(5.0*30) =150.0 cents	(150.0/194.0) =0.77 days
Non-bloody Diarrhea (loose stool with no visible presence of blood)	Zinc	200mg DT Plus 2 sachets of ORS	5 tabs (2-6 months children)	1/2 tab, once a day for 10 days + Half a 300ml every loose stool	5 Tabs + 2 ORS Sachets	(11.0*5) + (18.0*2) =91.0 cents	(91.0/194.0) =0.47 days	(6.0*5)+ (15.0*2) =60.0 cents	(60.0/194.0) =0.31 days
			10 tabs (7-59 months)	1 tabs once a day for 10 days+ Half a 300ml every loose stool	10 Tabs + 2 ORS Sachets	(11.0*10)+ (18.0*2) =146.0 cents	(146.0/194.0) =0.75 days	(6.0*10)+ (15.0*2) =90.0 cents	(90.0/194.0) =0.46 days

Caretakers' ratings of prices and cost of care in relation to their ability to pay

Table 4.6 summarises the effect of the iCCM intervention on the dimensions of affordability as elicited by care-seekers in relation to the ability to pay through the drug shop care-seeker exit interviews. Before the intervention, more care-seekers for under-five children (41.7%) in the intervention arm reported that prices of medicines at the retail drug shops were too expensive, as compared to care-seekers who reported medicine prices to be too expensive in the comparison arm (15.6%). However, after the intervention, 12% compared to 17% of care-seekers in the intervention and comparison districts reported that prices at drug shops were too expensive. The percentage difference (DiD) between the two districts before and after the intervention for care-seekers who reported prices to be too expensive was -27.8% which was statistically significant (CI: -34.2, -21.4. p<0.001p< =0.001). There are other intervention effects recorded across other dimensions of affordability, which changes may not be statistically significant, but are consistent with affordability estimates presented in Table 4.5.

Table 4.6: Effect of the iCCM intervention on perceived affordability of treatment for febrile childhood conditions among under-five children at retail drug shops in South Western Uganda; Difference-in-difference analysis

	Time points N (percent)		Change in percentage 95% CI	p-value
Study Arm	**Baseline**	**End line**		
Were you able to afford to buy all the drugs as prescribed/advised?				
	[3.7 (-10.9,3.5), p=0.315]	[-0.5 (-3.9,2.9), p=0.773]		
Comparison (Yes)	216 (84.3)	268 (96.1)	11.8 (6.4, 17.2)	
Intervention (Yes)	212 (80.6)	285 (95.6)	15.0 (9.1, 20.8)	
			3.2 (3.3, 9.6)	p=0.331
How do you rate the prices of drugs in this outlet with respect to your ability				
	*Too expensive		*Too expensive	
Comparison (Yes)	212 (15.6)	256 (17.2)	1.6 (-5.1,8.3)	P=0.642
Intervention (Yes)	206 (41.7)	269 (12.3)	-29.4 (-21.6, 37.2)	P<0.001
			-31.0% (-34.2, -21.4)	P<0.001
Were you able to meet the costs related to addressing the illness?				
Comparison (Yes)	189 (92.6)	257 (96.9)	4.3 (0.1,8.6)	P=0.038
Intervention (Yes)	56 (89.3)	276 (93.8)	4.5 (-4.1,13.1)	P=0.228
			0.2 (-6.4,5.9)	P=0.949

P-values indicate whether or not the outcome of measurement is significantly different between the two groups (comparison and intervention), when comparing baseline and end-line. Any p-values less than 5% imply that the difference in proportions reported between the two groups is significant.

Before the intervention implementation, 41.7% and 15.6% of caretakers of under-five children in the

intervention arm and comparison arms respectively, reported that drug prices at drug shops were too expensive. However, after the intervention those reporting that drug prices at drug shops were too expensive reduced to 12.3% and 17.2% in intervention and comparison arms respectively (Table 4.6 and Figure 4.3). The percentage difference (DiD) between the two study districts before and after the intervention was -31.0% which was statistically significant ($p<0.001$). Relatedly, care-seekers who reported that they were able to afford all drugs prescribed, increased from 80.6% (before the intervention) to 95.6% (after the intervention) in the intervention arm. There are other changes recorded across other dimensions of affordability, which may not be statistically significant but are consistent with the estimates of affordability based on costs of treatment courses in Table 4.5. It is important to note, however, that the perceptions of affordability are subjective and partly dependent on particular household characteristics or characteristics of respondents such as household socio-economic status as well as products that were being bought, and therefore the DiD results must be interpreted within that context.

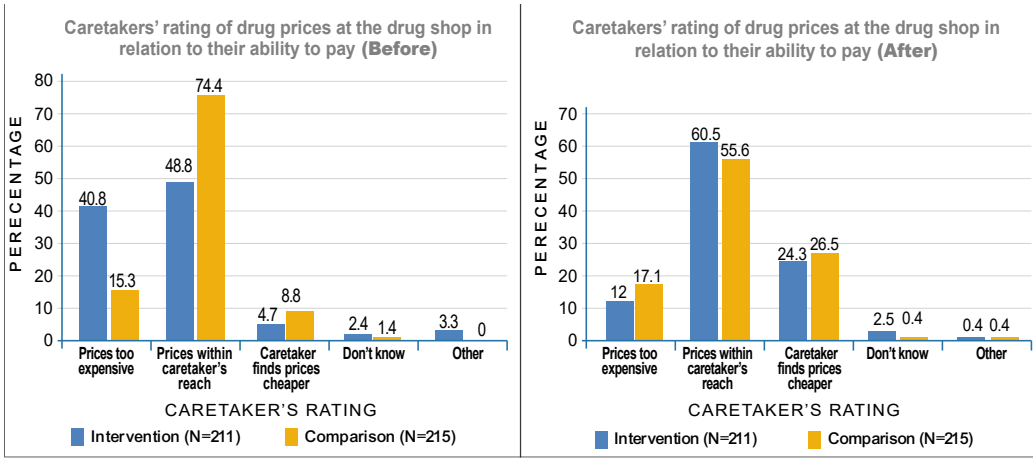


Figure 4.3: Caretakers' rating of drug prices at that drug shop in relation to their ability to pay (before and after intervention)

Of the 12 respondents who indicated they could not afford to buy prescribed drugs (in the intervention district) after the intervention, 8/12 responded that they did not have enough money to buy the complete dose. Related, out of 10 respondents who reported that they could not afford to buy prescribed drugs (in the comparison district) 10/10 reported that they did not have enough money to buy a complete dose. Those that expressed inability to meet costs associated with illness episodes for their children reported that they mobilized resources using various ways, including payment by items (barter system), selling an item to pay the costs, borrowing, and settling the costs using financial support from social networks.

Perceptions about prices, cost, and affordability of treatment. Many respondents appreciated the effect of the AXEX intervention on reducing the prices and cost of treatment and therefore making treatment affordable for the low-income users.

> *"Previously I was using other drug shops and I was one of those that used to spend a lot of money in drug shops. You would take a child for treatment and they put them on IV lines even when it was unnecessary – imagine five units through an IV line to a child. The drugs were also*

expensive but when I joined these services, I realized a child could be treated with tablets only, and the child recovers. The charges are also amazingly low. Pneumonia and malaria tablets cause the child to recover very quickly. I wanted to request that the awareness of these services be improved ***(R7, Caretaker FGD_2).***

The added package of diagnostics too did not increase the cost of treatment. Before the intervention, drug shops were not providing diagnostics before they could prescribe medicines. There was a general reliance on the experience of the drug sellers and the symptoms that were prescribed by the care seekers since they could not come with the child. The AXEX intervention, however, provided free malaria rapid diagnostic tests (mRDTs) and respiratory count machines. Before any treatment was prescribed, the drug seller was required to ascertain the tests and offer (or not) relevant treatment.

"….the nurse looked at my child and she put a device on the child's chest and told me that my child was so badly off and about to die. So she got me drugs and when I looked at them I was a bit scared. So she told me to pay 7000 shillings. I thought I had not heard well. I asked if she had said 70,000 shillings but she said that 7000 shillings. It was unbelievable compared to the amount of drugs she had given me. When I reached home my husband was shocked and thought I had spent a lot of money on the drugs. So he asked me where I had gotten all that money to buy the drugs, I told him that God was on my side and I had been charged 7000 shillings but he thought that I must have been mad but I assured him and he accepted. Two days later the child had improved and had even started to move" ***(R8, Caretaker FGD_1)***

Labelling of medicines facilitated affordability and reduced consumer exploitation

One of the factors identified to have influenced prices, and hence making the costs affordable was product labelling. The AXEX intervention provided subsidized pre-packaged medicines. Each pack or dosage was affixed with a price tag for consumers to know how much they were expected to pay. To the consumers and community role bearers, price labelling helped to reduce consumer exploitation and this helped the low-income care seekers to afford treatment. Any deviations from the prices indicated would likely cause a backlash from clients because they had been informed about these prices.

"…When these drugs were brought, they helped in reducing the exorbitant charges of the health workers in drug shops because they were used to high profits but the drugs came with recommended sale price tags. So the drug shop owner would also view it as a challenge because it would reduce the profit margin. So they first had a bad attitude towards them" ***(R1, VHT FGD_4).***

"… I have seen a lot of change in their services in the last two years. Even if we are saying that they charge higher, they have reduced their charges. I think some fear that they will be caught if they keep charging highly, maybe some of them feared that we had gone to the training too, so they would charge the exact prices for those drugs. They would only charge more for other drugs that they sell ***(R6, VHT FGD_4).***

The pursuit of profits may compromise the affordability of treatment

Even when medicines were labelled and rules had been agreed upon between the providers and the study team, some drug sellers could not follow the rules. The behaviour of reneging and going

against standard rules has been widely reported in studies as characteristic of retail health markets. One of the main reasons for circumventing the rules is the incentive to earn a profit. In this study, where drug sellers thought the rules were not favouring their profit motive, they chose to circumvent them. For example, one caretaker noted:

> *"…at times you go there and they tell you that the drugs which you people supply them are out of stock so they would sell you other drugs at high prices because they would want to profit on that"* ***(R5, VHT FGD_4).***

> *"…the other downside with these drug shops is that at times the diseases they are to treat has other drugs which are more costly than the ones you supplied them so they decide to give you the costly ones instead of the subsidized ones such that they can profit"****(R6, VHT FGD_4)***

The role of information dissemination in the success of interventions

Respondents noted that various channels of communication were used to ensure that community members received information. It was because of this information, that care-seekers were able to know what they expected to receive at the drug shop in terms of medicines and at what prices. The respondents also noted that because providers were aware that care-seekers had all the information, they could not easily behave unscrupulously. The respondents, therefore, feel that interventions should provide good information to the public and this can help the public or the users of services to make providers accountable. In addition, including the community leadership at all levels is paramount as a mechanism to co-create regulation, as one of the study participants as here noted:

> *"…to add onto that, I think what these leaders can is to make sure that they do not levy overwhelming taxes on these drug shops. Because if they levy high taxes, it means that even the person who goes there to buy drugs will be charged higher in order to meet the tax levels. So leaders should levy less tax so that the common people can get treatment at low prices"* ***(R5, VHT FGD_4)***

> *"…I also think our religious and political leaders have a role to play more than us. The role of advocacy is theirs because if you are in a church you cannot speak if you are not on the program. The same goes for political gatherings where you cannot speak if the political leaders do not allow you to speak. So, when the leaders speak, the health workers will improve on their services and people will know that they are going to places that have been well approved. It will also reduce family reliance in the drug shops where family members do work that they are not trained to do. So when the local leaders speak about it, those who are not trained may fear to practice"* ***(R1, VHT FGD_4).***

Price and non-price competition can crowd-out providers and guarantee affordability

Using an approach of social franchising, the AXEX intervention identified drug shops, trained drug sellers, and labelled study drug shops using an ACCESS TO LIFE (A2L) signage. The community was informed of the services of A2L drug shops and the low prices they charged. This created a shift away from other outlets to the A2L drug shops. It was reported that this created friction and conflict between the A2L and non-A2L drug shops and some non-study drug shops eventually closed out after being edged out of business.

> *"…you know that there are people you trained and those you did not train. Now when those you did not train got to know the prices of the drugs, they knew that they were going to run out of businesses so they took the sign posts off from those shops that were part of the project. For*

*example in Buteraniro they had taken them from almost three drug shops. This is because they knew that they were going to lose clientele once people knew that some drug shops were selling drugs at a cheap price" **[R6, VHT FGD_4).***

4.5 AXEX intervention implementation process, stakeholder views and opinions, and intervention effects (Sub-study IV).

Sub-study IV aimed at exploring the health system effects of implementing the iCCM intervention, the processes or mechanisms through which those effects were realised, and the dynamic interactions between and within the different health system components resulting from the intervention implementation. Sub-study IV also explored the views and opinions of stakeholders on the different components of the intervention and how those components were implemented. Exploring these different aspects was critical because the information could guide the possible scale-up of such an intervention.

The qualitative analysis adopted the health markets framework proposed by Bloom and colleagues [192] and Merton's theory on Unanticipated Consequences of Purposive Social Action [195]. A number of stakeholders that have a direct influence on the retail market or retail drug shops operations were identified **(Table 4.7).** It is important to note that each of these actors plays varied roles in facilitating market operations and can therefore be critical in improving outcomes of the medicines retail sector (MRS). We did not investigate in detail how these different actors interact together and the specific roles and influences that each may have on the retail drug shop, although this may be an important area for further investigations.

Table 4.7: Medicines retail market stakeholders with an influence on the retail drug shop market operations

Stakeholder category	Role	Stakeholder
Category 1	Regulators	Ministry of Health (MOH), National Drug Authority (NDA), professional bodies (e.g. Pharmaceutical society of Uganda, Allied Health Professionals), Uganda Healthcare Federation (for private providers), Local Government Actors particularly the District Health Team (DHT) under the lead of District Health Officer [196].
Category 2	Supply Chain Actors	Pharmaceutical Companies (both local and foreign manufacturers), Wholesale pharmacies, Drug Dealers mainly working for companies)
Category 3	Health Providers (supply)	Drug shop owners, drug sellers, health workers (at both public and private health facilities within drug shop neighbourhood), Community health workers (CHWs) or Village Health Teams (VHTS)) with iCCM kits within communities
Category 4	Consumers or beneficiaries (demand)	Care-seekers especially for children under-five years from geographically constrained communities and low socioeconomic households.

Based on the health markets framework and the unanticipated consequences framework, six thematic areas were identified, and the details are shown in **Table 4.9:**

Table 4.9: Themes and summary of findings from the qualitative analysis (paper IV)

Theme	Main focus	Summary finding
Initial fears, perceptions and reactions	Earlier perceptions and reactions about iCCM at the retail drug shop - from drug sellers, CHWs, care-seekers and government officials and how these perceptions changed with intervention implementation	• Some drug sellers initially thought the program was coming to register them for purposes of taxation, and this was seen as interfering with their private businesses. • Government officials were worried that the program was introducing medicines into Class C drug shops yet they are only recommended for class B, and this could result in abuse of antibiotics for example. • CHWs were pessimistic that drug sellers would not accept price-labelled medicines because they deny them the discretion to earn exorbitant profits, which they claim was virtually their goal. • Care-seekers were concerned about whether the drug sellers had enough skill and capacity to use diagnostics. They also expressed discomfort with new requirements of bringing sick children because they didn't see a difference between a drug shop and a formal health facility at this point.
Interface with the regulatory framework	Perceptions and experiences of the different actors and their interaction with the regulatory components of the intervention	• All stakeholders appreciated the involvement of different stakeholders in the monitoring and supervision right from local leaders to the district team. This enhanced the relationship between supervision and provision so that providers would not necessarily see supervisors as enemies focused on closing them down, but rather, as individuals who should support their work and make it better.
Information and dissemination	The channels of communication through which actors received information about the intervention and their opinions about the effectiveness of those mechanisms	• Most stakeholders received information about the intervention through radio talk shows, announcements, community sensitization workshops, and by word-of-mouth from CHWs. • Some care-seekers reported that price labels were instrumental in providing information about price and the drug instructions written on the packs. • The A2L signage placed on drug shops that were involved in the program attracted people to come and understand what exactly the signage was about and what services were being offered at the drug shop. Indeed, later, it was reported that A2L signposts created conflict with drug shops without them because they perceived the A2L drug shops as denying them clients.

Provider incentives	Views and opinions of the different actors about the benefits that came with the AXEX intervention that enhanced their routine operations.	• Drug sellers reportedly benefited from the intervention because they received additional clients especially those recommended by other clients. These additional clients were related to the reduced prices of medicines, but also the added diagnostic services that were provided to clients free of charge. • Providing diagnostics had made the community develop a sense of trust in the drug sellers, so much so that they even referred to them as "bashaho" (doctors). Many providers also reported earning high profits during the intervention period because of increased clientele. From the caretakers' perspective, the provision of medicines with price labels or tags enhanced their confidence to speak to the providers in case the provider asked for a different price than what was recorded. This enhanced provider accountability and reduced unscrupulousness.
Linkage to the formal health system	Views and opinions of actors about how drug shops and health facilities could link and collaborate, and complement each other in serving their communities	• Both drug sellers and government officials agreed that the formal health facilities need to appreciate the role drug hops are doing rather than alienating them. This partnership is critical to ensuring continuity of care and relieving health facilities of the workload given that facilities work amidst resource constraints. One way to streamline the referral system was for health facilities to recognize referral forms given to clients from drug shops. • The district should create a mechanism that makes it mandatory for drug shops to have records and submit them monthly to the district health information system. This way, it would be easier for the government to know what is happening at the drug shops and how the government can support them.
Perceived efficacy of the AXEX intervention	views and opinions of actors about efficacy of medicines and RDTs in managing febrile conditions	• Drug sellers reported that medicines that were sold at drug shops were efficacious. In addition, the medicines were easy to administer because they were pre-packaged in their doses and colours to adequately distinguish between them even by the uneducated caretaker. • Caretakers also noted that their flavours and tests were good for easy use by children. The additional diagnostic tests conducted to the child helped to prescribe appropriate medicines rather than relying on guesswork and experience as previously done.

CHAPTER 5: DISCUSSION AND CONCLUSIONS

5.1 Main findings

In **sub-study 1,** we found that most drug shops were operated by individuals with health-related training mainly midwifery, nursing, clinical medicine, and to some extent pharmacy assistants. Relatedly, the physical environment within which most drug shops operate is consistent with recommended standards and guidelines. The most commonly stocked medicines by drug shops were paracetamol, quinine, cough syrup, ORS/Zinc, Septrin (co-trimoxazole), and ACTs. Our study also found that prescription and dispensing decisions and practices were largely influenced by market factors, including client demand, client preferences, client finances, and profitability.

In **sub-study II,** retail drug shop start-ups were mainly motivated by the need to make a profit, although there were additional social benefits that accrued to drug shop operators, including the need to contribute to the community. Indeed, drug sellers enjoy social recognition, expanded social networks, and these social considerations partly influenced drug seller practices. In addition, drug prices varied significantly across outlets with mark-up prices ranging between 43% to over 100%, resulting in an estimated profits of more than 90% per month after offsetting operational expenses. Finally, the retail health market regulatory system within the study area was found to be largely poorly streamlined, and weak in capacity, and under-resourced, and certain regulatory actions often resulted in perverse incentives to the operations of the retail market.

Sub-study III: Overall, implementing an iCCM intervention increased the availability of iCCM recommended medicines for paediatric febrile conditions at the retail drug shops. A higher proportion of surveyed retail drug shop outlets reported a higher availability of medicines for paediatric febrile conditions in the intervention district compared to the comparison district, after implementing the intervention. In addition, a higher proportion of care-seekers in the intervention district reported that drug prices and costs of treatment were lower and within their ability to pay, compared to care-seekers in the comparison district, after the implementation of the intervention. Further analysis done for the intervention district shows that the intervention increased the affordability of medicines. The cost of treatment courses (doses) was lower and required less of the daily wage incomes after the intervention compared to before the intervention. In **sub-study IV,** we found that retail health markets constitute various actors and stakeholders, including community health workers, government health workers in health centers, district health officials, Ministry of Health officials, NDA, drug sellers and owners, care-seekers, and the community leadership. These actors operate and interact in a dynamic system with rules, beliefs, and incentives that influence the nature and quality of interactions and ultimately goods and services provided. Each of the actors appreciated and benefited from implementing iCCM at the retail drug shop. For example, the district health team, the NDA, and MOH appreciated the partnership and collaboration with the project team in monitoring and supervision, which resulted in an improved relationship with drug sellers and improved quality of services. The drug sellers appreciated the training and capacity building, the free RDTs and subsidized supplies, the improved trust that resulted in providing better quality services, as well as better sales and client retention. The care-seekers and the community appreciated the quality of care received and the efficacy of the medicines. Finally, the intervention implementation demonstrated that private market-based interventions generate spillover effects to the broader health system beyond the targeted actors and these effects can be both intended and or unintended. For example, if services were improved at drug shops, there would be a shift from the formal health service providers to the retail drug shops, which could also have positive and negative results. The main findings are further discussed in detail in sections 5.2 to 5.5.

5.2 CHARACTERISING THE RETAIL DRUG SHOP MARKET IN RURAL SOUTH-WESTERN UGANDA

5.2.1 Training and qualifications of drug sellers

Study I reported that most drug sellers had health related qualifications mainly nurses and midwives, Nursing Assistants, pharmacists, and clinical officers. However, the finding could be related to the fact that only registered and licensed drug shops were included in the study, and given the fact that qualified personnel is one of the criteria to grant a license [112, 177], it is reasonable to expect that most licensed outlets will have reasonably trained attendants. The finding on qualification is consistent with findings reported from a study in Eastern Uganda which reported that 70% of drug shop attendants belonged to the 'nursing assistant' cadre[197]. In Uganda, nursing assistants are a cadre of health workers with some knowledge and basic skills that have been attained through some not-so-regularised and accredited health-training programs. The level of training and skills of drug sellers are an important element that is closely associated with the provision of quality services. There are, for example, studies that have found that less trained providers were more likely to over-prescribe antibiotics compared to the more trained counterparts[36, 198]. However, even in cases where drug shop attendants have some health training, they would still benefit from additional capacity-building programs through on-job and refresher training, and support supervision, to improve their practice[136, 199]. The AXEX intervention study provided a package of on-the job training using MOH training guidelines on iCCM and a certified trainer. The training focused on understanding the ICCM guidelines on management of febrile illnesses, including identification of danger signs, testing using mRTDs, appropriate prescription, among others (Box 1), and indeed drug sellers reported to have benefitted from this training. Continuous training of providers helps to enhance skills development and acquisition of latest information about medicines and prescription practice, in the face of ever-changing disease presentations and clinical management guidelines [200].

5.2.2 Common conditions reported and drug stocking and dispensing practices.

Study I, further found that fevers, coughs, difficulty in breathing, and diarrhoea were the commonly reported childhood illnesses at the retail drug shop. This may not be surprising because these conditions currently constitute the major burden for under-five children in Uganda (Uganda Bureau of Statistics (UBOS) and ICF International Inc, 2016 #300). This finding is also consistent with what was found by Rutebemberwa and colleagues) who found that almost 60% of care-seekers of febrile children attend private drug shops as their first points of contact with the health system[32]. Indeed, in Uganda, 40-70% of medicines for fever, headaches, and coughs have been found to be delivered through drug shops, private clinics, and pharmacies [16, 157, 201, 202]. In fact, the estimates from WHO show between 30% and 70% of febrile children are treated in the private sector [203]. Relatedly, our study found that the commonly stocked medicines were paracetamol, quinine, septrin (co-trimoxazole) syrup, cough syrups, ORS/Zinc, ACTs, and multivitamins among others. In a similar drug shop study in Eastern Uganda[197], 91% of surveyed drug shops reported selling malaria drugs, 79% sold antibiotics, and 81% sold ORS, among others. However, many studies of this nature suffer challenges of accurately identifying medicines sold at outlets if they simply rely on observation and or interviews with the drug seller and our study may not have been immune from this challenge. This is because, in some cases, drug shops stock and sell products that they are not permitted to sell depending on the class of the drug shop, but take advantage of the regulatory limitations and sell them. In these circumstances, drug sellers will not display those products on the

shelves to avoid being reprimanded [204]. It is therefore likely that our study may not have captured an accurate picture of the commonly sold medicines because the drug sellers could choose not to display or even disclose during the interview, the type of drugs that are sold in their drug shops.

Our study also found that drug sellers made decisions on which medicines and products to stock, based mainly on MOH-recommended medicines, most demanded medicines on the market, most profitable medicines, and seasonal factors. Relatedly, dispensing (prescription) decisions were associated with client preferences, client finances, and those medicines that are profitable. Client demand and choice of medicines have been reported in studies elsewhere as critical factors that influence dispensing decisions. It has been reported that providers take clients as 'kings' and are very concerned with ensuring that clients are maintained as 'loyal customers' to the provider, lest they be taken up by other competitors[205-207]. In addition, the desire to maximize revenues and survive in business has been documented by other studies as a significant factor in influencing retail practice [20, 29]. In pursuing this objective and in light of maintaining client trust and relationships, providers end up dispensing medicines according to client preferences [206, 207]. In some cases, where clients have presented prescriptions from formal facilities, drug sellers tended to modify them or even substitute them with their own prescriptions and on some occasions, drug sellers have substituted low-priced medicines for high-priced ones so as to maximize their earnings [206]. These practices undermine efforts to improve quality of care and put considerable social costs on households, including inappropriate antibiotic use resulting in antimicrobial resistance (AMR), waste of limited out of pocket resources by sometimes procuring ineffective medicines, and this can lead to financial catastrophe and a broader range of other social costs [23, 25, 26]. Antibiotic resistance has been described by the WHO as a 'global health security emergency' problem that must be urgently addressed [208]. Improving dispensing practice and more generally quality of care, thus, requires more than just supply-side strategies of training and supervision, but also demand-side interventions such as information provision, in order to influence consumer behaviour, preferences, and choices[13, 205].

5.2.3 Retail drug shops and diagnostic capacity

Study I also found limited use of diagnostics such as mRDTs, respiratory count timers, and thermometers. Based on care-seeker exit interviews, only 21% of the respondents who brought sick children to the drug shops reported having been diagnosed with an RDT, 21% with a thermometer, and none with a respiratory timer. Yet, 39% received ACTs, and 57% received diarrhoea treatment. Most drug shops, however, had iCCM guidelines, clinical guidelines, and malaria and diarrhoea treatment algorithms and charts. In a study of both licensed and unlicensed drug shops in Eastern Uganda found that licensed drug shops possessed significantly more reference material than their unlicensed counterparts [197]. From that study, 75% of licensed drug shops had reference material compared to 24% of unlicensed drug shops. Limited diagnostic capacity for retail drug shops has been documented in Uganda and elsewhere [209, 210]. Enhancing diagnostic capacity for health providers is a critical starting point for improving the appropriateness of care. Inappropriate medications, unnecessary prescriptions, overuse of antibiotics, or even delays in receiving appropriate treatment are all associated with limited application of diagnostics [38, 211]. The WHO guidelines on malaria treatment, as well as the Uganda Malaria Control strategic plan, recommend the expanded use of RDTs across the public facilities, the private sector, and at community level [212]. Other studies in Uganda and other countries have also demonstrated that introducing RDTs into the private retail sector improves treatment practices, enhances access to appropriate care, and reduces any possible risks and costs to the child under medication [35, 213-216]. From a retail provider's perspective,

increasing the use of RDTs in retail drug shops may require provision of subsidized RDTs and distribution them across retail providers particularly in remote areas. Such subsidies would make the tests cheaper and accessible to rural folks [217]. This should be accompanied by corresponding effort on training and capacity building for providers, strengthening regulatory capacity to prevent abuse of RDTs, and ensuring compliance with diagnostic outcomes [218].

From the consumers' (demand-side) perspective, improving diagnostic capacity at drug shops alone may not yield the intended results. Rather, additional complementary measures are necessary, such as the provision of information to communities through targeted behaviour change campaigns so that communities can appreciate other non-malaria causes of fever [219], the rationale for diagnosis before treatment, the dangers associated with use of ACTs for non-malaria cases, building trust in RDT negative results to ultimately reduce pressure on providers to sell them medicines even in situations of RDT negative results [216, 217, 220] [38, 217, 220]. Additionally, care-seekers need to be sensitized to come with the sick child to the drug shop when they come to purchase medicines so that they can be tested before prescription, although this is a very uncommon practice in Uganda.

5.3 MOTIVATIONS AND INCENTIVES FOR RETAIL DRUG SHOP OPERATIONS

Given the importance of private retail drug shops in promoting access to essential medicine especially for under-five sick children in many LMICs, it is apparent that initiatives must be identified to engage the retail drug shops. The current global discourse on UHC implies that many players should be brought on board to expand access to health services. Retail drug shops are majorly critical in serving geographically constrained and underserved environments where formal health facilities and professionally trained providers are unevenly present. Although only registered drug shops are allowed to practice in Uganda, the regulatory and enforcement framework is so weak that non-licensed and unregistered drug shops often take advantage of it. The motivations and objectives of these retail drug shop establishments and operations have a strong bearing on their behaviour and practice and are therefore relevant for any policy reform discussions, yet they are not comprehensively understood.

5.3.1 Motivations and benefits for drug shop start-up and operation

Sub-study II examined the motivations for retail drug shop start-ups as well as the incentives for their operations. By drawing upon literature from industrial organizations, specifically the Structure-Conduct-Performance (SCP) paradigm [45], we analysed the various motivations and incentives that underpin market interactions and dynamic relationships between market agents. Our findings from sub-study II (paper II) show that retail drug shop start-ups were largely motivated by the need to provide a service to the community, generation of through profits, and creating an avenue for employment, especially for family members. Relatedly, retail drug shops provide benefits to operators and owners, for example, income obtained through profits helps to sustain families. Other benefits include; social recognition, and expanded social networks and capital [20, 29]. Traditional economics avers that each player within the market space has interests and therefore the dynamic interactions and relations that ensue within the market are largely driven by interests. These interests could be economic, political, social, or a combination of all. Individuals may, however, in the pursuit of personal interest, fulfill and contribute to other social goals that may not necessarily be their primary motivation [221]. From our results, it is clear that beyond the pursuit for income and profits, other social goals enter the utility functions of drug shop operators. There are many studies that

report that economic factors and especially profits are the main driving force for informal medicine providers [17, 222, 223], and this has perverse implications for the quality of services provided[224, 225]. In the face of information imbalances between providers and consumers, the profit motive may end up creating an environment where providers may induce unnecessary demand or induce some form of moral hazard [133]. Poor practices such as over-prescription of antibiotics and other rule violations have been closely linked to a reported pursuit of the profit motive [23, 25]. Weak or non-existent regulatory capacities and frameworks can compromise health, which is a public good. **Sub-study II** (Paper II), however, revealed that although the need to earn an income seemed to be the overriding objective, there were additional motivations that came to the fore, including serving the community, social recognition, and expanded social networks and capital. In our sub-study I, we noted that sometimes providers used these relationships to extend credit facilities to clients in some cases when clients they never had funds yet they need medicines. This mutual trust between the client and the provider creates long-term relationships that culminate into customer retention and business sustenance.

Indeed, social motivations and cultivated relationships are critical in acting as disincentives for unscrupulous behaviour among providers. For example, the fear of losing dignity, status, and community trust, may act to induce good behaviour [226]. Asha George & Lyer argue that social relationships that are cultivated over time between community and medicine vendors generate an environment where communities become threats to drug sellers' reputations. The socially embedded relationships and motivations that are built over time between the providers and care-seekers help to undermine the desire and ability of drug sellers to behave in unscrupulous ways [227]. The combination of economic and social motivations can be taken advantage of by policy-makers to design strategies that would improve retail market operations.

5.3.2 Price mark-ups, transaction costs, profitability and business sustenance

In paper II, we found that most drug shops are able to make some profit when we compared the operational costs and the net revenue from sales of a typical month. The study further found that price- mark-ups varied across medicines and outlets, but generally ranged between 43% (ACTs) and sometimes 100% and beyond (paracetamol and septrin/co-trimoxazole). The major factor that was attributed to price mark-ups was the high prices at the upstream wholesale outlets added to the transactional costs and an additional cost affixed in the calculation to ensure the business remains afloat. The results are somewhat consistent with other studies that report mark-up prices for medicines in private outlets ranging from 40% to beyond 100%, although generally, variations of price-mark-ups across studies can be an issue of methodology and setting [228]. A study in Nigeria found that ACTs generally had lower percentage price mark-ups ranging from 22% to 40% compared to other medicines although this was attributed to the subsidy program that exists for ACTs [229]. High price-mark-ups tend to drive product prices higher and apparently constrain access to essential medicines through the private sector. The use of out-of-pocket payment systems for medicines has been singled out as one of the factors that drive medicine prices and make them unaffordable [230]. Yet, the availability and affordability of child medicines have a demonstrable impact in terms of saving lives and improving child health [231]. In a country like Uganda, where more than 19% of the population still live under the poverty line (Uganda Bureau of Statistics (UBOS) & ICF, 2018 #753), high-cost medications can hinder access and utilization of medicines, unless clear and all-embracing health financing arrangements are put in place to cover all the population. In this study, drug sellers recognized that indeed prices might be high and unaffordable to some sections of the population.

They, thus, recommend the introduction of private sector subsidy programs by government and global medicines and supplies facilities such as the Global Fund through AMFm. However, to make these programs more effective, they need to be targeted to the upstream pharmaceutical supply-chain players, who would eventually trickle-down the subsidy benefits in form of reduced consumer prices [111]. There are indeed studies that demonstrate that subsidies reduce medicine prices and expand access to essential medicines by vulnerable groups [210, 232, 233]. Another strategy that has been used elsewhere is the 'price capping' or 'capping of mark-ups'. With this approach, a regulatory authority establishes 'bands' or 'ranges' within which a provider can vary their product prices but are not allowed to go beyond that cap[234, 235]. In China, retail providers are allowed a 15% mark-up to the wholesale price [236]. However, in circumstances where wholesale prices are relatively lower, providers never find those products profitable, and in the end, they switch to prescribing relatively expensive medicines in order to earn more revenue. Deciding which approach is best suited for application in each setting depends on careful consideration of the incentives and disincentives of each approach. There are other additional strategies that have commonly been associated with drug shops as they pursue profits and business sustainability – diversification and pilferage. On diversification, our study 1 found that, beyond medicines, drug outlets sold additional items such as toiletries, cosmetics, mobile phone airtime, among others. This was found to be a good strategy to sustain drug shop business operations rather than relying on a single business line of drugs and medicines which can sometimes be prone to seasonality or regulatory risks [237]. Some studies have recommended expanding the range of services that retail drug shops can offer to for example include: provision of nutrition and other health education, nutrition supplementation products, monitoring blood pressure and blood sugar levels of clients in the era of NCDs, family planning, services, etc. [238]. It is important to note, however, that even when diversification may be a recommended practice for business sustenance, suffice to say that these additional products should be closely related to the mainstream business line for purposes of business order and feasibility. On the issue of pilferage – an illegal, immoral, but yet common practice – there are some drug shops that dispense medicines stolen from government facilities as a way of making money. In Uganda, medicines in public health facilities are supplied through the National Medical Stores (NMS) and paid for by public resources. It has also been noted that in many cases, private drug shops, pharmacies, and clinics are owned and sometimes managed by health workers who are employed in the public sector [239]. In fact, a national survey of private health facilities in Uganda in 2005 (although old data) found that up to 54% of doctors that worked in the private sector were also employees of the public sector [240]. Given this blurred relationship between private sector providers and government/public sector providers, it is not uncommon to find government medicines in private drug shops and pharmacies being sold to clients even when they are clearly labelled "not for sale" [241, 242]. There is a perception that government medicines are brought into the private sector through pilferage means because of weak systems for monitoring and accountability on the part of public health providers. For some drug shops, these pilferage medicines supplement the drug shop profits and sustain their businesses. While these practices are perpetuated by some health workers for their own private gain, they are a source of huge economic loss to government, social burden to community arising from deaths associated with failure to access appropriate treatment due to unavailability, and erode public trust in the public system, and these unscrupulous practices need to be addressed

5.3.3. Retail market regulation and oversight

The findings of **sub-study II** (Paper II) show that a regulatory system exists but it is not adequately supported to undertake its mandate. In many instances, the regulatory processes were not clear and straightforward. This lack of clarity created inconveniences and resulted in unnecessary costs. While almost all drug sellers appreciated the role of regulation, there were concerns about the long waiting times, the corruption involved in the process, and this tended to undermine the regulatory system and generated perverse incentives. In many circumstances, monitoring and supervision were limited to only urban outlets, leaving the largest number in rural areas unattended. In fact, there were reported cases where a drug outlet spent a year without receiving any supervisor. Even for drug shops that were visited by supervisors, there were reported complaints about supervisors who were more vindictive in their operations rather than supporting providers to improve their practices. The regulators on their part, decried the lack of resources to conduct monitoring and supervision, backlog, and underhand methods that drug sellers use to fraudulently obtain certification. The issue of weak retail market regulation has been a longstanding one and has been widely reported in many studies elsewhere [13, 243]. In addition, the study identified the role of community and community leaders in 'failing' regulation. Indeed, regulators reported that communities are the biggest threat to regulatory work because they 'protect' drug sellers in moments when they are supposed to be sanctioned. In cases where the drug shop is located in a rural, distant, and hard-to-reach community with limited access to the formal health facilities, a drug shop is taken to be a 'community facility", and therefore from a community point of view, sanctioning such a drug shop or drug seller would potentially deny the whole community their needed services. This is a serious case of 'regulatory capture'. Regulation, therefore, goes beyond a mere concept and is influenced by broad and wider forces and relationships between the regulator, the community, and the regulated. Asha & colleague argue that medicine vendors are embedded within communities and enjoy social protection from community elites and elected leaders who they often call on, in case of upstream regulatory pressures. In their study, Asha & Lyer [227] reported that communities acted as shields against unpredictable regulatory efforts. Various regulatory failures and inadequacies such as infrequent inspections, failure to implement sanctions, and tacit collusions of regulators and the regulated, among others, have been reported by other studies [90, 244]. Since regulation is critical for improving retail provider practices, alternative approaches may be necessary.

One possibility is a shift away from a 'Command- and - Control' approach to an approach that recognizes consumers as a critical stakeholder in the regulatory process [108]. Communities are the main users of drug shops and interact on a regular basis with drug sellers, and are directly affected by wrongful actions of drug sellers. Communities, thus, have a great stake in the affairs of local drug shops and should play a role in their monitoring and inspection rather than waiting for national-level or district-level personnel who come periodically or may even never come if constrained. Once communities or citizens are empowered with information, they can identify violations on the part of service providers and report them through appropriate channels [108, 245]. Consumer or community involvement can also be through the co-option of community leaders into the regulatory framework. The Accredited Drug Dispensing Outlet (ADDO) model in Tanzania is an example of a success story of how involving local officials in the inspection process rather than full reliance on upstream inspection arrangements can improve regulatory compliance by service providers [246]. A recent study in East Central Uganda has successfully piloted peer-to-peer supervision as another model of regulating retail drug shops [114]. This pilot demonstrated that peer-to-peer supervision model has

a positive influence on regulatory practice among drug shops in Luuka district in Eastern Uganda Relatedly, from this Eastern Central Uganda pilot, drug sellers reported that indeed peer-to-peer supervision improved relationships within providers, encouraged peer learning, required minimal resources, and ultimately improved provider practice [114]. It is also important that the relationship and communication between regulators and providers be streamlined. Our study found that there was a lack of clarity on the process of obtaining registration, licensure, and the specific requirements to that effect. This communication gap tended to create a 'middleman' practice that was costly to providers. To that extent, there is a need to create clear channels of communication and dialogue between the regulators and the providers, including not only clarifying regulatory requirements, expectations but also mechanisms for support [113]. Furthermore, regulation should involve a component of providing support rather than only reprimands on all occasions. Regulators should rather focus on advising providers on best practices and why providing better quality service to their clients is in their best interest. Over-emphasis on reprimands often generates unnecessary tension between the regulators and providers, and may not necessarily result in improvement in provider practice. Finally, two critical issues need to be noted; first, no single approach to regulation may be successful, but rather a combination of approaches that are cognisant of the context within which regulation is happening. Secondly, but most importantly, a 'participatory approach' to establishing a regulatory architecture is critical. The regulator, the regulated, and all other stakeholders need to be involved. This will not only achieve the 'legitimacy' of the regulatory architecture but will also allow all actors to appreciate the rationale for regulation *per se* [247, 248].

5.4. EFFECT OF iCCM AT RETAIL DRUG SHOP ON AVAILABILITY AND AFFORDABILITY OF PAEDIATRIC MEDICINES

Effect of iCCM intervention on availability of paediatric medicines

Ensuring universal access to essential medicines is at the heart of the global SDGs and UHC and is now considered a fundamental human right [249]. Yet, access to essential medicines continues to be an elusive target for many LMICs. In areas where they may be available, they are either not in the recommended forms or simply unaffordable [250-252]. Improving the availability and affordability of essential medicines for children can be a game-changer in addressing childhood mortality. For countries where public health systems are characterised by intermittent medicines and supplies stock-outs, improving the availability and affordability of medicines in the private sector would go a long way in addressing the public sector inadequacies [253].

Our sub-study III findings highlight that availability of paediatric medicines recommended under the iCCM policy was generally higher in the intervention district compared to the comparison district. Major improvements in the availability of recommended medicines were recorded for ACTs, amoxicillin, and ORS/Zinc. Another important finding to note is that, the availability of quinine in the intervention district reduced from 77.5% before the intervention, to 12.5% after the intervention. The significant reduction in quinine availability needs to be understood in the context that quinine was generally a predominant medicine that drug sellers prescribed for sick children before the intervention. However, quinine was no longer a recommended drug for childhood fevers under iCCM. Therefore, with the emphasis on iCCM recommended medicines during the intervention implementation, it is reasonable to imagine that quinine stocks declined in the participating drug shops. It is also worth noting that there were some changes in medicine availability even for the comparison district, for

example, the significant decline in quinine and metronidazole. These changes can best be attributed to and explained by secular trends that may have been brought about by the iCCM policy as providers in various settings continued to try and adapt the new policy recommendations which could have influenced stocking decisions even in places where the intervention was not happening.

While there were notable improvements in the availability of iCCM recommended medicines in the intervention drug shops, the availability levels were found to be lower in our study compared to the recommended levels of 80% for high availability [254]. Low availability of essential medicines in the private sector is not a peculiar challenge to Uganda but has also been documented in other countries and settings, and for those that exist, the formulations may usually not be appropriate [255-258]. Inadequate availability of essential medicines in drug shops and private clinics has partly been attributed to limited financial capacities for drug shop owners to invest and stock enough medicines; weak monitoring, supervision, and more generally limited drug shop adherence to recommended medicines from regulators which are associated with weak regulatory oversight and a low incentive to extract compliance [32, 77]. There are, however, recent studies in Uganda that have reported high rates of availability of essential child medicines, which is a promising trend in light of the positive effect of increased access to essential medicines on reducing child mortality [197, 259].

In Uganda, the inadequate availability of essential medicines is not only a private sector challenge but also a public sector issue [260]. Limited availability of medicines in the public sector implies that individuals resort to private pharmacies, drug shops, and other medicine outlets to access medicines and this exposes households to the risk of catastrophic expenditures [261]. The Government through the MOH and the NDA should devise and implement strategies to increase the availability of essential medicines in the private sector generally but at private retail drug shops specifically. This would positively improve accessibility and hence contribute to reducing the high burden of under-five mortality in Uganda. To improve availability and address supply-chain constraints, our study worked with regional or local pharmacies to provide subsidized recommended medicines. A participating drug seller was only required to present a form that shows they are part of the beneficiaries and the pharmacy would sell to them the medicines. In addition, the study team recruited a regular supervisor who sometimes moved with medicines during the supervision visits in the fields and whichever drug shop wanted to replenish their stocks, they would do so without any additional transport costs (Box 1). These strategies of working with local pharmacies, subsidizing medicines, and the *"we can deliver to you*" had a demonstrable effect on increasing availability of medicines in the drug outlets that participated in the study. The provision of subsidized pre-packaged medicines to retail drug shops created an observable increase in the availability of medicines in the private retail drug shops. The Global Fund through its Affordable Medicines Facility-Malaria (AMFm) initiative launched in 2010, provided subsidies for ACTs through the public and private sectors [262]. An independent evaluation conducted after the Global Fund AMFm program found that indeed the initiative was successful in increasing the availability and affordability of ACTs [210]. A systematic review that assessed the effect of offering ACT price subsidies to private retailers on ACT use, availability, and price and market share, found that substantive subsidies combined with training and social marketing improved the availability of ACTs in the private retail sector by almost 32% [233]. Another strategy to improving the availability of medicines in retail drug shops is to strengthen regulation combined with incentives to ensure compliance to MOH-recommended essential medicines to stock and dispense. There is a need to increase monitoring, supervision, and other regulatory mechanisms to ensure that medicines sold by drug outlets are consistent with the recommended practice. On a

positive note, however, our study was able to report that MOH recommendation on medicines was an important consideration for drug sellers to make their stocking decisions [17]. The Uganda National Medicines Policy (NMP) is committed to increasing the availability, affordability, and financing of medicines in Uganda through streamlining procurements and supply chain, regulating consumer prices, implementing sustainable financing mechanisms, and improvements in the efficient use of resources to finance quality medicines [263]. Given that retail drug shops continue to support and complement the formal health systems, areas of policy reform should be identified to enhance the supply of essential medicines in the private sector generally but specifically the retail sector.

5.4.1. Effect on the affordability of recommended medicines

Our paper III findings show that providing subsidized pre-packaged and price labelled medicines to retail drug shops enrolled in the study increased the affordability of iCCM-recommended paediatric treatments. The affordability criterion is based on the WHO/HAI standard that considers wages paid to the lowest-paid unskilled government worker whose estimated earning is US$1.94 in wage earnings per day (for Uganda). The Uganda Bureau of Statistics (UBOS) estimated that the average nominal household incomes (all sources) for the financial year 2016/2017 was UGX 416,000 (US$121.6) translating into UGX 13,866 (US$4.1) per day (using 2016 official exchange rate, US$ 1 = UGX 3,420). Based on these estimates, the selected treatment regimens would indeed be affordable. However, more than 19% of Ugandans still live under one dollar a day with limited earning capacities. For this category of the population, the estimated regimen costs may still be unaffordable and may constrain access to the much-needed essential care for children by increasing household expenditure on health care. Household expenditure on medicines obviously contributes to household impoverishment due to catastrophic expenditure, and individuals in low socioeconomic quintiles are often the most affected [264]. In countries where health financing is dominated by household out-of-pocket expenditure with limited health insurance mechanisms, higher prices and cost of medicine constrain access and utilization of quality health care, hence undermining the Universal Health Coverage (UHC) goal [265]. Under such situations, subsidization of treatment in the private sector could provide a great deal of relief to enable some households to access the medicines. In other settings, price regulation has been used as a mechanism for containing prices of medicines and increasing affordability [234, 266]. Under price regulation, either price is capped or price mark-ups are allowed to oscillate within allowable margins. In some cases, high price mark-ups can be allowed for specified medicines to act as an incentive for providers to continue providing those medicines for the benefit of the consumers. However, price regulation and related approaches require a high level of regulatory capacity and a recognition of the likely disincentives and unintended consequences that may likely emerge [234].

It is also important to note that the affordability estimates found in our study, are based on a case of ‘one child’. However, the reality is that a household may have more than one sick child at any given point in time, or a single child may fall sick multiple times in a month, and therefore the conclusion about affordability could change depending on how much extra treatment costs are incurred and the economic status of that particular household. Relatedly, the estimated costs for treatment regimens do not include any other treatment-related costs that may be charged by providers, for example, consultations or additional complementary medicines that may be prescribed by the provider. It is quite common for medicines to be accompanied by paracetamol or another painkiller depending on the prescriber. Also, possible costs of diagnostic tests are not included. While our AXEX program provided free RDT kits to drug outlets enrolled under the intervention study and indeed the drug

shops provided diagnostic services free of charge during the study, it is not clear whether the free service has continued (will continue) even after the intervention. Previous studies in Uganda had reported limited usage of RDTs in retail drug shops [14]. Certainly, as private entities, there is limited control over whether or not such diagnostic services remain free or not. Therefore, the conclusion about affordability may be altered depending on which of the above issues come into play. What is clear though, is that the unaffordability of medicines constrain accessibility and undermines the goal of reducing under-five mortality and morbidity. In a retail market that is not so strongly regulated and professionalism is limited, providers have oftentimes had to strike a balance between what is professional and what brings economic benefit, and quite often they find the latter more attractive. Indeed, the Uganda Private Sector Assessment in Health reported that medicine prices in the retail sector are set on an ad hoc basis and because of this, price mark-ups vary significantly across providers. The variation can be as wide as between 50% to up to 600% [95] and this hurts the affordability of and access to medicines.

While our study found that the AXEX intervention package generally improved the availability and affordability of recommended paediatric medicines, the Ministry of Health has committed to improving this further and ensuring that every Uganda has access to affordable medicines. Through the National Medicines policy [263], MOH has committed to, among others: developing mechanisms for affordable national procurement and consumer prices in the public and private sectors, and increased sustainable financing and efficient use of resources to finance quality medicines. There are additional measures that have been proposed to minimize costs of medicines and promote affordability of medicines in Uganda. These include: 1) rationalization of drug prices - including the establishment of pricing guidelines and bands within which mark-up prices can be allowed to oscillate; and 2) implementation of innovative financing mechanisms such as the use of vouchers or establishment of a drug benefit plan for the poor to overcome barriers to accessing essential medicines in the private sector [95]. Implementation of these recommendations requires scrutiny and planning but also an evidence-base to ascertain the costs and health systems implications of each of the proposed measures.

5.5. THE EFFECT OF THE DRUG SHOP iCCM INTERVENTION

Sub-study IV applied the health market systems framework to analyse the retail health market broadly but specifically looking at the different actors within the market, the roles of each of these actors, and how contextual factors or the environment does influence the interactions within and between these different actors [192]. Study IV demonstrated that establishing a functioning health market requires multiple actors all pulling towards the same direction. The perception and attitudes of various actors towards an intervention may determine its success or failure. Even well intentioned and designed interventions may not succeed if no effort is made to bring all relevant stakeholders on board.

The AXEX intervention had multiple components that all worked together to generate the observable effects, and the success of the AXEX intervention reinforces the view that due to the complexity of health systems and a lot of interconnectedness across the system components, single-component interventions may not succeed, but rather a combination of components [267]. Intervention implementation also requires some degree of flexibility and a learning-by-doing approach with provision for feedback loops to improve implementation [194]. This approach helped to incorporate stakeholder concerns and expectations into the AXEX intervention implementation process.

Furthermore, the intervention components had some form of in-built incentives for each of the actors; the providers, the care-seekers, and the regulators, and this was paramount. To the providers or drug sellers, the provision of subsidized pre-packaged medicines coupled with diagnostics attracted more clients to the outlets which ultimately helped to generate good revenues from the high sales [23, 213]. To the regulator, the pre-packaging of medicines into recommended doses was a welcome initiative for it helped to address the long-held complaint against drug sellers that they provide incomplete dosages because providers prefer to normally dispense based on funds that clients present with [13, 17]. Pre-packaging, color-coding, and identification also helped drug sellers to easily provide instructions for administering the medicines by caretakers some of whom were illiterate [268]. Finally, to the care-seekers, the prices were low, the diagnostic services were free, and the medicines had good characteristics such as flavour that made them easy to administer to children. The pre-packaging also helped caretakers to easily follow the medicine prescriptions [269]. Among the therapy-related factors that influence therapeutic compliance, treatment complexity and bad taste of medication can significantly undermine compliance, resulting in negative health outcomes for the affected individual[270]. Caretakers reported that the pleasant flavours and tests of the medicines made the medicine more acceptable for the children. The intervention also created an opportunity for the different actors to work together in a more supportive and complementary manner rather than in a combative mode. For example, providers were able to interface with regulators and this cultivated a relationship based on trust and mutual support, and trust between and within actors is a precursor to better performance [271].

Finally, multi-component interventions like the AXEX are inherently complex to implement let alone evaluate. To this end, we argue that retail providers or drug shops are part of the broader health system that has a myriad of actors who are driven by incentives. Attempts to adjust behaviour of a single actor or system component can create feedback loops and unpredictable behaviour within other components or actors to stimulate outcomes that could either be anticipated or unanticipated [272]. In evaluating the AXEX intervention, we adopted a process evaluation approach which provided an opportunity to account for the implementation process as well as the outcomes both intended and unintended.

5.6. CONTRIBUTION TO KNOWLEDGE

This research contributes to understanding the medicines retail market (MRS) in South Western Uganda concerning the structure, operations, and incentives that influence the market dynamics and the ultimate effect on behaviour and practices of the market actors and the nature of services provided. Some studies on informal markets and retail drug shops in Uganda and other LMICs have mostly focused on the quality of services provided by retail drug shops, and informal health sector regulation. Other studies have focused on issues of introducing rapid diagnostic technologies in retail drug shop and quality of care, the effect of training and capacity building for providers on the quality of care, and more recently new models of regulation and supervision, among others [23, 28, 113, 114, 130, 202]. This thesis adds to this literature but also specifically provides information to aid a better understanding of characteristics of the retail drug outlets and their operators and the broader medicines retail market in Uganda, what motivates their establishment and operations, and the implication for health service provision. The thesis also provides an understanding of how best to design an intervention aimed at improving retail sector practices and services, and specifically that a market-based intervention must have an embedded incentive structure that has the potential to alter the behaviour of market actors for positive action. The use of a framework grounded in the Conduct Performance (SCP) paradigm of industrial organizations and the health market systems framework, helped to illuminate different factors that influence market performance and the various actors, stakeholders, and role-bearers that influence retail market performance. The frameworks further helped to elucidate how health systems are not only interlinked but also complex and that action in one component of the system has the potential to alter outcomes in peripheral components that were not a target of the intervention. Therefore, given that most of the children in many LICs access essential care through private retail outlets and markets, improving the provision, access, and utilization of quality care through the retail market is critical to reducing child mortality and contributes to the achievement of the UHC goal. However, achieving this requires a broader understanding of the structure of the market itself, the actors and stakeholders, the motivations for actions of actors, and the importance of these aspects in stimulating positive behaviour and actions towards the desired goals.

5.7. METHODOLOGICAL CONSIDERATIONS

This thesis used a mixed-methods approach where both qualitative and quantitative methods of data collection, analysis, and reporting was applied. There was a concurrent application of the various quantitative and qualitative methods across the sub-studies of this thesis including drug shop survey, care-seeker exit interviews, IDIs, and FGDs, which helped to triangulate, validate and lend credence to the results in this thesis. Sub-study III specifically adopted the quasi-experimental approach to present results on the effect of the iCCM intervention on the availability and affordability of care offered at private retail drug shops. Although this study design may not be considered the gold standard in providing robust inferences, sub-study III (paper III) of this thesis was able to apply it to demonstrate the effect of the intervention on availability and affordability.

While it is possible that by the very nature of a quasi-experimental non-randomized design, there are additional potential factors that could account for certain outcomes, the application of the DiD analysis may have partly addressed this concern. There were additional tests such as the t-test and t-exact test that were employed to test the extent of the claimed effect between the intervention and

comparison districts for some specific outcomes such as availability of care. Each of the sub-studies in this thesis had peculiar limitations that are presented in the specific papers appended. Broadly, however, the following limitations should be noted:

First, the sample size that was considered for the studies in this thesis may not have been reasonably large. A maximum sample of 74 retail drug shops was considered before the intervention (intervention district=40, comparison district=34) and 48 retail drug shops after the intervention (intervention district=32, comparison district=16). This may undermine the generalizability of the results given that even within the two study districts only drug shops located in the rural areas were considered for the study. In fact, sub-study II drew heavily on a sub-sample of 20 retail drug shops to explore the motivations and incentive structure of retail medicine markets, although we believe that drawing from both quantitative and qualitative lines of inquiry helped to enrich the data and provide the needed power to draw conclusions from the data. Furthermore, I believe that given that the findings are generally consistent with the results of studies from many others low-income settings, they contribute to the knowledge base.

Second but related, was the enrolment of only registered and licensed retail drug shops in the study and leaving out the unregistered and unlicensed ones. A survey of drug shops in rural areas of Uganda in 2010 found that only about 23% were registered [104]. This statistic may not have changed significantly in subsequent years. In fact, a more recent study of 123 licensed and unregistered drug shops in Eastern Uganda reported that up to 76% of the studied drug shops were unlicensed [197]. Leaving unregistered drug shops out of the study constrained eliciting views from the unlicensed but operational outlets. It would have been interesting to understand why they remain unlicensed but continue to operate, and probably how they circumvent the rules. There are anecdotal views in some settings that reflect fears among retailers that the more they attempt to formalize their businesses through acquiring licenses, the more they become alienated from their traditional market segments, and become less flexible. Once they formalise, the regulations will force them to play by the rules, thus, losing their appeal and the very reasons why they are attracted to and preferred by communities. This information is critical to improving the regulatory system and assuring the quality of services. The ethical and moral considerations could not, however, allow the inclusion of this category of providers, because including them in the study could easily be (mis)interpreted for encouraging them.

Third, the reliance on drug seller interviews for most quantitative data on prices, costs, and sales data could have opened up for recall bias and related challenges of self-reporting. However, to mitigate this limitation, we used a reference period of one week before the survey, as many studies that rely on this method have often been done, coupled with in-depth interrogation of respondents to correct any inconsistencies in reporting.

Fourth, the approach used in measuring the effect of the iCCM intervention on availability and affordability of paediatric medicines assumes "affordability" is uniform across the diversity of care-seekers, which may not be an accurate assumption. In addition, the aspect of self-report affordability is subjective and dependent on household socio-economic status as well as product that was being bought, because the products and their quantities were not standardized. Although perceptions were used to validate the quantitative measures of affordability in this study, there may not be accurately relied on to conclude on affordability of medicines.

Fifth, the data used in applying the DiD methodology used to measure or estimate the causal effect for the intervention particularly on affordability may have been of low quality to generate a very robust

assessment, and this may have affected the reliability of the results and the conclusions emerging from this assessment. However simplistic the analysis may have been, it still provides pointers to how such interventions could influence market incentives and practices to the detriment or benefit of the community.

Sixth, as already alluded to, the AXEX intervention study adopted a non-randomized quasi-experimental design. This implies that without randomization and matching, it is possible that bias could have been introduced in the study, and sub-study III, which utilized this design may have been susceptible to possible selection bias. However, we mitigated this by doing a DiD analysis particularly using data from care-seeker exit interviews at two data points - baseline and end-line - to examine how consistent the results were on ratings of medicine affordability. However, an additional qualitative analysis (sub-study IV) done also reported consistent views and perceptions from stakeholders on the effect of the intervention on the affordability of paediatric medicines.

Finally, care-seeker exit interviews used in sub-studies I, II, III were captured at selected retail drug shops that represented clusters. In fact, the detailed investigation on motivations and incentives of drug shop markets on which sub-study II was based, was conducted at the 20 randomly selected clusters (drug shops). Retail drug shops were considered clusters because they serve a particular definitive community. Besides, the cluster sizes were not uniform, for example, whereas there were definitive numbers of interviews expected to be conducted per cluster, there were some variations due to unforeseen circumstances and so different clusters returned varying amounts of care-seeker exit interviews. As often reported in other studies, clustering may influence results including reducing the size of the confidence interval and could ultimately generate wrong conclusions [273]. A clustering effect was anticipated in our sub-study III wherein, given that a definitive community is served by the same drug shop, the responses elicited through the exit interviews about the operations of the drug shop are likely to be similar. However, adjustments for the likely clustering effect were made in the construction of the sample size, but also at the level of analysing the exit interviews.

5.8. CONCLUSIONS

1) Most registered shops surveyed operated in environments that generally meet the minimum National Drug Authority (NDA) guidelines, are operated by drug sellers with health-related training, and their stocking and dispensing practices, are largely influenced by market factors; including client demand and preferences, client finances, and the profitability objective.

2) While the need to earn profit was a significant motivator for retail drug shops, there are additional social benefits that accrue to drug shop operators including social recognition, expanded social networks, and a positive feeling of service to the community. In some circumstances, the social motivations generate intrinsic pressure that stimulates positive provider behaviour and action.

3) The regulatory system and framework for the retail drug shop market exist, and all key players appreciate its role. However, the system is weak, under-resourced, and not well structured to carry out its regulatory mandate. There were reported constraints to licensing, monitoring, and supervision, and in some cases, regulatory actions tended to stimulate perverse incentives to compliance.

4) Implementing iCCM at retail drug shops improved availability and affordability of treatment for uncomplicated malaria, pneumonia symptoms, and non-bloody diarrhoea among under-

five children in a relatively low malaria transmission setting of South Western Uganda.

5) Identifying and implementing an appropriate package of market-based incentives and consumer empowerment actions can improve retail market practices and assure better health care provision as well as protect the public against negative practices that are detrimental to public and population health in a pluralistic health system.

6) Retail drug shops are part of a complex health system with multiple components and actors whose actions are influenced by multiple factors. The success of the AXEX intervention owes itself to the multi-component nature of the intervention which enabled the inclusion of different intervention packages each targeted at different actors and having different effects but all contributing to the objective of improving health care service delivery within the retail health market.

5.9. RECOMMENDATIONS FOR POLICY AND PROGRAMMING.

For Uganda to achieve the UN SDG 3.2, which is concerned with reducing neonatal and under-five mortality rates, a broad range of actors needs to be involved in the spirit of leaving no one behind. Relatedly, context-specific interventions and strategies must be designed and implemented to ensure that the benefits of ICCM are able to reach a broad spectrum of target populations. In the Ugandan context, informal health care providers specifically retail drug shops form an important part of the health service delivery spectrum that is critical to achieving SDG 3.2, given the extent of health care it provides particularly for childhood illnesses. Therefore, this thesis recommends the following if Uganda is to harness the contribution of the private retail drug shop market towards achieving the SDG 3.2.

1) Ministry of Health should involve the private retail drug shops in the implementation and scale-up of iCCM through the existing public - private-partnership framework to improve access to essential and quality care for children especially in rural communities of Uganda

2) The Ministry of Health together with implementing partners should support retail drug shops to improve their service delivery, including through the provision of diagnostic technologies to strengthening their diagnostic capacities for better quality and appropriate care.

3) The Ministry of Health and the National Drug Authority should streamline the drug shop or retail health market regulatory system. This should include the provision of adequate resources and capacity building to the regular – NDA, to ensure regular monitoring and support supervision, bringing all stakeholders together to discuss an appropriate regulatory approach, and ensuring constant information and communication between the NDA and the drug shops.

4) The National Drug Authority should work with communities where drug shops are located, for those communities to support the monitoring and supervision efforts and regularly report any observable provider malpractices. Related, the National Drug Authority as a regulator should explore the feasibility of encouraging the establishment of provider associations where peer-to-peer supervision could be adopted. The Involvement of local communities and peer associations will strengthen monitoring and supervision to eliminate any possible malpractices.

5) The Ministry of Health should fully integrate retail drug shops in the larger health care delivery system because what happens in the retail health market affects other components and service

delivery points of the health care system. Retail drug shops should be seen as complementary and not necessarily competitive entities to the formal health providers and therefore need to be supported rather than 'harassed'.

6) The Ministry of Health together with implementing partners should support retail drug shops by providing market incentives such as subsidizing essential medicines and supplies. This would make retail prices affordable to care-seekers yet also ensure sufficient profit to incentivise providers to make essential medicines available and accessible.

7) The Ministry of Health working together with the National Drugs Authority, and the local governments (districts) should build the capacity of drug sellers through continuous on-the-job training support that is tailor-made to their needs. This will ensure that they are up-to-speed with new products, technologies, and dispensing practices and guidelines, so as improve quality and safety of services provided.

AREAS FOR FURTHER RESEARCH

Further research in this area should, among others; focus on:

1) Identifying feasible mechanisms of involving communities and provider associations in retail health market regulation.

2) Identifying appropriate mechanisms or models of controlling prices charged by retail providers to ensure a balance between affordability and business sustainability

3) Comparing the operational characteristics of unregistered and registered drug shops, exploring the reasons why most drug shop outlets continue operating informally even when rules and guidelines exist, but also how they circumvent or 'game' regulation to continue in operation. While studying informal or unregistered outlets does present ethical challenges, it's a pragmatic step to understanding the reality on the ground so that feasible and practicable policy prescriptions can be designed and implemented.

4) Conducting an economic and value chain analysis on provisions of essential drugs/diagnostics in the context of costs and profitability considerations and the implications of these on private retail provider behavior. This analysis should include an investigation on whether mark-ups and profitability varies by type of medicine, location, demand or supply chain constrains, among others.

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Appendices

Appendix A: Ethical Clearance Certificate -Wits University HREC

R14/49 Mr Mayora Chrispus

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M151014

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DEPARTMENT:	School of Public Health Mbarara and Bushenyi Districts, South Western Uganda
PROJECT TITLE:	Intervening in Private Markets for Health : Case of Retail Drug Shops in Intergrated Community Case Management for Under-five Febrile Children in Rural Uganda
DATE CONSIDERED:	30/10/2015
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Dr Aziza Mwisongo
APPROVED BY:	Professor P. Cleaton-Jones,Chairperson, HREC (Medical)
DATE OF APPROVAL:	01/06/2016

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DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004,10th floor, Senate House/2nd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/We fully understand the the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated,from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. in this case, the study was initially review in October and will therefore be due in the month of October each year.

Principal Investigator Signature

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RESEARCH ARTICLE Open Access

Private retail drug shops: what they are, how they operate, and implications for health care delivery in rural Uganda

Chrispus Mayora[1,5*], Freddy Eric Kitutu[2,3], Ngianga-Bakwin Kandala[1,4], Elizabeth Ekirapa-Kiracho[5], Stefan Swartling Peterson[3,6] and Henry Wamani[7]

Abstract

Background: Retail drug shops play a significant role in managing pediatric fevers in rural areas in Uganda. Targeted interventions to improve drug seller practices require understanding of the retail drug shop market and motivations that influence practices. This study aimed at describing the operational environment in relation to the Uganda National Drug Authority guidelines for setup of drug shops; characteristics, and dispensing practices of private retail drug shops in managing febrile conditions among under-five children in rural western Uganda.

Methods: Cross sectional survey of 74 registered drug shops, observation checklist, and 428 exit interviews using a semi-structured questionnaire with care-seekers of children under five years of age, who sought care at drug shops during the survey period. The survey was conducted in Mbarara and Bushenyi districts, South Western Uganda, in May 2013.

Results: Up to 90 and 79% of surveyed drug shops in Mbarara and Bushenyi, largely operate in premises that meet National Drug Authority requirements for operational suitability and ensuring medicines safety and quality. Drug shop attendants had some health or medical related training with 60% in Mbarara and 59% in Bushenyi being nurses or midwives. The rest were clinical officers, pharmacists. The most commonly stocked medicines at drug shops were Paracetamol, Quinine, Cough syrup, ORS/Zinc, Amoxicillin syrup, Septrin® syrup, Artemisinin-based combination therapies, and multivitamins, among others. Decisions on what medicines to stock were influenced by among others: recommended medicines from Ministry of Health, consumer demand, most profitable medicines, and seasonal disease patterns. Dispensing decisions were influenced by: prescriptions presented by client, patients' finances, and patient preferences, among others. Most drug shops surveyed had clinical guidelines, iCCM guidelines, malaria and diarrhea treatment algorithms and charts as recommended by the Ministry of Health. Some drug shops offered additional services such as immunization and sold non-medical goods, as a mechanism for diversification.

Conclusion: Most drug shops premises adhered to the recommended guidelines. Market factors, including client demand and preferences, pricing and profitability, and seasonality largely influenced dispensing and stocking practices. Improving retail drug shop practices and quality of services, requires designing and implementing both supply-side and demand side strategies.

Keywords: Private sector, Retail market, Drug shops, Under-five children, Health care

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Background

Private retail drug shops play a significant role in health service delivery in low and middle income countries. Drug shops are small 'walk-in' health care shops that sell over-the-counter drugs. Sometimes drug shops sell other products other than medicines. A number of studies have indicated that in many low and middle income countries, retail drug shops are critical in providing health care services, and more so for common childhood illnesses [1]. In Togo for example, only less than 20% of under-five sick children visit the health facility, and up to 83% are managed at home using medicines procured from the retail market [2]. In Nigeria, more than 60% of malaria patients obtained their medication through patent medicine vendors (PMVs) – an equivalent of drug sellers [3, 4]. In Uganda and Tanzania, a sizeable amount of antimalarials are accessed through the retail sector market [5, 6]. Between 40 and 70% of pediatric fevers in Uganda are managed at retail drug shops, especially in rural areas. Retail drug shops are utilized as first points of call for health care for sick children especially in rural and geographically constrained communities [7–9]. The evidence on the extent of utilization of private retail sector by different socioeconomic groups is mixed, and largely context driven. There are reported variations in utilization of retail drug shops across and within countries. However, in urban areas, private retail sector services were more likely to be utilized by higher socioeconomic groups, compared to rural locations, where the private retail sector is commonly used by the lower socioeconomic groups [10].

The prominence of retail drug shops owes itself to existing constraints in access to public health services, including: long distances, household poverty, and limited or even lack of well-functioning public health facilities in some geographical areas – characterized by inadequate health workers, drug stock outs, and perceived poor quality services [6, 9, 11–16]. Retail drug shops are perceived to be accessible, convenient, flexible in terms of operating hours, offer credit facilities, trusted by communities, and are perceived to provide services at lower costs [15, 17–19]. However, there are also concerns about the quality of services retail drug shops provide. For example, there are reports that most drug shop attendants are unqualified and lack adequate knowledge and capacity to appropriately identify illnesses and offer appropriate treatment for illnesses, stocking and dispensing substandard, counterfeit, or even expired drugs, among others [1, 9, 20].

Notwithstanding the reported challenges, retail drug shops are a potential way to increase coverage of health services and achieve universal health coverage (UHC). Retail providers could relieve pressure off a health care system that is struggling to deliver comprehensive health services amidst resource challenges. The Global Fund's Affordable Medicines Facility Malaria (AMFm) conducted pilot program in eight countries, including Uganda, to test the feasibility of subsidizing medicines through the private sector on availability, affordability and access to medicines. Results from this AMFm pilot, indicated that, indeed, subsidizing medicines provided through the private sector can improve availability, affordability, and access, to medicines particularly for childhood conditions [21].

In Uganda, drug shops are recognized within the health care system as part of the private for profit (PFP) sector. Retail drug shops are registered, licensed and regulated by the national drug authority (NDA). Drug shops are classified as 'C' (permitted to sell a restricted list of medicines, including some antimicrobial formulations). Although drug shops are expected to be registered and licensed before they start operations [22], this sometimes is not the case. In addition, while the NDA Act stipulates the type of cadre supposed to run the drug shops, often times, there is lack of consistent enforcement and compliance. Sometimes drug shops to present qualified personnel when seeking for accreditation and thereafter recruit unqualified ones once licensure processes are complete. It is therefore not uncommon to find untrained staff working in drug shops in addition to stocking medicines that are not recommended for those classes or drug shops.

While retail drug shops have proliferated in the recent past especially in low and middle income countries, not much attention has been paid to them [23]. In Uganda, studies have focused more on understanding the role of retail drug shops, quality of services provided, feasibility of using rapid diagnostics at drug shops, delivering family planning products through drug shops, among others [9, 24–28]. However, in Uganda, there is limited information on the structure and operational characteristics of the retail drug shop market. Yet, this would provide an important starting point for designing feasible interventions aimed at improving the potential of retail drug shops to provide appropriate and quality services. The aim of this paper was to characterize private retail drug shops, their operational environment, as well as elicit factors that influence their day-to-day decisions in the management of febrile conditions among children less than five years old in rural South Western Uganda.

Methods

This study used data collected as part of the baseline survey conducted as part of a research project implemented by Makerere University School of Public Health (MakSPH), entitled – "ACCESS and EXCESS, EQUITY and INFORMATION: Point of Care Diagnostics and Pre-packaged Subsidized Drugs for Integrated Fever

Management for Malaria, Pneumonia and Diarrhea in Children at PRIVATE SECTOR Drug Shops in Uganda" In brief, the research project aimed to test the feasibility and effect of implementing integrated community case management (iCCM) for childhood illnesses, on pediatric care, at licensed retail drug shops in a low malaria transmission setting in Uganda. The baseline survey was conducted in May 2013, among licensed and operational retail drug shops in two districts of Mbarara and Bushenyi, in South Western Uganda. More detailed information about the research project has been published elsewhere [19, 28]. In the study area, health services are provided through public health facilities, private-not-for profit facilities, private hospitals and clinics, pharmacies, retail drug shops, and sometimes the traditional medicine providers. The districts health system is superintended by the district health teams (DHT) with the district health officer (DHO) as the overall technical head. The registration, licensure, accreditation, and regulation of retail drug shops is the mandate of the National Drugs Authority (NDA) which delegates authority to the District Drugs Inspector of each district (DDI). Among others, applicants intending to open up drug shops are required to present certificates of qualification for intending in-charges, letter of commitment from the in-charge, suitability of the premises, among others [22]. In terms of epidemiology, the prevalence of malaria among children (0–59 months) in this region (South Western Uganda) is reported to be 5.7% (by Rapid Diagnostic Tests (RDT)) and 4.1% (by Blood Smear Microscopy (BSM)) which is significantly lower than the national averages of 30% (by RDT) and 19% (BSM), among the same group. The same national malaria survey indicates that malaria prevalence was high in rural areas (10.1% for Urban versus 32.4% for rural, by RDT, compared with 6.3% for urban versus 22.3% for rural, by BSM) compared to the urban counterparts [29]. The study area is a rural setting with socioeconomic and infrastructural challenges of access to formal health care services. Therefore, retail drug shops have emerged to fill the gap in availability health care facilities within reach.

Sampling and sample size

A total of 217 drug shops in the study area were assessed for eligibility. The list was obtained from the National Drug Authority (NDA) register available at the District Drug Inspector (DDI). More detail on assessing the drug shops for inclusion in research project has been described elsewhere by kitutu et al. [28]. The eligibility for participation required that drug shops had to be in the rural area, functional, dealing with human drugs, and acceptance to participate in the survey. In Mbarara, out of 152 drug shops, only 61 drug shops met the inclusion criteria, but 40 accepted to participate in the survey. In Bushenyi, 65 drug shops, were eligible, and data was collected from 34 drug shops. Therefore, a total of 74 registered, licensed, and functional retail drug shops were included in this study. During the survey, drug shop attendants were interviewed. In addition to the drug shop attendants' interviews, exit interviews were conducted with caretakers of children under five years of age who had come to purchase medicines from the drug shop during the study period. Taking drug shops as clusters, and using the Bennet cluster sampling method [30], 428 exit interviews conducted at 24 clusters were estimated. However, only 12 and 10 clusters in Mbarara and Bushenyi Districts, respectively, were covered during the exit interviews. At each selected drug shop, an average of 20 exit interviews were conducted.

Data collection

Data for this study was collected at baseline (May, 2013) through a drug shop survey where drug shop attendants were interviewed using a semi-structured questionnaire that collected information on drug shop characteristics and practices: ownership, training of attendants, commonly stocked medicines, stocking, prescription and dispensing decisions, among others (see Additional file 1). Respondents in the exit interviews were caretakers of children under-five years of age that came to seek care or to purchase medicines for febrile conditions. These were contacted immediately as they left the drug shop and interviewed at a convenient place within the vicinity of the drug shop, so as not to allow drug seller's interference. The structured exit interview questionnaire specifically elicited additional information on client characteristics, drug shop diagnostic, prescription, and treatment practices, as well as client decisions around the drug shop use, nature of illness, onset of illness and time taken to make a decision to seek care, among others (see Additional file 2). All data collection tools were translated into, and interviews conducted in Runyankore, the local language used in the study area. Research assistants were selected from the study districts (local area), because it was necessary to have individuals who spoke and understood both local language and English. For exit interviews, interviewers were stationed at locations near drug shops all through the exit interview period. Exit interview respondents were recruited consecutively after they exited the drug shops, and interviewed if they accepted to participate. Interviewers also observed or checked the medicines provided to clients to verify the responses to posed questions.

Analysis and quality control

Research assistants were trained for two days and a pilot conducted before embarking on full data collection. All data were checked for completeness and accuracy by the

group supervisor, at the end of every data collection day. Data was double-entered in epi data (http://www.epidata.dk) and was analyzed using STATA version 12 (http://www.stata.com). All data entry, cleaning and transfer processes were supervised by the lead author for purposes of quality control. This study adopted first level descriptive analysis, to generate and report results in terms of means and proportions of variables. Appropriateness of treatment was assessed through exit interviews based on reported symptoms and medicines provided. It is common practice for care-seekers not to come with sick children to the drug shop, and instead drug sellers rely on description of symptoms by the caregiver. Clients were asked at exit, what diagnostic processes had been conducted, and in some cases what symptoms had been reported. The interviewers then checked medicines they had been provided including their dosages, frequency of use, and other indications. The reported symptoms and medicines dispensed were then compared with national and WHO guidelines [31, 32]. Particular variables or characteristics under study were analyzed and compared across the two study groups (districts) using a chi-square test, to understand if the study characteristics differed significantly across the two study groups. We presented *p*-values from the corresponding chi-square tests, with a p-value of < 0.05 being considered statistically significant.

Ethical considerations

This study used data collected through a baseline survey conducted as part of a research project implemented by MakSPH whose ethical approval was obtained from the Uganda National Council for Science and Technology (UNCST) (#HS1385), and the MakSPH Higher Degrees Research Ethics Committee (#IRB00011353). In addition, this particular study was approved by the University of Witwatersrand Human Research Ethics Committee (HREC) (#M151016). Further permission was obtained from the National Drugs Authority (NDA) and the Local Government authorities for the two districts. Written consent was obtained from drug sellers and exit clients who participated in this study.

Results

Characterizing drug sellers and care-seekers of children under five years of age who use retail drug shops

We profiled the drug shop attendants and the care-seekers of under-five children who came to seek care and purchase medicines at the retail drug shop during the survey period, based on selected socioeconomic indicators, such as training, education status of clients, and incomes. Results showed that the real owners of drug shops attended to 26 and 65% of the drug shops surveyed in Mbarara and Bushenyi respectively (Table 1). Most drug shop surveyed, were attended to by nurses or midwives, and the rest were nursing assistants, laboratory technicians, pharmacists, and clinical officers.

Retail drug shop operational environment and other services provided

The quality of medicines and other services provided by retail drug shops is partly related to the physical environment of the drug shops. The National Drug Authority (NDA) Act recommends that medicine stores should be free from moisture, direct sunlight, and other exposures. Medicine storage and exposure to moisture influences the quality and efficacy of medicines. This study investigated – through interviews and using an observational checklist – the physical conditions under which retail drug shops operated. In Table 2, most drug shops adhered to the guidelines specified in the NDA licensing guidelines. Most surveyed drug shops had storage area for medicines secured against thefts, direct sunlight, and moisture, had ceilings and controlled room temperatures, among others, although additional improvements could be made. Beyond, the sale and dispensing of medicines, some (12%) retail drug shops in Bushenyi offered immunization services, over two-third of drug shops in both districts offered Vitamin A supplementation, while others sold deworming, soft drinks, toiletries, cosmetics products, mobile telephone credit, among others.

Common signs and symptoms reported at drug shops

Based on results from the exit interviews, the common signs and symptoms that were reported at drug shops by care-seekers of children under five years of age, for which they came to seek medication were: fever (239/428 or 56%), cough (281/428 or 66%), rapid or difficult breathing (86/428 or 20%), and diarrhea (114/428 or 27%). Other common childhood illness signs and symptoms reported at retail drug shops accounted for 101/428 (24%).

Common medicine stocks and stocking decisions

From drug shop attendants' interviews and observations, this study found that the common medicines stocked by retail drug shops included Paracetamol, cough syrup, Amoxicillin dry syrup, Quinine, ORS/Zinc, and Artemisinin-based Combination Therapies (ACTs), among others (Fig. 1). Drugs shop attendants were asked to elicit the factors they put under consideration when deciding what medicines to stock at a particular point in time. The main factors were reported to be, consideration of Ministry of health recommended drugs (54%), medicines commonly demanded by clients (70%), most profitable medicines (26%), and seasonal disease patterns (30%) and the influence of sales agents from pharmaceutical companies (19%) who sometimes move around communities and small local towns selling medicines and other pharmaceutical products.

Table 1 Characterizing drug shop attendants and care-seekers of children under five years seeking care from retail drug shops

Drug seller Characteristics	Mbarara (*N* = 40)	Bushenyi (*N* = 34)			
	n (%)	n (%)	*P*-value*		
Who attends to the drug shop					
Owner	10 (25.6)	22 (64.7)	< 0.00		
Highest level of training for drug shop attendant interviewed					
Clinical Officer	8 (20.0)	5 (14.7)			
Nurse/Midwife	24 (60.0)	20 (58.8)	0.73		
Others*	8 (20.0)	9 (26.4)			
Monthly salary earnings for drug shop attendants interviewed					
USD 9 – USD 44	24 (80.0)	34 (100.0)			
USD 45 – USD 88	16 (20.0)	0 (0.00	< 0.00		
Care-seekers' characteristics (Exit interviews)	Mbarara (*N* = 212)		Bushenyi (*N* = 216)		
	n (%)	95% CI (in %)	n (%)	95% CI (in %)	*P*-value*
Highest level of education of care-seeker					
University	2 (0.95	[0.2, 3.7]	4 (1.8)	[0.69, 4.8]	
Tertiary	2 (0.9)	[0.2, 3.7]	13 (6.0)	[3.51, 10.1]	
High School	7 (3.3)	[1.5, 6.8]	7 (3.2)	[1.54, 6.6]	
O-Level	59 (28.1)	[22.4, 34.5	76 (35.1)	[29.07, 41.8]	< 0.00
Primary	123 (58.5)	[51.7, 65.0]	109 (50.4)	[43.79, 57.1]	
None	17 (8.1)	[5.0, 12.6]	7 (3.2)	[1.54, 6.6]	
Employment status of care-seeker	(*n* = 209)		(*n* = 214)		
Unemployed	8 (3.8)	[1.9, 7.4]	40 (18.6)	[13.92, 24.4]	
Housewife	25 (11.9)	[8.1, 17.0]	53 (24.6)	[19.32, 30.8]	< 0.00
Self-employed	92 (43.8)	[37.2, 50.6]	87 (40.4)	[34.07, 47.1]	
Civil Servant	5 (2.3)	[0.9, 5.6]	5 (2.3)	[0.96, 5.4]	
Others	80 (38.1)	[31.7, 44.8]	29 (13.4)	[9.51, 18.7]	

**P* values presented are derived from chi-square, and it is comparing indicators across the two study groups (districts)

Drug shop attendants' dispensing decisions

Drug sellers' decisions about what medicines to dispense, were mainly influenced by among others; prescriptions that some clients come with (47%) (Prescriptions are sometimes provided at public health facilities), amount of funds that a client comes with at the drug shop (30%) and client's patient preferences for particular medicines (12%), among others (Fig. 2). However, drugs shop attendants were asked what decisions they made in cases where clients did not have enough finances to procure the recommended medicines and dosages, drug sellers reportedly offered additional medicines on credit (69%), offered cheap alternatives (18%), or referred the client elsewhere (27%) (Results not shown).

Appropriateness of treatment practices by retail drug shops

We used exit interviews to understand treatment practices of drug sellers, particularly the use of appropriate diagnostics and prescription of medicines. We found limited use of diagnostics – malaria rapid diagnostic tests (RDTs), respiratory count timers, and thermometers. Only about 21% care-seekers who brought sick children reported having been diagnosed with RDTs, 21% with thermometer, and no child had their breathing rate counted using a respiratory timer. Relating the symptoms reported by care-seekers and medicines given at client exit, based on the Uganda iCCM Guidelines [32], and World Health Organization Guidelines on rationale medicines use [31], the study found only 4% had received correct antibiotics, 39% had received antimalarials (ACTs), and 57% had received correct diarrhea treatment. A number of retail drug shops surveyed however, had clinical guidelines, iCCM guidelines, malaria and diarrhea treatment algorithms and charts.

Discussion

In this study, we sought to characterize the private retail drug shops, explore their operational environment, as well as elicit factors that influence their day-to-day decisions in the management of febrile conditions among children less than five years old in rural South Western

Table 2 Operational environment and other services provided by retail drug shops

Variables at baseline ($n = 74$)	Mbarara District ($n = 40$) Number of drug shops (%)	Bushenyi District ($n = 34$) Number of drug shops (%)	*P*-value
Drug shop environment/ conditions			
There exists a ceiling to control room temperature	40 (100.0)	28 (82.3)	< 0.00*
There are windows that can control aeration	29 (72.5)	15 (44.1)	< 0.01*
No direct sunlight to area for keeping medicines	40 (100.0)	33 (97.0)	0.27
Medicine store free from moisture from leaks	37 (92.5)	27 (79.4)	0.10
Premises can be secured to prevent theft	38 (95.0)	32 (94.1)	0.86
Other services provided by drug shops			
Immunization Services	0 (0.0)	4 (11.7)	0.02*
Vitamin A supplementation	31 (77.5)	23 (67.6)	0.34
Deworming	4 (10.0)	5 (14.7)	0.53
Reporting adverse drug reactions	18 (45.0)	12 (35.2)	0.39
Presence of treatment guidelines			
Uganda Clinical Guidelines	16 (40.0)	22 (64.7)	0.03*
iCCM Guidelines	6 (15.00	9 (26.4)	0.22
Malaria treatment algorithms/charts	17 (42.5)	15 (44.1)	0.88
Pneumonia treatment algorithms /charts	2 (5.0)	5 (14.4)	0.15
Diarrhea treatment algorithms/charts	12 (30.0)	15 (44.12	0.20
Other products traded at drug shops			
Soft drinks	4 (10.0)	1 (2.9)	0.22
Toiletries	4 (10.0)	2 (5.8)	0.51
Household goods	1 (2.5)	0 (0.0)	0.35
Mobile airtime	3 (7.5)	1 (2.94	0.38
Cosmetics	1 (2.5)	0 (0.0)	0.35
Food items	0 (0.0)	2 (5.8)	0.12

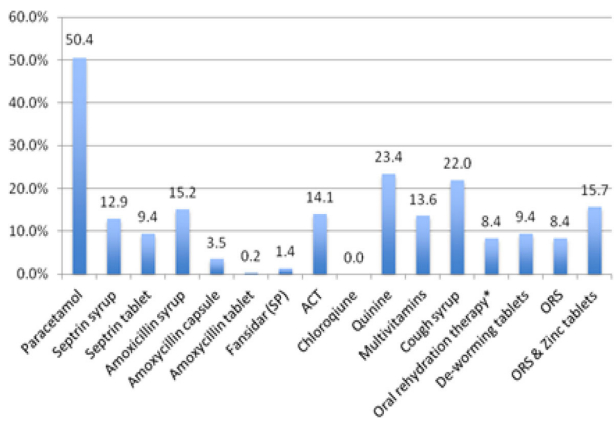


Fig. 1 Commonly stocked medicines by retail drug shops at time of survey. *ACT = Artemisinin-based Combination Therapies, SP=Fansidar, ORS=Oral Rehydration Solution.

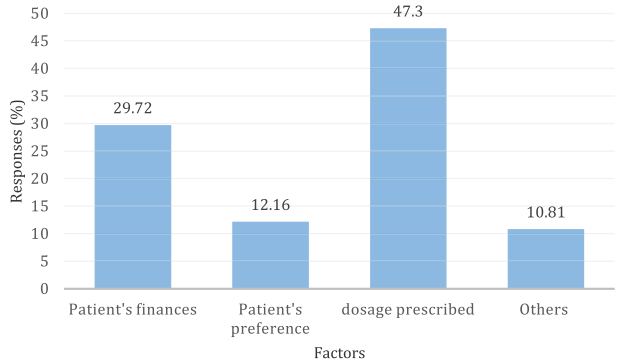


Fig. 2 Factors influencing drug sellers' dispensing practices

Uganda. Although the study focused on one segment of the retail health market – the registered retail drug shops – the results presented have indeed revealed interesting features of the retail drug shops, which are significant for policy and programming. The main findings indicate that most surveyed retail drug shop premises met the NDA requirements of setting up premises that deal in medicines. These guidelines were established to assure medicines safety and quality. Drug sellers had health-related qualification with majority being nurses or midwifes. The most commonly reported and managed childhood illness signs and symptoms at drug shops were fever, cough, rapid or difficult breathing, and diarrhea. It was also found that retail drug shops commonly stocked Paracetamol, Quinine, Cough syrup, ORS/Zinc, Amoxicillin dry syrup, Septrin® syrup, Artemisinin-based Combination Therapies, and multivitamins. Decisions on what medicines to stock were influenced by among others, Ministry of Health recommended medicines, medicines demand, most profitable medicines, and seasonal disease patterns. Relatedly, dispensing decisions were influenced by among others: prescriptions presented by the client, patients' finances, and patient preferences**.** In response to clients with insufficient resources, drug sellers either offered credit depending on the relationship and trust cultivated overtime, or offered cheaper product alternatives.

Our finding that most of drug sellers (attendants) had health related qualifications – with the common qualification being nurses or midwifes, and clinicians, could be related to the fact that only registered drug shops were enrolled for the survey, owing to the legal and policy challenges that would arise by engaging un-registered and hence unauthorized entities. It is not uncommon during registration and licensure to ensure drug sellers with appropriate qualification are responsible, otherwise a license may never be granted. It is relatively complex to enforce such requirements for unregistered drug shops that are essentially operating illegally. It is important however to note that while the new NDA Professional Licensing guidelines 2018 [33] allow nurses, midwives, and Pharmacy Technicians or dispensers to attend to human drug shops, within the context of Uganda's medical training system, nurses and midwives had no special training that would aid them to prescribe medicines. For long, it had been Pharmacy Technicians who were allowed these roles, but with the current health workforce challenges that characterize Uganda, manifesting in chronic shortages for human resources for health, this may not be possible. The training and skills of drug sellers or attendants has a significant bearing on the quality of services offered at retail drug shops. Mbonye and colleagues, found professional qualification of a provider to be highly associated prescriptive practice, with lower cadre staff (nursing assistants and enrolled nurses) overprescribed antibiotic [34]. There are other studies that have reported gaps on training and skills of drug sellers [35, 36] However, with minimal complementary training and capacity building support for example through continuous training, monitoring and onsite support supervision, drug sellers could improve their treatment and dispensing practices and hence improve quality of care provided [9, 37, 38].

Our study found that most drug shop premises met the NDA requirements allowed for premises that operate drug shops. We found that most surveyed drug shops had secure drug storage, medicines were protected against moisture and sunlight, and drug shops operated under controlled room temperature. Appropriate conditions for storage and dispensing of medicines are critical in maintaining their quality and safety during their shelf life. We found that some drug shops provided additional services and products beyond medicines, including soft drinks, mobile phone credit, deworming,

and immunization services. For the few drug shops that provided immunization services, additional storage capacities for vaccines (e.g. refrigeration and cold chain systems) were not available yet extremely necessary. However, it is important to note that the current NDA guidelines and policy framework does not allow retail drug shops to provide such services. Business diversification, the drug sellers argued, was a mechanism for business sustainability and mitigating high operational costs. The more diversified the business, the less likely that a drug shop would rely on one business line as source of business survival. Product and service diversification increases retail sales volumes and significantly reduces the average costs of production, with possibilities of transferring these cost cuttings to clients in form of reduced prices [39]. Aspects of incentives for business start-ups and operational costs in retail health markets, was investigated separately by the author and colleagues, and findings shall be shared in separate publication. It is important, however, that these additional lines of business are related to the mainstream service or products being offered. Drug shop operators must also balance this diversification agenda against its feasibility, risks, and limitations.

The most common childhood illnesses reported at the drug shops were found to be fevers, coughs, difficulty in breathing, and diarrhea. The current burden of childhood illnesses in Uganda, shows that malaria, acute respiratory illness and diarrhea are major contributors to mortality and morbidity for children under five years of age [29], and this is true for Sub-Saharan Africa (SSA). To achieve greater reductions in the burden of under-five mortality and improve child survival in Uganda, retail drug shops must be brought into perspective. Retail drug shop practices need to be improved. In this study, we found limited use of diagnostics – malaria RDTs, respiratory count timers, and thermometers. As starting point, there is need to improve diagnostic capacities of retail drug shops as a critical ingredient for appropriate treatment and care, and well in line with the current WHO "test and treat" policy [26, 40, 41].

The potential for drug shops to use RDTs and reduce the unnecessary prescription and use of antimalarials has been demonstrated by a number of studies conducted in many settings, including in Uganda [26, 42] [27, 28, 43]. The WHO "*test before treat policy*" now recommends parasitological confirmation of malaria before antimalarials are provided [44]. Indeed, the WHO Framework on malaria elimination under the Global Technical Strategy for Malaria 2016–2030, provides for creating an enabling environment for ensuring universal access to malaria prevention, diagnosis, and treatment [45]. Inappropriate treatment resulting from the limited application of diagnostics has been a consistent finding across a number of studies [46–49]. Inappropriate prescription and unnecessary use of antibiotics has been established to be associated with antimicrobial resistance (AMR) [50], which is currently a global public health challenge that must be addressed. The current Malaria Treatment Policy and the Uganda Malaria Control strategic Plan now recommend the use of RDTs at community level and in the private sector [51], and additional guidelines for using RDTs in private outlets in Uganda have been developed [52] . The Global Fund for HIV/AIDS, Malaria, and Tuberculosis (GFMAT) through the private sector co-funding mechanism, has also been supporting the private sector in improving the standards of malaria diagnosis and treatment in Uganda. However, there are important challenges such as training and supervision, waste management, streamlining the referral system from private outlets, surveillance, etc. that need to be considered [53]. The policy reforms being undertaken require careful planning and consideration of training, regulatory, supervisory, and other necessary capacities, coupled with necessary incentives for private outlets to improve their practices [26].

Our study found that prescription or dispensing decisions were not only related to existing diagnostic capacities, but were also influenced by other factors, including: the clients' finances, prescriptions that patients came with, and client's preferences. Wafula and colleagues, in a systematic review of drug shops in Sub-Saharan Africa, reported that, among others, client demand strongly influenced dispensing practices. They noted that most drug shops simply sold medicines that clients requested for or preferred, without necessarily following policy recommendations. The systematic review also reported that, rural drug shops provided credit facilities to their clients, in cases where they had no resources to afford the full dosages of medicines [54]. Similarly, Goel and colleagues, in their study of the behavior of retail pharmacies in developing countries, also reported that client demand or expectations as well as local regulatory factors strongly influenced drug selection and dispensing behavior [55]. Evidence from both our study and the literature, indicate that dispensing behavior is related to both demand and supply side factors, and thus, improving dispensing practices requires strategies or interventions on both the demand side and supply side of the market. For example, training, monitoring, supervision, and subsidies (supply side) are critical supply-side strategies. They alone, may not be sufficient in influencing dispensing behavior, rather, additional demand-side initiatives are necessary. Programs such as public health education and the provision of adequate information through mass media campaigns, may address issues of adverse effects of incomplete dosages, and the dangers of self-medication and prescription. Other demand-side

strategies may include social marketing and the provision of demand-side subsidies. Demand-side strategies are aimed at influencing consumer behavior, preferences, and choices, and this would ultimately influence dispensing practice [54]. The design of any package of interventions and market incentives, must however recognize the broader health system effects that may likely emerge from those interventions, beyond the market where they are implemented [19].

Relatedly, drug shop attendants indicated that their medicine stocking decisions were influenced by: medicines on demand, ministry of health recommended, most profitable medicines, and seasonal dynamics. These factors have also been identified in studies elsewhere [56–58]. According to the NDA Act, drug shops are not expected to store and dispense antibiotics, except in exceptional circumstances where a drug shop is allowed to sell antibiotics especially if the drug shop is the only sources of such life-saving medicines for particular communities [22]. Our study however, found that amoxicillin (syrup and capsules) was one of the commonly stocked and dispensed medicines at surveyed drug shops because of its high demand. In many cases, drug shops that stored antibiotics did not display them on the shelf for fear of reprisals from drug inspectors, but would provide the client the same on demand. In addition, drug shops were still found with stocks of medicines such as quinine that are no longer recommended as first-line treatment for malaria. Surprisingly, the study found that most drug shops had clinical guidelines and regulations available, yet it was clear that many drug sellers were not in many cases adhering to them. It was not apparently clear whether it was a deficiency in enforcement, inadequacy in training, or rather an issue of incentives for adherence. Reflecting on elicited factors that influence treatment practices, private retail drug shops were likely to promote the practice of self-medication, especially in circumstances where client preferences, and prescriptions that come with, were major considerations in dispensing decisions. Incentive mechanisms that enable drug shops to adhere to rules could be established, including strong monitoring and supervision and deregistration in cases of inappropriate practices [59, 60].

Finally, this study profiled the drug shop clients socioeconomically to get a basic understanding of the type of clients who procure medicines from the retail drug shops and the related equity issues. This study found that care-seekers of children under five years of age who sought care from retail drug shops during the survey period were mostly those who are unemployed, self-employed and less educated. In Uganda, it is not uncommon to find strong relationships between these strata and lower socioeconomic quintiles. It is important to note that the poor are also the most vulnerable to the burden of ill-health. Thus, interventions aimed at improving retail drug shop practices were likely to benefit the poor in society and ensure improved equity in access to health care. However to achieve higher equity, a mix of interventions, including consumer economic empowerment, and a stronger regulatory regime could cushion consumers against possible market distortions and exploitation in the form of high prices and poor quality of products and services. In addition, there is need to establish the right incentives that will influence provider and consumer behavior towards outcomes that are in public interest [19] [61, 62].

This study however, had some limitations that need to be underscored, including the fact that only registered retail drug shops were included in the study. Yet, there are many unregistered drug shops that partly influence what happens in that market, and so the results reported can only be relevant to the extent of registered drug shops. Unlicensed outlets were excluded from the survey because it would have been ethically unacceptable to promote "outlets" that have selected to defy an existing regulatory regime. Secondly, the determination of appropriate treatment was based on responses from care-seekers during exit interviews. We asked the client what signs and symptoms they had reported to the drug seller, observed the medicines that had been provided, and also compared with clinical guidelines and WHO guidelines on promoting rational use of medicines, to generate an "appropriate treatment" outcome. This may have inherent flaws especially the reliance on signs and symptoms reported without due diagnosis for conclusiveness. We however endeavored to validate the response with the drug seller on reported symptoms of immediate previous client, after the exit interview.

Conclusion

Retail drug shops were an important source of care for childhood conditions especially in rural and geographically constrained settings. Most retail drug shops' physical environment met the guidelines established by the National Drugs Authority (NDA). Most Drug shop attendants were nurses, midwifes, clinical officers and some pharmacists. A physical environment in line with the NDA guidelines, coupled with some health related training by drug sellers, offer a starting point to improve the quality of services retail drug shops provide. Drug sellers' stocking and dispensing practices were largely influenced by market factors including client demand, client finances, prices and profitability, client preferences, and seasonal factors. To ensure effectiveness, the factors influencing drug shop practices and care must be taken into account for any intervention or strategy. Mechanisms that influence the market demand and supply are necessary to improve drug seller practices.

Strategies such as regulation, monitoring and supervision, as well empowering communities with information, and provision of subsidies may be apparent. Additional support in terms of provision of subsidized medicines and diagnostic technology may go a long way in reducing prices of medicines and services provided by retail drug shops, for the ultimate benefit of the consumers. Beyond subsidization, however, retail drugs shops need to be, retail drug shops need to be supported through implementation of capacity building initiatives, such as periodic trainings of drug sellers to enhance dispensing capabilities.

Additional files

Additional file 1: Drugshop Survey Tool This is the questionnaire that was administered to drug sellers to generate information on the drug shop market. (DOC 216 kb).

Additional file 2: Client Exit Interview Tool This is the questionnaire that was administered to drug shop clients at their exit from the drug shop when they came to purchase medicines or drugs for under-five children, during the study period. (DOC 520 kb).

Abbreviations

ACTs: Artemisinin-based combination therapy; AMFm: Affordable Medicines Facility – Malaria; AMR: Antimicrobial Resistance; BSM: Blood smear microscopy; DDI: District Drug Inspector; DHO: District Health Officer; DHT: District Health Team;; GFMAT: Global Fund for HIV/AIDS, Malaria, and Tuberculosis; HREC: Human Research Ethics Committee; iCCM: Integrated Community case management; LICs: Low-income countries; MakSPH: Makerere University School of Public Health; mRDTs: Malaria Rapid diagnostic test kits; NDA: National drugs Authority; PFP: Private for Profit; PMVs: Patent Medicine Vendors; PPPH: Public Private Partnership for health; RDT: Rapid diagnostic test; SSA: Sub-Saharan Africa; UDHS: Uganda demographic and Health survey; UHC: Universal Health Coverage; UNCST: Uganda National Council for Science and Technology; UNHS: Uganda National Health Survey; UNICEF: United Nationals Children Fund; USD: United States Dollar; WHO: World Health Organization

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Availability of data and materials

All datasets and or material used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

CM, FEK, SSP & HW designed and conceptualized the study. CM & FEK developed and refined the study tools. CM &FEK conducted the survey and collected all the data. CM supervised data entry and undertook the analysis. FEK, EEK, NBK, SSP and HW contributed to data analysis and interpretation. CM wrote manuscript drafts. FEK, EEK, NBK, SSP and HW reviewed all drafts and contributed to writing the final paper. All authors read and approved the final manuscript.

Ethics approval and consent to participate

This study was approved by the Uganda National Council for Science and Technology (UNCST) (#HS1385), Makerere University School of Public Health (#IRB00011353), and the University of Witwatersrand Human Research Ethics Committee (HREC) (#M151016). Further permission was obtained from the National Drugs Authority (NDA) and the Local Government authorities for the two districts. Written consent was obtained from all study participants.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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For altruism or private gain? Analyzing the incentives associated with the retail drug shop market in rural Uganda

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List of Abbreviations

ACTs	Artemisinin-based Combination Therapy
ADDO	Accredited Drug Dispensing Outlet
ADS	Accredited Drug Shop
AMFm	Affordable Medicine Facility for Malaria
CHWs	Community Health Workers
DADI	District Assistant Drugs Inspector
DHT	District Health Team
FGDs	Focus Group Discussions
IDI	In-depth Interviews
MoH	Uganda Ministry of Health
MRS	Medicines Retail Sector
NDA	National Drug Authority
ORS	Oral Rehydration Solutions
SCP	Structure-Conduct-Performance
SDG	Sustainable Development Goals
UHC	Universal Health Coverage
UNCST	Uganda National Council for Science and Technology
VHTs	Village Health Teams
WHO	World Health Organization

Abstract: *Number of words (295)*

Background: Motivations for retail drug shop start-up and nature of market incentives have an influence on drug seller practices, health care services provided, and ultimate efforts to expand access to services to advance the Universal Health Coverage goals. We identified and investigated objectives for drug shop start-up, benefits of drug shops to operators, price mark-ups, operational costs, sales and profitability, and regulatory oversight, in Uganda's retail drug shop market.

Methods: A cross-sectional mixed methods survey of 74 drug shops, was conducted in September 2013, in Mbarara and Bushenyi districts, South Western Uganda. A sub-sample of 20 drug shops was selected for the detailed investigation of the major study variables, using a semi-structured questionnaire with both closed-ended and open-ended items. Additional four key informant interviews were conducted with government officials working in the district health system. Quantitative analysis was done using Stata and Excel software while qualitative data was manually analyzed. Qualitative information was used to supplement quantitative findings.

Findings: The need to earn income through profit was the main objective reported for establishing drug shops, in addition to the need to serve the community. However, additional benefits accrued to drug shop operators, including social recognition, expansion of social networks, and social capital. Product prices varied across products and outlets with median mark-ups ranging between 43% and 100%. The median profit for a drug shop in a typical month was USD 1,060, representing almost 90% profits. Finally, the regulatory system was found to be under-resourced, weak, not straightforward, and sometimes generated negative incentives to drug shop operations.

Conclusion: Motivations for drug shop operations were both business oriented and social or altruistic in nature. This mix of motivations can be harnessed to promote the public good, if additional effort is targeted towards strengthening and streamlining regulatory oversight.

Key words: Retail; Drug shop; Incentive; Profitability; Altruism

Summary

What is already known about the subject?

- Private retail drug shops are an important way through which people in many low-income countries access medicines.
- However, it is not uncommon to accuse retail drug shops of violating rules and providing questionable quality of care.
- These rule violations have partly been attributed to the pursuit of high profitability to enable them survive in the market.

What does this study add?

- Retail drug shops are not only motivated by the desire to earn an income through profits, but also have social or altruistic motivations and benefits that influence their practices.
- Furthermore, while a framework for regulating retail drug shops exist, it is weak, under-resourced, and sometimes associated with perverse performance incentives.

What do the new findings imply?

- Improving health care delivery within the retail market requires implementation of interventions that can influence the social (or altruistic) and bussines motivations of drug sellers. These interventions could include provision of product subsidies, and co-creation of regulation.

Introduction

Achieving Universal Health Coverage (UHC) is a major global goal that many counties of the world have committed to achieving by the year 2030. Universal Health Coverage entails ensuring that everyone can access quality health services without suffering financial catastrophe(1). Access to essential health services in many low-income countries continues to be a challenge, and more so for vulnerable and hard-to-reach communities (2). Children are among the most constrained groups in accessing essential health care services**(3)**. Health worker shortage, inadequate health facilities that are sometimes poorly stocked, high cost of care, among others, contribute to this challenge**(2)**.

Private retail drug shops can effectively be used to expand access to essential care for underserved groups in many low- and middle-income countries **(4-7) (8, 9) (10)**. In Uganda, between 40-70% of febrile children, and almost 80% of malaria cases seek services from the medicines retail sector (MRS) **(5, 11, 12)**. To some users, drug shops are the first point of contact with the health care system, and to others, they are the ultimate source of care for their illnesses. Preference for retail drug shops is explained by accessibility, flexibility in operating hours, convenience, responsiveness to client demands, and cost-saving, among others **(5, 6, 13)**. Thus, retail drug shops complement weak and resource-constrained health care systems **(7, 14-16)**.

However, the medicines retail sector (MRS) has received considerable accusations of dispensing poor quality services - including inappropriate treatment, stocking substandard, counterfeit, and sometimes expired medicines, among others **(5, 17, 18).** These practices have wider social costs, including antimicrobial resistance, and higher costs of health care resulting in catastrophic

expenditures **(19, 20)**. Medicine retail shop practices are closely linked to motivations or objectives for their establishment, existing incentives, and the broader institutional environment (including rules) in which the MRS operates **(21-23)**. Some MRS players adopt business models that focus largely on recouping profits which sometimes undermine the greater public health good **(24)**. The Accredited Drug Dispensing Outlet (ADDO) program evaluation in Tanzania reported that the pursuit of profits tended to generate perverse incentives for positive action, with attendant negative consequences on quality of care **(21, 25)**.

Whether retail shops pursue purely 'business' motives for private-gain or and have additional embedded social or altruistic motives that could influence their operational models needs to be investigated. This paper adopts the *Structure-Conduct-Performance (SCP) Framework* of organizational economics **(26-30)** to identify and analyze key retail market variables. The findings contribute to the understanding of the incentive structure under which retail drug shops operate, and how that structure could be harnessed to engender access to good quality health care and contribute to Universal Health Coverage.

Regulating retail drug shop operations in Uganda

In Uganda, the operations of retail drug shops are guided by the National Drug Authority (NDA) Act **(31)**. The NDA Act specifically provides that no drug shop should operate without being accredited and granted an operational license. Accreditation and licensing is a mandate of the National Drug Authority, upon presentation and fulfillment of specified criteria including inspection of the physical operational area, qualifications of operators, and payment of recommended fees, among others **(32)**. The NDA offices have been decentralized and currently,

every district has District Assistant Drugs Inspector (DADI). The DADI is expected to keep and maintain a list of accredited drug shops, in addition to carrying out routine monitoring and supervision of drug shop operations within the district.

The Structure-Conduct-Performance (SCP) Framework

We adapted the SCP framework or paradigm for industrial organizations, developed in the 1950s **(29, 30)** and later modified by other scholars **(28)**. According to this framework, the observable characteristics of the market (structure) determine how market agents behave (conduct), and this ultimately influences the measurable performance of that particular market (P). *'Structure'* connotes a degree of market competition, size and number of buyers and sellers, and extent of integration, among others. A modification by Neuberger includes the regulatory framework **(28)**. The concept of *'conduct'* involves the actions of market agents, drug sellers, in this case, and the rationale for those actions. Such actions include setting prices and selling costs, selection of products to stock or sell, operational costs, sales promotion strategies, among others **(26)**. Market '*performance'* is reflected in prices, quantity and quality of products and services offered, and profitability, among others. Based on this framework, market performance (output), and the conduct of agents can be altered by changing the structure of the market **(33)**. Using the SCP framework, we identified motivations for drug shop start-up, operational incentives, operational costs, prices and mark-ups, sales and profitability, and the regulatory environment, for inquiry in this study.

Materials and methods:

This was a cross-sectional mixed-methods study that utilized both quantitative and qualitative data collected as part of a baseline survey conducted in preparation for an intervention study entitled "ACCESS and EXCESS, EQUITY and INFORMATION: Point of Care Diagnostics and Pre-packaged Subsidized Drugs for Integrated Fever Management for Malaria, Pneumonia, and Diarrhea in Children at PRIVATE SECTOR Drug Shops in Uganda". The study was conducted in Mbarara and Bushenyi Districts, South Western Uganda. The study area has a pluralistic health system, with health services provided by public and private facilities, private clinics, pharmacies, retail drug shops, and sometimes traditional medicine providers under the stewardship of the District Health Officer. A district health system is supervised by a District Health Officer and retail drug shops are generally considered as part of the district health system **(34)**. The regulation of retail drug shops is a mandate of the National Drug Authority (NDA), with decentralized offices manned by District Assistant Drug Inspectors (DADI) located within each district **(31)**. Details of the AXEX intervention design, methodology, and study setting, are published elsewhere **(12, 18, 35).**

For this paper, a total of seventy-four (74) registered and licensed drug shops were studied, after being subjected to eligibility criteria that included; being registered and with an up to date operational license, dealing in human and not veterinary drugs, and is situated in the rural parts of the study districts. The list of registered drug shops was obtained from the National Drug Authority (NDA) register available at the District Assistant Drug Inspector (DADI) offices. Out of the sample of 74 drug shops, a sub-sample of 20 drug shops was selected based on a cluster sample survey method proposed by Bennett and colleagues**(36)**. This sub-sample was considered for the detailed

investigation of the selected retail market variables or elements that we present in this paper. The market elements included: motivations for drug shop start-ups, the regulatory and supervisory environment, pricing, sales volumes, marks-ups, and operational costs, among others. However, there were additional aspects of the study that were deduced from the main sample of the 74 drug shops. Additional aspects of motivations for drug shop start-up, experiences, and perceptions of regulation – including licensure and accreditation processes, and monitoring and supervision were explored qualitatively, to complement the quantitative results and provide useful context. The survey was conducted in 2013 in Mbarara and Bushenyi districts in South Western Uganda.

Data collection

Both qualitative and quantitative methods of data collection were applied concurrently for this study.

Quantitative methods: A survey was conducted among the 74 drug shops targeting drug sellers and owners, using a semi-structured questionnaire, to elicit a range of issues, namely, outlet characteristics, practices, and client volumes, among others. An additional questionnaire was administered to the sub-sample of 20 drug shops to elicit in detail the selected MRS variables, including motivations for start-up, benefits of operations, sales volumes, mark-ups, and operational costs. The semi-structured questionnaire guided interviews with drug operators. Reference was made to the week preceding the interview to limit the likely recall bias**.**

Qualitative methods: To supplement quantitative data, qualitative data were collected using two main tools: First, the self-reporting semi-structured questionnaire administered to the sub-sample had a section with open-ended questions. The aim of the open-ended section of the semi-structured

192 questionnaire was to elicit additional views and opinions of drug sellers and owners on particular
193 aspects that had been investigated through the quantitative method. The rationale was to generate
194 information that would complement as well as provide context to the quantitative data which
195 would not have been possible using only the quantitative approach **(37, 38)**. Additional aspects
196 that were explored in the open-ended questions included; views and opinions about regulation, and
197 suggestions about how the MRS operations could be improved. Two research assistants conducted
198 each of the twenty interviews, with one interviewer and the other a note taker. Research assistants
199 were trained in data collection and supervised by CM and FEK. Second, an additional 4 key
200 informant interviews (KIIs) with Government officials were also conducted – specifically with
201 members of the District Health Team (DHT) who are directly involved in the regulation and
202 supervision of medicine outlets. The number of Government officials interviewed was determined
203 by the principle of saturation **(39)**. Interviews with government officials were conducted at their
204 offices by CM and FEK. Each interview lasted between 30-45 minutes and the interview was
205 audio-recorded.
206
207 **Data management and analysis**
208 Research assistants who participated in data collection were trained for two days, and all tools used
209 were pilot tested and feedback incorporated into the tools before embarking on full data collection.
210 All qualitative interviews were audio-recorded in English and later transcribed. The lead author
211 checked all interview transcripts against the recordings to ensure their accuracy and then cleaned
212 the transcripts. All quantitative data were checked for completeness and accuracy by the study
213 team particularly the main authors. Data was entered in EpiData software and later transferred to
214 and analyzed in Stata version 13.0 (Stata Corp., College Station, TX, USA). Business data,

including sales volumes, mark-ups, operational costs, among others, was entered and analyzed in an excel spreadsheet. All data entry, cleaning, and transfer processes were supervised by the lead author for purposes of quality control.

For quantitative analysis, this paper adopted first level descriptive analysis, to generate and report results in terms of means, medians, and proportions of variables. For qualitative analysis, field notes taken from the open-ended questions were word-processed, cleaned, and organized along with main issues in the questions. Key informant interviews with government officials were transcribed and carefully read multiple times by the lead authors (CM, FEK), and using a content analysis approach and meaningful themes were generated **(40-42)**. Relevant quotations from the processed notes and the processed transcripts were applied to reinforce emerging quantitative findings, where necessary **(43)**.

Ethical Considerations

This study was part of the larger *Access, Excess Intervention research* (AXEX project), whose ethical review and approval were granted by the Research and Ethics Committees at Makerere University School of Public Health (IRB00011353) the Uganda National Council for Science and Technology (UNCST) (#HS1385), and the World Health Organization (RPC553). Additional approval for this study was obtained from the University of Witwatersrand Human Research Ethics Committee (HREC) (#M151016). All ethical procedures in the field were followed, including obtaining written consent from all study participants. Any likely risks of breach of confidentiality and anonymity were mitigated by ensuring that no personal information recorded was linked back to the participants during the analysis and reporting of results, except for use of identifiers.

Results

Characteristics of study participants

The study participants included drug shop sellers or attendants, owners, and government officials working in the district health system. The main sample of 74 drug shops was studied, with a subsample of 20 drug shops selected for detailed investigation of selected market variables. Details of the characteristics of the drug shops and related care-seeking are published in Mayora et al. **(12)**. In summary, most drug sellers have some health-related training, mainly as nurses or midwives, clinical officers, and pharmacists. Paracetamol, Quinine, Cough syrup, ORS/Zinc, Amoxicillin syrup, Septrin® (Co-trimoxazole) syrup, Artemisinin-based combination therapies (ACTs), and multivitamins, are the most commonly stocked medicines. Stocking decisions are influenced by the Ministry of Health (MOH) recommendations, consumer demand, profitability, and seasonal considerations. Relatedly, dispensing and prescription behavior are largely influenced by patients' finances, and patient preferences. Some drug shops offer additional services, such as selling non-medical goods and services as a diversification strategy.

The motivation for drug shop start-up

The sub-sample of twenty (20) drug sellers and owned interviewed, provided various reasons for opening up drug shops in the communities where they operated. The major motivations included: the need to provide a service to the community (18/20), drug shops as a source of income to sustain individuals and families (11/20), and drug shops as an avenue for self-employment (9/20) amidst the rampant unemployment in Uganda. For example, one respondent noted;

"….it is true we set up drug shops as an employment venture, both for self and some other community members. But we also help the community by counseling and advising the

community members on threats to their health and possible mitigation measures…." (Drug shop operator).

There were some limited views from drug sellers about drug shops as avenues to gain practical skills after clinical and nursing training and to contribute to the community by saving clients from hospital costs such as consultations, among others.

Benefits or gains from operating drug shops

The major benefit was that drug shops were a source of income through profits that accrued (90%). Other additional benefits reported were that: drug shops provided operators a platform for social recognition in the community (30%), operating a drug shop helped to accumulate social capital and networks (25%) and operating a drug shop offered an experience in dealing and handling different people (15%) (**Table 1**). The words of one drug shop operator were insightful;

"…there is popularity because everyone knows you as 'musaawo' (doctor) and you get known in the whole community. At least even if I am stuck along the road, I am able to get a 'boda-boda' (motorcycle) to take me because they know me and will give me a lift…" (Drug shop operator).

Others noted that the drug shop has offered an opportunity to offer additional services and products that complement their incomes. For example, one respondent reported

283 ***"…the drug shop acts as employment for my daughter, but in addition to the drug shop, when***
284 ***clients are not coming, she sometimes works on those that come for mobile money services, and***
285 ***this adds to the income that helps to pay rent and other utilities…" (Drug shop owner).***

286

287 **Table 1. Reported benefits of drug shops to drug sellers/owners**

	Response (n=20)	**Percentage (%age)**
Social recognition	6/20	30
Income/Profit	18/20	90
Experience in handling different people	3/20	15
Social capital and networks	5/20	25

288

289 **Operational costs for retail drug shops**

290 From interviews with drug sellers and owners (n=20), we identified and estimated the major
291 operational costs or expenditures for retail drug shops (estimated on a monthly basis) (**Table 2**).
292 We found that the major costs were: rent (median = USD 23.7), payments for workers (Median
293 = USD 30.6), and utilities, transport, and other related costs (Median = USD 16.1). License fees
294 were paid on an annual basis. The largest expenditure across the majority of the 20 surveyed outlets
295 was payment for workers' salaries with a mean monthly payment of USD 37.0 (Range: USD 25.3
296 - USD 43.4).

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302 **Table 2. Estimated main operational costs** (monthly)

Cost	Mean	Median	Min	Max
Rent payment	65,625 ($23.7)	65,000 ($23.5)	50,000 ($13.89)	110,000 ($30.6)
Payment of worker	102,188 ($37.0)	100,000 (30.6)	70,000 ($25.3)	120,000 ($43.4)
Utilities & related costs	52,375 ($18.9)	46,500 ($16.1)	15,000 ($5.4)	$130,000 ($36.1)
License fees (annual)	50,000 ($13.89)			

**Exchange rate is 1 USD=2,765 (2013)*

We however noted that some drug shops rely heavily on family labor or sometimes the owner is the drug shop attendant, and when estimating operational costs, these imputed costs are rarely estimated and included. This may lead to an underestimation of the operating costs. Relatedly, respondents reported that a lot of costs are incurred in the process of securing operational licenses and other authorizations, including "informal" payments to some government officials (such as inspectors). However, drug operators would hesitate to include them in formal estimates of operational costs, yet these costs can sometimes be significant, as one respondent noted:

"…the back and forth required to always go to the district health offices is very costly and inconveniencing. One incurs a lot of money like more than one million and it is not easy to get that money." [Drug shop operator]

Estimated weekly quantities of medicines sold

We estimated retail drug shop sales volumes by asking drug sellers in the subsample (n=20) about their weekly sales (based on the week preceding the interview) of the common childhood medicines. Once estimated weekly sales volumes were established at each of the considered drug

shops and medicines, then mean and median volumes (quantities) were estimated **(Figure 1**). The results show variations in sales volumes for the different medicines across the drug shops. The largest amounts of sales were recorded in Septrin™ (co-trimoxazole) Tablets with a mean of 63 dozes sold in the week preceding the survey (but also recorded the largest variation), and the lowest mean sales volumes were recorded in Deworming Tablets, Amoxicillin syrup, and Septrin™ (co-trimoxazole) syrup. Similarly, these medicines recorded the lowest variations across the responses from the different drug shops.

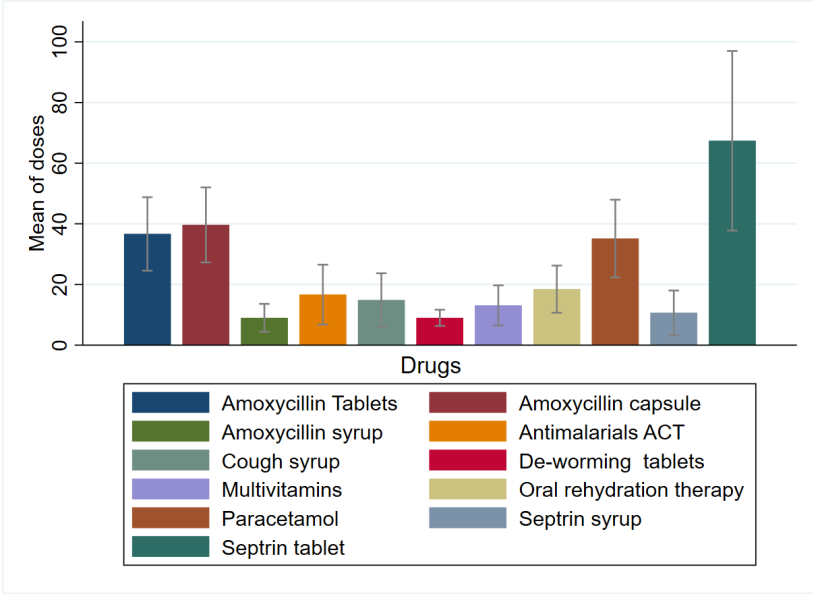


Figure 1: Weekly Mean estimates of sales for common childhood medicines (n=20)

Estimated drug shop sales and profitability

Based on the twenty drug shops for which the sales information was obtained, we estimated and quantified the weekly sales and converted the data into monthly sales (only for the selected and

considered child medicines). This was compared with the operation costs reported over the same monthly period. From our findings, the monthly (median) revenue - based on the reported median selling price for the different medicines and the median doses was UGX 6,258,000 (USD 2,263). Based on the cost of stock reported at median values, the purchase value for the same doses was estimated for a typical month as UGX 3,110,900 (USD 1,125). The total costs computed together (cost of stock plus operational costs) are UGX 3,326,567 (USD 1, 203). The estimates show that in a typical one month, a drug outlet earns in profits an equivalent of UGX 2,931,433 (USD 1, 060) after offsetting for cost obligations. However, this estimate should be interpreted within the context of certain noticeable limitations, discussed later in this paper. It is also important to note that the purchase costs and revenue estimates are based on the selected medicines. However, given that drug shops provide a range of other medicines, medical products, and supplies, and sometimes non-medical products and services, the revenue estimates are likely higher compared to our estimates, but the operational cost estimates would relatively remain the same.

Estimated weekly client visits

Using the main sample of 74 drug shops, we investigated the number of clients a drug shop serves in a typical week. We referenced the one week preceding the study. In terms of total clients (irrespective of age), 38/74 (51%) had served less than 20 clients, 18/74 (24%) had served between 21- 40 clients, and 17/74 (22%) had served more than 40 clients, with the maximum being 200 clients. About the sales made or services provided to children below 5 years, most drug shops (69/73) reported having served less than 20 clients, and only 5/73 served more than 21 children with the maximum being 50 children. The majority of drug shops (70/73) handled between 0-20 children (weekly) with febrile conditions.

Retail drug shop price mark-ups

We estimated mark-ups based on cost (purchase) prices and selling prices, as obtained from interviews, based on data for the week preceding the survey. Our findings showed that mark-ups varied across retail drug shops, but also across medicines and dosages (**Table 3**). The lowest median mark-ups were reported antimalarials ACT (43%), followed by Amoxicillin capsules (46%). By contrast, the highest percent median mark-up was reported on paracetamol (100%) and Septrin™ (co-trimoxazole) syrup (100%), followed by multivitamins (86%).

Our interactions with drug sellers (data unreported), revealed several explanations for these observed differences in median mark-ups (selling prices) on medicines across drug shops, including variations in purchase prices at wholesale stores, and related transportation costs, and unpredictability in the availability of products of choice in the market. Also, to the drug sellers, mark-ups represented a mechanism to cover purchase costs incurred upstream and through the supply chain, any additional transactional costs involved (operational costs), but also to ensure 'business' profitability and sustainability.

Table 3. Estimating retail drug shop mark-ups

	Mark-ups (n= 20 drug shops)			
Child Medicine	Median (%)	**Mean UGX (USD)**	**Median UGX (USD)**	**IQR UGX (USD)**
Paracetamol (Packet)	100%	1,854 (0.67)	2,250 (0.81)	1,000 (0.36)– 2,650 (0.96)
Septrin Syrup (bottle)	100%	1,096 (0.40)	1,000 (0.36)	700 (0.25)–1,300 (0.47)
Septrin Tablet (Sachet)	86%	3,208 (1.16)	3,350 (1.21)	1,750 (0.63)–5,125 (1.85)
Amoxicillin Syrup (bottle)	50%	1,250 (0.45)	1,000 (0.36)	500 (0.18)–1,600 (0.58)
Amoxicillin Capsule (Sachet)	46%	3,380 (1.22)	3,100 (1.12)	2,275 (0.82)–3,725 (1.35)
Amoxicillin Tablets (Sachet)	61%	4,080 (1.48)	3,800 (1.37)	1,500 (0.54)–5,500 (1.99)
Antimalarials ACT (Packet)	43%	1,544 (0.56)	1,500 (0.54)	1,000 (0.36)–2,000 (0.72)
Multivitamins (Packet)	75%	11,541(4.17)	14,000 (5.06)	8,000 (2.89)–14,500 (5.24)
Cough Syrup (bottle)	54%	825 (0.30)	950 (0.34)	500 (0.18)–1,000 (0.36)
Oral Rehyd. Therapy (Sacket)	59%	560 (0.20)	200 (0.07)	178 (0.06)–230 (0.08)
De-worming Tablets (Tablets)	67%	427 (0.15)	400 (0.14)	350 (0.13) – 500 (0.18)

Licensing and accreditation

Most drug shop attendants recognized that licensing and accreditation is critical in ensuring that quality services are provided. They believed that an unregulated retail market can be very dangerous for the population, but also 'devalued' their 'businesses'. Licensure and accreditation protected the communities against quack providers and weeded out substandard medicines and services, as one respondent noted;

"…obtaining certificates or a license is good because it protects the community from quacks but the cost is high…" [Drug shop operator].

However, there were concerns about the complexities and inconveniences involved, including the cost of the process. For example, the concerns related to the high costs required for securing an annual license, the long time it took to obtain a license, and the amount of inconvenience in pursuing the same. One respondent noted that:

"…it takes a lot of time to get the license because there is a lot of back and forth where you have to go to the district health offices almost every week and this is very costly and inconveniencing…" [Drug shop operator].

The National Drug Authority (NDA) officials explained that the delays were due to limited resources to conduct site visits. The regulations required that an operational license could only be approved if the drug shop site had been fully inspected and recommended. However, because resources might not have allowed for inspection of one drug shop at a time, officers rationalized by allowing accumulation of applications, so that they could plan a single inspection and handle all applications from a particular area in one inspection. In the words of one government official,

"…now this is a licensing season, people come and pick the forms, fill them and bring them back. We then arrange to visit them. You cannot just go and visit an individual place, because the resources are not there, and secondly, these drug shops are too many. So you plan, wait for everybody to bring back the application and then you can route your journey and cover as many shops as possible in a single route". (KII, Government Official)

It was also noted that drug sellers and owners were unscrupulous and sometimes used underhand methods to obtain licenses. Applicants would in most cases fulfill the application requirements. For example, the application required proof that the operator (drug seller) is qualified. The submitted application sometimes demonstrated that the applicant fulfilled this requirement, yet when you visited the drug shop, the applicant is different from the actual drug seller in the shop. A government official noted

"…one thing is, some of these drug shops are owned by non-medical personnel who just want to do business. What they do is, when it is licensing season, they send qualified people to come and pick the forms, apply and get a license. As soon as the shop is licensed, the qualified person disappears, and the shops are left in the hands of spouses and some other untrained people to manage the medicines. And you know what this means for the quality of services". (KII, Government Official)

Drug sellers' views and opinions about monitoring and supervision

We elicited views and opinions of drug shop operators about the current structure of monitoring and supervision. Several operators noted that supervisors often concentrated in urban areas and rarely went to rural areas, yet a lot of consumer manipulation happened in the rural remote and hard to reach areas. Some operators attributed this practice to the personal interests of supervisors and incentives related to urban businesses. These operators were of the view that supervisors preferred to visit urban drug shops because those urban-based drug shops had some resources to "appreciate" the supervisors in return, or it was easier for the supervisor to receive some 'compensation from those drug shops, whenever they visited them. In the words of one drug operator;

436

437 ***"…supervisors operate in urban places mostly and do not afford to go to rural areas due to***
438 ***personal interests and monetary attachments with bigger drug shops in town".***

439

440 Some drug sellers also observed that some government officials were very harsh and did not even
441 allow room for discussions with the drug seller on what was missing and how the operations could
442 be improved (9/20). In most circumstances, supervisors would just close down the shops. It was
443 also noted that some officials were corrupt and sometimes applied extortionary methods in
444 conducting their work (4/20), as one of the respondents noted, thus:

445

446 ***"…these officials are sometimes corrupt and extort a lot of money from us, in case they close***
447 ***your shop or sometimes they carry your drugs, and to recover them you have to pay a higher***
448 ***price" [drug shop operator].***

449

450 Other comments include failure to communicate supervision visits to allow for adequate
451 preparations, and routine changes in service requirements without due communication to
452 stakeholders, among others.

453

454 Government officials decried several challenges to monitoring and supervision of drug shops.
455 First, they had limited resources to conduct routine supervision and therefore could only work
456 within existing resource constraints. Sometimes, they were constrained to limit the number of
457 supervision rounds to only a single round per year and this was a challenge to ensuring that good
458 quality services were provided. Second, the communities cherished drug shops as critical centers

of care within their localities, and hence perceived supervisors as being against the operations of the very facilities that served the community. The government official explained that communities often acted as shields for poorly operating drug shops. Communities viewed the drug shops as their very own and were willing to resist any supervisor or inspector who wanted them closed. This was because the drug shops were in most cases the community's first and sometimes last resort in times of medical need. As such, whenever a supervisor wanted to take any action that was viewed as unfavorable to the drug shop, the community turned against the supervisor or the government official. One government official noted,

"…we have even problems closing illegal drug shops. You go to close the illegal drug shop, the community leader comes, and everybody comes and at times confronts us. So any drug shop regardless of its licensing state is valued in the community. They feel it is really what treats them and saves them from all those long distances and others". (KII, Government Official)

Challenges in operating a drug shop 'business'.

Drug shop attendants elicited some of the challenges that they encountered in their operations. These challenges included: 1) failure by clients to pay back whenever they are given medicines on credit, leading to losses, and 2) loss of clients or even trust whenever one refused to give them credit facilities. Additionally, drug sellers also noted that clients took half doses against professional advice. One responded noted:

"...clients come with small money and they just tell you what they want, and when you advise them to take the full dose, they will tell you they don't have the money. Sometimes they will come

482 ***back to tell you their child did not recover, and now are asking for another type of medicine,***
483 ***which is a big problem in our community…"*** **(Drug Seller).**
484
485 **Views and opinions on streamlining drug shop operations**
486 Opinions were elicited from both drug sellers and government officials, on how to improve drug
487 shop operations. Key among the opinions elicited by drug sellers were: 1) reduction in operating
488 license fees (14/20); 2) supervisors should conduct regular sensitization forums by supervisors to
489 provide information to drug sellers, more especially about the prevailing practices and new
490 medicines (4/20); and 3) communication of supervision schedules before the visits to allow for
491 adequate preparation (4/20). Additional proposals include: the government to relax the stringent
492 laws imposed on drug shops, decentralize supervision to local levels, and subsidize essential drugs
493 to ensure that prices were low and manageable for people who needed them.
494
495 From the government officials' perspective, drug sellers needed to be trained while on-the-job, or
496 through periodic refresher training. This would enhance their skills and keep them abreast of the
497 latest information in the area of medicines and dispensing practice. Additionally, they mentioned
498 that there was a need to allocate more resources for monitoring and supervision, ensuring full
499 implementation of guidelines that were provided for in the legal framework, and to streamline the
500 licensing process while plugging all possible loopholes. In the words of one government official,
501
502 ***"…there is a legal framework which provides for a number of things that need to be in place***
503 ***for accreditation and operation of drugs shops, but the issue is implementation. If you go to visit***
504 ***them now, you will find them with the licenses. But the acquisition of these licenses, the process***

505 ***that they went through to receive these licenses, is the one that is found wanting and needs to***
506 ***be revised". (KII, Government Official)***.
507

508 **Discussion**

509 This study demonstrates a link between drug shop practices and the objectives for which they were
510 established and the incentive framework prevailing within the market, including making sales and
511 profitability, operational costs, regulation, among others, as per the SCP framework (29). A deeper
512 understanding of these objectives and market incentives is critical for developing sustainable
513 strategies for improving service delivery within the medicines retail market.

514 Drug shops start-ups were mainly motivated by; need to provide a service to the community,
515 generation of income, and creating an avenue for employment. Relatedly, drug shop operators
516 reported the main benefits to include: a source of income through profits which helps to sustain
517 families, social recognition, and expanded social capital and networks. Drug shops, however,
518 incurred transactional costs that were mainly related to; payment for rent, payment for workers,
519 and utilities. There were, however, costs that were not recorded – and these mainly related to costs
520 of family labor, and sometimes informal payments to government officials to facilitate licensing
521 and supervision. Furthermore, this study found that drug shops added mark-ups to product prices
522 so as to break-even. However, the mark-ups varied across products and outlets but generally
523 ranged from 43% to sometimes 100%. The lowest mark-ups were recorded for antimalarial ACTs
524 and the highest for paracetamol and septrin™ (co-trimoxazole) syrup. The estimated profitability
525 for a drug shop in a typical month was USD 1,060, representing over 90% profitability. Finally,
526 most drug shops appreciated the role of licensing and accreditation but were concerned that the

cost of the process was high and unnecessarily complex to navigate, and sometimes generated perverse incentives for drug sellers.

The low quality of services provided by retail drug shops has been a longstanding concern across many low and middle countries. Some drug shops reportedly provide substandard and sometimes expired medicines, as well as inappropriate dosages. These practices tend to generate perverse externalities, including antimicrobial resistance, high costs of treatment, adverse effects on health, and sometimes deaths **(5, 19, 20, 44-48)**. To this end, while drug shops complement the formal health system in expanding access to health care, especially for underserved communities, they could compromise global gains in addressing high child mortality.

The perverse practices have largely been linked to the pursuit of profits rather than serving public health **(19, 25)**. Conventional economic theory suggests that the behavior of economic agents is highly influenced by incentives and the amount of information available within a particular market **(49)**. The SCP framework for industrial economics, similarly postulates that the structure, conduct, and performance of market agents (for example firms), is indeed influenced by the market structure and the incentive obtaining in that particular market **(29)**. In markets with limited or asymmetric information, agency relationships emerge - where providers, by and large, determine what services to provide to the principals or clients and at what prices. Ultimately, the objective is not so much to benefit the client, but rather to the benefit of the provider in form of profits or income **(50)**. In this study, the reported objectives for start-up were both social and business-related, although 90% reported that profits were the main benefit they derived from operating drug shops. A study of the Indian retail pharmacy sector reported that independent pharmacies and medicine shops were more business-oriented, sometimes selling medicines without a prescription, deliberately selling medicines that were highly profitable at the expense of less profitable yet efficacious, and

dispensing antibiotics that sometimes are not allowed to be dispensed by class C drug shops **(51)**. We have found in our earlier work that prescriptive practices were largely influenced by profitability and the need to satisfy client demand in order to sustain trust **(12)**. Bart Jacobs and colleagues in 2005 also reported that economic factors such as the pursuit of higher profit margins have a major influence on retail behavior **(52, 53)**. Apparently, if economic incentives predominantly occupy retail behavior, this may have a negative impact - such as undermining patient safety - on the public health objective whose focus is maximizing patient and community health.

Our analysis of medicine prices in this study indicates that drug sellers instituted substantial price mark-ups that varied across medicines and outlets but generally ranged between 43% (on antimalarials ACT) to sometimes 100% (on paracetamol, and septrin™ (co-trimoxazole) syrup). The purchase price at upstream (wholesale) stores, costs incurred along the supply chain, and additional transactional costs significantly influenced the amount of price mark-up. This is consistent with other studies that have reported mark-ups ranging from 40% and sometimes going beyond 100% **(54)**. The variations have largely been attributed to variations in methodologies used in determining price mark-up, with self-reported price mark-up being lower than those estimated based on selling and purchase prices for example **(54)**. High mark-ups raise the retail prices of medicines and ultimately impedes access to essential medicines. High prices of medicines have been a longstanding constraint to accessing essential medicines through the private sector, and this has contributed to a high burden of morbidity and mortality. A medicines prices survey earlier undertaken in Uganda in 2004 indicated that even within the private sector, prices varied across providers, sometimes with significant ranges **(55)**.

To address the issue of high prices and assure affordability, respondents in this study proposed the need to subsidize wholesale prices, and this was expected to lower purchase prices and trickle down to consumers in the form of reduced retail prices. Indeed a number of studies have reported demonstrable effects of subsidies on reducing prices and expanding access to essential medicines by the vulnerable communities **(56-58)**. Indeed a systematic review by Alexandra Morris at el. **(59)**, reported that subsidizing ACTs reduced their prices and ultimately increased the use of private sector ACTs, even within poorer, more remote, and populations most at risk of malaria mortality. This systematic review, however, noted that in deciding whether or not to subsidize, evidence on the local context, treatment-seeking behavior, and malaria prevalence are necessary. The other option to reduce prices which have been proposed in the literature is the need to regulate pricing within the supply chain, where prices can either be capped or the allowable percentage mark-ups determined beforehand **(60, 61)**. However, such an approach must recognize the possible disincentives that may emerge, including a likely shift to high priced medicines rather than those regulated, or even a desire to amass profits to the benefit of providers, yet it is detrimental to consumers. Regulation also requires building a high level of capability to enforce, while maintaining a monitoring mechanism that not only ensures that the regulation is working but also minimizes the unintended consequences of regulatory practice **(62, 63)**.

Beyond the economic motivations of business establishments, our study also found that there were other additional social incentives that came with drug shop operations – including increased social capital, expanded networks, and social recognition. Respondents reported that a drug seller is highly regarded and taken as a *"musawo"* (doctor) within the community which raises their social status and motivates them to continue serving the community. Social status as a motivator for

596 community service has also been expressed among volunteer community health workers (CHWs)
597 or Village Health Teams (VHTs), who by virtue of their interaction with health workers within the
598 formal health system earns them a title of 'doctor' in many local communities **(64)**. In fact, in some
599 circumstances, social motivations and cultivated relationships that providers respond to may act
600 as disincentives to bad and unethical behavior by providers. The possibility or fear of loss of
601 dignity, status, and trust, may partly induce good behavior from providers, and therefore
602 interventions aimed at improving drug shop practice must recognize and integrate these social
603 contexts and realities ((35).
604
605 Turning to the regulatory environment, for many settings, the 'business' motive and the nature of
606 regulation, strongly influence retail market behavior. Our results show that the regulatory process
607 was not clear and straightforward right from accreditation to monitoring and supervision. The
608 accreditation requirements, for example, were sometimes unclear and the enforcement mechanism
609 was not strong. Despite the importance of strong regulation, monitoring, and supervision, and its
610 potential benefit in improving public health practice and protecting the community against the bad
611 practices, this area seems to be less invested in. In terms of licensing and accreditation, there were
612 concerns of the long process that was both time and resource consuming, and sometimes involved
613 corruption to 'facilitate' the process, and this tended to undermine the regulatory process and
614 objectives. In terms of monitoring and supervision, it was noted that there are areas where
615 supervisors could even spend a year without conducting a field supervision, and the lucky ones
616 would be visited once in a year. Even for those areas supervised, there were concerns about the
617 nature of supervision – as being vindictive, and extortionary rather than supportive. In some cases,
618 supervisors merely closed down shops on rather flimsy grounds rather than supporting the shop to

619 do better. On their part, regulatory officials complained of limited resources to fully enforce
620 regulations and other standard operating procedures. In Wafula et al., drug shop operators also
621 reported that inspectors never allowed any time for engagement and were always determined to
622 find fault, every time they visited and this would generate what was referred to as regulatory "cat-
623 and-mouse games" as operators are tipped off by their colleagues to close shops in an attempt to
624 elude inspection. In fact, some operators in Kenya developed long-term relations with inspectors
625 and would send money through mobile platforms, purposely to keep away from being inspected
626 **(7)**.
627
628 An additional regulatory challenge reported, was in relation to the role of the community and
629 community leaders. In this study, it was found that communities acted as 'shields' to drug sellers,
630 to the extent that supervisors would not be allowed to either sanction a particular drug seller or
631 close the shop. The community views the drug shop as their own and whenever supervisors come
632 in, the community is mobilized around the drug shop to resist its closure. From a community
633 standpoint, enforcing laws that negatively impact drug shop operations would potentially deny
634 many people access to essential medicines. This is typically another form of 'regulatory capture'.
635 It is clear that regulation is not a very straight forward process, but rather, is influenced by other
636 factors, including social expectations from the community, market incentives, and the relationships
637 that may exist between the regulator and the operators **(7)**. This calls for alternative approaches to
638 regulation, including a move away from the traditional '*Command and Control'* approach to an
639 approach that increasingly recognizes and involves stakeholders such as the community in
640 monitoring and supervision. Communities are the main users of drug shops, interact with drug
641 sellers on a more regular basis, but are also the main victims of their bad practices. Thus, the

642 community has an important role to play in co-creating regulation and holding the drug sellers
643 accountable for quality of products, services, and standards, and reigning-in on drug sellers in case
644 of exorbitant prices. Communities could form an important part of supervision, rather than relying
645 on inspectors who only come in periodically when their resources allow **(65-67)**. The ADDO
646 model in Tanzania demonstrated that working with local officials acting as inspectors rather than
647 relying on upstream inspection arrangements can address monitoring and inspection challenges
648 **(25)**. Other models of supervision such as peer-to-peer supervision have also been proposed and
649 piloted in some settings. In Uganda, an Association-Based peer-to-peer supervision was piloted in
650 Mityana District under the Accredited Drug Shops (ADS) program in 2013. Under the peer-to-
651 peer supervision model, peers would make supervisory visits every two to three months and
652 discussed with the ADS seller issues related to improving performance, rational medicine use,
653 among others **(25)**. Evaluation results from this peer-to-peer program showed improvements in the
654 management of common conditions, dispensing practices, and product availability, among other
655 indicators. Additional experiences on peer-to-peer supervision among drug shops can be found in
656 Bagonza et al. **(68)**. These are promising models that could complement and address the limitations
657 of the government regulatory mechanism.
658
659 Most discussions and research on retail drug shops and other informal health care providers in
660 low-income countries have focused on understanding what informal providers do, how they do
661 what they do, and some limited research on regulating informal providers. However, there has
662 been limited discussion on broader incentive structure, including the regulatory environment under
663 which the retail health market operates. Notwithstanding the role of drug shops in health service
664 delivery in Uganda, many health sector players still view retail drug shops as business-oriented,

665 profit-minded entities that must be eliminated from the health service delivery chain. This study
666 has shown that while the profit motive exists as exhibited by the extent of mark-ups on products,
667 there were other social and 'altruistic" motivations that enter their behavioral functions such as
668 social recognition, social networks, and social capital, and service to the community. Behavior and
669 practice change interventions could take advantage of these social motivations to improve drug
670 shop operations and ensure they serve the greater public health good. Additional research on social
671 motivations and how they could be taken advantage of to design feasible interventions may be
672 necessary.
673
674 This study had potential limitations that need to be underscored: First, the results are based on a
675 small sample of registered drug shops, which leaves out many registered and unregistered drug
676 shops that would have potentially provided useful insights to the study. Particularly, it would have
677 been interesting to investigate why some drug shops continue to operate without licenses and how
678 they navigate the regulatory system. Second, we did not include community voices, yet the
679 community is a critical stakeholder that would have generated additional perspectives on how best
680 they can guarantee better quality services from providers, as well as working with the upstream
681 authorities as complementary role bearers. However, our previous related work brought out some
682 of the community insights on drug shop operations **(35)**, although a deeper investigation may be
683 necessary. The third is a methodological limitation. Most of the quantitative data were generated
684 through interviews with drug sellers, which makes it susceptible to recall bias and other challenges
685 of self-reported data. Relatedly, many drug sellers have not conceptualized the difference between
686 sales, cost of sales, and profit margins. Some costs that go into running the drug shop operations
687 are either excluded or grossly underestimated (for example remunerations to the workers, daily

688 food expenses, etc.) and this has an effect on estimates. Lastly, the estimates reported are based on
689 a typical period (a week or a month), yet there are fluctuations in sales due to changes in seasons
690 and other factors that have played into the medical retail sector business models and analyses. Our
691 results, therefore, should be interpreted within this context. The findings are unlikely to represent
692 the full picture and may not be generalizable across all retail drug shops, and regulatory
693 interactions in all districts in Uganda. Nonetheless, the findings provide very useful insights and
694 add to the growing body of literature on the place of informal providers in health care service
695 delivery in low- and middle-income countries.
696
697 **Conclusion**
698 This study has established that the need to earn an income through profits was a significant
699 motivator, and indeed in some cases outlets earned up to 90% in profits. Beyond profits, however,
700 there were additional social or 'altruistic" motivations and benefits associated with operating a
701 drug shop, including social recognition, expanded social network, and social capital, and a better
702 feeling of serving the community. Furthermore, while a regulatory framework exists and is
703 appreciated by the retail market players, it was generally weak, constrained, and not well structured
704 to support improvements in service delivery within the medicines retail sector. In some cases, some
705 regulatory actions tended to generate perverse incentives for operators.
706
707 As a result, we recommend, first, that the mix of the business and social or altruistic motivations
708 should be harnessed to identify and implement practice-change interventions that can facilitate
709 access to quality services at retail drug shops. Second, providing market incentives such as
710 subsidizing medicines at the upstream of the supply chain, would likely reduce retail price mark-

711 up and ensure the affordability of essential medicines. Third and finally, the regulatory system
712 needs to be streamlined, well resourced, and strengthened. One way to strengthen regulation is to
713 co-create regulation by rethinking the relationship between the regulator, the regulated, and the
714 ultimate beneficiaries of a well-regulated market – the community. For example, a bottom-up
715 approach that provides for community-led monitoring and supervision, peer-to-peer supervision,
716 among others, could help to surmount the current regulatory challenges. Furthermore, a financing
717 mechanism such as community health insurance or social health insurance could help to minimize
718 the pervasive motivations to providers when clients purchase services using out-of-pocket
719 payments. An insurance scheme could provide an avenue to moderate the interaction between
720 "vulnerable" buyers and "powerful" providers. A more strong and streamlined regulatory system
721 would ensure convergence between the private 'business' interests and the broader public or
722 societal interests.
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Other information

Declarations

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Ethics approval and consent to participate:

This study was part of the larger *Access, Excess Intervention research* (AXEX project), whose ethical review and approval were granted by the Research and Ethics Committees at Makerere University School of Public Health (IRB00011353) the Uganda National Council for Science and Technology (UNCST) (#HS1385), and the World Health Organization (RPC553). Additional approval for this study was obtained from the University of Witwatersrand Human Research Ethics Committee (HREC) (#M151016). Informed consent was obtained from participants prior to data collection.

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753

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756

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768

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774 FEK & HW conducted the experiments. CM&FEK led data collection. CM entered, cleaned,
775 prepared, analyzed, and interpreted data. FEK, NBK, EEK, SSP, and HW contributed to data

analysis and to interpretation of findings. CM wrote the first draft of the paper. FEK, SSP, NBK, EEK, and HW reviewed, revised and contributed to writing and review of all manuscript drafts. All authors read and approved the final manuscript.

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972 Time Series Analysis (In Press).

973

Paper III

Published Paper III

Availability and Affordability of Essential Paediatric fever medicines at Private Drug Shops with Integrated Management of Malaria Pneumonia and Diarrhea in rural South-Western Uganda. A Quasi-Experimental Study.

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Abstract

Background: Most children in low-income countries access health care through private drug shops where availability and affordability of quality essential medicines is still a challenge. We assessed the effect on availability and affordability of essential paediatric medicine, of implementing a modified Integrated Community Case Management intervention (iCCM) at registered private drug shops in rural South Western Uganda.

Methods: The modified iCCM involved training drug shop attendants on managing febrile conditions, including performing rapid diagnostic tests for malaria and respiratory timers for pneumonia symptoms, and use of algorithms to identify and classify illnesses. In addition, drug shops were provided with subsidized pre-packaged color-coded and price labelled paediatric dosage medicines for malaria, pneumonia, and diarrhoea. The communities, as key stakeholders, were also sensitized about the different components of the intervention as well as the implementation process. Two districts were selected for the study with one district as intervention and another as comparison. A Drug seller survey, care-seeker drug shop exit interviews, Focus Group Discussions with care-takers of children below five years and Village Health Team members, and in-depth interviews with drug sellers and government officials were conducted before and after the intervention between 2013 and 2015. The World Health Organization/Health Action International (WHO/HAI) methodology was used to determine availability and affordability of essential medicines for the management of pediatric fever at the private drug shop.

Results. The iCCM intervention increased the availability for ACTs from 65.0% to 69% in the intervention district compared a recorded reduction from 67% down to 38% at drug shops in the comparison district. Availability of amoxicillin also increased from 28% to 68% in the intervention

district compared to a decline from 35% to 19% for the comparison district. Median Price Ratios also declined from 1.17 to 0.49 for ACTs, 7.28 to 2.46 for amoxicillin, 4. 47 to 4.26 for Zinc Sulfate, and from 2.75 to 2.70 for Oral rehydration salts. Apart from Oral rehydration salts and Zinc Sulfate, the prices for ACTs and amoxicillin were comparable to their international reference prices after the intervention. Care-seekers who reported medicine prices high reduced by 31% after the intervention compared to before (CI: -34.2 – 21.4, $p<0.001$). Affordability for all medicines improved with the intervention compared to before the intervention based on proportion of wages required to purchase the medicines.

Conclusions: Implementing a modified ICCM has the potential to increase the availability and affordability of essential treatment for children at the private drug shop in a rural setting in South-Western Uganda. There is an urgent need to involve the private drug shops in scaling-up iCCM taking advantage of the public - private-partnership framework in order to improve access to essential and quality medicines for children in rural areas of Uganda.

Keywords: Availability and affordability, essential medicines, pediatric fever, Uganda.

Background

Ensuring universal access to essential medicines as part of access to health care is at the heart of the global Sustainable Development Goals (SDGs) and Universal Health Coverage (UHC), and is considered a fundamental human right [1, 2]. Yet, access to essential medicines continues to be a significant challenge in many low and middle income countries and children are often the most affected [3-5]. Availability and affordability of medicines are significant factors in ensuring access to medicines [6]. Availability and affordability of medicines are closely linked to existing medicines financing mechanisms, rational use of medicines, level of supply chain efficiencies, and medicines regulation [7, 8]. Uganda's under-five mortality rate is still high at 45 per 1000 live births [9], yet the new SDG requires a further reduction of under-five mortality to 25 per 1000 live births by 2030 [10]. Ensuring access to paediatric medicines by improving their availability and affordability will be critical in achieving this new target.

Uganda is a highly pluralistic health system where health care for under-five children is accessed through both the public and private health sectors. While by the government policy, access to health care in public health facilities is free of charge (except for the private wings), there are systemic constraints related to underfunding, high patient loads, frequent medicine stock-outs, among others, which hinder efficient health service provision [11]**.** Within the context of these public health care delivery constraints, the private sector has been a critical source of under-five child care in many low and middle income countries [12]. Within the private sector, retail medicine markets have been key in expanding health care access for children [13]. The retail sector in Uganda, for example, serves between 40-70% of sick children and adults through selling over the counter medicines [14-16].

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97 However, there is reportedly limited access to appropriate and good quality medicines through the
98 informal private sector, and this has partly been attributed to high prices that make medicines
99 unaffordable. The high prices of medicines have among others been related to the pursuit of profit
100 motives [14, 17]. Unaffordable care has adverse clinical, economic, and social effects to
101 households and communities – including treatment interruptions, catastrophic household
102 expenditures, among others [6]. For countries like Uganda where public health systems are
103 characterized by intermittent medicine supplies and drug stock-outs being a common phenomenon,
104 improving availability and affordability of medicines in the private sector would help to overcome
105 the public sector inadequacies [18].

106

107 Between 2013 and 2015, Makerere University School of Public Health (MakSPH) together with
108 other partners and the districts of Mbarara and Bushenyi, South Western Uganda, implemented a
109 modified integrated Community Case Management (ICCM) intervention in private retail drug
110 shops. The "ACCESS and EXCESS, EQUITY and INFORMATION: Point of Care Diagnostics
111 and Pre-packaged Subsidized Drugs for Integrated Fever Management for Malaria, Pneumonia
112 and Diarrhea in Children at PRIVATE SECTOR Drug Shops in Uganda" (AXEX intervention
113 study) aimed at determining the effect of ICCM on paediatric fever care provided by licensed
114 private retail drug shops in rural setting of South Western Uganda. Specifically, the AXEX
115 intervention study aimed at evaluating the effect of ICCM at the retail drug shop on quality,
116 appropriateness, availability, and affordability of care provided for paediatric febrile children at
117 the private retail drug shop.

118

Results from the AXEX intervention study published elsewhere demonstrate that ICCM at retail drug shops improved appropriate treatment of paediatric febrile illnesses[19] and improved perceived quality of care [20]. The AXEX intervention further demonstrated that using an appropriate package of market incentives can alter behavior of market agents towards improved care, and that intervening in the medicines retail sector has wider health system intended and unintended effects beyond the retail market itself [21]. This paper utilized data from the AXEX intervention study to assess the effect of iCCM implementation at retail drug shops on availability and affordability of treatment for paediatric febrile illnesses at retail drug shops in rural western Uganda.

Methods

Study setting.

This paper utilizes data from the AXEX intervention study which was conducted in the rural areas of Mbarara and Bushenyi districts, South Western Uganda, between June 2013 and September 2015. By the time of the study implementation, the total population was 472,629 and 234,440 for Mbarara and Bushenyi districts respectively. [22, 23]. The two districts are located in the Ankole sub-region of Western Uganda with a 3% prevalence of the malaria parasite among under-five children (using microscopy) compared to the national average of 9% based on 2018 data [24]. The sub-region generally operates a pluralistic health system with government health facilities, private health facilities, clinics, pharmacies, and informal health providers operate side-by-side in providing health services, albeit at different levels of care. The public and private health facilities have symbiotic relationships such that each sector refers clients to the other particularly in circumstances where one is constrained to provide the needed services. Household choices on

when and where to seek care for sick under-five children in this sub-region area are mainly influenced by local beliefs and cultures, social economic status, health system and medicines supply chain related factors, among others [19].

Study design:

The AXEX intervention study was a quasi-experimental study conducted in two districts – with Mbarara district as an intervention, and Bushenyi district as a control. The details of the study design have been published in Kitutu & Kalyango et al.[19]; Kitutu & Mayora et al. [21]; and Mayora et al. [25]. In brief, however, data collection for assessment was conducted in both intervention and comparison districts before and after the intervention. This paper focused on assessing the effect of the intervention on availability and affordability of care for febrile conditions at retail drug shops.

The intervention package

Box 1: The intervention package [19].

1. **Supply mechanism for medicines and diagnostics.** The AXEX project purchased pre-packaged medicines—ACTs, amoxicillin, zinc sulfate and ORS – from manufacturers and provided them to selected pharmaceutical wholesalers within the study area. Study drug sellers were then able to access the medicines at those wholesale pharmacies at subsidized prices upon presenting *study medicine order forms* to the pharmacy. The medicines were single-dose packed, and color-coded for age. In addition, study drug shops were supplied free malaria rapid diagnostic tests (mRDTs), respiratory rate counters for pneumonia symptoms, iCCM treatment algorithms, and patient registers.

2. **Training of drug sellers.** A five-day training was conducted with drug sellers in the study drug shops. The training was led by a Ministry of Health certified trainer, using an approved MOH/WHO approved ICCM curriculum. The training focused on case detection, classification, and management, clinical signs and/or diagnostic testing of three febrile child illnesses of acute respiratory illness (ARI), malaria and diarrheal diseases, identifying danger signs and symptom, transmission, prevention, diagnostic testing and identifying populations at risk of pneumonia, malaria and diarrhea. Additionally, drug sellers were trained on filling in patient registries, referral, managing drug supplies, counseling care-seekers, adverse reaction monitoring and patient follow-up for outcomes. The training was practical, involving role plays and a visit to a public health facility for practical purpose.
3. **Monitoring and support supervision.** Field visits were conducted monthly for every drug shop, by field supervisor, other project staff and district health team. The drug shops maintained a standard ICCM registry in triplicate copies where they recorded children seen, their symptoms, diagnosis done, the test results, treatment given and follow up action taken, respectively. These copies of filled iCCM register pages were retrieved from each study drug shop monthly. The supervisors also discussed with drug sellers any new information and areas of improvement after checking the filled registers.
4. **Information, education and communication (IEC).** Intervention drug shops were branded with A2L (access to life) posters and communities notified about the services they offer. Additional community sensitization campaigns using the MoH child health and malaria messages were delivered through monthly radio talk shows by study and district staff and radio announcements. In addition, Community Health Workers attended

sensitization workshops organized by study and district staff. In these forums, the discussions and messaging focused on: management of febrile illnesses among children, importance of diagnostic testing, treatment adherence, and what to do if symptoms of the sick child persist, referral procedures, and more generally the implementation of iCCM at the drug shops. The CHWs later delivered these messages to households with U5 children by word-of-mouth within their communities.

Comparison: The comparison district (arm) continued with the existing practice of selling subsidized ACTs only, relying on previous training.

Data collection and tools:

The data used for this paper were collected as part of the larger AXEX intervention study data collection conducted at before (2013) and after (2015) points of the intervention using qualitative and quantitative methods as follows:

a. **Survey of drug sellers.** A total of 74 registered, licensed, and operational drug shops were included in the survey before the intervention (40 drug shops in intervention district and 34 in comparison district). After the intervention, data was collected from 48 drug shops (32 in intervention district and 16 in comparison district). The included drug shops were subjected to an inclusion criteria that included: being registered, licensed and operational, dealing in human medicines, and willingness to participate in the survey and intervention, among others [19, 25]. The lists of drug shops were obtained from the District Assistant Drug Inspectors (DADIs) in each district. Using a semi-structured questionnaire, drug sellers were interviewed on availability of selected medicines and services for management of febrile conditions. In

addition, data collectors or research assistants ascertained physical availability of the medicines.

b. **Care-seeker exit interviews.** Exit interviews were conducted with care-seekers who came to seek care for under-five children at the drug shop during the study period. Before the intervention, 428 exit interviews were conducted (intervention =212, comparison=216) at 20 selected clusters. Each drug shop was considered a cluster because it serves a particular community. The sample sizes for exit interviews was determined by the cluster sampling methodology proposed by Bennet et al. [26]. The details of the sampling process has been published elsewhere [19, 21]. After the intervention, a total of 553 exit interviews were conducted (intervention=285, comparison=268). Exit interviews were conducted at the same drug shops before and after the intervention. Exit interviews were guided by a questionnaire and respondents were invited to participate at the drug shop exit and only those who accepted to participate were interviewed. The interviews were conducted within the vicinity of the drug shop in a convenient place to avoid interruptions from the drug seller. The exit interviews included issues of what medicines have been purchased, whether appropriate prescriptions have been provided, care-seekers' views and perceptions about prices, cost and affordability of medicines vis-a-vis their ability to pay for the medicines, among others. Interviewers stayed at the drug shop from 9.00 am to 6.00pm every day until the targeted sample was met for that particular cluster.

c. **In-depth interviews.** These were conducted with a total of 47 and 19 selected drug sellers and government officials, respectively, across baseline, midline and end-line in both intervention and comparison arms. In-depth interviews were conducted at drug shops and offices for the drug sellers and government officials respectively. In-depth interviews lasted between 30-45

minutes and were conducted using a structured in-depth interview guide. The number of in-depth interviews to conduct was determined by topical saturation [27].

d. **Focus Group Discussion (FGDs).** A total of 26 Focus Group Discussions (FGDs) were conducted with Village Health Teams (VHTs) and caretakers of children under the age of five years An FGD had between 4-11 participants in the respective categories, and each FGD was conducted at conveniently identified community places. Each FGD was conducted by a lead interviewer and a note-taker who were social scientists that had been adequately trained in conducting FGDs.

Data Management and quality control

Data was collected by research assistants who were trained for two days and the tools used in data collection were pilot tested and feedback incorporated into the tools before embarking on full data collection. Data collected through care-seeker exit interviews, and drug shop survey was double-entered in epi data (http://www.epidata.dk) and later transferred and analyzed in STATA version 13.0 (Stata corp., College Station TX, USA). For qualitative data, FGDs were conducted in Runyankole, the local language, and then transcribed directly into English. In-depth interviews were conducted in English because the respondents spoke and understood English and these were directly transcribed. All data collection, entry, cleaning, and transcription of qualitative data was supervised by mainly FEK and CM with support from the broader study team.

Data analysis

This paper focused on two key outcomes: availability and affordability of recommended medicines for three main under-five febrile conditions – uncomplicated malaria, pneumonia symptoms, and

214 non-bloody diarrhea. The corresponding medicines considered in the analysis were amoxicillin,
215 ACTs, ORS, and ORS/Zinc.
216 **Availability of medicines:** The concept of availability connotes the degree of fit between existing
217 resources and the demand for them [28]. Medicines availability was calculated as the percentage
218 of drug shops in the survey that had the medicine on the day of the survey, irrespective of the
219 quantity and form or even pack size. The calculated availability was compared to the WHO
220 benchmark of >80% for highly available and <30% of low availability [29]. To determine the
221 effect of the intervention on availability of iCCM recommended medicines, we compared the
222 proportion of outlets that had a particular medicine in the intervention district and comparison
223 district before and after the intervention and estimated the percentage change. Chi-square test was
224 conducted to ascertain the significance of difference at 5%, and differences were deemed
225 significant at p<005.
226 **Medicine prices:** All medicines purchased by care-seekers and their prices were recorded during
227 the exit interview. Only exit interviews conducted in the intervention district, before and after the
228 intervention were considered, and therefore the effect of the intervention on affordability of
229 treatment regimens is only analyzed by comparing affordability before and after the intervention
230 only in the intervention district. Medicine prices were recorded in local currency (Uganda
231 shillings) and then converted into US$ using the average exchange rates for 2013 (1 US$ = 2,763
232 UGX) and 2015 (1 US$ = 3,226.5 UGX), the years in which baseline and end-line data was
233 collected, respectively, and as reported by the Uganda Bureau of Statistics (Uganda Bureau of
234 Statistics [22, 30]. The local median price (per tablet, capsule, per sachet) were calculated and used
235 to generate the Median Price Ratios (MPRs) by dividing the local median prices by the
236 International Reference Prices (IRPs) extracted from the MSH International Medicines Price

Indicator Guide for 2013 and 2015 (after intervention) (Management Sciences for Health [31, 32]. The MPR for Zinc 200mg DT was not calculated because of unavailability of the MSH reference price for that specific medicine strength. The MPR was used to determine, for the studied medicines, whether local prices are generally higher, lower, or comparable to international prices. Generally, the cut-offs for MPR have been arbitrary and study specific. Some studies have adopted the threshold of MPR<=2.0 as the efficiency level for private sector medicines [33, 34] and others have adopted MPR<=2.5 for the private sector [29, 35]. There are also other assessments in LMICs that have found MPRs even as high as >5 in the private sector [36]. In this study, we decided to adopt a more realistic MPR<=2.5 threshold.

Affordability of medicines: The concept of *affordability* reflects the clients' ability and willingness to pay for the service or treatment course that is required to treat a particular reported illness based on the standard of care or recommended course [28, 37, 38]. Affordability of medicines was determined by initially calculating the total cost of a recommended treatment regimen for a particular febrile condition. The cost of a treatment regimen or standard dose was calculated by initially identifying the combination of medicines and number of tablets or quantities for each medicine required for a particular treatment condition [39, 40]. This medicine combinations constituting a treatment regimen and quantities required were determined based on the Uganda National treatment guidelines for ICCM and the WHO recommendations for rational use of medicines [41, 42]. The estimated local median prices for each medicine were applied to the medicine combinations within the recommended regimen to arrive at the cost of the treatment regimen.

260 The cost of the recommended treatment regimen was then compared with the daily wage of the
261 lowest paid unskilled government worker based on the Uganda system [39, 40]. The daily wage
262 rate for a lowest paid unskilled worker in Uganda at the time of the survey was derived from the
263 Ministry of Public Service salary structure. Given that the study data was collected between 2013
264 and 2015, the public service salary structures do not show any significant changes in salary over
265 the three years, and so based on this fact, the salary structure for financial year 2015/16 was used
266 [43]. Monthly wage payments were converted to daily payments using a typical 30-day month.
267 For standardization and comparison purposes, wages were converted into United States Dollars
268 (USD) based on the official average exchange rate for the year 2015[30].
269
270 Treatment regimens or doses were considered unaffordable if the cost of the recommended
271 treatment regimen for a particular febrile condition required more than one day's wage for the
272 lowest paid worker, otherwise it was affordable[39, 40]. Based on this calculation, we compared
273 affordability before the intervention and affordability after the intervention (intervention district
274 only) to ascertain the effect of the ICCM intervention on affordability.
275
276 Affordability was further analyzed using care-seekers' perceptions using three dimensions:
277 whether the care-seeker was able to afford the drugs prescribed, care-seeker's rating of prices in
278 relation to ability to pay, and caretaker's ability to meet the costs related to the illness. These
279 perceptions were captured through care-seeker exit interviews in both the intervention and
280 comparison districts before and after the intervention. The difference-in-difference (DiD) analysis
281 approach was used to determine the effect of the intervention by comparing the proportions of
282 responses to these dimensions of affordability before and after the intervention in both study

groups[44]. The DiD approach helps to control for possible time-invariant unobserved heterogeneity that could have caused cofounding. The DiD "isolates" the effect of the intervention from the 'natural' changes in order to make inference on the intervention effect especially under situations where unobservable conditions may influence or confound the likely effect [45]. The DiD analysis simply shows the difference in the outcome measure in the intervention group before and after the intervention, minus the difference in the outcome measure in the comparison group before and after the intervention. The DiD model was used by fitting the mixed effects regression model where proportions were modelled as proportions with robust standard errors to get an absolute difference, respective confidence intervals, and associated probability values. The model as follows:

$$\text{Model: } Y = \beta 0 + \beta 1*[\text{Time}] + \beta 2*[\text{Study Arm}] + \beta 3*[\text{Time* Study Arm}] + \beta 4*[\text{Covariates}]$$

Among the assumption we assessed for the DiD estimation were: 1) that the allocation of intervention was not determined by outcome; 2) that the composition of intervention and comparison groups is stable for a repeated cross-sectional design; and 3) that there are no spillover effects. However, the assumption that without the intervention, the changes in outcome in both intervention and comparison groups was expected to be the same, was not tested.

The care-seekers were randomly selected at both baseline and end-line, and this was based on the assumption that care-seekers at both points, who were interviewed (bassline and end-line), had generally homogenous characteristics

Analysis of qualitative data from the drug seller interviews and VHT and care-seeker FGDs was also conducted. Transcripts were read by CM and FEK and separately coded in Open Code

Software V.4.03 (University of Umea, Sweden). Preliminary codes were refined and agreed upon to eventually formulate the final codes. Using thematic content analysis approach, meaningful themes were generated [46-48]. Additional notes taken during the interviews supplemented the transcript data. Only themes related to availability and affordability were relevantly applied in this paper to supplement and reinforce quantitative analysis, but also further illuminate the health care providers and caregivers' perspectives on affordability of care provided at private drug shops in the study area [49].

Ethical considerations

The AXEX intervention study was approval by the Makerere University School of Public Health Higher Degrees Research and Ethics Committee (#IRB00011353) and the Uganda National Council for Science and Technology (UNCST) (#HS1385). Additional approvals were obtained from the World Health Organization (RPC553) and the University of Witwatersrand Human Research Ethics Committee (#M151016). Each participant signed a full consent form before any interviews were conducted.

Results

Availability of essential paediatric medicines

Table 1 shows the availability of selected paediatric medicines recommended for paediatric febrile conditions under the iCCM guidelines. We included quinine and metronidazole because they were found to be common medicines prescribed for children before the intervention and therefore wanted to track them especially in light of the iCCM recommendations. We also demonstrate the effect of the AXEX intervention on availability by comparing the proportions of outlets with the

medicines on the day of the survey in the intervention and comparison districts before and after the intervention.

Table 1: Availability of essential paediatric medicines before and after the intervention

		Before			After		
		Intervention N=40	**Comparison N=34**	**Pvalue**	**Intervention N=32**	**Comparison N=16**	**Pvalue**
ACTs++	Yes	26 (65.0%)	23 (67.6%)	0.810	22 (68.8%)	6 (37.5%)	0.038*
	No	14 (35.0%)	11 (32.4%)		10 (31.3%)	10 (62.5%)	
Amoxicillin	Yes	11 (27.5%)	12 (35.3%)	0.470	22 (68.3)	3 (18.8%)	<0.001*
	No	29 (72.5%)	22 (64.7%)		10 (31.3%)	13 (81.2%)	
Diarrhea Medicine+	Yes	27 (27.5%)	19 (55.9%)	0.304	16 (50.0%)	8 (50.0%)	1.000
	No	13 (32.5%)	15 (44.1%)		16 (50.0%)	8 (50.0%)	
Quinine	Yes	31 (77.5%)	20 (58.8%)	0.084	4 (12.5%)	1 (6.25%)	0.504
	No	9 (22.5%)	14 (41.2%)		28 (87.5%)	15 (93.8%)	
Metronidazole	Yes	7 (17.5%)	9 (26.5%)	0.8727 0.350	2 (12.5%)	2 (12.5%)	0.460
	No	33 (82.5%)	25 (73.5%)		30 (93.8%)	14 (87.5%)	

+Diarrhea medicine combines oral rehydration salts and zinc sulphate

++ACTs include all brands – including Arthemether, Lumefantrine, Lumartem, Lonart, Artefan, Coartem, etc.

**Significant at 5%.*

Comparing across the study districts before and after the intervention, we found that 65% compared to 67% of outlets in the intervention and comparison districts respectively reported availability of ACTs. After the intervention, however, the intervention district reported a relatively higher availability of ACTs (68.8%) compared to 37.5% for the comparison district and this different was statistically significant (chi2=4.2857, P=0.038). Relatedly, only 27.5% of outlets in the intervention district compared to 35.3% in the comparison had reported availability of amoxicillin before the intervention. However, after the intervention, there was a statistically

significant difference in availability of amoxicillin in the intervention district (68.8%) compared to availability (37.5%) in the comparison district (chi2=10.6852, P<0.001) (Table 1).

There is an observed change in availability of diarrhoea treatment (ORS, ORS/Zinc) particularly for the intervention district from 27.5% of outlets reporting availability before the intervention to 50% of outlets reporting availability after the intervention. There was also a noticeable reduction in availability of quinine in the intervention district from 77.5% before the intervention to 12.5% after the intervention.

From the qualitative analysis, drug sellers noted that improving and streamlining the medicines supply chain can significantly increase the availability of essential medicines for paediatric fevers. Many drug sellers averred that the medicines procurement system which the study established worked well in ensuring regular supply of study medicines to the participating outlets and this led to increased availability of the targeted medicines. The words of one drug seller were insightful;

> *"It has been easy for me because they were supplying them to us. 'C' would bring them for us but at times she would not have the drug that you want and then you find that it would not be easy to get them sooner. Otherwise we do get the drugs. It has been easy to get the drugs because I do not incur transport costs so when she brings I pick what I know will push me on till she brings the next batch" (**Drug seller IDI_3**).*

Medicine prices

The median prices for paediatric essential medicines under consideration were estimated per unit (per tablet or per sachet, whichever the case) using data from care-seeker exit interviews and converted to United States dollars (US$). There was an overall reduction in local median prices for essential medicines after the intervention compared to before the intervention in the intervention district. For example, ACT 20/120mg DT prices reduced from US Cents 11.0 to US

Cents 8.0 per tablet. Relatedly, prices for amoxicillin 125mg DT reduced from US Cents per 11.0 to US Cents 6.0 per tablet (Table 2). There were also an overall observed reduction in the median price ratios (MPR) for the medicines under consideration after the intervention compared to before the intervention. Significant reductions in MPR were recorded for ACT 20/120 mg DT from 1.17 before the intervention to 0.49 after the intervention, and for amoxicillin 125mg DT from 7.28 before the intervention to 2.46 after the intervention (Table 2).

Table 2: Median prices for different medicines (Prices in US Cents per unit (cap/tab, g, ml, vial)

	Before Intervention		After Intervention	
Medicine name (including strength and dosage form)	**MSH Price (2013)**	**Local Median price (MPR)**	**MSH Price (2015)**	**Local Median price (MPR)**
Arthemether/Lumefantrine 20/120mg DT.	9.42	11.0 (1.17)	16.22	8.0 (0.49)
Amoxicillin 125mg DT	1.51	11.0 (7.28)	2.03	5.0 (2.46)
Zinc Sulfate 20mg DT	2.46	11.0 (4.47)	1.41	6.0 (4.26)
Oral Rehydration Solution 500ml (Sachet)	6.54	18.0 (2.75)	5.55	15.0 (2.70)

Average exchange rate 1 USD =UGX 2765 (2013), and 1 USD =UGX 3,226.5 (2015)

****Missing MSH IRP*

ACT 20/120mg DT had the lowest MPR after the intervention compared to other child medicines such as amoxicillin and oral rehydration salts (ORS). For ACTs, MPR was less than the threshold both before and after the intervention compared to amoxicillin and Zin sulfate whose MPR was slightly above the threshold (2.46 & 4.26). The implication is that patient prices ACTs appeared to be similar to their IRPs while those for amoxicillin, while slightly above the threshold, were relatively close to their IRPs.

Affordability of ICCM recommended standard treatment regimens

According to the 2015/16 Uganda Ministry of Public Service Salary structure, the lowest paid public servant in Uganda is an *Office Attendant.* In the financial year 2015/2016, an *Office Attendant* earned a monthly gross salary of Uganda Shillings 187,660, an equivalent of US$ 58.2 based on the official 2015 average exchange of US$1=UGX 3,226.5 (UBOS 2016). This monthly wage translates into a minimum daily wage of For the *Office Attendant*, selected government official, the monthly wage translated into a minimum daily wage of UGX 6,255 (194.0 US. Cents). Table 3 shows the cost of treatment regimens for the selected paediatric fevers – uncomplicated malaria, pneumonia symptoms, and non-bloody diarrhoea. Findings show that the treatment regimens were affordable both before the intervention and after the intervention because they required less than one day's wage for the lowest paid worker, except for two treatments both for pneumonia symptoms for age 2-11 months (1.13 days' wage) and 12-59 months (1.70 days' wage) that were costly before the intervention. We also observe that on the whole, after the intervention, all standard treatments cost less than one day's wage (ranging between 0.25 days' wages and 0.77 days' wages) compared to affordability before the intervention (ranging between 0.34 days' wages and 1.70 days' wages). It was noteworthy that amoxicillin for treating pneumonia symptoms in children of all ages had the largest effect in terms of increased affordability. Relatedly, ACT for treating uncomplicated malaria was most affordable both before (0.34 days' wages) and after (0.25 days' wages) the intervention.

406 **Table 3: Cost and affordability of treatment regimens of recommended strengths (United States Cents)**

Febrile condition	Appropriate/recommended medicines	Strength [mg/tbl./cps.]	Dosage Regimen[tbl. or cps./day	Treatment Duration	No. of tbl/cps/ treat course	Total cost of treatment course	Number of days' wages required	Total cost/ treatment course	Number of days' wages required
Uncomplicated Malaria(+RDT)	Artemether/ lumefantrine	20/120 mg DT	6 Tabs in yellow pack (4-35 months)	1 tab twice daily for 3 days	6 Tabs	(11.0*6) =66.0 cents	(66.0/194.0) =0.34 days	(8.0*6) =48.0 cents	(48.0/194.0) =0.25 days
			12 tabs in blue pack (36-59 months)	2 tabs twice daily for 3 days	12 Tabs	(11.0*12) =132.0 cents	(132.0/194.0) =0.68 days	(8.0*12) =96.0 cents	(96.0/194.0) =0.49 days
Pneumonia symptoms (confirmed by respiratory time counter)	Amoxicillin DT	125mg	20 tabs in pink pack (2-11 months)	2 tabs twice daily for 5 days	20 Tabs	(11.0*20) =220.0 cents	(220.0/194.0) =1.13 days	(5.0*20) =100.0 cents	(100.0/194.0) =0.52 days
			30 tabs in green pack (12 – 59 months)	3 tabs twice daily for 5 days	30 Tabs	(11.0*30) =330.0 cents	(330.0/194.0) =1.70 days	(5.0*30) =150.0 cents	(150.0/194.0) =0.77 days
Non-bloody Diarrhea (loose stool with no visible presence of blood)	Zinc	200mg DT Plus 2 sachets of ORS	5 tabs (2-6 months children)	1/2 tab, once a day for 10 days + Half a 300ml every loose stool	5 Tabs + 2 ORS Sachets	(11.0*5) + (18.0*2) =91.0 cents	(91.0/194.0) =0.47 days	(6.0*5)+ (15.0*2) =60.0 cents	(60.0/194.0) =0.31 days
			10 tabs (7-59 months)	1 tabs once a day for 10 days+ Half a 300ml every loose stool	10 Tabs + 2 ORS Sachets	(11.0*10)+ (18.0*2) =146.0 cents	(146.0/194.0) =0.75 days	(6.0*10)+ (15.0*2) =90.0 cents	(90.0/194.0) =0.46 days

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Care-seekers' ratings of prices and cost of care in relation to their ability to pay

Table 4 summarises the effect of the iCCM intervention on these dimensions of affordability as elicited by care-seekers in relation to ability to pay through the drug shop client exit interviews. Before the intervention, more care-seekers for under-five children (41.7%) reported that prices at the retail drug shops were too expensive as compared to care-seekers in the comparison arm (15.6%). However, after the intervention, 12% compared to 17% of care-seekers in the intervention and comparison districts reported that prices at drug shops were too expensive. The percentage difference (DiD) between the two districts before and after the intervention for care-seekers who reported prices to be too expensive was -31% which was statistically significant (CI: -34.2, -21.4. p<0.001). There are other intervention effects recorded across other dimensions of affordability, which changes may not be statistically significant, but are consistent with affordability estimates presented in Table 3.

Table x: Effect of the iCCM intervention on perceived affordability of treatment for febrile childhood conditions among under-five children at retail drug shops in South Western Uganda; Difference-in-difference analysis

	Time points N (percent)		Change in percentage 95% CI	p-value
Study Arm	Baseline	End line		
Were you able to afford to buy all the drugs as prescribed/advised?	[3.7 (-10.9,3.5), p=0.315]	[-0.5 (-3.9,2.9), p=0.773]		
Comparison	216 (84.3)	268 (96.1)	11.8 (6.4, 17.2)	
Intervention	212 (80.6)	285 (95.6)	15.0 (9.1, 20.8)	
			3.2 (3.3, 9.6)	p=0.331
How do you rate the prices of drugs in this outlet with respect to your ability *Too expensive				
Comparison	212 (15.6)	256 (17.2)	1.6 (-5.1,8.3)	P=0.642
Intervention	206 (41.7)	269 (12.3)	-29.4 (21.6, 137.2)	P<0.001
			-31% (-34.2, -21.4)	P<0.001
Were you able to meet the costs related to addressing the illness?				
Comparison	189 (92.6)	257 (96.9)	4.3 (0.1,8.6)	P=0.038
Intervention	56 (89.3)	276 (93.8)	4.5 (-4.1,13.1)	P=0.228
			-0.2 (-6.4,5.9)	P=0.949

1

P-values indicate whether or not the outcome of measurement is significantly different between the two groups (comparison and intervention), when comparing baseline and end-line. Any p-values less than 5% imply that the difference in proportions reported between the two groups is significant

Of the 12 respondents who indicated they could not afford to buy prescribed drugs (in the intervention district) after the intervention, 8/12 responded that they did not have enough money to buy the complete dose. Related, out of 10 respondents who reported that they could not afford to buy prescribed drugs (in the comparison district) 10/10 reported that they did not have enough money to buy the complete dose. Those that expressed inability to meet costs associated with illness episodes for their children reported that they mobilized resources using various ways, including payment by items (barter system), selling an item to pay the costs, borrowing, and settling the costs using financial support from social networks.

Qualitative analysis of views and opinions on ICCM intervention effect on affordability

Effect of ICCM intervention on medicines prices

Many care-takers appreciated the effect of the AXEX intervention on reducing the prices and cost of treatment and making treatment affordable for the low income users.

> *"Previously I was using other drug shops and I was one of those that used to spend a lot of money in drug shops. You would take a child for treatment and they put them on IV lines even when it was unnecessary – imagine five units through an IV line to a child. The drugs were also expensive but when I joined these services, I realized a child could be treated on tablets only and the child recovers. The charges are also amazingly low. Pneumonia and malaria tablets cause the child to recover very quickly. I wanted to request that the awareness of these services be improved* ***(R7, Caretaker FGD_2).***

The added package of diagnostics too did not increase the cost of treatment. Before the intervention, drug shops were not providing diagnostics before they could prescribe medicines.

There was a general reliance on experience of the drug sellers and the symptoms that were prescribed by the care seekers since they could not come with the child. The AXEX intervention, however, provided free malaria rapid diagnostic tests (mRDTs) and respiratory count machines. Before any treatment was prescribed, the drug seller was required to ascertain the tests and offer (or not) relevant treatment.

> *"….the nurse looked at my child and she put a device on the child's chest and told me that my child was so badly off and about to die. So she got me drugs and when I looked at them I was a bit scared. So she told me to pay 7000 shillings. I thought I had not heard well. I asked if she had said 70,000 shillings but she said that 7000 shillings. It was unbelievable compared to the amount of drugs she had given me. When I reached home my husband was shocked and thought I had spent a lot of money on the drugs. So he asked me where I had gotten all that money to buy the drugs, I told him that God was on my side and I had been charged 7000 shillings but he thought that I must have been mad but I assured him and he accepted. Two days later the child had improved and had even started to move"* ***(R8, Caretaker FGD_1)***

Labelling of medicines reduced consumer exploitation and facilitated affordability

One of the factors identified for having influenced affordability is the labelling of medicines. The AXEX intervention provided subsidized pre-packaged medicines, with each dosage pack affixed with a price tag for consumers to know how much they were expected to pay. To the consumers and community role bearers, price labelling reduced consumer exploitation and this helped the low income care seekers to afford treatment. Any deviations from the prices indicated would likely cause a backlash from clients because they had been informed about these prices.

> *"…When these drugs were brought, they helped in reducing the exorbitant charges of the health workers in drug shops because they were used to high profits but the drugs came with recommended sale price tags. So the drug shop owner would also view it as a challenge because it would reduce the profit margin. So they first had a bad attitude towards them"* ***(R1, VHT FGD_4).***

"… I have seen a lot of change in their services in the last two year. Even if we are saying that they charge highly, they have reduced their charges. I think some fear that they will be caught if they keep charging highly, maybe some of them feared that we had gone to the training too so they would charge the exact prices for those drugs. They would only charge more for other drugs which they sell ***(R6, VHT FGD_4).***

The pursuit of profits by providers compromises affordability of treatment

Even when medicines were labelled and rules had been agreed upon between the providers and the study team, some drug sellers could not follow the rules. The behavior of reneging and going against standard rules has been widely reported in studies as characteristic of retail health markets. Of the main reasons for circumventing the rules is the incentive to earn profit. In this study, where drug sellers thought the rules were not favoring their profit motive, they chose to circumvent them. For example, one caretaker noted:

"…at times you go there and they tell you that the drugs which you people supply them are out of stock so they would sell you other drugs at high prices because they would want to profit on that" ***(R5, VHT FGD_4).***

*"…the other downside with these drug shops is that at times the diseases they are to treat has other drugs which are more costly than the ones you supplied them so they decide to give you the costly ones instead of the subsidized ones such that they can profit"****(R6, VHT FGD_4)***

Information dissemination reduced price escalations and kept treatment costs within allowable limits

To ensure the success of a market-based intervention such as iCCM at the drug shop, reasonable amounts of effort need to be directed towards community sensitization and communication. This will allow the community to appreciate the role of the intervention, defining their expectations and roles within that new program. This would also involve taking advantage of wider and populous platforms to ensure the message can gain wider attention and reach. It would also awaken the public to become monitors themselves which would eliminate unscrupulousness of drug sellers.

In addition, involving leadership at all levels is paramount as a mechanism to co-create regulation. Indeed, this is appreciated by the study participants as here noted:

"…I also think our religious and political leaders have a role to play more than us. The role of advocacy is theirs because if you are in a church you cannot speak if you are not on the program. The same goes for political gatherings where you cannot speak if the political leaders do not allow you to speak. So, when the leaders speak, the health workers will improve on their services and people will know that they are going to places that have been well approved. It will also reduce family reliance on the drug shops where family members do work that they are not trained to do. So when the local leaders speak about it, those who are not trained may fear to practice" ***(R1, VHT FGD_4).***

A combination of price and non-price competition can assure quality and affordability

Using the social franchising approach, the AXEX intervention identified and enrolled drug shops and trained drug sellers. In addition, the enrolled drug shops were labelled with an *ACCESS TO LIFE* (A2L) signage. The community was informed of the services available at A2L drug shops and the low prices they charged. This created a shift away from other outlets to the A2L drug shops. It was reported that in some areas within the intervention district, this branding of drug shops created friction and conflict between the A2L and non-A2L drug shops. There were reports that A2L signage would be plucked and stolen off during the night. Eventually some non-study drug shops were crowded out and started closing out after being edged out of clients.

"…you know that there are people you trained and those you did not train. Now when those you did not train got to know the prices of the drugs, they knew that they were going to run out of businesses so they took the sign posts off from those shops that were part of the project. For example in Buteraniro they had taken them from almost three drug shops. This is because they knew that they were going to lose clientele once people knew that some drug shops were selling drugs at a cheap price" ***[R6, VHT FGD_4).***

Discussion

Our paper draws from a large quasi-experimental study of implementing ICCM at the private drug shop. This paper specifically evaluated the effect of the intervention on the availability and affordability of essential medicines for paediatric fevers at the private drug shop in a rural setting in the districts of Bushenyi and Mbarara in South-western Uganda. This paper is part of a series of related papers from the AXEX intervention study whose findings have demonstrated that implementing ICCM at the private retail drug shop improves appropriate treatment and perceived quality of care for febrile illnesses [19, 20, 50].

Our study has shown that availability of ICCM recommended medicines for febrile conditions in private retail drug shops following the AXEX intervention was generally higher in the intervention district compared to the comparison district. The difference in availability for ACTs and amoxicillin after the ICCM intervention between the intervention and comparison districts was statistically significant. The qualitative analysis reveals that the high availability in the intervention drug shops was attributed to the streamlined medicines procurement system which the AXEX study established. This system involved identifying wholesale pharmacies where study medicines were placed and participating drug shops only required filling a form to access the medicines. At some point the field supervisor moved with medicines and whichever drug shop required to re-fill did not need to travel far but could get a re-fill from the study supervisor. An additional explanation may be the fact that subsidizing coupled with labelling the medicines made them relatively cheaper and this attracted more clients which made them more profitable because from economic theory, the lower the price the higher the expected sales and revenue and this may act as an incentive to stock more. However, even for outlets that showed increased availability after the intervention,

559 they were all below the recommended level of 80% [51]. The inadequate availability of essential
560 medicines in Uganda is not only a private sector challenge but also for the public health sector. In
561 Uganda, access to health services through the public sector is free, except, at the private wings of
562 public facilities. However, the public sector has challenges of inadequate supplies and frequent
563 drug stock-outs [52, 53]. These challenges are related to, among others, inadequate financing,
564 supply chain challenges, patient overloads, corruption, and profligate [53, 54]. Limited availability
565 of medicines in the public sector implies that care-seekers resort to private pharmacies, drug shops,
566 and other medicine outlets to access essential medicines which exposes households to high out-of-
567 pocket expenditures and financial catastrophe [55]. Relatedly, availability of medicines have been
568 found to be positively associated high provider trust and increased health care seeking behavior
569 [56-58]. Efforts aimed at increasing availability of essential paediatric medicines in the private
570 sector would be critical in expanding access to much needed medicines. One approach that can
571 demonstrably increase availability of essential medicines in the private sector is the subsidization
572 of medicines. The AXEX study provided subsidized pre-packaged medicines to study drug shops
573 and the observed availability in the findings may partly be related to this effort. The Global Fund
574 through its Affordable Medicines Facility-Malaria (AMFm) initiative that subsidized ACTs
575 through the public and private sector was found to have been successful in increasing the
576 availability and affordability of ACTs [59]. A systematic review assessed the effect ACT price
577 subsidies to private sector retailers on ACT availability, price, use, and market share, found that
578 substantive subsidies combined with training and social marketing improved availability of ACTs
579 in the private retail sector by almost 32% [60]. The Uganda National Medicines policy (2015) has
580 specifically committed to increasing availability, affordability, and financing of medicines in
581 Uganda. Specifically, the National Medicines Policy is committed to, among others: developing

582 mechanisms for affordable national procurement and consumer prices in the public and private
583 sectors and increased sustainable financing and efficient use of resources to finance quality
584 medicines [61]. Given that retail drug shops continue to support and complement the formal health
585 system, areas of policy reform need to be identified to ensure that essential and quality medicines
586 are available and can be accessed at all points of care, including retail drug shop outlets if Universal
587 Health Coverage is to be attained in Uganda. To this however, regulation is necessary to ensure
588 that private drug shops stock and dispense appropriate and recommended medicines as per the
589 National Drug Authority regulations[62, 63].
590
591 In terms of affordability of medicines, a previous study has reported that between 41% and 56%
592 of household health expenditures in low and middle income countries are expended on medicines
593 alone through out-of-pocket expenditures [64]. The estimates may be higher in these very recent
594 years given that medical inflation has been rising overtime. Household expenditure on medicines
595 contributes to household impoverishment due to catastrophic expenditure and individuals and
596 households in the low socioeconomic quintiles are often the most affected [64, 65]. In countries
597 where the health financing architecture is dominated by household out-of-pocket expenditure and
598 limited health insurance mechanisms, higher prices and cost of medicine can constrain access and
599 utilization of essential and quality medicines, ultimately undermining the UHC goal [39, 66]. In
600 pluralistic health systems like Uganda and other LMICs, access services is both through the public
601 complimented by the private sector where medicines are perceived to be expensive. Even for
602 systems where services are freely provided courtesy of public financing, drugs and medicines
603 stock-outs are not uncommon and patients have to procure essential medicines through the private

604 sector [11, 39, 67]. Strategies that reduce prices and cost of services particularly in the private
605 sector would go a long way in enhancing affordability, utilization, and better population health.
606
607 Our study showed a reduction in local median prices for the selected medicines, for example local
608 median price for ACTs declined from 11.0 United States Cents to 8.0 United States Cents. Local
609 median prices for amoxicillin dropped from 11.0 US Cents to 6.0 US Cents and the trend was
610 similar for other medicines considered. Relatedly, there was a noticeable reduction in median price
611 ratios (MPRs) across all medicines after the intervention compared to before the intervention.
612 Before the intervention, the MPRs ranged from 1.17 (ACTs) to 7.28 (Amoxicillin) and from 0.49
613 (ACTs) to 2.70 (ORS sachet). Before the intervention, except for ACTs whose MPR was below
614 the 2.5 threshold, the rest of the MPRs were above the threshold implying that local prices for
615 those medicines were relatively higher in comparison with international prices. Similarly, after the
616 intervention, the MPRs for ACTs and amoxicillin declined to below the threshold. However, MPR
617 for ORS (2.70) and Zinc sulfate (4.26), although they declined, were still above the threshold.
618 Furthermore, results of this study show that, based on the affordability criterion that takes into
619 consideration the currently recommended treatment options under the ICCM guidelines (MOH-
620 ICCM Policy ref), all medicines under consideration – ACTs, Zinc Sulphate, amoxicillin, and ORS
621 were generally affordable by Uganda standards both before and after the intervention (range: 0.34
622 days – 1.70 days, compare with daily wage of 1.94). However, compared to before the intervention,
623 these medicines become even more affordable after the intervention (range: 0.25 days – 0.77 days,
624 compare with daily wage of 1.94). Antimalarial ACTs was the most affordable both before and
625 after the intervention but the major improvement in affordability was recorded for amoxicillin (for
626 all under-five age categories). It may certainly not be surprising that ACTs were reportedly the

most available at most retail drug shop outlets before and after the intervention in the intervention district. Findings from our study compare well with a study in selected provinces of China which found that most of low-priced generic medicines in both public and retail pharmacies were generally found to be affordable ranging between 0.12 and 0.90-days' wages [34] and another similar study by Wang et al. [5]. However, some two studies done in Ethiopia and Guatemala – similar low-income settings – that found that many low-priced medicines in both the public and private sectors required more than one day wage to purchase and were therefore unaffordable [4, 68]. These differences in findings may perhaps be related more to levels of economic growth that eventually permeate into the salary levels of public servants and general incomes of individuals hence influencing the purchasing power of respective earnings across countries.

The overall recorded high affordability of the selected treatment regimens in our study may also be inconsistent with general perception that medicines at retail outlets are expensive which compromises the capacity of the poor to access them [39]. However, this could be attributed to the definition of affordability which focuses on wage earnings rather than probably a poverty-based criterion. In countries like Uganda where rural household poverty rates are high and individuals' earning capacities are critically compromised (more than 21.4% for Uganda as of 2016/17 are below the poverty line) [69] and the standard criterion of US$1.94 which was calculated in this study may be unrealistically high. To this category of individuals, the estimated treatment regimen costs for the essential medicines for treatment of pediatric fever may still be unaffordable. It is also important to note that affordability estimates in this study, as with many studies, are based on one child who may need care. The reality, however, is that many households in our setting find themselves unlucky with more than one sick child at any single moment. Under this situation, the

conclusion about affordability could certainly change depending on how much extra treatment costs are incurred vis-à-vis the economic status of that particular household. Relatedly, the estimated costs for treatment regimen costs excluded other treatment related costs that may be charged by providers over and above the standard regime. Finally, the AXEX study provided free rapid diagnostic test kits to the study drug shops and during the study period, rapid diagnostic services were provided free of charge. After the study, however, we are not certain if the outlets continued to offer such services free of charge. Certainly, as private entities, there is limited control over whether or not such diagnostic services remain cost-free. Therefore, the conclusion about affordability may likely be altered depending on which of the above issues play into the total cost of treatment.

What is for sure, though, is that, poor availability and unaffordability of medicines constrain access to essential medicines – especially by the poor – and undermines efforts to reduce under-five morbidity and mortality. The issue of availability and affordability of medicines in both public and private sectors in Uganda needs utmost attention given the complimentary role that private sector plays in service delivery. It is good to note that in the Uganda National Medicines policy (2015), the issues of medicines availability, affordability, and financing in Uganda has been included [61]. Among the strategies in the NMP, the Uganda government has committed to among others: 1) developing mechanisms for affordable national procurement and consumer prices in the public and private sectors; and 2) increasing sustainable financing and efficient use of resources to finance quality medicines. The Uganda Private Sector Assessment in Health (UPSAH), reported that medicine prices in the retail sector are ad hoc and price mark-ups can widely range from 50% to up to 600% and this had a negative impact on affordability of medicines [70]. The assessment

673 noted that for retail markets that are not strongly regulated and unprofessionalism is limited,
674 providers are confronted with a delicate balance between doing is professional and what brings
675 economic benefit, and quite often they have found the latter more attractive. To address these
676 challenges, the UPSAH recommended the 1) rationalization of drug prices - including the
677 establishment of pricing guidelines; and 2) implementation of innovative financing mechanisms
678 such as use of vouchers or establishment of a drug benefit plan for the poor to overcome barriers
679 to accessing essential medicines in the private sector [70].
680
681 Subsidization is another strategy that has increasingly been used to motivate availability and
682 affordability of essential medicines in the private sector. The biggest portion of product prices are
683 attributed to the 'add-on' costs through the supply chain. A subsidy that mainly targets the
684 upstream of the supply-chain, for example, targeting wholesalers is expected to lower the purchase
685 price by retailers and ultimately trickle down to the consumers as low prices. Subsidization has a
686 demonstrable effect on reducing medicine prices, boosting affordability, and expanding access to
687 essential medicines [59, 60, 71, 72].
688
689 The other mechanism to reduce prices and improve affordability that is proposed in the literature
690 is price regulation. With this strategy, prices can either be capped or price margins determined
691 within which providers are allowed to determine product prices. Sometimes, high mark-up prices
692 can be allowed only on low-priced medicines so as to offer incentive for providers to sell profitable
693 low-priced medicines, to the benefit of the consumers [39, 73]. Additional strategies commonly
694 used to contain price and cost escalations in the private sector include non- price competition, such
695 as product price labelling or tagging, information dissemination and communication, and social

franchising. These strategies require a reasonable level of regulatory capacity but also a recognition of the disincentives and unintended effects that could be generated which may be detrimental to consumers and the broader health system [74]. Therefore, implementation of any of the prescribed recommendations requires careful scrutiny and planning but also an evidence-base to ascertain the costs and health systems implications of each.

Study limitations

There are a number of limitations of this study that should be recognized in the context of interpreting and applying the findings. First, the data for availability refer to availability on the day of the survey irrespective of the quantities, and this may not be an accurate reflection of the situation that obtains on medicines availability in a typical month or year at the outlets. Second, the effect of the intervention on affordability was calculated for only the intervention district by comparing the treatment costs before and after the intervention and not comparing the change in the intervention and comparison districts which may likely undermine attribution of effect to the intervention.

Second, the approach used in measuring the effect of the iCCM intervention on affordability of paediatric medicines assumes "affordability" is uniform across the diversity of care-seekers, which may not be an accurate assumption. In addition, the aspect of self-report affordability is subjective and dependent on household socio-economic status as well as product that was being bought, because the products and their quantities were not standardized. Although perceptions were used to validate the quantitative measures of affordability in this study, there may not be accurately relied on to conclude on affordability of medicines.

718 Third, the data used in applying the DiD methodology used to measure or estimate the
719 causal effect for the intervention particularly on affordability may have been of low quality to
720 generate a very robust assessment, and this may have affected the reliability of the results and the
721 conclusions emerging from this assessment. However simplistic the analysis may have been, it
722 still provides pointers to how such interventions could influence market incentives and practices
723 to the detriment or benefit of the community. Finally, treatment costs and MPRs were calculated
724 without consideration for medicine quality, medicine type (whether generic or original brand
725 names) and country of source, although we think this in itself may not have significantly
726 compromised the findings on availability and affordability. Despite these limitations, we think our
727 study was able to contextualize the application of the recommended WHO/HAI methodology to
728 provide detail on the availability, cost, and affordability of the ICCM specific recommended
729 standard treatments in retail outlets in the two studied districts of South Western Uganda, and the
730 results is generalizable to the retail markets and outlets in other parts of Uganda and similar
731 settings.
732
733 **Conclusion**
734 This study assessed the effect of implementing ICCM at the retail drug shops on availability and
735 affordability of ICCM recommended febrile medicines in drug shops in Mbarara and Bushenyi
736 districts of South Western Uganda. Availability of ICCM recommended paediatric medicines was
737 higher in the intervention district after the intervention compared to the comparison district. ACTs
738 20/120mg and amoxicillin 125mg were significantly more available in the intervention district
739 compared to the comparison district after the intervention. The availability levels of medicines
740 were however below the 80% threshold recommended by the World Health Organization. Before

741 the intervention, amoxicillin 125mg DT and ORS 500ml were sold at prices higher than their IRPs,
742 except for ACT 20/120mg whose price was below its IRP. After the intervention, except for ORS
743 500ml, the rest of the medicines were sold at prices below their IRPs, based on the threshold of
744 MRP<=2.5. Using the cost of one day's wage criterion, all medicines were affordable both before
745 and after the intervention although affordability was higher after the intervention compared to
746 before the intervention. ACTs 20/120mg was the most affordable medicine both before and after
747 the intervention. This study clearly demonstrates that implementing targeted intervention such as
748 ICCM into the private sector, designed with appropriate market incentives such as subsidization,
749 pre-packing, price and non-price competition, and information, can increase availability and
750 affordability and expand access to essential medicines for children and ultimately contribute to
751 attaining universal health coverage in Uganda.
752
753 **Competing interests**
754 The authors declare no competing interests
755
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772

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777

778 **Authors' contributions:**

779 CM, FEK, HW, and SSP designed and conceptualized the study. CM, FEK & HW conducted the
780 experiments. CM&FEK led data collection and supervised data entry. CM & FEK cleaned the data
781 and transcripts. CM led the data analysis and interpretation for this paper with contributions from
782 FEK, NBK, EEK, SSP, & HW. CM wrote the manuscript drafts. FEK, SSP, NBK, EEK, and HW
783 reviewed, revised and contributed to writing and review of all manuscript drafts. All authors read
784 and approved the final manuscript.

785

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Paper IV

Research

BMJ Global Health

Health system effects of implementing integrated community case management (iCCM) intervention in private retail drug shops in South Western Uganda: a qualitative study

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ABSTRACT

Background Intervening in private drug shops to improve quality of care and enhance regulatory oversight may have health system effects that need to be understood before scaling up any such interventions. We examine the processes through which a drug shop intervention culminated in positive unintended effects and other dynamic interactions within the underlying health system.

Methods A multifaceted intervention consisting of drug seller training, supply of diagnostics and subsidised medicines, use of treatment algorithms, monthly supervision and community sensitisation was implemented in drug shops in South Western Uganda, to improve paediatric fever management. Focus group discussions and in-depth interviews were conducted with stakeholders (drug sellers, government officials and community health workers) at baseline, midpoint and end-line between September 2013 and September 2015. Using a health market and systems lens, transcripts from the interviews were analysed to identify health system effects associated with the apparent success of the intervention.

Findings Stakeholders initially expressed caution and fears about the intervention's implications for quality, equity and interface with the regulatory framework. Over time, these stakeholders embraced the intervention. Most respondents noted that the intervention had improved drug shop standards, enabled drug shops to embrace patient record keeping, parasite-based treatment of malaria and appropriate medicine use. There was also improved supportive supervision, and better compliance to licensing and other regulatory requirements. Drug seller legitimacy was enhanced from the community and client perspective, leading to improved trust in drug shops.

Conclusion The study showed how effectively using health technologies and the perceived efficacy of medicines contributed to improved legitimacy and trust in drug shops among stakeholders. The study also demonstrated that using a combination of appropriate incentives and consumer empowerment strategies can help harmonise common practices with medicine regulations and safeguard public health, especially in mixed health market contexts.

Summary box

What is already known about this topic?

- Private retail drug shops are an important source of care and management of paediatric fevers, especially in low-income and middle-income countries; however, the quality of care offered needs to be improved.

What are the new findings?

- Using a package of market incentives can alter the behaviour of market agents and improve agent practices.
- Furthermore, intervening in private health markets could generate health system effects beyond the market itself.

How might this impact on practice?

- Health systems have complex and dynamic interactions and therefore intervention designs must recognise these complexities.
- Intervention evaluation models must adopt a systems approach to analyse broader impact.

INTRODUCTION

Acute febrile illnesses of malaria, acute respiratory illness and diarrhoea account for more than half of deaths among children aged 1–59 months globally.[1] Majority of fever cases in low-income countries (LICs) such as Uganda seek care from private drug shops,[2 3] which have good reach in communities. Compared with government health facilities, drug shops are more accessible in terms of convenience, cost and time spent on care-seeking, and they have more reliable stocks of medicines and better social relations with their clients.[4–6] Clients are aware that they provide income to drug sellers and hence are able to exert agency in the care-seeking process.[7] In

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contrast to encounters with government health workers, clients are *active customers* rather than *passive patients* in an interaction with health providers that is friendly, and in which their opinions are respected.[5 8 9] However, drug shops operate in a largely unregulated retail health market where infringements of medicine regulations are commonplace.[9 10] They fill a void created by the absence of government and formal private health services in hard-to-reach communities.[9 10]

In Uganda, drug shops are part of an overall health system characterised by blurry boundaries between government-run and privately owned health facilities.[9–11] Government health workers supplement their incomes by working at private drug outlets,[10 12] charge unofficial fees[6 13] and they often advise patients to source medicines from private drug outlets in the face of stock outs at government health facilities.[5 14 15] Challenges faced by the health sector are compounded by high levels of poverty, with half of the population subsisting on <US$1.25 per day and a gross national income per capita of US$680.[16] Uganda is a low-income country and the government contribution to health of US$13.7 per capita[17] leaves health services severely under-resourced. Thus, out-of-pocket expenditure is high at 40% of total health expenditure [18] ,and technical quality of health services at low-level health facilities is poor.[3 11] This leads to catastrophic expenditures for households, it endangers under-five (U5) child health and nutritional status[3] and it perpetuates inequality. With regard to health indicators, the U5 mortality rate is 55/1000 live births, neonatal mortality rate is 23/1000 live births and infant mortality rate is 53/1000 live births .[16 17 19]

With most Ugandans (97%–99%) at risk of *Plasmodium falciparum* infection,[20 21] malaria is a leading cause of mortality. Other illnesses also present as acute febrile episodes. Therefore, presumptive treatment of all fevers with antimalarial medicines or antibiotics, as occurs in drug shops, is no longer recommended or acceptable. It delays seeking appropriate treatment and promotes an overuse of antimicrobials, which are known to promote resistant strains and to waste scarce healthcare resources. Without significant investment in scaling up public sector health services, care-seeking from drug shops in rural areas will continue. Drug shops operate in a retail market largely influenced by care-seeker preferences, provider incentives, drug sellers' reputations in the institutional environment and the pharmaceutical supply chain,[4 22] and sometimes these influences diverge from promoting public health. They can pose a challenge for health market regulation, to assure that good quality, affordable and equitable, healthcare services are provided to the population at a reasonable price while maintaining accountability to society.[23 24]

Top-down interventions by governments to enhance regulatory oversight such as government enforcement of 'unrealistic' practice standards can be impractical and undesirable, and may adversely affect access to medicines for children. They are likely to be interpreted by drug sellers as interference in their market space, as reported by the study by Goodman *et al* in Tanzania,[25] and could be met with resistance and evasion. If such interventions are to succeed in enhancing population health, scholars recommend that their implementation take into account a systems thinking perspective. These scholars argue that interactions among the various components of these interventions, and the intended and unintended consequences on the diverse range of stakeholders be kept in mind.[25 26]

We conducted an intervention study to evaluate the effect of an integrated community case management (iCCM) for childhood illnesses intervention[27–29] on paediatric fever care in licensed drug shops, in a low malaria transmission setting of South Western Uganda,[30 31] between May 2013 and September 2015. The intervention consisted of multiple components (described below) and it is referred to as the *AXEX (access and excess) intervention* for simplicity. Using a *factorial model*, we conceptualised the intended effects on drug seller treatment practices into predefined discrete, static and quantifiable variables.[32] We measured and compared appropriate management of childhood febrile cases (intended effects) in the intervention and comparison arm, before and after the *AXEX intervention*. Trained enumerators collected data in care-seeker drug shop exit interviews. The *AXEX intervention* improved appropriate treatment of uncomplicated malaria by 80%, of acute respiratory infection by 66% and of non-bloody diarrhoea by 31%. Results of these predefined (intended) effects have been discussed in detail elsewhere.[33]

However, it is important to understand the context, as well as the intervention's implementation and mechanism of effect, to better interpret the outcomes.[34] The hypothesis for this paper borrows from Robert Merton's social theory, and we argue that the *AXEX intervention*, like other purposive social actions, has unintended consequences.[35 36] Some of these can be foreseen and prevented, and others cannot be predicted. Whereas the intended and anticipated consequences of the purposive action are always relatively desirable to the actor, unintended effects are not always undesirable. In this paper, we adopt a health market theoretical framework[37] to describe and analyse the *AXEX intervention*. We aim to understand how the *AXEX intervention* was implemented, its intended and unintended consequences and their interconnections, and examine the dynamics and processes by which the effects were achieved.

Other studies have reported on the effects of child survival interventions in drug shops in Uganda.[5 9 11 14 38–40] On the subject of unintended consequences of introducing malaria Rapid Diagnostic Tests (mRDT) in drug shops, Hutchinson *et al* report that mRDTs interact with care-seeker desire for trustworthy providers and are useful in targeting medicines for their illness.[40] However, inadequate regulation of retail drug shops makes the mRDT appear more powerful than it is.[40] Our study goes farther than analysing the processes

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through which mRDTs became part of the assemblage in the drug shop space. Our study evaluates a social franchising system, which is currently popular among global health actors despite the lack of sound empirical evidence on its role or effects.[41] It incorporates an account of components that would improve the regulation of drug shops and retail health markets and forge formal linkages to government health services, which is missing in previous studies.[5 38 40] Lastly, it evaluates the iCCM of childhood febrile illnesses rather than just malaria tests. Our paper provides important lessons on the design and implementation of multicomponent interventions that seek to improve access to medicines and quality health services through an often neglected—yet critical—group of healthcare providers in low-and-middle-income countries (LMICs).

Implementation of the *AXEX intervention*

The implementing team included Makerere University School of Public Health in collaboration with the Alliance for Health Policy and Systems Research, World Health Organization, Karolinska Institutet and Uppsala University. A prospective evaluation of the *AXEX intervention* in 61 registered drug shops was done in Mbarara district from May 2013 to September 2015. Mbarara is located approximately 250 km South West of Kampala, the Ugandan commercial and administrative capital.[31] The district had a population of 472 629 people served by 58 government health facilities, private medicine outlets and the informal sector. The South Western region has a typical tropical climate with rainfall peaks in April and October.[16] Recent surveillance studies estimate the malaria parasite prevalence in the region to be between 4.1%[31] and 9.3%.[30]

The *AXEX intervention* adapted the integrated case management intervention[28 42] recommended by WHO/UNICEF[28 42] and the Ugandan Ministry of Health (MoH).[27] It consisted of three components that were adapted for implementation in private licensed drug shops.

The first was the drug seller component that aimed to improve integrated case management skills for those tending to U5 febrile child, based on case detection using simple clinical signs and rapid diagnostics to guide choice of treatment. Drug sellers from enrolled licensed drug shops were trained by a MoH-certified trainer. Using the MoH iCCM curriculum, drug sellers attended a 6-day training of lectures and hands-on sessions. It addressed how to assess, test, classify and treat the childhood illnesses of malaria, acute respiratory illness (ARI) and diarrhoeal diseases. Use of diagnostic testing, referral, filling in registers and managing drug supplies were also explained. Monthly support supervision was done by a project pharmacist or clinician to reinforce the skills acquired.

The second was the service component, which focused on the distribution of medicines, diagnostics and other logistics necessary for service provision. Medicines included artemether-lumefantrine dispersible tablets (DT), DT amoxicillin, DT zinc, oral rehydration salts (ORS) and artesunate suppositories. The medicines were single dose-packaged and colour-coded for specific age groups. The diagnostics included mRDT, specific for *P. falciparum* and respiratory counters. Other logistics included access to life (A2L) sign posts to mark study drug shops, drug shop registers, referral slips, resupply order forms (to enable uninterrupted supply of medicines) and treatment algorithms. The medicines (at subsidised price) and diagnostics (free-of-charge) could be procured from the pharmaceutical wholesaler in the nearest town to the study area on presentation of the resupply order forms. This was to ascertain that the medicine supply was from a trusted source and also to be able to channel the subsidy to the study drug shops.

The third was a community component, which sought to improve household and community care-seeking practices with potential impact on U5 child health. To this end, messages on fever care-seeking, diagnostic testing and treatment adherence were delivered through community health workers (CHWs), radio talk shows and announcements and by word-of-mouth by community members. CHWs interacted directly with the *AXEX intervention* team in quarterly project workshops.

Theoretical framework

We adapted the theoretical framework (figure 1) for health market systems proposed by Bloom *et al*[43] to take into account key stakeholders in Uganda.

At the centre of the framework, are *care-seekers* as users interacting with *drug sellers* as health providers, and this interaction is affected and shaped by *support functions* that include institutional[i] arrangements, infrastructure, information and related services shown in the middle (grey) concentric circle. The components of the *AXEX intervention* (explained above) acted on these support functions and introduced new ones. The outer most concentric circle lists the other *market players* who influence and are affected by the *support functions*.

A review of the relevant literature, in-depth interviews and focus group discussions (FGDs) were used to gather data for this study. In the initial phase, stakeholders, also referred to as actors or market players were identified through a desk review of relevant literature and consultation with professional organisations and personnel,[44] informed by the authors' perception of the position or influence they may hold.

Five key player categories were identified through this process, namely: i) health providers (drug shop owners, sellers and community health workers (CHWs)); ii) beneficiaries (care-seekers); iii) central government agencies (MoH and the National Drug Authority (NDA)); iv) local government institutions of Mbarara and, v)

[i] The term institutional here refers to rules, laws, norms and customs, and is distinct from its synonym organisational which refers to social settings.

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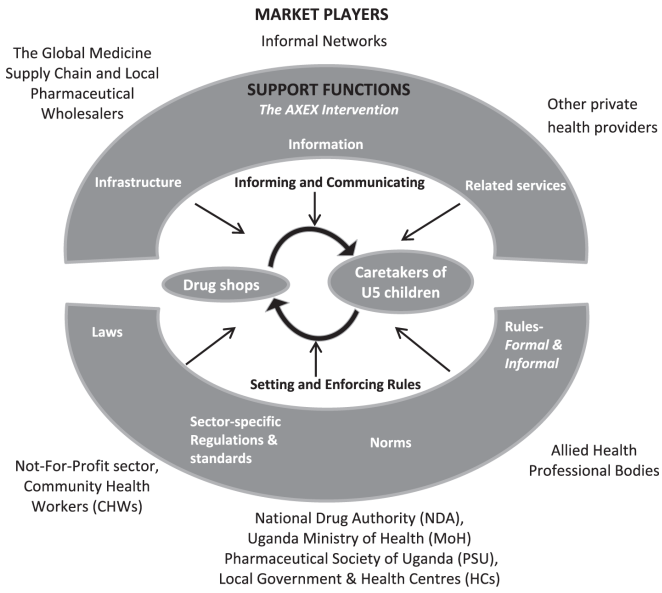


Figure 1 Theoretical framework for the access and excess (AXEX) intervention in drug shops in a mixed health system.

pharmaceutical supply chain actors (manufacturers and wholesalers). Other stakeholders were not-for-profit health providers, health professional bodies (Pharmaceutical Society of Uganda (PSU) and allied health professional council), other private health providers outside the study and the global pharmaceutical supply chain.

METHODS

At baseline, we explored common childhood illnesses treated at the drug shops, why community members sought care from them, and challenges care-seekers and drug sellers faced. Drug sellers were asked about their interactions with care-seekers, community health workers, how they obtained operation permits and experiences of their encounters and interactions with district and NDA officials. Care-seekers, drug sellers and community health workers were asked about their sources of health and medicine information. Drug sellers, care-seekers and community health workers were asked hypothetically about their views and perceptions on implementing an intervention that trained drug sellers to use diagnostic tests to assess and classify children, prior to recommending medicines or otherwise. These interviews aimed to understand the positions occupied by each of the key stakeholders within the theoretical framework for retail health markets in mixed health systems. They also highlighted the direct and indirect relationships and interactions among them. Midline and end-line interviews asked similar questions with a focus on first-hand accounts of experiences with the intervention or its components, perceptions formed, emergent opinions among the key stakeholders and challenges and opportunities posed by the *AXEX intervention*.

DATA COLLECTION

A team composed of a social scientist, graduate in Bachelor of Arts and a pharmacist conducted face-to-face interviews using interview guides. Participants were purposively selected; drug sellers in study drug shops were invited to participate in the in-depth Interviews (IDIs) and care-seekers at baseline were identified by CHWs. The inclusion criteria were having a child U5 as a dependent and previous care-seeking from private drug shops. CHWs within the catchment area of the drug shop were enrolled for FGDs. Data collection methods and stakeholders are listed in table 1.

Baseline data collection was done in May 2013 and an end-of-study evaluation was done in June and July 2015. Care-seekers who participated in FGDs were those with an U5 child who had sought care from a drug shop in the 2 months preceding data collection. CHWs participated in the FGDs if they were resident in the study area. FGDs were conducted in the study area at locations deemed convenient to participants including at subcounty halls, school classrooms and at health centres (HCs).

IDIs with drug sellers were conducted at their drug shops and IDIs with government officials were held at their offices. Sample sizes for all categories of FGDs and IDIs

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Table 1 Number of focus group discussions and in-depth interviews conducted

Data collection method	Stakeholder	Baseline	Midline	End-line	Total
Focus Group Discussions	Care-seekers with under-five child	6	7	5	18
	Community Health Workers	6		2	8
In-depth Interviews	Drug sellers	15	19	13	47
	Government officials*	4	10	5	19

*Government officials included district health team, officials of drug regulatory agency and Ministry of Health and government health centre personnel.

were determined by topical saturation.[45] Written informed consent was obtained from participants for the study and to digitally record the interviews. At the end of each interview, the lead interviewer or facilitator, note taker and lead author debriefed to improve the interview guide. Each interview was transcribed and translated into English by bilingual research assistants under supervision of the lead author. The lead author maintained a field journal and had a record of project activity reports. Total numbers of participants per interview and background characteristics are shown in table 2.

Data management and analysis

All interviews and conversations were audio-recorded and complemented by field notes. The lead author checked all the transcripts against the recordings to ensure accuracy, and reviewed and cleaned the transcripts. All transcripts were carefully read multiple times by the authors FEK (lead) and CK, and they were separately coded in OpenCode Software V.4.03 (University of Umeà, Sweden)[46] using the content and thematic analysis approach.[47] Data were extracted into meaning units. Together with predefined areas of interest identified from the theoretical framework for health market systems, the meaning units were used to draw up the initial coding scheme. Preliminary codes were refined by the lead author and applied back to the transcripts. These were further refined into final categories that reflected actual experiences and encounters of the different stakeholders with all or some of the components of the *AXEX intervention*.

At baseline, the overarching aim of the analysis and iterative process was to understand the roles and functioning of each key stakeholder and how those roles and functions

Table 2 Numbers and background characteristics of the participants

Characteristic	Description	Drug sellers	Care-seekers	Community health workers	Government officials*
Data collection method		IDIs	FGDs	FGDs	IDIs
Number of respondents		47	154	50	29
Respondents per interview		1	5 to 11	4 to 8	1
Sex	Female	40 (85%)	139 (90%)	30 (60%)	14 (48%)
	Male	7 (15%)	15 (10%)	20 (40%)	15 (52%)
Marital status	Married	22 (46%)	95 (62%)	47 (94%)	-
	Cohabiting	7 (15%)	48 (31%)	0	-
	Single	18 (39%)	11 (7%)	3 (6%)	-
Highest level of education	Degree	-	1 (1%)	0	7 (24%)
	A-level or certificate	-	19 (12%)	5 (10%)	22 (76%)
	O-level	-	37 (24%)	27 (54%)	0
	Primary		83 (54%)	18 (36%)	0
	None		14 (9%)	0	0
Work experience	3 or more years	-	-	48 (96%)	28 (97%)
	<3 years	-	-	2 (4%)	1 (3%)
Mean age (range)		32 (24 to 45)	30 (18 to 59)	40 (24 to 60)	39.7 (23 to 59)

*At midline, only 10 IDIs (out 20) of health workers in health facilities within the catchment area of the study drug shops were included in the study.
FGD, focus group discussions; IDIs, in-depth interviews.

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influenced the existing local retail health market. The lead author guided by emerging themes reflected on how implementing the *AXEX intervention* would alter or reinforce existing relationships and dynamic interactions. Themes around how drug sellers and care-seekers access health and medicine information, fears and negative perceptions and potential reactions towards the proposed intervention were examined. Preliminary findings subsequently led to adaptations in the implementation of the *AXEX intervention*.

A similar analytical and iterative process was followed at end-line. During this analysis, emerging themes, reflections and interpretations were checked against field notes and project activity reports. The lead author undertook deeper analysis, guided by the study objectives and domains from 'systems thinking' as applied to retail health markets in LMICs,[26 48 49] to understand how these experiences had shaped stakeholder perceptions, opinions, attitudes and behaviours at different points in the life of the *AXEX intervention*. The final categories at end-line included interface with the regulatory framework, information and dissemination, perceived efficacy of the *AXEX intervention*, linkage to the formal health system and provider incentives.

FINDINGS

Drug shops were recognised as an important source of healthcare; one that was more accessible, respectful and responsive to care-seeker needs and expectations than public facilities.[9] Drug sellers were aware of their position as physically and socially closer to communities, but they were perceived by health workers in the formal HCs as existing on the margins.[5] They understood that they operated in a local market influenced by knowledge and actions of care-seekers, CHWs, government health workers and regulators and also how formal and informal rules and norms were applied.[37] At baseline, these actors, drug sellers inclusive were cautious of how the *AXEX intervention* would impact on existing relationships and interactions among actors, rules and norms in the retail health market in which drug shops operated, and whether the emerging consequences would be beneficial or detrimental to care-seekers and the community. Implementation of the *AXEX intervention* was in turn modified and shaped by the emerging perceptions and behaviours of the actors identified in the theoretical framework adopted for this study.

The findings are presented as follows: first, the fears, perceptions and reactions of each actor—drug sellers, care-seekers, CHWs and government officials— prior to and in the early days of implementation are reported. The second section reports the perceptions and experiences of the actors, their interactions among each other and with the multiple components of the *AXEX intervention* and how these shaped the intervention, from the lens of foreseen and unintended consequences as they emerged. These are presented under the following categories: interface with the regulatory framework, information and dissemination, provider incentives, linkage to the formal health system and perceived efficacy of the *AXEX intervention*.

INITIAL FEARS, PERCEPTIONS AND REACTIONS

The initial attitude was that of fear of regulation on the part of drug sellers, that of drug sellers' opportunistic behaviour on the part of government officials, that of loss of status in the community on part of CHWs and apprehensions of whether drug sellers had the ability to apply diagnostic testing on the part of the care-seekers, respectively.

Drug sellers

Several drug sellers viewed the *AXEX intervention* with caution. They had fears that either the intervention or CHWs would be disruptive to their drug shop operation and business. Some viewed it as a veiled avenue for strict enforcement of regulations by the government, as well as controlling their activities.

> … when I come to understand, that you have come to take me down (interfere with my business), I leave it (the intervention)… (IDI, DS3)

Most drug sellers understood the role of diagnostic testing in guiding their treatment decisions but still expressed doubts on how well the mRDTs and respiratory timers differentiated presence and absence of disease among children.

Government officials

Government officials explained that the *AXEX intervention* enabled them to provide permits to drug shops to sell selected antibiotics , opening the door for further loosening of regulations. In the words of a government official,

> …Drugs like amoxicillin are in class B. They are not supposed to be (sold) in drug shops. Those could be the preliminary steps to see that may be, you declassify things like amoxicillin and allow it to be sold by drug shops. (IDI, GO1)

One government official stated that drug sellers tended to behave in an opportunistic manner. They sold medicines at high prices and provided some treatments that could harm children. The government official observed that they sold paracetamol and made a profit of it but then this treated the symptom and delayed care-seeking for the underlying cause in public health facilities.

Community Health Workers

Some CHWs observed that drug sellers would be hesitant to sell *AXEX intervention* medicines because of the price-marking, which appeared to limit the mark-up that could be obtained. The price-marking restricted their discretion to set prices and potentially conflicted with the sale of more profitable alternative treatments.

They also felt aggrieved that the iCCM intervention, which was designed to be implemented by CHWs, was adapted to drug shops. Other complaints included assertions that most drug shops were not licensed and tended to supply inadequate doses or even wrong medicines to clients.

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In the words of a CHW,

> Even if they do treat us, some of them are illegal which is not good. … they are expensive, they give you drugs according to the amount of money you have, so you find that at times you take an under-dose which does not help you, … the disease is not effectively treated and it recurs. (FGD4, CHW3)

On the other hand, a few CHWs were optimistic that drug shops would provide better fever care to their communities. This thinking was rationalised in terms of drug sellers having more health-related training and higher literacy skills than CHWs.

Care-seekers

Some care-seekers occasionally questioned drug seller's adeptness to use diagnostic tools to inform choice of treatment, given their previous treatment experience with drug sellers.

In the words of a care-seeker,

> You do not know how to test because we have been with you and you were not testing. Did you study how to test? Are you a laboratory technician? Then, how can you test? (FGD3, care-seeker 2)

Other care-seekers seemed to reject the notion of point-of-care diagnostics and thus were hesitant to accept the test outcome, especially when it indicated absence of disease.

> … Does this thing really work? Where is the microscope? You are not using electricity; you are not using power, where will you plug? Where are the chemicals then? (FGD4, care-seeker 3)

Care-seekers considered 'new requirements'—including the need for face-to-face interactions with the child before dispensing drugs (for examination and diagnostic testing) and collection of patient information (contact and demographic information for the drug shop patient registry)—initiated by drug sellers as mundane and typical of the poor customer care seen at government health facilities.

INTERFACE WITH THE REGULATORY FRAMEWORK

Government officials revealed some challenges encountered in previous efforts at regulating drug shops. Insufficient resources, underqualified drug sellers, lack of community engagement and poor recordkeeping practices were mentioned.

> …the problem is that we are constrained with the resources, both in terms of finances and human resources so there is a tendency of concentrating all our efforts to the government sector. (IDI, GO3)

Also highlighted were lack of price control regulation, minimal collaboration with district structures and opposition to interventions in drug shops by CHWs and health professional councils. Local politicians were reported to interfere with enforcement of regulatory standards as seen below:

In the words of government officials,

> … and then politicians in the district protect illegal shops. There are two types (of drug shops); illegal shops—those shops managed by non-health trained people. Someone did not go to school but he is managing a drug shop. We close these ones automatically because they are a danger to society. The second type is managed by people who have gone to school, have done their certificate as nursing assistant (some health-related training), and have (previously) worked in a health facility and (now) they are working in their (drug) shop… So sometimes these politicians protect the illegal shops. (IDI, GO2)

> If you try to close even an illegal drug shop, you will be surrounded (threatened). Even the Local Council one chairman (politician) will come and tell you, "You cannot do this to us". (IDI, GO1)

The government officials noted that the *AXEX intervention* addressed a number of these challenges by requiring drug sellers to interact with the regulatory institution in a number of areas. These included possession of a valid NDA licence to be eligible to participate in the study, adaptation and implementation of the MoH iCCM strategy, the use of single-dose, colour-coded packs approved by the NDA and the procurement of medicines and diagnostics via licensed pharmaceutical wholesalers, in accordance with existing regulations.

Most government officials commended the involvement of multiple stakeholders. Drug sellers observed that officials from the subcounty, HCs and district served as supervisors, mentors and health educators to enhance their practice standards, and care-seekers were sent from health facilities to purchase medicines from drug shops, on the other hand CHWs and local leaders liaised with the community.

In the words of a government official,

> …you took (trained) them through ICCM and gave them malaria RDTs. And malaria RDTs are helpful in reducing the usage of antimalarial drugs, so that negative cases are not treated (given ACTs)… (IDI, GO3)

In the words of a drug seller,

> …when a patient sits for a long time at the government health centre, the doctors send them to drug shops to be assisted, because sometimes there are no drugs at the government health centre. I think government should be grateful for that. (IDI, DS11)

Government officials and drug sellers alike noted that drug shops had access to novel medicines and diagnostics that were normally outside their medicine licence permits.

In the words of one drug seller,

> … before going for the training, we were not allowed to do any blood tests so we got a chance to do blood tests (mRDTs). In addition, we were given a respiratory timer.' (IDI, DS6)

The community sensitisation conducted as part of the intervention was considered to have shifted customers away from unlicensed drug outlets.

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In the words of a care-seeker,

> We used to go to drug shops, they would never ask us anything, we would just be given the drugs we asked for and asked to pay up and we would go our way. We would not even be explained to, why this drug cost this much and the other that much. The difference now with these new ones (drug shops) is that they cannot give you a drug without knowing what the child is suffering from. (FGD1, care-seeker 8)

This had an indirect effect that unlicensed drug outlets closed shop.

In the words of a government official,

> …that also helped us by reducing the mushrooming drug shops (drug shop start-ups) which were useless and dangerous to our people "…as drug shops without valid licenses segregated (self-selected and closed business operations) themselves". (IDI, GO2)

> …we used to have three or four drug shops, but some did not have enough capacity to serve, so those ones closed, and one was left. This one improved the appearance of its premises, brought equipment and the medicines. (FGD3, care-seeker 6)

Over time, some government officials considered drug sellers to be better suited than CHWs to implement the iCCM intervention and the *AXEX intervention* provided an avenue to review legal permits of drug shops so as to increase access to medicines and promote public-private partnerships for health (IDI, GO3).

In the words of a government official,

> …We have a whole component on private sector and community engagement; private sector partnership and private sector engagement. (IDI, GO3)

Taken together, the intervention was interpreted by authors to have improved regulator-drug seller interpersonal relations and motivated drug sellers to comply with practice standards. The mutual relationships could have led to more open and meaningful interactions, necessary to improve drug shop compliance to regulations.

INFORMATION AND DISSEMINATION

Key stakeholders (drug sellers, CHWs, care-seekers and government officials) reported receiving information about the *AXEX intervention*; most importantly that drug sellers had been trained on integrated case management of U5 febrile children. Most heard the information from radio talk shows and announcements, community sensitisation workshops, by word-of-mouth from CHWs, drug sellers themselves and from care-seekers with previous contact with study drug shops. A few drug sellers and CHWs reported informing their church congregations.

The care-seekers and CHWs mentioned that the medicines, although not free, were provided at lower prices, as marked on the medicine packs, and study drug shops were marked with the A2L poster for easy identification (FGD1, care-seekers 1, 3, 4, 5; FGD4, CHW6). However, some drug sellers mentioned that the A2L poster caused conflict with some drug shops not in the study. The non-study drug shops either vandalised the A2L posters or transferred them to their premises with a hope to attract customers (IDI, DS8; IDI, DS6).

In the words of a CHW,

> You know that there were drug sellers you trained and those you did not train. Now when those you did not train got to know that the prices of the drugs were lower, they knew that they were going to run out of business, so they took the sign posts off (down) from those shops that were part of the project. … Uhmm (in affirmative) because they knew that they were going to lose clientele once people knew that some drug shops were selling drugs at a cheaper price. (FGD4, CHW6)

A few drug shop sellers felt that dissemination had been inadequate and argued for the use of posters, mass mobilisation and more focus on diagnostic testing of febrile children before treatment (IDI, DS6). Some drug sellers and CHWs stated that some care-seekers over time would test from the drug shops and seek medicines from government health facilities (FGD4, CHW1; IDI, DS11).

PROVIDER INCENTIVES

All drug shop sellers mentioned that taken together, the acquired competencies in integrated case management of paediatric fevers, presence of novel, effective medicines and diagnostics and perceived affordability of fever-care due to the medicine subsidy enhanced their reputation as health providers within the community.

Drug sellers also stated that adding diagnostic testing to their repertoire of services and insisting on face-to-face interaction with the care-seeker and sick child transformed them from 'mere' sellers to '*bashaho*' loosely meaning 'medical doctors' or 'biomedicine experts' who appeared to make decisions based on some judgement. Additionally, drug seller collaboration with key stakeholders—district officials, regulators (MoH, NDA and researchers), and CHWs—served to move them from the *margins of legitimacy* to *insiders of the formal health system*. In the drug sellers' and care-seekers' views, the community sensitisation that often referred to the A2L poster that marked study drug shops increased this effect. Care-seekers satisfied with drug shop fever-care recommended their friends and neighbours to seek care from drug shops, thereby increasing their customer numbers and sales.

In the words of drug sellers,

> The number (of care seekers) increased … (pause) because of good services and drugs at a low cost. (IDI, DS2)

> On our side, we accessed money. Someone would have a problem and you would solve it, so they would go and tell others and they bring others too. (IDI, DS3)

Drug sellers spontaneously mentioned adding adjunct medicines such as iron supplements and cough syrups to willing caretakers to increase their profit margins, an unintended effect, possibly with negative consequences.

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Contrastingly, care-seekers felt empowered to hold the drug sellers accountable for their prices because of the price labels on intervention medicines.

In the words of CHWs,

> When these drugs were brought, they (drugs) helped in reducing the high charges of the health workers in drug shops because they were used to high profits, but the drugs came with recommended sale price tags. So the drug seller would also view it as a challenge because it would reduce the profit margin. (FGD4, CHW1)

> I think some feared that they will be caught if they kept charging high prices, may be some of them suspected that we had attended the (iCCM project) training too, so they would charge the exact prices for those drugs. They would only add charges for the other drugs if they were part of your purchases. (FGD4, CHW6)

LINKAGE TO THE FORMAL HEALTH SYSTEM

Both government officials and drug sellers mentioned that they favoured a recognisable and formal linkage between drug shops and the nearest government HCs.

> …The private sector should operate concurrently with the public sector. And the private outlets normally go to where the services are needed. They know where there is a gap and the government cannot provide. (IDI, GO1)

In the words of a drug seller,

> So when a child would come with danger signs, I would refer them (to Bwizibwera—the nearest government health centre). Once came a two year old baby with danger signs of malaria, I did mRDT and it turned out positive, so I referred this baby to Bwizibwera. (IDI, DS6)

> I also went to the government health centre and told them, if they got U5 child with pneumonia symptoms and drugs were out of stock, they could refer them to me. (IDI, DS6)

Drug sellers suggested that government health workers could collaborate more by participating in training of drug sellers and should not be dismissive of drug shops' patient referrals without due diligence. For instance, drug sellers often recommended treatments depending on the amount of money provided by the care-seeker. And thus putting blame squarely on drug sellers for truncated doses or inappropriate treatments did not reflect that reality and was considered unfair by drug sellers.

Government officials, drug sellers, CHWs and care-seekers argued that a formal partnership presented mutual advantages; continuity of care for care-seekers, decongestion of government HCs and increased penetration of government-led interventions.

In some cases, the *AXEX intervention* rode on already existing informal linkages between private providers and government HCs, with examples of dual practice and referral of patients by government health workers to drug shops for medicines.

> Eighty percent, if not ninety percent of the people who own those drug shops work in the public sector. It is only of recent that people are emerging to be solely private, but even as we speak seventy or eighty percent work in the public sector. (IDI, GO3)

The *AXEX intervention* was noted to have initiated patient registry and referral mechanisms at the drug shops, and drug shops were providing monthly reports to the district health management information system. Government officials observed that these interventions were critical to strengthening the underlying linkages between drug shops and the formal district health system.

PERCEIVED EFFICACY OF THE *AXEX INTERVENTION*

Drug sellers mentioned that the intervention medicines were efficacious, particularly amoxicillin in pneumonia and zinc/ORS in diarrhoea treatment, respectively. In their view, pneumonia and diarrhoea symptoms resolved in U5 children given these medicines, and faster than when given alternative medicines.

> The drugs are also effective so it is helping people, most especially those (medicines) for fast breathing (pneumonia symptoms) and diarrhoea. (IDI, DS1)

The drug sellers noted that the intervention medicines had favourable attributes; the single-dose and colour-coded packaging was easier to handle in distribution and treatment counselling of care-seekers, the dispersible tablets were easy to reconstitute into solutions that were child-appropriate in dosing and administering and thus convenient to use. Care-seekers also explained that the medicines in blister strips and single-dose packs were easier to keep safe than loose tablets, the treatment instructions were easy to understand and children liked their palatable taste. Care-seekers noted the reduction in their cost of treatment for similar illnesses.

> The good thing with these drugs is that when you would give them to a child and tell them, "Here, have; they are sweet". They would take them, so they are not sour. (IDI, DS2)

In the words of care-seekers,

> The difference is with the prices because previously, you would go to the hospital and find that the money is high and you find yourself paying about Uganda Shillings (UGX) 12 000 (USD 4) but now it has changed, the drug seller can give you medicine at reduced prices, so you find that the drugs we used to buy at UGX 12 000 are now given at UGX 3000 (USD1). (FGD2, care-seeker 3)

> The drugs they give us cure the child. So whether it (the cost) is much (high) or less, it still cures. (FGD2, care-seeker 5)

Most drug sellers mentioned that the diagnostic tests were transformative to their practice. The mRDTs and respiratory rate timers were easy to use and performed well. A negative malaria test indicated that the child did not have malaria and the respiratory timer detected pneumonia symptoms.

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> The RDTs quickly give you results. And RDT's do not need electric power… with the way we were trained; I learned that you can carry out tests on children even without microscopes. (IDI, DS3)

However, there were complaints about discrepancies between the RDT results at the drug shops and malaria tests done at other private facilities. Overall, drug sellers observed that the *AXEX intervention* had contributed to saving children's lives and requested for an extension of the project life and expansion of services to cover febrile illnesses in adults.

DISCUSSION

The *AXEX intervention* was found to increase appropriate treatment of symptoms of pneumonia, malaria and diarrhoea substantially. It is an example of a multicomponent intervention towards creating a functioning health market, which provides equitable access to good quality, efficacious medicines while maintaining transparency and accountability. Care-seeker expectations of quality of fever care at drug shops were reconfigured, from trial and error to care that was based on definitive knowledge based on rapid tests. The medicines provided in the *AXEX intervention* had attributes that improved regulator—drug seller interaction, and care-seeking behaviour. The presence of quality-assured single-dose packaged, colour-coded medicines that were easy to handle at drug shops and promoted patient adherence[50] to prescribed doses was appreciated by regulators and care-seekers, although for different reasons. On the regulator's side, these products met medicine packaging standards and regulations[51] and encouraged dispensing of full treatment courses and maintaining good drug shop records. Care-seekers referred to the enhanced treatment experience due to the convenience of handling single-dose prepackaged medicines and the palatable taste of medicines to the children as being important to the children's adherence to treatment. This care-seeker experience and interpretation is consistent with observations by anthropological researchers who have inquired into the human dimension of medicine access, which goes beyond the product's efficacy and touches on perceived quality and acceptability of treatment (including social and cultural dimensions).[4 52]

Pre-*AXEX intervention*, drug shops were largely seen as outside the formal system and suspicious of regulation, regulators looked on them as opportunistic profit makers, CHWs too largely looked at them as this and communities went mostly to get medicines on demand. However, the medicines' and diagnostics' essence as '*materia medica*' could explain the observations from the current study, of how the presence of medicines and diagnostics transformed the relationship between drug sellers and their customers and other stakeholders,[4] potentially shifting drug sellers from *outsider* to *insider* in the formal health system. Other intervention studies in drug shops in Uganda have reported similar findings.[5 38 40] In the study by Hutchinson *et al*, drug sellers demonstrated their ability to test blood by using visibly medicalised items—gloves, lancets, mRDTs—considered solely the domain of trained, formal health workers. This reinforced care-seeker confidence in drug seller skill and ability.[38] Presence of diagnostics engendered trust between drug sellers and care-seekers, and created legitimacy, thereby bringing the drug shops closer to the formal health system.[5 38 40] However, the current study is different as it evaluated a multicomponent intervention with a franchise system, components to improve health market regulation and forge linkages with the formal health system, and it evaluated the iCCM of childhood febrile illnesses rather than just malaria tests.

The *AXEX intervention* used community sensitisation through radio talk shows, radio messages and workshops for CHWs and local leaders. The CHWs, local leaders and care-seekers then participated in informing individual households with U5 children by word-of-mouth. The drug shops studied here were marked with a franchisee A2L logo for easy identification and community awareness. Another component was the provision of medicine subsidies as incentives to drug sellers and communities to participate. Recommended retail prices were marked on medicine packs which engendered care-seekers to enact their agency in negotiations with drug sellers during the care-seeking process. This contributed to creating transparency among the stakeholders and accountability of drug sellers to their communities, helping the intervention achieve its objectives.[23]

The intervention resulted in the inclusion of the informal market into systems of regulation through stakeholder acceptance, which matched reality rather than ignoring the existence of a market and pretending it did not exist. In the current study, regulation of the retail market was approached as an outcome of a series of relationships between state agencies (NDA, MoH, PSU and local government), private drug outlets and beneficiary communities[53] to shape the norms, and rules—formal and informal—that influence interactions between drug sellers and care-seekers and other key players. Additionally, sector-specific regulations and standards (such as requiring a NDA licence) were enacted in the *AXEX intervention* as de facto while modifying other aspects of regulation to bring them closer to what was de jure considered legitimate (expanding the legal permits to include antimicrobials and diagnostics and training underqualified drug sellers) in a retail market such as in South Western Uganda.[25]

While the earlier market had enabled physical access, questions remained about quality, prescribing patterns and overuse of antimicrobials in febrile children who may not have needed them. The *AXEX intervention* was taken up by drug sellers, and its implementation in drug shops was accepted by other stakeholders within the study area. As a result, children with febrile illnesses could be assessed in an integrated way for common childhood illnesses. Those diagnosed with uncomplicated malaria, ARI or diarrhoea

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obtained recommended treatments according to the national iCCM algorithm. Similar findings are reported by Hutchinson *et al*,[40] who found that good diagnostic ability was closely associated with ethical and effective practice. The difference with the current study is that the study by Hutchinson *et al* assessed only malaria tests rather than the effect of an iCCM intervention that offers additional options for the health worker including respiratory timers (to assess for pneumonia symptoms), antibiotic medicines and diarrhoeal treatment.

Coupled with training, the provision of drugs and commodities and information, helped create incentives for drug shops to allow or cede to regulation, together this increased legitimacy and status and helped build trust, both between regulators and drug shops and between drug shops and care-seekers. The authors portend that the approach to implementation of the *AXEX intervention*, analysing relevant stakeholders and engaging them along with the multipronged character of the intervention led to conditions necessary for establishing trust among the actors. Trust is an important ingredient for cooperative relations.[54] It is a precursor to aligning divergent interests among multiple actors towards *collective action*. Above all, trust enables actors to assimilate all evidence and secures *communication* and *dialogue*.[54]

Whereas supply of medicines, diagnostics and healthcare is necessary, acceptance and use by care-seekers is vital to complete the loop of effective fever care delivery (figure 1). The trust established enhanced the quality of interaction between drug seller and care-seekers, a prerequisite for greater disclosure and behavioural change by care-seekers. Similar effects of a trusting provider/patient relationship have been described by Mechanic.[55 56] As reasoned by other scholars,[57] the provider/patient relationship is shaped by the institutions embedded within the health system, underscoring the importance of support functions (figure 1); namely, training of drug sellers, involvement of district officials and formal HCs, community sensitisation and the presence of medicines and supplies. The interplay among all the *AXEX intervention* components—presented in the theoretical framework (figure 1)—created conditions where drug sellers' behaviours were aligned with care-seekers interests.

The success of the *AXEX intervention* in improving the functioning of drug shops in a pluralistic health market also brings to light critical issues for consideration by health system analysts. First is the need for caution in overconfidence of drug sellers which could manifest in prescribing beyond what they are trained to. Drug sellers applied diagnostic testing to guide their treatment decisions. Care-seekers on the other hand changed their care-seeking practices and expectations of the care provided by drug sellers. Thus, the interaction between drug sellers and care-seekers was elevated from a purely '*economic or commercial transaction*' to an at least partially '*clinical or therapeutic transaction*' as described by Cross and MacGregor.[58] Whereas, this was a welcome observation in the current study, the authors call for caution since drug sellers could use this legitimacy to go beyond their basic training and undermine the public health sector and abuse public trust.

Second, how does one sustain aspects of the *AXEX intervention* responsible for its success beyond the project duration? These include subsidies for diagnostics and medicines, which maybe essential to maintain affordability by care-seekers, the co-production of regulation by multiple stakeholders including government officials, CHWs, research staff, caretakers, communities and drug sellers and regulation, of selling other drugs—vitamin and mineral formulas and supplements of little therapeutic value—as a drug seller coping mechanism to remain profitable in a rapidly changing retail health market. A possible approach to sustaining the subsidies for diagnostics and medicines is to expand the Affordable Medicines Facility for Malaria[59] to include other commodities used in the integrated management of paediatric febrile illness. Peters *et al*[60] and Leonard *et al*[53] suggest approaches that exploit the roles of actors towards co-production to regulate health markets.

Third, it is important to address tensions in the community that arise from drug shops left outside the *AXEX intervention*, CHWs and government HCs. CHWs felt aggrieved that the iCCM intervention designed to be implemented by them had been taken to drug sellers probably due to fear of loss of their status and power in the community.

CONCLUSION

Drug shops in rural areas remain an important source of care for U5 children[61] and should be part of the solution as low-income countries aim to achieve Universal Health Coverage.[62] We intervened to create a functional health market that improved access to life-saving medicines and technologies for U5 febrile children using a health systems approach[49] by adopting a health market systems framework.[23]

The *AXEX intervention* was beneficial as it acted on the legitimacy and reputation of drug sellers, and it provided a platform on which trust between drug sellers and regulators, and drug sellers and care-seekers was enacted and allowed to thrive. Trust enabled improvement in the quality of interaction among the multiple actors in the retail health market, promoted behaviour change among drug sellers and care-seekers and created conditions for convergence of their interests. Whereas drug seller reputation is important for their existence and profitability, it is also difficult to manage given the information asymmetry that exists in such health markets.

Drug shops were part of complex retail health systems with multiple actors. The actors and the system adapted. Cognisant of the complex multiple factors that influence drug seller practices[63] and the shortcomings of single interventions in such retail health markets,[63–65] the *AXEX intervention*, was a multicomponent intervention as reported in this paper. The importance and advantage of a multipronged intervention for similar markets cannot be overemphasised. It enacted realistic regulation to help increase

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and maintain quality, sustain provision of drugs and commodities as well as incentives to sellers to comply and users to come to licensed drug shops along with communication to enhance trust in drug shops among communities. Each of these, done alone would not have had similar effects. This conclusion is consistent with other researchers who have argued against single interventions that focus on knowledge alone[63] or problematise need narrowly and offer enhanced supply as the sole solution[66] or interventions that conceptualise regulation as a purely command and control activity.[23 53] The *AXEX intervention* was thus more than the sum of its parts.

We therefore recommend that interventions in retail health markets should comprise components that target the multiple actors or influences that shape that market. Examples could include inputs for service delivery, consumer empowerment and demand generation, modifications in regulation or the creation of conditions for co-creation of regulation. Second, multicomponent health system interventions are complex to implement and also create complexity in their evaluation. Their evaluation should be based in realism and should include analysis of the process of implementation. When medicines and technologies are one of the components, they should not be analysed only as products, but rather as items that encapsulate interests of different actors, some of which maybe converging with or competing against overall societal goals.

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