The rise of chain pharmacies in India: implications for public health

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
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Abstract

Pharmacy retail markets in low and middle-income countries (LMIC) have traditionally been dominated by independently owned pharmacies, but economic growth has spurred the entry of pharmacy chains into these markets. Chains could be argued to have the potential to both improve quality and reduce price in comparison to independent pharmacies, however this has been little studied in LMICs.

Using mixed methods, including a standardised patient survey, exit interviews with patients, and key informant interviews, research was undertaken to understand the effect of chain pharmacies, in India, on key public health concerns.

The management of childhood diarrhoea and suspected tuberculosis was similarly substandard in chains and independents for most areas of assessment. However, chains sold significantly fewer harmful and prescription-only medicines for the diarrhoea patient. No significant price difference was found between chains and independents for the management of the TB case but the diarrhoea consultation was significantly cheaper at chains. Chains offered discounts on medicines, made possible by bulk purchasing and efficiencies in the supply chain. Customers patronising chain pharmacies were both more educated and relatively wealthier than those using independent pharmacies. In-depth interviews explored a set of hypotheses regarding how being organised in a chain may affect key behaviours relating to quality failures. In practice, few differences were identified: chains did not all have qualified pharmacists; the chain structure was not used to enforce regulation; and chain sales staff faced quite high-powered financial incentives. Chains did exert strong influence over customer service and sales, but the potential to exploit this control to improve quality was not realised.

Given that the chains are not currently serving poorer groups, and the impact on quality of care was limited, any attempt to leverage this organisational model for public health improvement would require implementation of appropriate regulatory constraints and incentives.

Acknowledgements

This thesis is dedicated to the loving memory of my best friend, Lucy Dawson.

Never could I have imagined that you would not be here to see the completion of this work.

Thank you for holding my hand through life, from little 5 year olds through to adulthood.

Your memory continues to inspire me in all that I do.

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List of Abbreviations

ADC	Assistant drug controller
AIOCD	All Indian Organisation of Chemists & Druggists
AMR	Antimicrobial resistance
ASHA	Accredited Social Health Activist
BPL	Below Poverty Line
C&F	Carry and forwarding
CHC	Community Health Centre
CIOMS	Council for International Organizations of Medical Sciences
DLHS	District Level Health Survey
ESRC	Economic and Social Research Council
GDP	Gross Domestic Product
GOI	Government of India
HDI	Human development indicator
IDI	In-depth interview
IIPS	International Institute for Population Studies
INRUD	International Network for Rational Use of Drugs
IQR	Interquartile range
KI	Key informant
LMIC	Low- and middle-income country
LSHTM	London School of Hygiene and Tropical Medicine
MRP	Maximum retail price
NFHS	National family health survey
NGO	Non-Governmental Organisation
NPPA	National Pharmaceutical Pricing Authority
NPRP	Non pharmacist-run pharmacy
NTP	National Tuberculosis Programme
ORS	Oral rehydration solution
ORT	Oral rehydration therapy

OTC	Over-the-counter
PCA	Principal component analysis
PHC	Primary Health Centre
POM	Prescription only medicine
PRP	Pharmacist-run pharmacy
RNTCP	Revised National Tuberculosis Control Programme
RSBY	Rashtriya Swasthya Bima Yojana
RTIs	Respiratory tract infections
SES	Socioeconomic status
SOP	Standard operating procedure
SP	Standardised patient
STI	Sexually transmitted infection
TB	Tuberculosis
THE	Total health expenditure
UK	United Kingdom
US	United States
WHO	World Health Organization

PART I: BACKGROUND TO THE THESIS

1 Introduction

1.1 Role of pharmacies in low- and middle-income countries

An effective pharmaceutical service is a key component of the health system and recognised, as such, by the World Health Organization (WHO) (World Health Organisation 1988, 1994). Private retail pharmacies are present in many communities in low- and middle-income countries (LMICs), where they are widely utilised for filling prescriptions, purchasing medicines and seeking health advice (Smith 2009). Pharmacies are used as the first point of care in a number of LMICs for a range of medical conditions, including respiratory infections, fever, malaria, injury, body and dental pains, skin infections, diarrhoea and sexually transmitted infections (Igun 1987, Kamat and Nichter 1998, Saradamma, Higginbotham, and Nichter 2000, Smith 2009, Wafula, Miriti, and Goodman 2012). Their appeal lies in long opening hours, availability of medicines (including the possibility of credit and the option to purchase medicines in small quantities), geographical accessibility, and personal familiarity (Van der Geest 1982, Kloos et al. 1986, Igun 1987, Logan 1983, Price 1989, Greenhalgh 1987, Haak 1988, Mayhew et al. 2001). Further, many patients have neither the time nor money to consult a physician (Haak 1988, Ferguson 1981, Seeberg 2012, Wolffers 1987, Saradamma, Higginbotham, and Nichter 2000).

Pharmacy staff can be viewed as the gatekeepers of medicines. They stand at the interface between producers and consumers of medicines and it is their responsibility to ensure that they are used safely, effectively and rationally (Anderson 2002). When used correctly, medicines can save lives and improve people's health; irrational use, however, is wasteful and can be harmful at both the individual and population level. Firstly, it is associated with causing significant morbidity and mortality (Holloway and van Dijk 2011). Secondly, misuse of antibiotics has led to the selection and spread of resistant bacteria. As a result, antibacterial drugs have become less effective and in some cases, ineffective. Antimicrobial resistance (AMR) is now recognised as a 'global health security emergency' (World Health Organization 2014). A final concern is the economic impact of spending on households, especially the poor. Customers typically pay for the medicines purchased at pharmacies out of their own pocket and where these medicines are inappropriate this represents a waste of scarce resources.

1.2 Organisational arrangements of pharmacies in low- and middle-income countries

Retail pharmacy markets in LMICs have historically been dominated by independent retailers. In recent times, economic growth has led to the entry of chain pharmacies into these markets. A retail chain consists of number of outlets (definitions range from a minimum of 2-5) operating under a single brand and central management. All outlets are owned by the company and managers are employed to run individual outlets. Such pharmacies are now operating in a number of countries, including India, The Philippines, Thailand, China, Mexico, Brazil, Argentina, Chile, South Africa, Nigeria, Kenya and Uganda (IMS consulting group 2014, Lowe and Montagu 2009). In LMICs, chains are most entrenched in South America, in particular in Mexico and Chile where they account for 34% and 51% of the retail pharmacy market respectively. In most markets, a few major chains are responsible for driving business. Some corporations operate a proportion of their stores through a franchise model, whereby a franchisee pays an upfront fee and ongoing sales royalties in order to own and run a retail business using the franchisor's brand name, often buying inputs or goods for resale from the franchisor (Brickley, Dark, and Weisbach 1991). The franchisor often provides training, advertising and other services.

The chain that has arguably received most attention, in a low- or middle-income setting, is the Mexican giant, Farmacia Similares- the brain child of 'physician-pharmacist-industrialist' Victor Gonzalez Torres (Shadlen 2009). Farmacia Similares's business model of selling low cost generics to the bottom of the pyramid has garnered the attention of policy makers and global health organisations alike to the possibilities of pharmacy chains. Yet we are unaware of other chains, elsewhere in LMICs, with a similar offering. Instead, pharmacy chains in other settings tend to follow the traditional model of selling both generics and branded medicines, the latter being favoured by both doctors and patients (Nguyen et al. 2008).

1.3 Pharmacies in India

India's healthcare system is highly privatised in terms of both financing and service provision (Reddy et al. 2011). Public spending on health (as a % of GDP) ranks amongst the lowest in the world (1.1%) and has barely risen over the past decade. The health system is highly dependent on out of pocket payments (which account for over 70% of health care spending) and a poorly regulated private sector (Kumar et al. 2011, Mackintosh et al.). Within this pluralised private sector pharmacies, otherwise known as 'chemists and druggists' and 'medical and general stores', are used extensively by the public to purchase medicines and obtain health advice (Saradamma, Higginbotham, and Nichter 2000, Seeberg

2012). In some areas, chemists have been found to act as '*de facto* primary healthcare providers' (Seeberg et al. 2014). There are no official figures for the number of medicine retailers operating nationally, but it is estimated to be around 800,000 (All Indian Organisation of Chemists & Druggists (AIOCD) 2014 , IMS consulting group 2014). Despite their accessibility and frequency of use, national health policy has historically maintained a 'stoic silence about pharmacists' (Basak and Sathyanarayana 2009).

On paper, in order to obtain a pharmacy licence (or continue to run an existing pharmacy), a set of requirements must be fulfilled. These include a specified minimum area and equipment; compounding of prescription medicines should be done by a pharmacist; sale of prescription medicines should be done under direct supervision of a pharmacist; sale of prescription medicine should be recorded in a prescription register, and in a cash or credit memo for other medicines; no prescription medicines should be sold without a prescription; prescription medicines belonging to schedule X need duplicate prescription (Government of India). In terms of the expectations of pharmacists, guidance is laid out in the 'Pharmacy Practice Regulations', 2015 (Pharmacy Council of India 2015). These are the first updates to be made to the 70 year-old laws governing the regulation of the profession, practice of pharmacy, and the sale of medicines (the Pharmacy Act 1948 and the Drugs and Cosmetics Act 1940) (Government of India , Government of India). These new regulations include a code of pharmacy ethics and the duties of the registered pharmacist. In addition to dispensing prescription medicines and selling over the counter (OTC) medication in accordance with legal regulations, community pharmacists' duties are expected to include counselling and advising the public on the treatment of minor ailments; instructing patients regarding intended use of medicines, directions for use and proper storage requirements; advising patients of any adverse side-effects of medicines or potential interactions with other medicines; and promoting rational drug use.

In reality, a large gap exists between the regulations described and the everyday practice of pharmaceutical use. Licensing requirements are frequently flouted and pharmacy practice falls woefully short of this ideal (Saradamma, Higginbotham, and Nichter 2000, Seeberg 2012, Greenhalgh 1987, Kamat and Nichter 1998, Basak, van Mil, and Sathyanarayana 2009, Tiwari 2009). Through an analysis of the pharmaceutical sector in India, Jeffery and colleagues report that enforcement of regulation is poor, bribes are common and regulations 'have no real intrinsic significance'. On the functions that licenses play, they comment that 'protecting the consumer or ensuring professional practice come rather low down in the priorities' (Jeffery et al. 2007). They conclude that the Indian drug distribution system meets

the International Narcotics Control Board's[1] criteria for being 'unregulated' (Brhlikova et al. 2011, Jeffery and Santhosh 2009).

Given the weak regulatory environment, it is perhaps not surprising that research has found that pharmacies are commonly staffed by unqualified personnel, and that practice is characterised by insufficient history taking; the illegal sale of prescription only medicines without a prescription, including over use of antibiotics (often sold in incomplete courses); the provision of clinically inappropriate medicines; and limited advice giving (Greenhalgh 1987, Kamat and Nichter 1998, Saradamma, Higginbotham, and Nichter 2000, Satyanarayana S et al. 2016, Seeberg 2012). Further, there has been little effort to address these shortcomings (Basak and Sathyanarayana 2009, Konduri, Delmotte, and Rutta 2017).

1.3.1   Chain pharmacies in India

Within the Indian pharmacy landscape, pharmacy chains are a new, but growing, phenomenon. Their current market share is estimated to be around 4% but it is reportedly one of the fastest growing markets globally (IMS consulting group 2014). Chain growth in India has been reported at an average of 25% per annum, and this rate is expected to increase to between 35-40% in the coming years (Northbridge Capital 2011). Chains are concentrated in the country's metropolises, and they account for 9% of outlets in Bengaluru (the site of this PhD research).

For the purpose of this research, chains are defined as organisations where two or more pharmacies operate under the same name and each outlet uses the organisation's distinctive branding. The pharmacy chains operating in India are heterogeneous and range in size from two outlets to 1000 plus. Some restrict their business to one Indian city or state, whilst others have a multi-state or pan India presence. The advent of chains has bought new trends to the sector, such as extended opening hours, discounts on medicine prices and additional customer services including home delivery and health camps (these involve free screening for various health problems such as diabetes, bone mass density, eye and dental checks, and are used to stimulate business).

The organisational structure of chains tends to consist of some or all of the following in the senior management team: a managing director or chief executive, an operations director, human resources, purchasing and business development directors. Below this team sit the regional managers. Branches are staffed with an in-charge, who may or may not be a

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[1] According to the International Narcotics Control Board, a drug distribution system can be described as unregulated if it meets the following criteria: *'From a more technical perspective, an unregulated market for drugs can be considered to exist where: (A) Unlicensed individuals and/or entities trade in drugs that they are not authorized or entitled to deal with or in contravention of the applicable laws, regulations and norms; or, (B) Licensed individuals and/or entities trade in drugs that they are not authorized or entitled to deal with or in contravention of the applicable laws, regulations and norms.*

pharmacist[2], 2 or more pharmacy aides (assistants who require no qualifications) depending on the size of the outlet, and a delivery person. The individuals who own and run these chains, especially the larger outfits, tend to be educated to a high (university) level and often abroad. Whilst most independent stores have an open, on-the-street shop frontage, chains are often fully enclosed. Chain branches commonly have air conditioning, are neatly organised, and some aim for a more 'international' feel compared to independent shops. At the current time, chains are subjected to the same regulatory controls as independent pharmacies.

Thus far, little attention has been paid to the health-related questions arising as a result of these new arrangements. There are reasons to believe that being organised as a chain may affect the public health concerns of quality of care, prices of and access to medicines, and the quality of medicines. As such, there is a need to understand the effects of these new organisational forms. This thesis sets out to address this research gap.

1.4 Aims and Objectives

The aim of this PhD is to better understand the effects of chain pharmacies on the functioning of Indian pharmacies, compared to independent pharmacies, and the implications for public health.

In order to achieve this aim, the specific objectives are as follows:

A. To compare the quality of case management (of two tracer conditions) at chain and independent pharmacies.

B. To compare the price of consultations (for two tracer conditions) at chain and independent pharmacies

C. To assess the socioeconomic status of clients shopping at chain and independent pharmacies

D. To explore how and why the organisational structure of pharmacy chains may affect the quality of service provision and prices of medicines, compared to independent pharmacies.

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[2] Under the Pharmacy Act 1948 pharmacists working in India are required to possess a registration certificate issued by the state in which they wish to practice. To obtain this certificate one must first acquire either a DPharm, BPharm or MPharm from a recognised institution. The DPharm (most common qualification for those working in a retail pharmacy) involves a minimum of 2 years study plus practical training. The BPharm is a 4 year degree (DPharms can enter directly into the 2nd year) and the MPharm is a 2 year postgraduate course that one can enter on completion of the BPharm.

1.5 Thesis outline

Part 1 of the thesis continues with a published review of pharmacy performance and determinants of performance in LMIC in Asia (chapter 2). In part II, I draw on empirical literature on the effects of chains and economics literature to consider the theoretical effects of chains on key public health concerns- quality of care, quality of medicines, prices of medicines and access (chapter 3). This chapter culminates with the presentation of a set of hypotheses which informs the programme of work that follows. I then provide a description of the study site, the study design and methods used for data collection and analysis (chapter 4). Part III comprises three results chapters, all presented as research papers (either published or currently under consideration with a journal). These papers cover a comparison of the quality of case management of standardised patients[3] (SPs) for two tracer conditions (chapter 5) and prices of medicines and socioeconomic status (SES) of customers (chapter 6) at chain and independent pharmacies; as well as an exploration of the mechanisms by which these outcomes may vary (chapter 7). Part IV explores the implications of the results, including the scope of the study, methodological limitations, contribution of this thesis to the literature, and policy implications (chapter 8).

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[3] Individuals recruited from the local community and trained to present an identical case of a clinical condition to many healthcare providers in a study sample.

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2 Systematic literature of pharmacy performance

2.1 Introduction

In order to inform this thesis, I first conducted a systematic literature of pharmacy performance in low and middle-income Asian countries. The aim of this work was to fully understand the nature of pharmacy practice in these settings, and to gain a comprehensive overview of any shortcomings. Further, I examined the literature to understand which factors contribute to poor practices. The results of this review are presented in research paper 1 entitled "Performance of retail pharmacies in low- and middle-income Asian settings: a systematic review". The paper was published in *Health Policy and Planning* in March 2016. The supplementary material for this paper can be found in Appendix 1.

2.2 Research paper 1: literature review

(Cover sheet on next page)

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OXFORD

Performance of retail pharmacies in low- and middle-income Asian settings: a systematic review

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Abstract

In low- and middle-income countries (LMIC) in Asia, pharmacies are often patients' first point of contact with the health care system and their preferred channel for purchasing medicines. Unfortunately, pharmacy practice in these settings has been characterized by deficient knowledge and inappropriate treatment. This paper systematically reviews both the performance of all types of pharmacies and drug stores across Asia's LMIC, and the determinants of poor practice, in order to reflect on how this could best be addressed. Poor pharmacy practice in Asia appears to have persisted over the past 30 years. We identify a set of inadequacies that occur at key moments throughout the pharmacy encounter, including: insufficient history taking; lack of referral of patients who require medical attention; illegal sale of a wide range of prescription only medicines without a prescription; sale of medicines that are either clinically inappropriate and/or in doses that are outside of the therapeutic range; sale of incomplete courses of antibiotics; and limited provision of information and counselling. In terms of determinants of poor practice, first knowledge was found to be necessary but not sufficient to ensure correct management of patients presenting at the pharmacy. This is evidenced by large discrepancies between stated and actual practice; little difference in the treatment behaviour of less and more qualified personnel and the failure of training programmes to improve practice to a satisfactory level. Second, we identified a number of profit maximizing strategies employed by pharmacy staff that can be linked to poor practices. Finally, whilst the research is relatively sparse, the regulatory environment appears to play an important role in shaping behaviour. Future efforts to improve the situation may yield more success than historical attempts, which have tended to concentrate on education, if they address the profit incentives faced by pharmacy personnel and the regulatory system.

Key words: Asia, developing countries, pharmacies, private sector, quality of care

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Key Messages

- Pharmacy practice in Asia is characterised by insufficient history taking; a lack of appropriate patient referral; poor adherence to treatment guidelines, inappropriate supply of medicines and insufficient counselling.
- Adequate knowledge alone is not sufficient to ensure appropriate management of patients presenting at the pharmacy. Profit incentives and the regulatory environment must be taken into consideration when designing interventions to improve pharmacy practice in these settings.
- Intervention research in this area appears to be lacking and more research is particularly required on non pharmacist-run pharmacies and unregistered drug shops.

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Introduction

The role of the private sector in the provision of medicines has traditionally been neglected by governments and the international public health community alike (Bigdeli *et al.* 2014). Yet in most low-and middle-income countries (LMIC) it is widely established that private pharmacies and drug stores are typically patients' first point of contact with the healthcare system and the preferred channel through which to purchase medicines (Smith 2009b). For example, in Asia, pharmacies have been found to be the dominant source of healthcare for all common problems amongst poor populations in Bangladesh (Khan *et al.* 2012) and in Western Nepal, amongst mothers seeking care for their children, pharmacies were the most popular source (46.2%) (Sreeramareddy *et al.* 2006). Their appeal lies in long opening hours, availability of medicines (including the possibility of credit and the option to purchase medicines in small quantities), geographic accessibility and personal familiarity (Van Der Geest 1982; Logan 1983; Kloos *et al.* 1986, Greenhalgh 1987; Igun 1987; Haak 1988; Price 1989; Mayhew *et al.* 2001). Further, many patients have neither the time nor money to consult a physician (Ferguson 1981; Wolffers 1987; Haak 1988; Saradamma *et al.* 2000; Seeberg 2012). These drug shops range from high end outlets staffed by pharmacists, to small, rural, roadside stalls staffed by someone without formal health qualifications. Unfortunately, it is all too common that drug selling at these outlets meets the World Health Organization's (WHO) criteria for being 'irrational'. That is, patients do not receive the appropriate medicines, in doses that meet their individual requirements, for an adequate duration, and at the lowest cost (Holloway and Van Dijk 2011). To develop appropriate interventions to address this, it is first necessary to understand the nature of the problem and also the determinants of provider behaviour to reflect on how this could best be changed.

Many papers have reported on the inadequacies of pharmacy practice in LMIC, and some reviews have been conducted (Smith 2009b; Wafula *et al.* 2012). However, no up to date systematic review is available on performance of pharmacies and drug stores across Asia's LMIC. This article aims to address that gap, and in addition, present the first systematic review of the determinants of poor practice in these settings, substantially updating and expanding previous reviews in this area (Goel *et al.* 1996; Radyowijati and Haak 2003).

Methods

Scope of review

In many LMIC, there are a wide range of outlets selling medicines to their local communities. This review is concerned with the full range of establishments whose primary business is selling medicines. Papers reporting on pharmacist-run pharmacies (PRPs), non pharmacist-run pharmacies (NPRPs) and both registered and non-registered outlets were eligible for inclusion. Despite the legal requirement to have a trained pharmacist on duty at all times, in reality, in many countries in Asia, these pharmacies are typically operated by staff who are not authorized to do so (Wolffers 1987; Kamat and Nichter 1998; Chuc and Tomson 1999; Seeberg 2012; Vu *et al.* 2012). In countries where a shortage of pharmacists exists, NPRPs are permitted; these are registered outlets but the presence of a graduate pharmacist is not mandatory. These pharmacies are typically staffed by personnel with limited medical training and are sometimes restricted in the repertoire of medicines they are permitted to sell. Unregistered drug shops sell medicines informally and are not legally recognized by the health system of the countries in which they operate (Wafula and Goodman 2010). From this point onwards, 'pharmacy' will be used as an umbrella term to denote all types of outlets selling medicines.

The first part of the review is concerned with performance of pharmacies which, in this instance, is conceptualized as behaviour relating to the sale of medicines, either with or without a prescription, or the provision of advice (the importance of the sale of substandard and counterfeit medicines in Asia is also recognized (Cockburn *et al.* 2005; Newton *et al.* 2006; World Health Organization 2006; Institute of Medicines 2013), but considered beyond the scope of this review). The second part of the review concerns the determinants of poor practice, that is, the factors that contribute to practices that are deemed inappropriate.

Search strategy

A broad search strategy combining MeSH and free text terms was used to search PubMed, Embase, Econlit, PsychInfo, Web of Science, Global Health and International Pharmacy Abstracts with the aim of identifying all studies of pharmacies in LMIC in Asia (World Bank 2014) (see Table 1).

In addition to the aforementioned databases, the International Network for Rational Use of Drugs (INRUD) bibliography and the WHO's essential medicines and health products information portal were searched.

The search was restricted to English language studies published between 1 January 1984 and 29 August 2014. A total of 21 898 papers were initially identified; after removing duplicates, 19 214 titles and abstracts were screened by R.M.; the full-text of 107 records were obtained; 53 met our inclusion criteria for part 1 of the review and 38 met the criteria for part 2 (see Figure 1). Bibliographies of eligible texts were scanned to identify any further relevant papers.

For part one, papers needed to report on performance relating to the sale of medicines, either with or without a prescription, or the provision of advice. This included studies employing both quantitative and qualitative methodologies. In order to collect the most accurate data on pharmacy practice, only studies utilising methods that collected data at the outlet and relied on a third party observation of practice were included (studies relying on self-reported practice were excluded due to the risk of desirability bias and those collecting data on medicine use through household surveys were excluded due to the high risk of recall bias). Intervention studies were included, only where they provided baseline data; this was thought to reflect standard practice. Where baseline data could not be disentangled from post-intervention results, studies were excluded from part one.

Eligible studies for part two reported on both pharmacy performance (applying the same method criteria as for part one) and possible determinants of that reported performance. Where changes in practice could be attributed to an intervention strategy, these intervention studies were included and strategies were viewed as determinants of practice. For example, a training intervention could shed light on the importance of knowledge as a determinant of practice. Additionally, qualitative studies which sought to understand the determinants of practice behaviours were also included. Of the studies included in part two, 31 of these were a subset of papers from part one; three papers were intervention studies where the baseline results were not clear; three papers were intervention studies where the baseline results were described by other papers from the same research study and one paper reported results from a qualitative study solely focussing on determinants of poor practice.

Data from the included studies were extracted into an excel database under the following headings: date and location of study, which aspects of performance measured, sampling and study design, data collection methods, details of intervention, main findings—performance, main findings—determinants of performance. Key emergent themes recurring across the data were discussed between the authors and a

Table 1. Search strategy

Target population (combined by 'OR')		Geographic location (combined by 'OR')	
Free text terms	**MeSH terms**	**Free text terms**	**MeSH terms**
Chemist	Pharmacy	Developing countries	Developing countries
Drug retailer[a]	Pharmacies	Developing country	Asia
Drug shop[a]		Low-income country	
Drug seller[a]		Low-income countries	
Drug vendor[a]		Middle-income country	
Drug store[a]		Middle-income countries	
Drug dispensing		Asia	
Drug outlet[a]			
Druggist			
Medicine retailer[a]			
Medicine shop[a]			
Medicine seller[a]			
Medicine vendor[a]			
Medicine store[a]			
Medicine dispensing shop[a]			
Medicine outlet[a]			
Medicine dealer[a]			
Pharmacies			
Pharmacy			
Pharmacy service[a]			
Pharmacist[a]			
Pharmaceutical service[a]			

narrative synthesis was conducted. See Supplementary Appendix 1 for a full list of included studies and key characteristics.

Results

Part one: performance of pharmacies in LMIC in Asia

This literature review reveals a number of shortcomings in pharmacy practice. We have organized our findings according to the stages of an encounter in the pharmacy (Figure 2). Following an overview of the included studies, we report on six key stages, namely, the nature of requests from patients, filling of prescriptions, history taking, referral for medical attention, sale of medicines and advice giving.

Overview of included studies

This part of the review identified a total of 53 papers from 43 studies in 14 countries (some studies collected data in more than one country). Papers coming from the same research project have been grouped together and the term 'study' is used to denote distinct pieces of research. The most researched countries were India and Vietnam, with 10 and 9 studies, respectively. Five studies reported on each of Thailand, Bangladesh and Nepal, three on Indonesia, two on Sri Lanka and Pakistan and one on The Philippines, Mongolia, Malaysia, Yemen Arab Republic, Syria and Lao PDR. Bangladesh and Nepal are low-income countries, Thailand and Malaysia are higher-middle and all the others are classified as lower-middle income economies (World Bank 2014).

Studies reported on the full range of pharmacies. PRPs were included in the majority of research projects. Several papers reported on outlets legally entitled to operate without a pharmacist, including type II pharmacies in Thailand, class II and III pharmacies in Lao PDR, type C pharmacies in Pakistan, drug stores in Indonesia and drug retailers in Nepal (Kafle *et al.* 1996; Stenson *et al.* 2001a; Hadi *et al.* 2010; Saengcharoen and Lerkiatbundit 2010;Hussain and
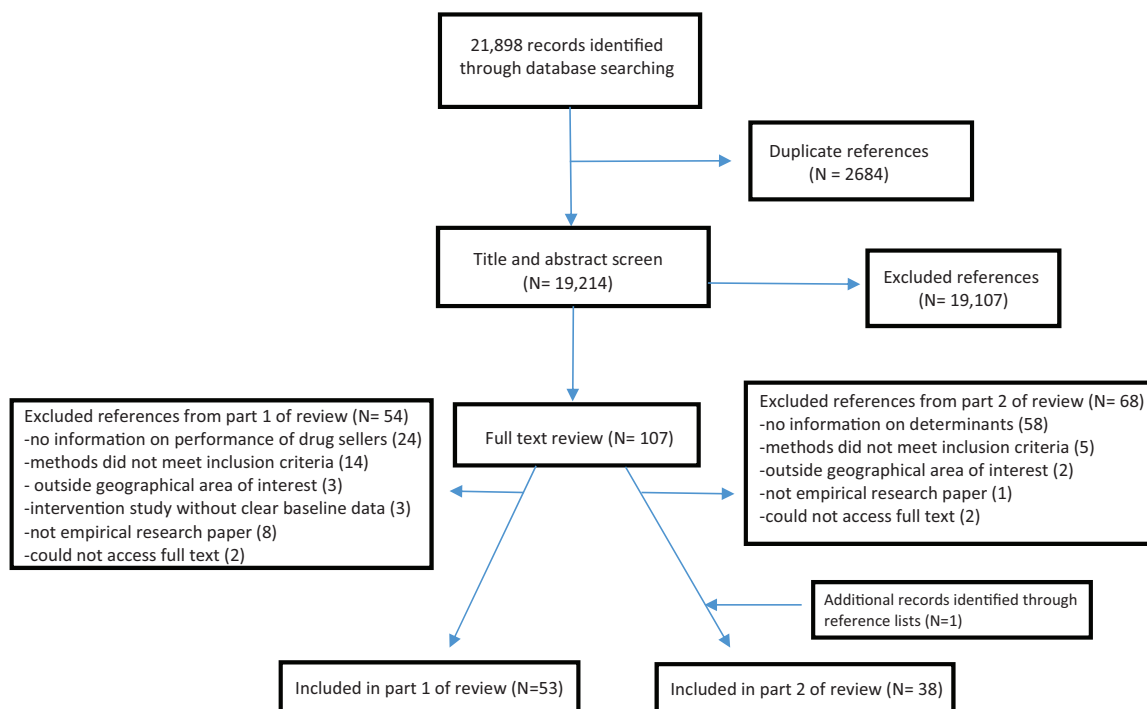
Figure 1. PRISMA flow diagram.
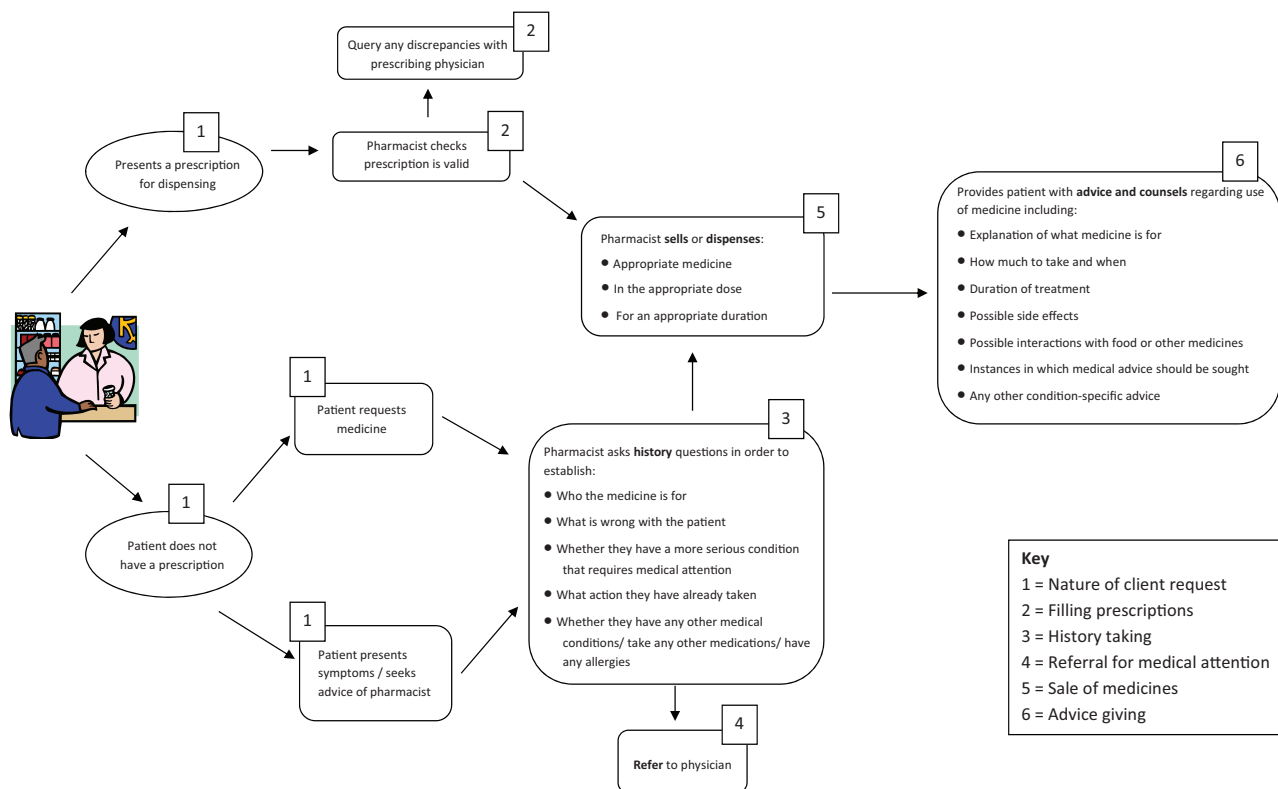
Figure 2. Appropriate retail pharmacy practices for patients with and without a prescription.

Ibrahim 2011). Only one study from Indonesia reported on unregistered outlets (Hadi *et al.* 2010).

Researchers employed a range of methods to collect data on pharmacy practice. Simulated client methodology was used widely (31 studies) to investigate how a range of requests and conditions are managed. These included requests for specific prescription only medicines (POMs), contraceptives and treatment for fever, skin abrasions, diarrhoea, sexually transmitted infections (STIs), respiratory tracts infections (RTIs), tuberculosis, asthma, migraine and anaemia. 12 studies used observation in order to record the details of transactions between pharmacy staff and customers. Exit interviews with patients were used less frequently (seven studies) to gather information about medicines purchased and staff behaviour.

1. Nature of client requests

Clients with health concerns visited the pharmacy for three main reasons: to fill a prescription following a medical consultation; to purchase a specific medicine(s) or to seek medical advice from the pharmacy staff. In order to examine staff behaviour and to put certain practices into perspective, it is useful to understand the frequencies of these different types of scenarios. Eight studies observed all transactions in sampled pharmacies for a fixed period of time, ranging from 2 h to 2 weeks per pharmacy. The proportion of transactions where medicines were purchased without a prescription ranged from around half in studies from Pakistan and India (Krishnaswamy *et al.* 1985; Greenhalgh 1987; Kamat and Nichter 1998; Basak and Sathyanarayana 2010; Hussain and Ibrahim 2011), to over 80% in a study from Lao PDR (Chuc and Tomson 1999; Syhakhang *et al.* 2001) and virtually all transactions in studies from Vietnam and Malaysia (Chua *et al.* 2013). Of the medicines purchased without a prescription, three studies reported that around one-third were recommended by the pharmacy staff

(Syhakhang *et al.* 2001; Basak and Sathyanarayana 2010; Chua *et al.* 2013). Other studies reported that the vast majority of medicines sold without a prescription were requested by the client, with pharmacists advising on <5% of these purchases (Krishnaswamy *et al.* 1985; Kamat and Nichter 1998; Chuc and Tomson 1999; Hussain and Ibrahim 2011). Only studies from India reported on common ways patients requested medicines. These were by name, on a scrap of paper, or by bringing in an old sample (Greenhalgh 1987; Kamat and Nichter 1998; Saradamma *et al.* 2000). Studies from Vietnam, India and Bangladesh reported that at least half of clients were buying medicines for someone other than themselves, most commonly a family member (Dua *et al.* 1994, Duong *et al.* 1997b; Roy 1997; Kamat and Nichter 1998). One study noted that domestic servants were commonly sent to purchase medications on behalf of their employers (Kamat and Nichter 1998).

2. Filling prescriptions

Only a few studies made reference to the handling and processing of prescriptions in the pharmacy. Several poor practices were reported. Prescriptions were rarely validated by dispensers (Hussain and Ibrahim 2011), old prescriptions were frequently honoured (at the extreme, patients were seen to be reusing prescriptions 5 years out of date) (Greenhalgh 1987; Kamat and Nichter 1998; Basak and Sathyanarayana 2010), and prescriptions were returned to customers after dispensing for reuse in the future (Puspitasari *et al.* 2011). Further, doctors' prescriptions were not always dispensed as intended. Some studies indicated that where patients cannot afford to buy all items on a prescription, the pharmacists played an important role in advising patients what they should purchase in light of their financial constraints (Greenhalgh 1987; Roy 1997; Kamat and Nichter 1998). Studies did not report a single example of a pharmacist

querying a prescription with the doctor (despite ample description of inappropriate prescribing practices).

3. History taking

In general, history taking in pharmacies was found to be inadequate. The majority of these data come from studies where mystery shoppers presented with symptoms of various conditions, including childhood diarrhoea and STIs. Most questioning was limited to enquiring about the presence of other related symptoms and often this was only observed in a subset of the study pharmacies (Ross-Degnan *et al.* 1996; Chuc *et al.* 2001, Bista *et al.* 2002; Van Sickle 2006; Saengcharoen and Lerkiatbundit 2010; Minh *et al.* 2013). It was rare for pharmacists to ask whether the patient suffered from any other conditions or allergies, took any other medication or had tried any treatments before consulting at the pharmacy (Wachter *et al.* 1999; Chuc *et al.* 2001; Van Sickle 2006; Saengcharoen and Lerkiatbundit 2010; Hussain and Ibrahim 2012). Worryingly, a common finding was that very few, if any, pharmacists enquired about danger signs that would indicate a more serious underlying cause and warrant immediate medical attention (Modal and Lamba 1994; Kafle *et al.* 1996; Duong *et al.* 1997a; Wachter *et al.* 1999; Saengcharoen and Lerkiatbundit 2010; Rathnakar *et al.* 2012). At the extreme end of poor practice, some pharmacists were found to ask not a single question (Duong *et al.* 1997a; Chalker *et al.* 2000; Rathnakar *et al.* 2012).

Only three studies measured pharmacists' responses to direct requests for medications. Questioning was insufficient on who the medicine was for, what symptoms they were experiencing, whether they took any other medication or whether they suffered from drug allergies (Ratanajamit and Chongsuvivatwong 2001; Ratanajamit *et al.* 2002; Larsson *et al.* 2006; Puspitasari *et al.* 2011). Additionally, Kamat and Nichter (1998) describe the 'quick presentation of tablets and fast exchange of money'.

4. Referral for medical attention

Some studies used simulated clients to present with symptoms of conditions that necessitate referral for medical attention; these included diarrhoea (of 3 day duration) in an 11 month old, cystitis in a man, STIs, asthma and tuberculosis. These conditions require examination, diagnostic testing or POMs and hence their management is outside the remit of a pharmacist's expertise. Referral practices of pharmacists were found to be unsatisfactory. Tuberculosis was the condition most commonly referred outside the pharmacy—46% of 138 pharmacies in Vietnam, although only 9% of patients were directed to a designated TB facility (Vu *et al.* 2012). For the other conditions, referral proportions ranged from 7% to 37% (Tomson and Sterky 1986; Tuladhar *et al.* 1998; Wachter *et al.* 1999; Chalker *et al.* 2000; Van Sickle 2006; Apisarnthanarak *et al.* 2008).

5. Sale of medicines

In terms of medicine provision, a number of concerns are raised by the literature regarding the appropriateness of medicines sold (with attention to the legal, clinical and physical aspects of their sale), dosing and duration of treatment.

a. Appropriateness of medicines

i. Legal appropriateness

The sale of POMs without a prescription was a phenomenon found to be prevalent in all 14 countries reported on. A wide range of medicines, which are only legally permitted to be sold with a prescription, were freely available without a prescription including: antibiotics, steroids, antimalarials, narcotic analgesics, psychotropics, anti-epileptics, antihypertensives, anti-diarrhoels, antihistamines, sedatives, tranquilisers, hypoglycaemic medicines, anti-tuberculosis agents and even, on occasion, abortifacients (Krishnaswamy *et al.* 1985; Tomson and Sterky 1986; Greenhalgh 1987; Wolffers 1987; Lansang *et al.* 1990; Dua *et al.* 1994; Modal and Lamba 1994; Dineshkumar *et al.* 1995; Duong *et al.* 1997a,b; Roy 1997; Cong *et al.* 1998; Kamat and Nichter 1998; Chuc and Tomson 1999; Wachter *et al.* 1999; Saradamma *et al.* 2000; Chuc *et al.* 2002; Larsson *et al.* 2006; Mac *et al.* 2006; Mamun *et al.* 2006; Qidwai *et al.* 2006; Basak and Sathyanarayana 2010; Hadi *et al.* 2010; Nakajima *et al.* 2010; Al-Faham *et al.* 2011; Puspitasari *et al.* 2011; Hussain and Ibrahim 2012; Ngo *et al.* 2012; Rathnakar *et al.* 2012; Seeberg 2012; Vu *et al.* 2012; Huda *et al.* 2014; Nga *et al.* 2014). In Thailand, antibiotics are legally permitted to be sold by class I drug stores but not in lower class stores. This restriction is reportedly not observed in practice (Podhipak *et al.* 1993; Saengcharoen and Lerkiatbundit 2010). In Indonesia, antibiotics were found to be freely available through unregistered roadside kiosks (Hadi *et al.* 2010).

ii. Clinical appropriateness

The majority of the literature paints a dismal picture of treatment practices in pharmacies across Asia. More often than not, medicines that are dispensed are not clinically appropriate for the patients' needs. Table 2 shows treatment choices by pharmacy staff for a number of conditions in response to visits from simulated clients. At best, studies report that recommended practices are followed in less than half of encounters (Chuc *et al.* 2001; Bista *et al.* 2002). At worst, only a handful, and in some cases no staff were found to follow best practice guidelines (Duong *et al.* 1997a; Van Sickle 2006; Hussain and Ibrahim 2012; Vu *et al.* 2012).

These studies also reveal that a number of inappropriate treatments are given, either in addition to, or, instead of recommended treatments. Some of the medicines, such as tonics for anaemia, have no therapeutic value (Kafle *et al.* 1996). Others can be harmful, for example the use of anti-diarrhoels and antitussives in infants and children (Tomson and Sterky 1986; Podhipak *et al.* 1993; Modal and Lamba 1994; Ross-Degnan *et al.* 1996; Duong *et al.* 1997a; Chuc *et al.* 2001; Qidwai *et al.* 2006; Saengcharoen and Lerkiatbundit 2010; Hussain and Ibrahim 2012; Minh *et al.* 2013).

Another concern is the overuse of antibiotics. A number of papers, report that antibiotics were commonly sold for young babies through to adults for a host of symptoms and conditions for which they are not indicated, including: diarrhoea, asthma, upset stomachs, coughs, colds, runny noses, influenza and (non-infected) skin abrasions (Tomson and Sterky 1986; Thamlikitkul 1988; Podhipak *et al.* 1993; Modal and Lamba 1994; Ross-Degnan *et al.* 1996; Duong *et al.* 1997a,b; Wachter *et al.* 1999; Chuc *et al.* 2001; Chuc *et al.* 2002; Qidwai *et al.* 2006; Van Sickle 2006; Apisarnthanarak *et al.* 2008; Saengcharoen and Lerkiatbundit 2010; Hussain and Ibrahim 2012; Minh *et al.* 2013). Further, even where antibiotics are indicated, inappropriate choices were made (Tuladhar *et al.* 1998; Bista *et al.*

2002). In studies from the Philippines, India, Vietnam and Lao PDR antibiotics were found to make up between a fifth and a third of all purchases (Lansang *et al.* 1990; Dua *et al.* 1994; Syhakhang *et al.* 2001; Basak and Sathyanarayana 2010; Nga *et al.* 2014). Tetracycline was reportedly sold to children (for whom it is contraindicated) in studies from Vietnam, India and Thailand (Thamlikitkul 1988; Dua *et al.* 1994; Chuc and Tomson 1999). Further, the widespread use of chloramphenicol for minor conditions is a concern due to the risk of bone marrow suppression (Greenhalgh 1987; Thamlikitkul 1988; Syhakhang *et al.* 2001).

Vitamins, tonics and nutritional products with dubious pharmacological value were found to constitute a significant proportion of medication costs in studies from India, Bangladesh, Vietnam and Nepal (Krishnaswamy *et al.* 1985; Greenhalgh 1987; Dineshkumar *et al.* 1995; Kafle *et al.* 1996; Duong *et al.* 1997b; Roy 1997; Chuc and Tomson 1999; Saradamma *et al.* 2000; Basak and Sathyanarayana 2010). They were often seen as an essential accompaniment to antibiotics (Greenhalgh 1987; Dua *et al.* 1994; Roy 1997; Saradamma *et al.* 2000). A final observation was the popularity of (often irrational) combination products (Tomson and Sterky 1986; Greenhalgh 1987; Lansang *et al.* 1990; Dineshkumar *et al.* 1995; Kafle *et al.* 1996; Chuc and Tomson 1999; Wachter *et al.* 1999; Saengcharoen and Lerkiatbundit 2010).

iii. Physical appropriateness

Few studies investigated or commented on the physical state of the medicines sold to patients. Those that did, reported that drugs were often sold in loose strips, as opposed to in their original package; they were rarely labelled; and different medicines were mixed together in the same package (Kamat and Nichter 1998; Stenson *et al.* 2001a; Van Sickle 2006; Hadi *et al.* 2010; Hussain and Ibrahim 2011). As a result, information regarding dose, expiry date and active ingredients was not clear. In six of 28 shops visited in Sri Lanka, tetracycline was not stored in a refrigerator as it should be (Wolffers 1987).

b. Appropriateness of dose and duration of treatment

Several studies report that medicine dosing was outside of the therapeutic range for a variety of conditions (both sub-therapeutic and over dose) (Thamlikitkul 1988; Tuladhar *et al.* 1998; Rahman *et al.* 2000; Bista *et al.* 2002). Saradamma et al. (2000) study of antibiotic purchases in India found that those without a prescription were three times more likely to purchase an inadequate dose than those with a prescription (66% vs 40%). The problem of incomplete courses of antibiotics was reported in India, Thailand, Vietnam, Bangladesh, The Philippines and Sri Lanka (Tomson and Sterky 1986; Greenhalgh 1987; Lansang *et al.* 1990; Duong *et al.* 1997a,b; Cong *et al.* 1998; Chuc and Tomson 1999; Chalker *et al.* 2000; Saradamma *et al.* 2000; Mamun *et al.* 2006; Basak and Sathyanarayana 2010). At the extreme, more than half of antibiotic purchases were for <2 days (Greenhalgh 1987; Thamlikitkul 1988; Chuc and Tomson 1999). An interesting finding from Vietnam was that a higher percentage of incomplete antibiotic courses were sold for under 1s (Chuc and Tomson 1999).

6. Advice giving

Clients purchasing medicines in the pharmacy were found to receive very little counselling and advice from pharmacy staff. Provision of any unsolicited advice ranged widely from 2.5% to over 70%. Where it was given, however, it was usually limited to dose and frequency instructions; very few staff mentioned potential side effects, drug or food interactions, or advised to visit a physician if symptoms continued, worsened or complications arose (Dua *et al.* 1994; Modal and Lamba 1994; Kafle *et al.* 1996; Ross-Degnan *et al.* 1996; Duong *et al.* 1997a; Wachter *et al.* 1999; Chalker *et al.* 2000; Chuc *et al.* 2001; Ratanajamit and Chongsuvivatwong 2001; Van Sickle 2006; Basak and Sathyanarayana 2010; Hussain and Ibrahim 2011; Puspitasari *et al.* 2011; Saengcharoen and Lerkiatbundit 2013; Huda *et al.* 2014). Disease and medicine-specific advice and counselling was also poor, especially for STIs and contraceptive requests (Tuladhar *et al.* 1998; Chalker *et al.* 2000; Rahman *et al.* 2000; Ratanajamit and Chongsuvivatwong 2001; Minh *et al.* 2013). Advice regarding dietary and fluid intake for clients suffering from diarrhoea or anaemia was given by a minority of pharmacy staff (Kafle *et al.* 1996; Duong *et al.* 1997a; Wachter *et al.* 1999; Saengcharoen and Lerkiatbundit 2010; Minh *et al.* 2013). Finally, there was little evidence of signposting to other health services. This is highlighted by a study from Vietnam where simulated clients requested an abortifacient. None of the 30 pharmacies visited offered referral materials or contact details for a specialist service (Ngo *et al.* 2012).

Part two: determinants of poor pharmacy performance in LMIC in Asia

Overview of included studies

The literature search yielded 38 relevant papers, from 28 distinct studies which conducted research in 11 countries: Pakistan (two), Thailand (five), Nepal (four), India (seven), Bangladesh (three), Lao PDR (one), Sri Lanka (one), Yemen Arab Republic (one), Vietnam (six), The Philippines (one) and Indonesia (one). The studies included in this review are very varied in terms of methodology and approach but they all shed some light on the determinants of pharmacy practice in these settings. Ten studies collected data on both 'actual' pharmacy practice (e.g. using mystery shopper surveys or spending time observing transactions) and knowledge and stated practice (through semi-structured interviews with store staff), with discordance between the two providing insight into factors affecting certain poor practices. In uncontrolled analyses, three studies tested for associations between a number of predictor variables and provider practices. Four studies conducted regression analyses using aspects of practice as the dependent variable and tested a number of explanatory variables (such as retailer characteristics or attitudes) as potential predictors of behaviour. Twelve studies evaluated the effectiveness of an intervention strategy and this provided evidence for whether or not these were important determinants of practice. Finally, 10 studies employed qualitative methodology, including in-depth interviews, participant and non-participant observation and focus group discussions.

From the literature, information on determinants of poor pharmacy practice can be distilled into three main categories: knowledge, profit motives and state intervention. The role of each is discussed.

1. Knowledge

One possible explanation for the poor pharmacy practice observed in Asia is simply lack of knowledge. There is wealth of

Table 2. Treatment choices for a range of conditions presented at pharmacies in Asia by simulated clients

Condition	Countries, number of distinct studies and references	Recommended treatment	Sample percent giving appropriate treatment	Details of inappropriate treatment
Watery diarrhoea (in children and adults)	–Pakistan, Thailand, India, Sri Lanka, Bangladesh, Yemen Arab Republic, Indonesia, Vietnam, Nepal –11 studies –(Tomson and Sterky 1986; Podhipak et al. 1993; Modal and Lamba 1994; Ross-Degnan et al. 1996; Duong et al. 1997a; Wachter et al. 1999; Qidwai et al. 2006; Saengcharoen and Lerkiatbundit 2010; Hussain and Ibrahim 2012b; Kafle et al. 2013; Minh et al. 2013; Pham et al. 2013)	International recommendations (WHO) –Oral rehydration salts (ORS) –Zinc supplementation	–Pharmacies recommending ORS ranged from 3% to 45% (Two studies <10%; three studies 10-19%; six studies 20-45%)	–Unnecessary antibiotics were recommended in every study and anti-diarrhoels in nine studies –Pharmacies recommending antibiotics ranged from 2% to 97% and anti-diarrhoeals from 19% to 88% –Other unnecessary medicines recommended were anti-spasmodics and anti-motility drugs
Sexually transmitted infections	–Nepal, Vietnam, Bangladesh –5 studies –(Tuladhar et al. 1998; Wachter et al. 1999, Chalker et al. 2000; Rahman et al. 2000; Bista et al. 2002)	National guidelines (Nepal- not stated for Vietnam or Bangladesh): –Uncomplicated cystitis in men: course of antibiotics[a] –Gonorrhoea: ciprofloxacin 500 mg stat –Chlamydia: doxycycline 100 mg twice a day (patients with vaginal or urethral discharge in Nepal are to be treated for chlamydia and gonorrhoea)	–Three studies where clients presented with discharge, treated with correct medicines in 34% and 2% of cases in Nepal and 0% in Vietnam –Dysuria (indicative of cystitis) was treated with antibiotics in 38% of cases –0% treated according to national standardised guidelines for urethral discharge or genital ulcer in Bangladesh	–Injection recommended for urethral discharge –Urinary alkalizers commonly sold –Other medicines recommended included vitamins, topical antibiotics, antihistamines and, occasionally, disinfectants
Mild respiratory tract infection in children	–Vietnam –1 study –(Chuc et al. 2001)	National guidelines: (Vietnam) –In absence of danger symptoms advise to treat: -fever with paracetamol –Chesty cough with expectorants –Sore throat and cough with traditional medicines -do not prescribe antibiotics or remedies containing codeine or antihistamine	–36% of advice was in line with national guidelines	–Antibiotics were given in 42% of encounters –83% of pharmacies gave antibiotics in at least one encounter –Antitussives commonly prescribed, of which 40% contained codeine or an antihistamine
Asthma	–India –1 study –(Van Sickle 2006)	International guidelines for mild asthma: –Daily inhaled corticosteroid –Inhaled β_2 - agonist for symptom relief when required	–93% of pharmacies dispensed medication; 0% gave either of the recommended inhalers	–Most commonly recommended medicines were oral β_2 - agonists, methyl-xanthines, antibiotics and oral corticosteroids –40 unique combinations of drugs were sold to clients
Tuberculosis	–Vietnam –1 study –(Vu et al. 2012)	National guidelines: –Combination treatment with anti-tuberculosis drugs (isoniazid, rifampicin, pyramzinamide and ethambutol)	–53% of pharmacists dispensed drugs; 0% gave anti-tuberculosis medicines	–Details of drugs dispensed not given

(continued)

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Table 2. Continued

Condition	Countries, number of distinct studies and references	Recommended treatment	Sample percent giving appropriate treatment	Details of inappropriate treatment
Pregnancy-related anaemia	–Nepal –2 studies –(Kafle et al. 1996, 2013)	International recommendations: –Simple iron-folate combination –Ferrous sulphate	–1% of pharmacies gave iron-folate alone and none gave ferrous sulphate –58–71% gave an iron preparation of some kind (whilst not the recommended product, still clinically effective, but more costly)	–12% gave a vitamin or mineral product that was not therapeutic for pregnancy-related anaemia –9% dispensed tonics that were not therapeutic
Migraine	–Thailand –1 study –(Saengcharoen and Lerkiatbundit 2013)	International recommendations: –NSAID for mild migraine –Ergotamine for moderate migraine	–33% dispensed appropriately for mild migraine –54% dispensed appropriate medicine for moderate attack	–Inappropriate prophylactic medicines such as propranolol and atenolol were recommended by 28% and 18% for moderate and mild attacks respectively

[a]Details of specific antibiotics unspecified by study.

evidence, however, to suggest that knowing what constitutes good performance, whilst necessary, is not sufficient to ensure that this knowledge is employed in practice. A number of studies report vast discrepancies between knowledge or stated practice and actual practice; the qualifications of staff or level of training accomplished appears to make little difference to treatment behaviour and finally, educational programmes, whilst improving practice in the short-term, do not improve practice to a satisfactory level in the long-term. Each of these bodies of evidence will be examined in turn.

a. Discrepancies between knowledge and practice

Several studies employed different methods in order to elicit information on both provider knowledge or stated practice and actual practice. Vast discrepancies were noted between the two, suggesting that knowledge is not the key determinant of poor practice. Differences between stated practice and actual practice were observed for the sale of medicines, referral for medical advice, history taking and advice giving. For example, in hypothetical scenarios, 32% of pharmacists said they would sell any drugs for a man with urethral discharge and pain on urinating (the recommended management would be referral to a physician) (Chalker et al. 2000), 20% antibiotics for a child with a viral upper respiratory tract infection (Chuc et al. 2001), 40% corticosteroids and 0% antiepileptic medicines without a prescription (Larsson et al. 2006; Mac et al. 2006). In mystery shopper surveys, however, these actions were carried out by 85%, 83%, 98% and 21%, respectively. Adherence to recommended treatment practices was also found to be poorer in practice. Compared to the stated medication treatments for childhood diarrhoea, fewer pharmacy staff sold oral rehydration salts (ORS) and more sold inappropriate antibiotics and anti-diarrhoels (Ross-Degnan et al. 1996; Saengcharoen and Lerkiatbundit 2010; Minh et al. 2013). Similar patterns were observed in the management of other conditions, such as STIs (Khan et al. 2006). One study reported that despite 81% of pharmacists knowing that antibiotics were not effective in short courses, 48% of courses dispensed were for <5 days. Stated referral practices of patients presenting with conditions that need to be treated by a doctor were three to four times higher than in reality (Chalker et al. 2000; Khan et al. 2006). Finally, history taking and advice giving in questionnaires was found to be superior to the service simulated clients experienced (Ratanajamit and Chongsuvivatwong 2001; Khan et al. 2006).

b. Qualifications/training and experience

Studies from Thailand and Nepal, using simulated shoppers to investigate the management of childhood diarrhoea, pregnancy-related anaemia and requests for contraceptives, revealed that staff with higher levels of training or qualifications asked more questions and gave better advice but little differences were observed in terms of appropriate medication dispensing (Kafle et al. 1996; Ratanajamit and Chongsuvivatwong 2001; Saengcharoen and Lerkiatbundit 2010). Other studies found no association between qualifications of pharmacy personnel and the quality of history taking and counselling (Hussain and Ibrahim 2011; Saengcharoen and Lerkiatbundit 2013). Despite, recording no differences in actual practice, one of these papers reported that, in interviews designed to measure their knowledge, pharmacists achieved significantly higher scores

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compared to non-pharmacists in the areas of history taking and advice provision (Saengcharoen and Lerkiatbundit 2013). Experience was shown not to be a predictor of appropriate dispensing in the two studies which collected data on this variable (Apisarnthanarak *et al.* 2008; Saengcharoen and Lerkiatbundit 2010).

c. Impact of education programmes

Nine studies report the findings of educational interventions. All of these studies employed simulated client methodology to assess the impact of training; only four assessed performance by comparing outcomes to a control group. On the whole, training was found to improve the treatment behaviour of various conditions, including diarrhoea and STIs, as well as provision of contraceptives (Ross-Degnan *et al.* 1996; Kafle 1998; Tuladhar *et al.* 1998; Ratanajamit *et al.* 2002; Qidwai *et al.* 2006; Kafle *et al.* 2013; Minh *et al.* 2013; Pham *et al.* 2013). Despite the improvements noted, inadequacies in treatment practice remained. For example, in Indonesia, 46% of staff continued to sell anti-diarrhoels for children with diarrhoea (Ross-Degnan *et al.* 1996); and in Nepal, 55% of drug sellers continued to prescribe an STI treatment regimen that was inconsistent with national guidelines (Tuladhar *et al.* 1998). Further, most of the study follow-up times were <6 months. One study with follow-up at 7–9 months noted the waning of effect (Tuladhar *et al.* 1998), and another at 32 months reported no sustained improvements in the use of ORS, anti-diarrhoels or antibiotics for the treatment of diarrhoea, despite promising results at 6 months post intervention (Minh *et al.* 2013; Pham *et al.* 2013). In Nepal, small group training led to significant improvements in a number of aspects of management of childhood diarrhoea, acute respiratory infection and anaemia in pregnancy at 2 months but most of these effects were not sustained at the 5-month follow-up (Kafle 1998). One study did not report baseline data but the post-training results concerning the management of STIs were very poor (Khan *et al.* 2006). Another showed no significant impact of training on ORS use for the treatment of diarrhoea or dysentery, but it did show improvements in antibiotic dispensing, only for drug sellers, however, not for pharmacists (Podhipak *et al.* 1993).

2. Profit motives

Pharmacies are retail businesses operating within a competitive marketplace. Several papers described the proliferation of medicine outlets over recent decades, especially in countries that underwent economic liberalisation. For example, in Vietnam following the privatization of drug provision in 1986, the number of private pharmacies increased from none to >6000 by 1996 (Chuc *et al.* 2002). These papers also noted the intensified competition that resulted (Kamat and Nichter 1998; Chuc and Tomson 1999; Stenson *et al.* 2001b; Chuc *et al.* 2002). An illustration of the nature of competition comes from Mumbai, India, where pharmacies hire agents to persuade patients leaving hospitals to patronise their pharmacy (Kamat and Nichter 1998). Qualitative work confirms that pharmacies report feeling intense competition and staff seek to maximize profit in order to survive in the market (Dua *et al.* 1994; Kamat and Nichter 1998; Chuc and Tomson 1999; Kotwani *et al.* 2012; Seeberg 2012). Essentially there are three ways to maximize profits: maximizing the number of customers, maximizing the revenue from each individual customer and minimizing costs. From the literature, we identified a number of strategies employed by pharmacy staff to

achieve these goals, each of which can also be linked to poor practice.

a. Complying with customer demands

The literature reveals that pharmacy staff are very responsive to patients wishes, adhering to a 'customer is king' mentality. In the name of maintaining clients, inducing loyalty and preventing customers from fulfilling their requests elsewhere, pharmacies resort to a number of poor practices. These include honouring improper prescriptions, such as those that are out of date, and selling POMs without a prescription (Dua *et al.* 1994; Larsson *et al.* 2006; Kotwani *et al.* 2012; Nga *et al.* 2014). Further, incomplete courses of antibiotics are frequently sold. Patients request these short courses due to economic constraints, a desire to test the therapeutic efficacy and presence of side-effects before purchasing larger quantities, and a belief that a full course is unnecessary (Lansang *et al.* 1990; Dua *et al.* 1994; Dineshkumar *et al.* 1995; Roy 1997; Duong *et al.* 1997b; Kamat and Nichter 1998; Mamun *et al.* 2006).

b. Selling medicines based on perceived efficacy

Several studies reported that pharmacy staff chose medicines based on their ability to produce a rapid recovery or temporary relief from symptoms, even where they were not appropriate (Kafle *et al.* 1996; Van Sickle 2006; Saengcharoen and Lerkiatbundit 2010,). For example, anti-diarrhoels for the treatment of childhood diarrhoea (Saengcharoen and Lerkiatbundit 2010) or airway relaxers for the respiratory symptoms associated with asthma (Van Sickle 2006). In addition, they sold medicines in which clients were believed to have great confidence, again, even if such medicines were not necessary. Examples include tonics as an accompaniment to antibiotics, and complex vitamin preparations (Dua *et al.* 1994; Kafle *et al.* 1996).

c. Mimicking doctors

Four studies reported that it was common practice for medicine retailers to study the prescriptions bought in by patients and then model their own prescribing on the practices of local doctors (Greenhalgh 1987; Kafle *et al.* 1996; Ross-Degnan *et al.* 1996; Seeberg 2012). This may simply be a way to improve knowledge. It could, however, be inferred that it is a strategy used by pharmacies in order to be viewed as more legitimate by customers.

d. Maintaining good relationships with doctors

When presented with clinically inappropriate prescriptions, pharmacies in Asia tended to dispense them rather than query their appropriateness with the doctor. Pharmacists interviewed in Kotwani et al's qualitative study of irrational antibiotic use in Delhi described their low status in the medical hierarchy and how doctors would rebuke them for challenging their authority (Kotwani *et al.* 2012). Other research, also in India, has identified symbiotic relationships between doctors and chemist shops, and doctors have been observed to mention names of shops where patients should fill their prescriptions (Kamat and Nichter 1998; Seeberg 2012). Further, at the request of medical representatives, doctors reportedly prescribe more of particular products when local pharmacies experience an overstock (Kamat and Nichter 1998). It is understandable, in such a context, that pharmacists do not query more prescriptions for fear of aggravating local physicians.

e. Medicine sales

Two explicit strategies for maximizing profits from medicine sales were identified from the literature; selling large volumes

of low priced drugs and recommending medicines that yield the greatest profit (Ross-Degnan *et al*. 1996; Chuc and Tomson 1999; Saengcharoen and Lerkiatbundit 2010). Antibiotics are singled out as high profit generators (Chuc and Tomson 1999; Chuc *et al*. 2001; Saengcharoen and Lerkiatbundit 2010; Nga *et al*. 2014); this may partly explain their rampant overuse.

f. Medicine purchasing

The pharmaceutical industry employs aggressive marketing techniques which involve promotional offers to pharmacies. This includes bonus schemes whereby the purchase of *x* amount of a product includes *y* amount for free (Kamat and Nichter 1998). Retailers are then incentivized to sell more of this product, regardless of its appropriateness, because it will yield high profits. The following quote from Kamat and Nichter's (1998) ethnographic study of pharmacies and pharmaceutical-related behaviour in India gives an insight into such practice (the product mentioned, Superaction, an OTC product for cough, cold, fever and pain, is sold on a buy 12 strips get 7 free basis):

I make a profit of anything between 75% and 100% on "Superaction." During the past 2 week, I sold two boxes (20 strips) of this item for which I got a pocket calculator worth 80 rupees from the company. I make a lot of profit on this product, but I have to counter-push it because local doctors do not prescribe it. I do not recommend this product to every customer who asks for medicines for headache or body pain but mostly to angutachapwallas (illiterates) who come and ask me to give some medicine for cold and pain (Kamat and Nichter 1998).

Dineshkumar *et al*. (1995) comment on the aggressive marketing of vitamins which are used extensively in India. Seeberg describes how chemists in Orissa purchase substandard medicines from local production facilities at a 50% discount and then sell them on to customers thus making additional profit (Seeberg 2012).

It is important to note that there are examples in the literature which illustrate that medicine retailers are only prepared to go so far in risking the health of their patients in the name of making a quick profit. Pharmacists described how it was not suitable to use substandard medicines for patients who had undergone surgery or faced life-threatening conditions (Seeberg 2012). Additionally, when patients sought pharmacists' advice in the event of not being able to afford all medicines on a prescription, they were found to recommend the medicines which 'cure' over those with the highest profit (Kamat and Nichter 1998).

3. State intervention

A few studies in this review provide information on the impact of government intervention on pharmacy performance.

a. Regulation

Two intervention studies reported on the effect of regulation on service quality. An intervention in Lao PDR involving inspection visits, punishments in the case of gross violations of the sanctions, up-to-date supply of regulatory documents, and reinforcement of the rules found marked improvements in the availability of essential medicines, order in the pharmacy and provision of information; and less mixing of different drugs in the same package (Stenson *et al*. 2001b). The regulatory component of a multi-component (sequentially applied), intervention on dispensing practices in Bangkok (Thailand) was the only

component of the intervention that resulted in a significant change in practice (reduced dispensing of a prescription-only steroid compared to the control group). This intervention focussed on the illegality of the act and the threat of punishment should such practice be observed. The same study reported that in Hanoi (Vietnam), where less focus was placed on sanctions, the regulatory component of the intervention did not lead to an immediate change in behaviour (Chalker *et al*. 2005).

b. National Public Health Programmes

A study from Vietnam investigating the management of tuberculosis patients in the pharmacy found, in a multivariate analysis, that staff who were aware both of the National Tuberculosis Programme (NTP) and that tuberculosis medicines were provided for free were 5.8 times more likely to refer a suspect directly to a tuberculosis facility than those who were not (Vu *et al*. 2012). Another study concerned with management of childhood diarrhoea investigated practice in three countries: Bangladesh, Sri Lanka and Yemen Arab Republic. The authors reported that ORS was more commonly dispensed in Bangladesh and they noted the presence of a national ORS programme as one potential explanation (Tomson and Sterky 1986).

Discussion

Combined, the reviews identified 60 papers reporting on pharmacy practice and/or determinants of poor practice in 15 LMICs in Asia. The majority of studies were from lower middle-income countries. Asides from studies from Mongolia, Yemen Arab Republic and Syria, all other studies focussed on countries from South and South-East Asia. As such, the results tell us little about pharmacy practice in North Asia, Central Asia, West Asia or the Middle East. Most research was carried out on PRPs, with less on NPRPs and research on unregistered shops was found to be practically non-existent.

Given the diversity of studies found in the search, quality appraisal proved to be a particular challenge. Relevant papers included a range of designs including randomised controlled trials, cross-sectional descriptive surveys and ethnographies. The lack of clear criteria by which qualitative studies should be judged in the systematic review process has been raised by others but remains an unresolved issue (Dixon-Woods *et al*. 2006). In light of this, it was decided to include all papers which met the inclusion criteria providing the methodology employed was clear. Data on both methods and study design were extracted and any potential threats to validity were recorded. The main concerns noted were small sample sizes and non-random sampling (quantitative papers). The findings of poorer quality studies, however, were found to be consistent with more rigorously designed ones. In interpreting the findings, care has been taken to emphasise those which were found in a number of studies and across countries.

In terms of pharmacy performance, the findings across countries and over time are remarkably consistent. Pharmacy practice in Asia appears to have changed little in the past 30 years. The same problems documented by studies in the 1980s are true of practice in recent times (Tomson and Sterky 1986; Greenhalgh 1987; Hussain and Ibrahim 2012; Seeberg 2012; Vu *et al*. 2012; Chua *et al*. 2013; Minh *et al*. 2013; Saengcharoen and Lerkiatbundit 2013). Practice appears to fall short throughout the pharmacy encounter. The key inadequacies documented throughout the literature are: insufficient

history taking prior to the sale of medicines; a lack of referral of patients whose management is outside of the remit of a pharmacist's expertise; the illegal sale of a wide range of POMs without a prescription; the sale of medicines that are either clinically inappropriate and/or in doses that are outside of the therapeutic range; the sale of incomplete courses of antibiotics; and finally, limited provision of information and counselling to accompany the sale of medicines. Similar challenges have also been documented in Sub-Saharan Africa (Wafula *et al.* 2012)

Staff working in pharmacies can be seen as the gatekeepers of medicines. They stand at the interface between producers and consumers of medicines and their role is to ensure that they are used safely, effectively and rationally (Anderson 2002). When used correctly, medicines can save lives and improve people's health; irrational use, however, can have harmful consequences. A number of conditions were found to be treated inadequately in the pharmacy, including diarrhoea, asthma, anaemia, tuberculosis, STIs, RTIs and migraine. This mistreatment can lead to unnecessary morbidity and mortality. For example, many studies reporting on the management of childhood diarrhoea found under-provision of ORS and over-provision of anti-diarrhoeals and antibiotics. The use of anti-diarrhoels in infants has been shown to be harmful (Minton and Smith 1987; Li *et al.* 2007) and it is estimated that correct treatment with ORS may prevent 93% of diarrhoeal deaths in children under 5 (Munos *et al.* 2010). In South Asia, diarrhoea is thought to account for 23% of all deaths in children under 5 (Morris *et al.* 2003).

Overuse of antibiotics is a particular concern for public health, as misuse of antibiotics over recent decades has led to the selection and spread of resistant bacteria. As a result, antibacterial drugs have become less effective and in some cases, ineffective. Earlier this year, a WHO global report on the surveillance of antibiotic resistance described the problem as a 'global health security emergency' (World Health Organization 2014).

A further concern is the economic impact of spending on households, especially the poor. Customers typically pay for the medicines purchased at pharmacies out of their own pocket and where these medicines are inappropriate or ineffective this represents a waste of scarce resources. Work in Asia has shown that, in many countries, a large proportion of out of pocket payments is spent on medicines. For example, in Bangladesh, Vietnam and India, this share is 70% (Van Doorslaer *et al.* 2007). Further, in these countries, out of pocket payments for healthcare can be 'catastrophic', accounting for >25% of household resources (excluding food costs) in at least 10% of all households (ibid).

Turning to the determinants of the poor practice documented above, the picture is less clear. Despite the importance of pharmacies and the potential benefit for public health if practice were to improve, efforts to understand and address the problem have been surprisingly few. Historically, the small number of attempts to improve pharmacy practice in Asia has focussed on training interventions. This review finds that whilst a necessary condition, adequate knowledge alone is not sufficient to ensure appropriate management of patients presenting at the pharmacy. Profit motives and the regulatory environment appear to play a role but the research evidence is relatively sparse. In terms of the methods used to unpick the underlying determinants of pharmacy behaviours, we found that in-depth qualitative studies, particularly those employing an ethnographic approach, provided the richest data (Kamat and Nichter 1998; Seeberg 2012). Unfortunately, studies using this approach are rare.

Whilst a number of studies have been published in the two decades since Goel *et al.* (1996) first reviewed this literature, there is little new insight into the problem of poor pharmacy practice. They

noted that regulatory factors had been 'strikingly neglected by researchers' and called for new research on the 'impact of professional ownership on professional freedom'. Researchers have, on the whole, continued to neglect these areas. The pursuit of regulatory enforcement is, however, not a straightforward solution and we must be aware that enforcing laws surrounding the sale of POMs would potentially deny many people access to essential medicines, thus violating a basic principle of public health.

Based on the intervention literature both within and outside Asia, the menu of evidence-based options for professional bodies and policy-makers to inform improvement and development of pharmacy services is limited (Smith 2009a). Arguably, some cadre of trained pharmacy workers should be in place in order to provide a basis for improvement, yet in many settings human resource limitations undermine the ability to provide this (Smith 2009b). Asides from training and regulation, other schemes that have been implemented include peer review, accreditation (such as the Accredited Drug Dispensing Outlets scheme in Tanzania) and social franchising (Chalker *et al.* 2005; Wafula and Goodman 2010). However, the evidence on the impact and sustainability of these strategies remains quite limited, highlighting this area as an important priority for future research (Center for Pharmaceutical Management 2008; Wafula and Goodman 2010; Valimb *et al.* 2014).

It is worth noting that new organisational arrangements of pharmacy retail in the form of chains and franchises are a growing phenomenon in LMIC both in Asia and elsewhere (Lowe and Montagu 2009; IMS Consulting Group 2014). This phenomenon raises important questions about the impact of professional and organised ownership on pharmacy practice. Further, theoretical literature suggests that the organisational structure of the pharmacy firm may affect both the regulatory environment and financial incentives, as well as provider knowledge (Klein 1980; Blair and Kaserman 1994; Frant 1996; Bloom *et al.* 2008).

Cross and Macgregor (2010) have criticised the current debates around 'informal providers' (including drug sellers) which, they argue, are myopically focused on 'small time economic actors' rather than giving attention higher up in the pharmaceutical supply chain (Cross and Macgregor 2010). This focus indeed leads to a distraction away from the pharmaceutical industry, which, thus far, has largely remained absent from discussions of inappropriate medicines use. A few papers in this review touch on the pressures that providers face from industry but this does not come out strongly. Whilst it is necessary to study frontline behaviours, research upstream is also a necessity.

Conclusion

Pharmacies are an important component of the health system in LMIC in Asia. In many areas they act as '*de facto* primary healthcare providers' (Seeberg *et al.* 2014). The service they provide, however, does not live up to international expectations of pharmacy practice. The consequences of poor practice can have harmful effects for public health and, as such, these outlets warrant more attention from public health researchers. The nature of the problem with pharmacies in Asia is well established, although more attention could be paid to NPRPs pharmacies and unregistered drug shops. Future research efforts should focus their attention on investigating the underlying causes and ways to improve the current situation. The little evidence that is available suggests that intervention strategies should take into account the regulatory environment and profit incentives faced by pharmacy personnel and not continue to focus

solely on improving knowledge. If efforts are focussed accordingly it is hoped that the realities of the past 30 years of poor pharmacy practice in Asia will not continue for the next 30.

Supplementary data

Supplementary data are available at *HEAPOL* online.

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PART II: HYPOTHESES AND METHODOLOGY

3 Towards a set of hypotheses: theoretical and empirical insights from the literature

3.1 Introduction

This chapter is divided into three parts. Firstly, I review the empirical literature on the effects of pharmacy chains in both high, middle and low-income countries. Secondly, I draw on theoretical insights from economics literature to hypothesise how pharmacy chains may affect the public health concerns of quality of care, quality of medicines, prices of medicines, and access. Finally, I bring together this set of hypotheses into a single framework in order to inform this study on the public health effects of pharmacy chains in a LMIC setting.

3.2 Empirical data on the effects of pharmacy chains

A systematic approach was employed to search for empirical literature on the effects of pharmacy chains. PubMed, Embase, Econlit and Global Health databases were searched. Searches were also conducted in Google Scholar and bibliographies of relevant papers were scanned to identify further references. A number of terms for medicine retailers were identified from an initial scope of the literature and these were combined (using AND) with terms used to described chains and franchises (see Table 1 for details of search strategy). The majority of the literature comes from studies conducted in high income settings, and the results of these studies are presented first. An overview of the limited studies from LMICs follows.

Table 1: Search strategy used to identify literature on pharmacy chains and franchises

Target population (combined by 'OR')		Pharmacy type (combined by 'OR')
Free text terms	**MeSH terms**	**Free text terms**
chemist	pharmacy	chain*
drug retailer*	pharmacies	franchise*
drug shop*		corporate
drug seller*		corporatisation
drug vendor*		corporatization
drug store*		organised
drug dispensing		organized
drug outlet*		
druggist		
medicine retailer*		
medicine shop*		
medicine seller*		
medicine vendor*		
medicine store*		
medicine dispensing shop*		
medicine outlet*		
medicine dealer*		
pharmacies		
pharmacy		
pharmacy service*		
pharmacist*		
pharmaceutical service*		

3.2.1 High income settings

A number of studies from high income countries (mostly in North America) report on a wide range of outcomes (see Appendix 2 for study details). Some outcomes such as role affinity, autonomy, workplace stress and job satisfaction were deemed to have limited relevance to this research. Others looked at more pertinent outcomes, such as quality of care, service provision and price. The following paragraphs summarise the evidence on the effect of pharmacy type on these three outcomes.

Several studies measured outcomes related to quality of care including counselling of patients, adherence to medication, provision of medication information, counselling, error reporting, patient satisfaction, dispensing errors, screening and discussing opioid abuse. Findings of these studies were mixed, with some reporting more favourable results for chains and others for independents. Further, a number of studies found no differences between the two. Research from the United States (US) reported that chain pharmacies provided longer medicine information leaflets which met a larger percentage of expert-required contents than independent pharmacies (Winterstein et al. 2010); were more likely to self-report screening patients for prescription opioid abuse (Cochran, Field, and Lawson 2015); and had higher rates of patient-initiated counselling (Raisch 1993). On the other hand, independents were found to counsel a significantly higher proportion of patients compared to chains in a US study; have patients with better adherence to antihypertensives and oral hypoglycaemics in the US and Canada respectively (Kalsekar, Sheehan, and Peak 2007, Winslade and Tamblyn 2017); and submitted more error reports than their chain counterparts (Kennedy and Littenberg 2004). Several studies did not find any differences between chain and independent pharmacies. For example, a study from Canada found no significant differences in adherence to statins for patients filling prescriptions at chain and independents (Evans et al. 2009). In Saudi Arabia, a study utilising standardised patients visits found no significant differences between pharmacy types for provision of information on inhaler technique for newly diagnosed asthma patients (Khan and Azhar 2013). Finally, dispensing accuracy results did not significantly differ by pharmacy type in a study of 6 cities across the US (Flynn, Barker, and Carnahan 2003).

In terms of service availability, one national study in the US found that chain and supermarket pharmacies offered a wider array of services, eg immunisation and health screening, compared to independents. Another paper, also from the US, reported on services that could improve access to prescription medication. A significantly larger proportion of chains were open 24 hours and reported having a drive-up window. Conversely, independent pharmacies fared more favourably in terms of offering a home delivery service and presence of multilingual staff.

Two studies compared drug prices at chain and independent pharmacies in the US. Both studies reported that independent pharmacies accounted for a larger proportion of community pharmacies in low income postcodes (Arora et al. 2017, Gellad et al. 2009). A study from Florida used a publicly available directory of drug prices to look at 3 commonly used medicines and found chain pharmacy prices to be cheaper than independents (Gellad et al. 2009). The other research, conducted in Los Angeles, collected the prices of two generic medicines by telephone and found the lowest average prices at independent pharmacies.

Both studies found chain price variation to be less than that of independents. Doucette and colleagues found that the proportion of independently owned pharmacies (vs chain pharmacies) in an area was positively associated with the percentage of the population earning less than the poverty line and with the percentage of population living in highly rural areas, suggesting a reluctance of chains to operate in highly rural and poorer areas (Doucette et al. 1999).

A large programme of work conducted in the United Kingdom (UK) in order to identify organisational factors associated with clinical productivity (levels of service delivery and service quality) recently published their findings (Jacobs et al. 2017). They found that levels of service delivery were related to ownership type, and the highest levels were found in large chains and supermarkets. They used a number of different tools to measure service quality and some of these were found to be related to pharmacy type. In terms of safety climate[4], more favourable organisational learning (willingness to develop and maintain safety) scores were found in large chains and supermarkets but working conditions in these environments were significantly worse than in independents. No differences were reported in satisfaction with the pharmacy visit or adherence to medication between pharmacy types.

In sum, the evidence available on the effects of chain pharmacies in high income countries comes mostly from the US. This research offers some information on the effect of price, access, services offered and some aspects of quality, but the results are mixed. Further, given the well-functioning nature of regulatory frameworks in high income contexts, the research pertaining to pharmacy chains in this setting, whilst providing some useful insights, is likely of limited applicability to lower income settings.

3.2.2   Low and middle-income settings

No studies were found that reported on pharmacy arrangements in low income settings, and only five from middle-income countries. Arkaravichien and colleagues employed a cross-sectional survey, aimed at assessing quality, in accredited chain (n=26) and independent (n=34) pharmacies in a region of North East Thailand (Arkaravichien, Wongpratat, and Lertsinudom 2016). Their quality indicator tool comprised 40 items covering five domains-premise and facility; personnel; drug inventory and stocking; dispensing and patient care; and patient satisfaction and health promotion. Assessment of quality involved both direct observation (items that could be clearly seen) and an interview with the pharmacist in-charge (for items that could not be observed). The study reported that chains had significantly higher scores in a number of domains (personnel, drug inventory and stocking, patient

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[4] Safety climate was measured using the Pharmacy Safety Climate Questionnaire, a validated measure which captures the "pharmacy's collective attitudes and behaviours regarding patient safety p.11" (Jacobs et al. 2017).

satisfaction and health promotion) resulting in a significantly higher overall median quality score of 3.6, compared to 3.3 for independent pharmacies (p=0.008). Scores were measured out of 4, and overall found to be quite high for most domains. These scores must be interpreted with some caution, given that most items were self-reported. Elsewhere in Asia, Bennet and Yin have examined the effect of chain store entry on prices and drug quality in the retail pharmacy market in Hyderabad, India (Bennett and Yin 2014). Through collaboration with a pharmacy chain, they gathered baseline data in 18 markets the firm wished to enter and later resurveyed 7 markets one year after chain entry. A mystery shopping audit was conducted in which antibiotics were purchased, prices were recorded and the quality of samples was assessed in a laboratory. The paper reported that compared to independent retailers, chain prices were 6% lower (p=0.02) and pharmacopoeia compliance was 6% higher (p=0.46). The resulting effect of chain entry on the market (compared with control markets) was a relative 5% improvement in drug quality and a 2% decrease in prices at existing independent retailers. The paper also noted that the chain initially targeted affluent neighbourhoods (Bennett and Yin 2014).

Two studies from Mexico report on the sale of misoprostol (which can be used to induce abortion) from pharmacies. A subset of their analyses is conducted by pharmacy type (chain or independent). Asides from its use as an abortifacient (for which 4 tablets are taken as a single dose), misoprostol can also be used to treat gastric ulcers, if taken on a long-term basis. Lara and colleagues (2011) hypothesised that the individual sale of pills indicated that they were used to induce abortions. In their study of 192 pharmacies in four regions of Mexico, using mystery client methodology, they report that a logistic regression model to explore the characteristics associated with the sale of misoprostol by individual pill found the odds to be three time higher for independents compared to chain pharmacies (Lara et al. 2011). The other study, in which mystery clients requested medicines for 'bringing down the period' and then asked for misoprostol at 169 pharmacies in one state of Mexico, investigated spontaneous and prompted discussions of the drug. No statistically significant differences were found by pharmacy type (Billings et al. 2009).

A final study, conducted in South Africa, investigated equity in the geographical distribution of pharmacies (Ward et al. 2014). The authors show that whilst in 2008 and 2009 there were more applications for pharmacy licences from independent than chain pharmacies, since 2010 this trend has been reversed, with more applications from chains. Applications by both pharmacy types peaked in 2009 for independents, and 2010 for corporate pharmacies, and have since both dropped. The authors discuss the concern of access in light of the decline of new independently-owned community pharmacies, citing that they are 'more likely to be

established close to poor communities than corporate businesses'. However, it is not clear from the paper whether there is strong evidence to back this claim.

3.3 Theoretical insights from economics literature

The existing empirical research pertaining to the effects of pharmacy chains in high-, middle- and low-income settings has, on the whole, been limited in terms of theoretical underpinning. Various bodies of theory provide insights into the study of pharmacy arrangements, such as those from neo-classical economics, industrial organisation and regulatory theory. Conventional economic analysis of pharmacy markets in LMIC typically focuses on the high likelihood of various market failures. There are arguably two reasons why retail pharmacy markets, specifically, do not fit the free market model: the assumptions of perfect information do not hold, and externalities exist. Mushkin (1958) was the first to describe the problem of imperfect information in health. She argues that consumers have an 'absence of accurate knowledge'. In the pharmacy context this relates to poor information regarding diagnosis, appropriate treatment and drug quality. This can hinder rational choice, leading to a suboptimal allocation of resources (Mushkin 1958). Arrow (1963) went on to recognise that the nature of information in health markets is asymmetric, meaning that the drug seller will, in general, have better information about the medicines than the buyer. The patient is therefore unable to completely enforce standards of care.

Within the agency relationship that results, it has been suggested that providers do not always act as perfect agents; rather they influence demand for their own self-interest, trading off income against patient welfare (Morris, Devlin, and Parkin 2007, McGuire 2000). Within the pharmacy context, where revenues can be increased by prescribing additional treatments, the quantity of items recommended is likely to be larger than it would be for patients with perfect information. The fee for service system of provider payment (as in a pharmacy) is most associated with 'overserving' patients (Hennig-Schmidt, Selten, and Wiesen 2011, McGuire 2000). The second issue is that inappropriate prescribing of medicines can be associated with negative externalities (Laxminarayan 2003); for example issuing a shorter than optimum course of antibiotics contributes to the emergence of antibiotic resistant strains of bacteria. Regulation is one method of addressing the welfare loss associated with market failure and protecting patients from drug sellers abusing their market position (Rice and Unruh 1998).

In addition to the general theories of market operation such as those described above, we draw on ideas from regulatory theory and industrial organisation to develop hypotheses regarding the effects of chains on the public health concerns of quality of pharmacy treatment behaviour, price of medicines, quality of medicines, and access.

3.3.1 Quality of care

It is first necessary to recognise that healthcare quality is a multidimensional construct. Donabedian (1980) describes three key aspects of health provider performance: the technical component, involving providers' knowledge and judgement skill, which is measured by comparison with best practice. The interpersonal component, concerning the interaction between patient and provider, for which information is difficult to obtain and measurement is not well-defined; and the amenities of care, namely the comfort and appeal of service provision. The quality shortcomings of pharmacy practice described in the literature review on performance largely fall under the technical component (Miller and Goodman 2016) and it is this aspect of quality that this thesis is primarily concerned with.

I now turn to the potential effects of chain pharmacies on technical quality. The literature review on pharmacy performance in chapter 2 identified three key determinants of pharmacy provider behaviour: regulation, knowledge, and profit motives. I consider how being organised as a chain may influence these determinants.

3.3.1.1 Regulation

The fragmented nature of pharmacy retail in India makes enforcing regulation costly and logistically difficult. Through consolidation, chains could improve regulation in two ways. First, state regulation can be concentrated on central management structures. Essentially, the regulator can make firms take responsibility for local branches, thus relieving pressure on overburdened regulatory agencies.

Second, firms may self-regulate in order to preserve brand identity and image. In his classic article on 'lemons' in the used car market, Akerlof (1970) showed that when sellers are aware of the car quality, but consumers are not, then only lemons will be traded. In contrast with the market for used cars, consumers of medical care usually have some indication of quality either from past experience, discussions with others about their past experiences or other sources (Haas-Wilson 2001). Where information regarding reputational quality can be obtained, the problem of quality deterioration can be lessened (Klein and Leffler 1981). Several authors have alluded to the potential of 'market-based' regulatory mechanisms, including self-regulation, within pluralised, unregulated health markets where traditional approaches (enforcing regulation through administrative and bureaucratic controls) have failed (Ensor and Weinzierl 2006, Bloom, Kanjilal, and Peters 2008, Bloom, Standing, and Lloyd 2008, Peters and Muraleedharan 2008). Bloom et al (2008) describe how an institutional reputation is built into a brand and this can be damaged if products or services are of low quality, thus creating an incentive to ensure quality (Bloom, Standing, and Lloyd 2008). They argue that these reputation-based ways of delivering health care build trust and

can help to overcome the information asymmetry which characterises transactions in pharmacy markets.

Self-regulation would involve chains developing their own rules or codes of conduct that guide the behaviour, actions and standards of those working within the organisation. The chain would then take responsibility for developing self-regulatory instruments, monitoring compliance and ensuring enforcement. A concern, however, is that some aspects of quality in health markets are easier to learn about than others and patient satisfaction has been shown to be positively linked to interpersonal quality but less sensitive to technical quality (Haas-Wilson 1994). This may result in chains focusing their attentions on controlling the quality of these aspects of their service provision, rather than focusing on current technical failings.

3.3.1.2   Knowledge

The importance of brand identity may lead to qualified pharmacists at the point of service delivery, who would be expected to be more knowledgeable than unqualified staff. Currently, such personnel are reportedly often absent in independent pharmacies (Basak and Sathyanarayana 2009). The websites of a number of Indian pharmacy chains already promote the presence of qualified pharmacists in all of their stores (c.f. Frank Ross Pharmacy 2011, Hetero Pharmacy 2010, Trust Chemists and Druggists 2014).

3.3.1.3   Profit-motives

A final reason why quality may improve in a chain situation arises from the different incentive structures in place for pharmacy owners as opposed to managers. High-powered incentives exist when the profits of transactions flow directly to the parties involved (Williamson O 1985, Frant 1996). In the case of independent pharmacy owners, the potential for excess profits provides incentives to behave dishonestly. This is based on the assumption that clients are poor judges of technical quality and that pharmacy workers do not have reservations about exploiting their position of power within the provider-patient relationship. A hierarchical structure (as in a chain) can attenuate opportunism because the incentives faced by salaried personnel working in the pharmacy are low-powered. The literature review presented in chapter 2 found that a number of poor practices, for example the sale of medicines with high profit margins, were linked to profit-maximising strategies. In the event that chain employees are salaried, the removal of profit considerations from medicine sales may lead to improved prescribing practices. However, in order to better align the incentives of the employees with the goals of the organisation, chains may commit more resources to monitoring and verification

(Milgrom and Roberts 1992). Further, they may instigate incentive schemes (Hölmstrom 1979, Harris and Raviv 1979). Whereas others argue that whilst incentives can improve efficiency, they do not necessarily maximise profits (Miller and Whitford 2007). It is currently unknown whether pharmacy chains in India link pay with performance.

3.3.2 Price and quality of medicines

Organisational arrangements could also affect price and quality in a number of ways. Chains can take advantage of scale economies to invest in cost-reducing and quality-enhancing technologies (Bennett and Yin 2014). Chains may also be able to realise larger margins on medicines than their independent counterparts through a variety of mechanisms. Firstly, they could create their own supply chains and buy directly from manufacturers. Secondly, firms may also partner with manufacturers to offer 'own brand' or 'private label' products. Such products are obtained at a lower cost (than nationally established brands) thus offering higher margins. Finally, if firms became large enough to experience buying power in the market chains could realise larger margins than independents. All of these actions could lead to cheaper medicines for clients. On the other hand, firms may use their brand power to raise prices. In high-income settings, consolidation in the hospital sector has led to price increases (Cutler and Morton 2013, Gaynor and Town 2012).

With regard to drug quality, concerns include appropriate storage, and counterfeits. Heat and humidity can be extreme in India and medicines must be stored appropriately to prevent degradation. Most leading chains advertise their use of refrigerator units to maintain medicines at appropriate temperatures (MedPlus Pharmacy 2011, Hetero Pharmacy 2010). This may signal their willingness to invest in quality control. Further, the ability to shorten the supply chain by potentially bypassing parts of the supply chain may give chains more control over drug quality.

3.3.3 Geographical access

According to Rubin, firms organised as chains may restrict their operations to urban areas due to the costly nature of monitoring units (to prevent shirking) in dispersed geographical locations (Rubin 1978). Given that independent pharmacy owners tend to work in the pharmacy themselves, they do not face the difficulty or cost of monitoring at a distance and are thus not restricted to urban locations. Rather, they are likely to open a business wherever they have personal ties. Basak and colleagues describe how India struggles with a stark urban-rural imbalance with regards to pharmacists, with few working outside cities and almost none in remote areas (Basak, van Mil, and Sathyanarayana 2009). Were chains to adhere to minimum staffing standards in their branches, they would likely struggle to recruit

qualified personnel outside the urban metropolises. Further, a business model employing a qualified pharmacist may not be viable in sparsely populated areas with low purchasing power.

3.4   A note on franchises

Franchises are another organisational form through which pharmacy services can be delivered. This arrangement has not been a major consideration of this thesis, because in India the vast majority of corporate pharmacies operate centrally-owned outlets (i.e. a chain format). Medicine Shoppe, perhaps the most well-known pharmacy franchise in India, enjoyed rapid growth to become one of the country's leading corporate players but was ultimately unsuccessful and closed down operations after 10 years in the market (Chanchani 2009). Some retailers operate franchised stores in addition to their centrally-owned outlets, but these represent a small proportion of the total. Whilst this thesis does not explore franchises, I have briefly considered the theoretical effects of such businesses.

Franchised pharmacy companies would be expected to work through the same mechanisms as chains with a view to cost-reducing and quality-enhancing technologies; also in terms of regulation. They too would be trading on the premise of various promises to customers that enable their brand to be distinguished from the competition. Rubin suggests that because franchisees share substantially in the profits of their outlet, they have a greater incentive than managers to be efficient and avoid shirking and this reduces the need for costly monitoring (Rubin 1978, Milgrom and Roberts 1992). Franchising may, therefore, allow a firm to offer stores in more dispersed locations, thus expanding services and increasing access in untapped peri urban and rural areas. Whilst the high powered incentives of being a franchisee act to align interests with the franchisor, the profit motives of both parties can clash with public health concerns. The high powered incentives created by the use of a franchise contract inadvertently create a horizontal agency-related problem for the firm- that of free riding. The owner of a single franchisee unit has a profit motive to offer a lower level of quality than that which maximises the franchisor's profit (Blair and Kaserman 1994).

3.5   Set of hypotheses

Drawing on the literature presented above, figure 1 summarises the set of hypotheses arising from the literature about the implications of pharmacy chains for public health in a LMIC setting. The main outcome of interest is the effect of chains on quality of care, related to treatment behaviour. At the top of the figure, a pharmacy provider, working within a market characterised by negative externalities and asymmetry of information, is depicted. The mechanisms by which chains are hypothesised to affect the determinants of quality of care

(knowledge, regulation and profit motives) are shown. The mechanisms by which price, access, and quality of medicine are hypothesised to be affected are also included. For logistical and budgetary reasons drug quality was not be measured in this study but potential mechanisms by which it may be affected have been included to provide a more complete picture.

Figure 1: Hypothesised effects of pharmacy chains on public health concerns of quality of care, price, quality of medicines, and access
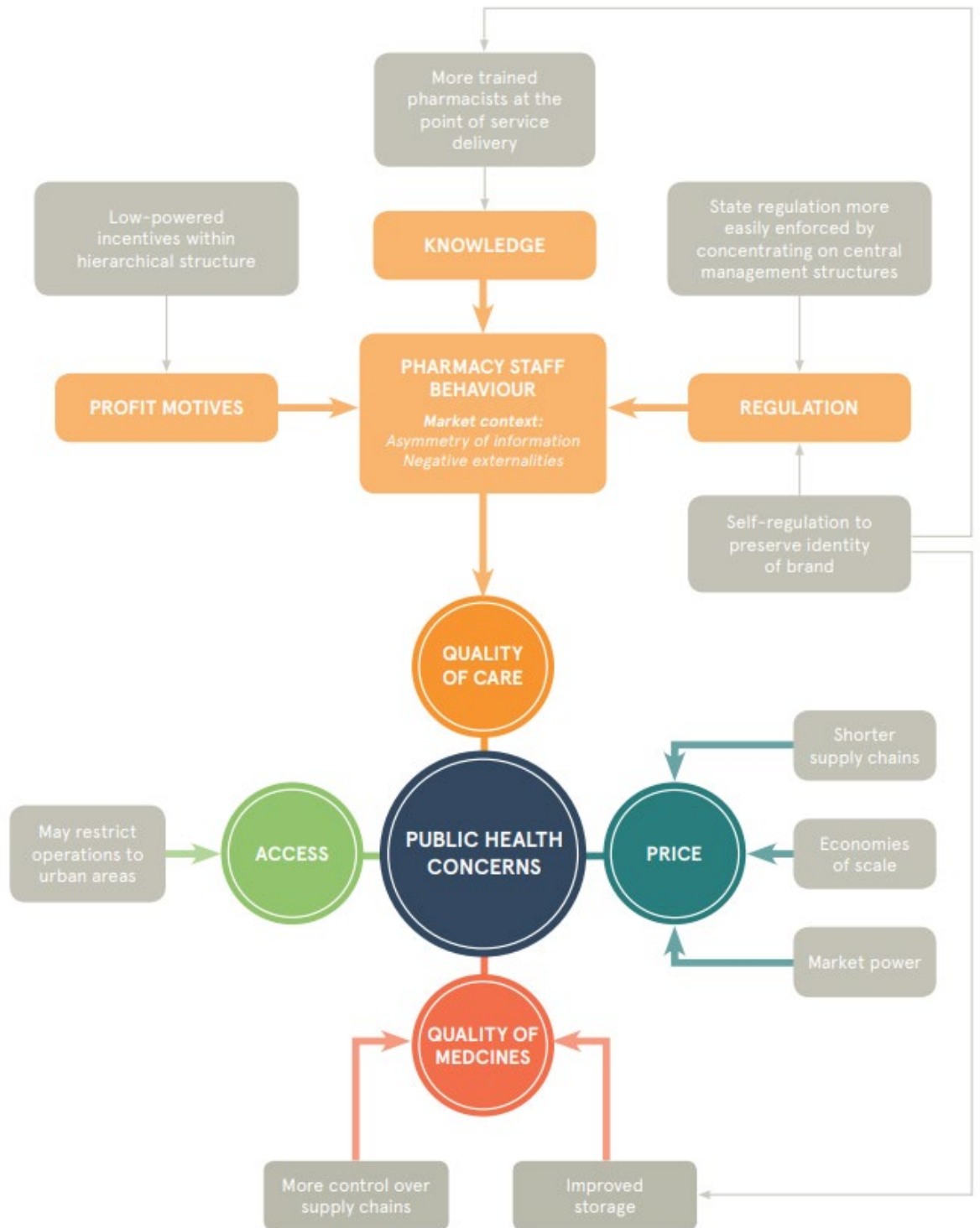
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4 Study site, study design, and methods

4.1 Introduction

In order to achieve the stated objectives of this thesis, it was necessary to employ multiple methods. Following a description of the study site where the research was conducted, this chapter provides details of all methods used, including a standardised patient (SP) survey, in-depth interviews with key informants, and exit interviews with clients.

4.2 Study Site

In this section I provide a general overview of the Indian health system and details of both the state (Karnataka) and city (Bengaluru, previously known as Bangalore) where the research was conducted.

4.2.1 India

India is the world's second largest country in terms of population (over 1.2 billion as per the 2011 census) and the seventh largest in terms of land mass (Census of India 2011). It is comprised of 29 states and seven union territories and is both culturally and linguistically diverse. The most recent census identified 122 different languages that were spoken by more than 10,000 people. 69% of the population live in a rural area and female and male 7+ literacy rates were 69% and 85% respectively (80% and 90% in urban areas). India gained its independence from British rule in 1947 and has gone on to become one of the world's fastest growing economies, with an average annual growth rate of Gross Domestic Product (GDP) of 7.4% over the last decade (World Bank 2018). Despite this growth, there is vast income disparity and 268 million citizens (21.2% of the population) were living on less than $2 a day in 2011 (World Bank 2018 -d).

4.2.2 Healthcare in India

Whilst the overall state of health is improving (life expectancy at birth has increased from 55 in 1965 to 72 in 2015) (World Bank 2018 -a), India faces a mismatch between its health problems and its health system. In tandem with its social and economic development, India is undergoing a major epidemiological transition, with a shift in burden to non-communicable diseases. Not only are these new threats associated with an ageing population emerging, but the country continues to struggle with communicable diseases and historic health problems, including high rates of infant mortality (30.5 per 1000 live births) (World Bank 2018 -c); maternal mortality (174 per 100,000 live births) (World Bank 2018 -b); and malnutrition (of children under 5, 38% affected by stunting and 21% either 'wasted' or

'severely wasted', and over half of women of reproductive age suffer from anaemia) (Development Initiatives 2017). Further, huge variations in disease burden exist across states and a disproportionate burden of disease falls on marginalised groups including the poor, women, and scheduled tribes and castes (Peters 2002).

As per the Indian constitution, each state is responsible for organising and delivering healthcare for its population. The central government, under the direction of the Ministry of Health and Family Welfare, is responsible for coordinating national disease programmes e.g. the Revised National Tuberculosis Control Programme (RNTCP), promoting of traditional systems of medicines, and oversight. In terms of service provision, government health services coexist alongside private services. Healthcare in rural areas is characterised by a network of government facilities (Chokshi et al. 2016). Health Sub Centres, run by Auxillary Nurse Midwives cater to a population of around 3000-5000 offering health promotion, basic medicines, and referral opportunities. Primary Health Centres are supposed to have a qualified medical doctor, offer primary care including laboratory and pharmacy services as well as minor surgery, and serve a population of 20,000-30,000. Primary Health Centres feed into Community Health Centres, which offer inpatient facilities (around 30 beds), and, in theory, access to specialists including a physician, surgeon, paediatrician, and obstetrician or gynaecologist to a population of 80,000-120,000. However, the shortfall of health workers in all of these settings is well documented. For example, in community health centres 83% of physician, 83% of surgeon, 82% of paediatrician, and 76% of obstetrics and gynaecology posts are vacant (Sharma 2015). The top tier facilities are First Referral Units for 24/7 emergency care and blood storage. Community health workers- Accredited Social Health Activists (ASHAs) work in each village and act as a link between communities and formal health services. As of 2015, there were 153,655 Sub Centres, 25,308 Primary Health Centres (PHCs) and 5,396 Community Health Centres (CHCs) in the country, yet these numbers are not sufficient to meet population needs (Ministry of Health & Family Welfare 2015). In urban India, there is not such an elaborate government network, rather a mix of primary and secondary/tertiary facilities (Ministry of Health & Family Welfare 2013). In theory, this network of government facilities provides universal healthcare, free of charge. Yet it is well documented that, in practice, the delivery of health services in the public sector is beset with problems. This includes a lack of adequate human resources (0.725 doctors, 2.049 nursing and midwifery personnel, and 0.519 pharmaceutical personnel per 1000 population), medicine shortages, poor management, low service quality, and weak finances (World Health Organisation 2018 , Peters 2002).

Health appears to be a low priority for the Indian Government. It consistently ranks as one of the world's lowest spending nations on public healthcare (as a proportion of GDP). In 2008-

9 they committed a mere 1.1% of GDP to healthcare (National Health Systems Resource Centre 2017). This inadequate financing has led to the overwhelming dominance of the private sector. The private share of total health expenditure (THE) is a vast 71% and pertinent to this thesis, 29% of THE is spent at private retail pharmacies on either prescribed or non-prescribed medicines (ibid). 63% of THE is accounted for by out-of-pocket payments by households. This high level of out-of-pocket expenditure is one of the highest amongst LMICs (Mackintosh et al.). Large and unpredictable health-related expenditure can expose households to sizeable financial risk, and it has been reported that such payments push around 3.5% of the population below the poverty line each year (Van Doorslaer E et al. 2006, Berman, Ahuja, and Bhandari 2010, Garg and Karan 2009). Heterogeneous in nature, the private sector includes a full spectrum of providers and facilities including large corporate multispecialty hospitals, small inpatient facilities with fewer than 30 beds, medically trained general practitioners, and unqualified 'quacks' or traditional healers (Peters 2002). There are also a number of non-profit entities. Although Western (allopathic) medicine dominates, there are many providers of Indian systems of medicine, eg Ayurveda and Unani. Many untrained practitioners offer a combination of these systems of medicine (ibid). Private healthcare practitioners and pharmacists account for 71% and 79% of outpatient visits in rural and urban areas respectively (Mackintosh et al.).

The combination of a high burden of ill health, low public spending on healthcare, high private healthcare expenditure (largely accounted for by out of pocket payments), and limited coverage of existing health insurance schemes, has led to calls for major reform to India's health system, in a bid for 'universal healthcare for all by 2020' (Reddy et al. 2011). Health planners have advocated the expansion of health insurance as an essential component of the country's healthcare reform and poverty reduction strategy (Reddy 2012). In terms of coverage, 0.3% of the rural and 3.5% of the urban population have private insurance, most recipients being in the top wealth quintile (Sundararaman and Muraleedharan 2015). Government-funded schemes cover 13.1% and 12% of rural and urban populations respectively. Since 2007 a plethora of state and central insurance schemes have been initiated in a bid to improve social protection. Rashtriya Swasthya Bima Yojana (RSBY), the world's largest public health insurance scheme was launched in 2008 for Below Poverty Line (BPL) families. Despite stated objectives of some of these public schemes to cater for the poor, insurance remains iniquitous, with lowest quintile vs highest quintile coverage figures of 7.7% vs 15.1% in urban, and 10.1% vs 17% in rural areas (ibid). Further, many of the government schemes only cover inpatient costs at the tertiary level (Shahrawat and Rao 2012). Health insurance in India is a dynamic policy issue and in February 2018, Modi's

government announced new plans to offer health coverage to 100 million families, as part of the government's 2018-19 budget (Goel and Kumar 2018).

4.2.3 Karnataka and Bengaluru

The state of Karnataka is situated in South India. It is the eighth largest state in terms of land mass and ninth in terms of population (61.1million inhabitants according to the 2011 census). In terms of key development and health indicators, Karnataka's performance compares favourably with national averages but it lags behind neighbouring Southern states, Kerala and Tamil Nadu (see Table 1). The official language is Kannada but many other languages, including Urdu, Tamil, Telugu, Marathi, and Tulu, in addition to Hindi and English, are spoken.

The disease burden in the state is attributed 25.1% to communicable, maternal, neonatal and nutritional diseases; 62% to non-communicable diseases; and 12.9% injuries. The top 5 causes of Daily Adjusted Life Years in 2016 were ischaemic heart disease (11.0%), coronary obstructive pulmonary disease (4.9%), self-harm (4.3%), stroke (3.8%), and diarrhoeal diseases (3.5%) (Indian Council of Medical Research 2017).

Within Karnataka, there is a stark rural-urban divide, with those living in rural areas experiencing poorer health outcomes (Seshadri et al. 2013). Further, the majority of economic development, roads, infrastructure and public services have concentrated on Southern Karnataka, thus neglecting Northern regions (ibid). This inequality is manifested in gross disparity in development indicators, as evidenced by the human development indicator (HDI) scores of Raichur in the North (0.547) and Bengaluru Urban in the South (0.753) (ibid). Health outcome indicators also vary widely across the districts, for example, 74.5% of women in Bengaluru Urban received a full antenatal check-up compared with only 19% in Koppal (a Northern district) (International Institute for Population Sciences (IIPS) 2014).

Table 1: A comparison of India's nationwide key health and development indicators with the Southern states of Karnataka, Kerala and Tamil Nadu

Key health and development indicators	India	Karnataka	Kerala	Tamil Nadu
Life expectancy females	70.3	71.1	78.7	73.5
Life expectancy males	66.9	67.1	73.8	68.9
Women who are literate (15-49) (%)	68.4	71.7	97.9	79.4
Households with any usual member covered by a health scheme or health insurance (%)	28.7	28.1	47.7	64.1
Total fertility rate	2.2	1.8	1.6	1.7
Maternal mortality ratio (per 100,000 live births)	167	133	61	79
Infant mortality rate (per 1000 births)	41	28	6	20
Under 5 mortality rate (per 1000 births)	50	32	7	27
Institutional births (%)	78.9	94.3	99.9	99
Children age 12-23 months fully immunized (BCG, measles, and 3 doses each of polio and DPT) (%)	62	62.6	82.1	69.7
All women age 15-49 years who are anaemic (%)	53	44.8	34.2	54.8

Data source: National family health survey (NFHS) 4, except maternal mortality from Sample registration system and life expectancy from The India State Level Burden Initiative (Indian Council of Medical Research 2017, Ministry of Health & Family Welfare 2016, Ministry of Home Affairs). Note: These figures have been compiled from the most up-to-date sources available but some of the all India figures differ from those provided above from the World Bank database.

The urban district of Bengaluru, India's third most populous city, is the site of this PhD research. It was selected as one of the few Indian cities with significant chain entry. Bengaluru is the capital of Karnataka and is situated in the South of the state. Bengaluru is divided into 198 administrative units, all of which fall under the responsibility of the Bruhat Bengaluru Mahanagara Pike (the third level of government). The city has an estimated population of around 10 million, and despite its relatively favourable HDI (reported above) compared to the rest of the state it is, like much of India, a city of contrasts. On the one hand, it is known as 'The Silicon Valley of India' with a booming IT industry and a growing middle class. Yet on the other, it is home to 597 of Karnataka's 2804 identified slum communities, where many inhabitants are living below the poverty line (Government of Karnataka). The median income of inhabitants living in one of Bengaluru's slums has been reported to be is $1.5 (US) per day (Bhojani et al. 2012).

4.2.4 My Institutional Home in Bengaluru

As this research was independently conducted and was not part of a larger project, I felt it was important to establish a local institutional home in order to have some local insights into conducting research in Bengaluru and logistics such as visas and research assistant recruitment. During data collection, I was based at the Society of Community Health Awareness Research and Action (SOCHARA). SOCHARA is a Non-Governmental Organisation (NGO) that houses an 'interdisciplinary group of community health professionals utilising multiple pathways to facilitate and promote the goal of Health for All'. It is run by alumni of the LSHTM.

4.3 Methods

Table 2 provides an overview of the methods used to achieve each objective, and the details of the corresponding results papers.

Table 2: Overview of thesis objectives and corresponding methods and results papers

Objectives	Methods	Results papers
A. To compare the quality of case management (of two tracer conditions) at chain and independent pharmacies	Standardised patient survey	1. Miller R and Goodman C 2018, *BMJ Global Health.* Status: published. Chapter 5.
B. To compare the price of consultations (for two tracer conditions) at chain and independent pharmacies	Standardised patient survey	2. Miller R and Goodman. Status: under review with *Health Policy and Planning.* Chapter 6.
C. To assess the socioeconomic status of clients shopping at chain and independent pharmacies	Exit interviews with clients	2. Miller and Goodman. Status: under review with *Health Policy and Planning.* Chapter 6.
D. To explore how and why the organisational structure of pharmacy chains may affect the quality of service provision and prices of medicines, compared to independent pharmacies	In-depth interviews	3. Miller R, Hutchinson E and Goodman C. Status: revise and resubmit with *Social Science and Medicine*. Chapter 7.

4.3.1 Method 1: Standardised patient survey

A cross-sectional standardised patient (SP) survey was used in order to compare both the quality of case management and the prices of consultations at chain and independent pharmacies.

4.3.1.1 Choice of data collection method

A number of options exist for assessing the performance of health workers, including: exit interviews with clients, direct observation of pharmacy encounters, and administration of medical vignettes; however, SP methodology is regarded as the gold standard (Das et al. 2012). It involves researchers presenting with a fictitious case scenario and requesting assistance. It is a covert technique and the provider is unaware of the patient's research agenda. The SPs (also referred to as mystery shoppers, simulated clients, confederates, or surrogate patients) subsequently record the outcomes of their interaction. Performance is then assessed based on pre-defined criteria. It has a number of advantages relative to other measures of assessing performance (Das et al. 2012). It is free from the recall bias associated with exit interviews, the observation bias (Hawthorne effect) associated with direct observation, and the desirability bias associated with medical vignettes. In addition, exit interviews and observation techniques can be logistically difficult and time consuming because only patients seeking care for the tracer condition of interest are eligible for inclusion. Further, as different pharmacies are likely to have varying case-load mixes; the standardised nature of the mystery shopping method allows direct comparison of case management across different pharmacies.

4.3.1.2 Choice of quality measures

Donabedian (1988) warns that proceeding to measurement "without a firm foundation of prior agreement on what quality consists in is to court disaster p1743". Quality of care was assessed by measuring adherence to case-specific treatment guidelines[5] for two tracer conditions. This included all aspects of managing a condition in the pharmacy, including relevant history questions, treatment recommendations, and advice provision. According to Donabedian's three dimensions of quality of care (structure, process and outcome), these constitute process indicators (Donabedian 2005), which seems appropriate as process of care is in the hands of the provider. Measures of structural quality[6] have been cited as poor proxies of quality of care in terms of diagnoses and treatment (Rethans et al. 1991, Das and Gertler 2007, Das et al. 2012) and outcome measures are often not direct measures of care quality; they can be highly influenced by patient-related factors (Donabedian 2005).

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[5] In the early 90s, the WHO, in collaboration with the International Network for Rational Use of Drugs (INRUD), developed a set of indicators for measuring quality use of medicines and prescribing behaviour in health facilities [(World Health Organization 1993)] These have been revised, updated and incorporated into the more recent package for evaluating country pharmaceutical situations [(World Health Organization 2007) These documents informed the choice of quality measures.

[6] I initially intended to collect data on structural aspects through an outlet survey but this was not possible because all major chain pharmacies refused to participate.

4.3.1.3 Choice of tracer conditions

According to the WHO (1993), a good tracer condition for measuring quality of care is one which has clear guidelines for treatment. It should also be either frequently presented, or of particular clinical or economic importance. The WHO's specific suggestions include non-bacterial diarrhoea in children under age 5, mild/moderate pneumonia in children under age 5, and non-pneumonia acute respiratory tract infection in patients of any age. For India, childhood diarrhoea (as suggested by WHO) and pulmonary tuberculosis were felt to meet all these criteria (Boschi-Pinto, Velebit, and Shibuya 2008, World Health Organization 2013). In addition, care for both conditions is reportedly sought at the pharmacy, which ensures the scenarios are realistic and prevents drawing attention to the study (Madden et al. 1997, Sudha et al. 2003, Kapoor et al. 2012); and they represent contrasting examples of recommended management- a suspected tuberculosis case should be referred outside the pharmacy for treatment, whereas diarrhoea is commonly wholly treatable in the pharmacy environment.

4.3.1.4 Cases

Table 3 provides details of the case presentations, including the exact script used by the SPs, the responses given to varying lines of questioning, and the expected management against which performance was measured. According to the Government of India (GOI) and the Indian Pharmaceutical Association guidelines, community pharmacists should refer patients with symptoms indicative of TB for sputum examination. Further, under the Drugs and Cosmetic Rules 1945, which governs the sale of medicines from pharmacies, they should not sell medicines requiring a prescription. This act categorises medicines as either OTC or prescription only. POMs are then sub-classified as either H, H1 or X. Schedule H medicines require a prescription from a qualified doctor. The 46 H1 medicines are subject to an extra set of restrictions on dispensing - identity of the patient, contact details of the prescriber, and the name and dispensed quantity of drug must be recorded in a separate register. This schedule was introduced in 2013 in a bid to restrain the OTC over-use of medicines of public health concern (mainly antibiotics). Schedule X, which comprises a small group of medicines subject to abuse, including narcotics, is the most restrictive list and prescriptions for these medicines must be retained by the dispensing pharmacy for two years.

In this study, the provision of antibiotics (including anti-TB medicines) and/or steroids were deemed to be 'harmful', in line with the research of Satyanarayana and colleagues (2016) (who also utilised SPs to investigate the management of TB at Indian pharmacies); unnecessary courses of antibiotics or incomplete or incorrect dosing regimens can lead to the

development of antibiotic resistance and steroids can mask TB symptoms and thus delay an accurate diagnosis.

Surprisingly, there are no pharmacy-specific national or international guidelines for the management of diarrhoea. Considering one of the responsibilities of pharmacists in India is to treat minor ailments, guidelines aimed at 'physicians and senior health workers' were used for this non-complicated case of diarrhoea (World Health Organization 2005). WHO guidelines (adopted by GOI) advise that physicians should manage a 2 year old with acute diarrhoea (without blood) with oral rehydration solution (ORS), supplemental zinc, energy-rich foods, and continued breast-feeding. Further, POMs should not be sold and antibiotics, antidiarrhoeals, and antispasdoics are considered harmful (ibid). Medicines that are not listed in the guidelines, yet are not recognised as 'harmful', have been categorised as 'not recommended' for the purpose of this research. For both cases presented by the SPs, pharmacy staff were expected to ask appropriate questions to confirm the diagnosis and to provide fitting advice. Appropriate history taking, treatment, and advice provision, all drawn from the relevant guidelines, are laid out in table 3.

Table 3: Standardised patient case details and expected management

Case details		Expected management		
Case description	Details of scenario	History	Treatment	Advice
Acute watery **diarrhoea** in a child	'I need to buy something for my niece who has diarrhoea. She is 2 years old?' Further questioning would reveal: -4 episodes during the last day; -more thirsty than usual; -may have had a slight fever; -no blood in the stool, abdominal pain or vomiting; -no medication had been taken.	Pharmacy server to ask: • Blood in stool? • Duration of diarrhoea? • Number of stools per day? • Number of episodes of vomiting? • Presence of fever? • Pre-illness feeding practices? • Type of fluids and foods during illness? • Child passing urine? • Tried any medication?	• Oral rehydration therapy using oral rehydration salts (ORS) solution; • Zinc supplementation; • No sale of anti-diarrhoeals, antibiotics or antispasmodics.	• Explain how to use ORS; • Importance of more fluids; • Usual diet should be continued (including milk); • Take to health worker if signs of dehydration or other problems e.g. blood in stool.
Suspected pulmonary **tuberculosis** in an adult	On completion of diarrhoea advice: 'Also for myself…I have had cough and some fever for 3-4 weeks. We have had a relative staying with us who has TB. Can you suggest something?' Further questioning would reveal: -sputum in the cough; -sweating at night; -loss of appetite; -no medication had been taken.	Pharmacy server to ask: • Consulted doctor? • Chest pain? • Sputum or blood in cough? • Weakness or fatigue? • Weight loss? • Loss of appetite? • Chills? • Night sweats? • Any other symptoms? • Tried any medication?	• Referral to TB clinic or other healthcare provider for sputum examination; • No sale of antibiotics (including anti-TB medication) or steroids.	• Advise that treatment is available free of charge from government hospitals

Table reproduced from Miller and Goodman (2017)

4.3.1.5   Training and piloting

Six research assistants (one female and five male) were recruited from Bengaluru and trained as SPs. The SPs ranged in age from 20 to 45, with the average age being 31. The SPs were trained in a group by myself, with input from a local researcher, over the course of one week.

During the training, we spent time learning the standardised cases and going through the debrief questionnaire in detail. Role play has been shown to be a useful training tool for SPs (Goel et al. 1996) and as such a large proportion of the training time was spent rehearsing the scenarios in the classroom. All SPs spent time clarifying their back story and practised answering numerous possible questions relating to their personal situation. SPs did not start visiting the pharmacies in the sample until a number of pilots had been completed and a senior research assistant was satisfied that the standardised case was being presented as intended, in a convincing manner. During the training, the research team discussed how they should dress in order to ensure that they would appear of a similar social background to a typical customer who might present with these conditions.

4.3.1.6 Data collection

The SPs presented the pre-rehearsed scenario of the two tracer conditions in Kannada (the local language), during a single visit, at a random sample of 333 of Bengaluru's pharmacies. These visits took place between May and June 2015. Other studies using standardised patients have tended to present one condition per pharmacy visit, but due to time and budget restrictions both were presented in one encounter (see Table 3 for the exact script). Any medicines recommended by the pharmacy staff were purchased. Following the consultation, the SPs were immediately debriefed by another researcher, using a structured questionnaire. The questionnaire covered details of the questions asked by pharmacy staff, referral instructions, medicines dispensed, and advice given. The price of each medicine and the overall price of the consultation were also recorded.

4.3.1.7 Sampling

On request, the Karnataka State Drug Control Department, based in Bengaluru, provided us with a list of all registered pharmacies in the Bengaluru urban district. Before using this list as a sampling frame, a census was conducted of pharmacies in three neighbourhoods in order to assess its accuracy. Local informants helped to identify three neighbourhoods with differing wealth profiles - broadly, a wealthy, a middle-income range, and a poor area with a large slum population. In one neighbourhood this work had already been conducted by a local research organisation (Institute of Public Health, Bengaluru), through their 'urban health action research project'. One of their initial tasks was a private provider mapping exercise and they shared the details of this work with us. These censuses enabled us to verify of all the pharmacies identified; 97% were on the Government list (all pharmacies on the list were identified, although some addresses were not precise) and hence provided a comprehensive sampling frame.

Pharmacies on the list were then categorised as either 'chain' or 'independent'. In the literature, chains are often defined as pharmacies with five or more outlets. Having spent time piloting in the city and spending time in pharmacies to get an understanding of how they worked, it was not clear that this definition fitted the context. In some instances, family members would own a few pharmacies, sometimes under the same name, but on visiting them it would not be clear that they had any links. Similarly, there were a few very small chains with more than 2 but fewer than 5 outlets that I felt should be classified as chains. In light of this, chains were defined as organisations where two or more pharmacies were operating under the same name and the business used distinctive branding across all outlets. From the list alone it was not possible to categorise all pharmacies and where there was uncertainty, phone calls or site visits were made, as appropriate, to verify the pharmacy's status. The focus of this research was on retail pharmacies and therefore any pharmacies that could not be accessed from the street, including those operating in hospitals and clinics, were excluded. From the resulting list of 5135 independents and 529 chain outlets (from 13 chains) a random sample of pharmacies was selected, stratified by pharmacy type ie chain or independent. The sample included outlets deriving from eight chains - seven of the city's largest and one with fewer than five outlets. Table 4 provides information on the size of Bengaluru's pharmacy chains and the breakdown of those included in the sample.

Table 4: Size of pharmacy chains in Bengaluru and in sample

Number of outlets	Number of chains	Number of chains in study sample	Number of outlets in study sample
2 to 5	6	1	1
6 to 10	2	2	4
11 to 50	2	2	6
51 to 100	1	1	14
101+	2	2	78

Of the 333 SP visits, 103 were at chain pharmacies and 230 at independents (figure 1). These numbers satisfied sample size calculations based on a level of significance of 0.05, 80% power, effect size of 0.2 (ability to detect a 20% difference in measurements of quality between pharmacy types) and a proportion of interest of 0.5 for the outcome of correct case management.

Figure 1: Geographical locations of chains and independents visited in standardised patient study
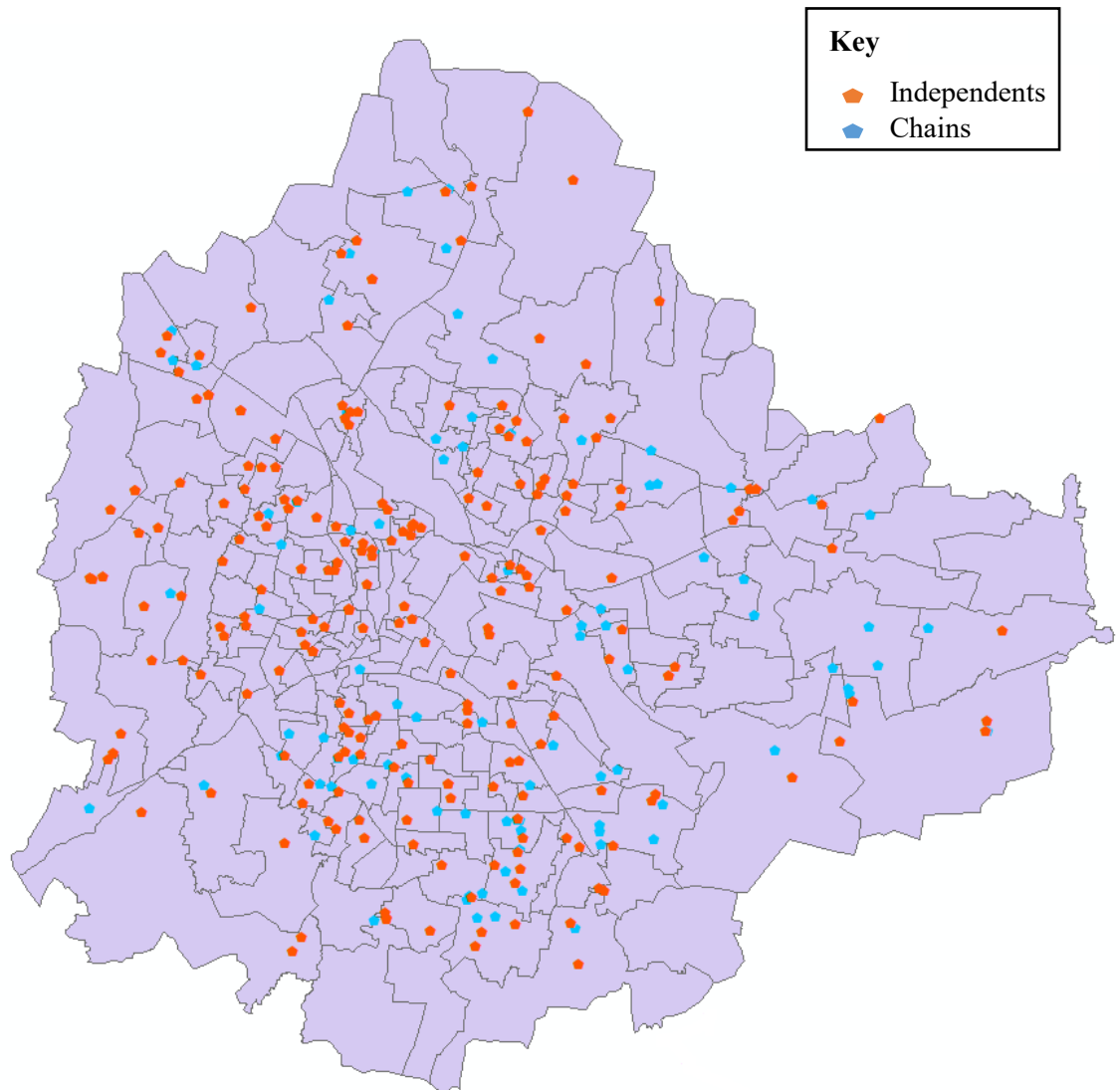
4.3.1.8   Statistical analysis of data

The performance of chains and independents was assessed by measuring adherence to case-specific checklists of recommended care (presented in table 3). Data from the manual survey questionnaires was double entered into CSPro and from here, exported into Stata 14 for analysis. Data from the TB and diarrhoea cases were analysed separately, with the unit of analysis being the pharmacy. Adherence to items on recommended care checklists was treated as dependent variables and the independent variable was type of pharmacy (chain or independent). In an uncontrolled analysis, Pearson chi-squared tests were used to examine

the effects of pharmacy type on the various aspects of history taking, referral, treatment recommendations, and advice (all of which were treated as categorical binary variables).

Price data from the SP survey were analysed at a later date, using Stata 15. Given that the price data were skewed, I looked at the difference in median price, interquartile range, and p value from the Wilcoxon rank sum test of the hypothesis of equal medians in chains and independents.

4.3.2   Method 2: Exit interviews with clients

4.3.2.1   *Choice of data collection method*

Given the renewed concern for inequalities in health in LMIC and the need to understand the influence of poverty on health, there has been a growing interest in measuring socioeconomic status (SES) of health survey respondents in these settings (Boerma et al. 2008, Gwatkin 2000, Howe et al. 2012). Standard measures of SES tend to use data on income or expenditure but these indicators are both difficult to collect and are often inaccurate for reasons such as recall bias and seasonality (Montgomery et al. 2000, McKenzie 2005). As a result, it has become common practice to measure wealth by collecting data on variables that capture living standards, including assets (eg TV or motorbike) and housing characteristics (eg water source or roof material) (Vyas and Kumaranayake 2006, McKenzie 2005). Based on asset ownership, households are then organised into socioeconomic categories enabling calculation of relative, but not absolute, measures of poverty or wealth. This approach was deemed to be feasible and appropriate for measuring the wealth of pharmacy clients at both chain and independent pharmacies in the sample and comparing them with both each other and the general population.

4.3.2.2   *Sample and data collection*

Exit interviews were used to assess the socioeconomic and educational status of pharmacy clients shopping at chain and independent pharmacies. For this work, we used the same random sample of pharmacies used in the SP survey described above (although due to time restrictions we visited fewer of the independents). Following the completion of the SP survey, the pharmacies were visited a second time (researchers were allocated different pharmacies to those where they completed their SP visits). At each pharmacy, a member of the research team approached every client leaving the pharmacy and asked if they would be willing to take part in the research. After going through the information sheet and gaining written consent, the exit interview was administered to all those who agreed. This process was repeated until three questionnaires were completed at each outlet. In total, 808 exit interviews were completed, deriving from 103 chain outlets and 166 independent outlets.

The exit interview questionnaire collected data on personal characteristics, reasons for visiting the pharmacy, education history, and ownership of a number of assets.

4.3.2.3   Data analysis

To allow for a comparison of customers in my sample with the general population, data was collected on the same assets as those used by the most recent national District Level Health Survey (DLHS-4), a household survey powered at the district level. Data from 'Bengaluru urban', the district in Karnataka in which the exit interviews were conducted, were downloaded from the International Institute for Population Studies (IIPS) website. In order to limit the time needed to collect these data during the exit interviews, and hence improve participation, data was not collected on all assets in the DLHS-4, rather a subset of 14 assets relevant to the Bengaluru city context[7]. For example, interviewees were not asked about ownership of a tractor or cart driven by an animal as these are more applicable for rural areas. This has been shown to be a valid approach in both India and other contexts (Bassani et al. 2014, Chakraborty et al. 2016).

The SES indices were derived using principal components analysis (PCA), a multivariate statistical technique that allows a large number of variables to be reduced into a small number of dimensions, in Stata 15 (Howe et al. 2012). Initially, the PCA was completed on a merged dataset (data from the DLHS-4 and the exit interview data), using a common set of assets, to assign standardised wealth scores to each individual (Vyas and Kumaranayake 2006). Quintile cut-offs were then created, as described by Filmer and Pritchett (Filmer and Pritchett 2001), using only the DLHS-4 data. Finally, these cut-offs were applied to the exit interview customers, enabling us to examine the relative economic status of clients patronising chains and independents compared to the general population of Bengaluru urban district.

In addition, the DLHS was also used to compare the educational status of pharmacy customers in my sample by pharmacy type and with the general population. In the DLHS-4 survey, the 'highest educational qualification attained' was unclear for around a quarter of the data. Not wanting to use the wrong classifications for this large portion of the dataset, it was decided to use the earlier DLHS-3 (2007-8), which used clearer classifications, acknowledging the limitation that the DLHS-3 is less up-to-date.

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[7] Refrigerator, telephone (landline) only, mobile phone only, sewing machine, tap/running water, radio, scooter/motorcycle, washing machine, car/jeep/van, watch/clock, computer without internet, computer with internet, cooler/AC, number of bedrooms

4.3.3   Method 3: In-depth interviews

The methods described above were used to quantitatively measure various outcomes, such as quality of care and price of medicines, at chain and independent pharmacies. To complement this work I was interested to explore how and why being organised as a chain may affect the quality of service provision and prices of medicines, compared to independent pharmacies. Considering the complex nature of the phenomenon under study and the little that is currently known about the operation of different pharmacy arrangements, qualitative research methods were chosen to explore this in more detail. The qualitative work included in the literature reviews on performance of pharmacies and determinants of provider behaviour illustrated a level of detail regarding the operation of pharmacies and provider behaviour that could not be captured using quantitative approaches (cf Kamat and Nichter 1998, Seeberg 2012, Chuc and Tomson 1999). It is increasingly acknowledged that qualitative research methods can make important contributions to health economics, due to their unique ability to aid understanding and provide explanation (Coast, McDonald, and Baker 2004).

An understanding of our own epistemological approach allows for a better understanding of how our knowledge is produced. In this thesis I adopt an approach of 'subtle realism' which recognises that research involves subjective perception but that there is an underlying reality that can be studied (anti-realists reject this belief). Essentially, it is an attempt to represent that reality rather than to attain 'the truth' (Mays and Pope 2000). I acknowledge that in attempting to uncover the practices of pharmacy workers, there was a reliance on the participants' own accounts of their practices, and the knowledge generated reflected the dynamic of the interview setting and both my characteristics and those of my research assistant's.

4.3.3.1   *Choice of data collection method*

Semi-structured, in-depth interviews were selected as the instrument of choice because they allowed for in-depth exploration of pre-defined topics (Green and Thorogood 2013). As per the suggestion of Miles and Huberman, the interviews were used to test the hypotheses laid out in chapter 3, relating to the mechanisms by which quality, access and price are expected to vary (Miles and Huberman 1994). This framework informed both the development of the interview guides and the analysis, although it was not followed rigidly and I was open to any new ideas or issues that arose. The flexible nature of the semi-structured interview allowed for such discussions, whilst still ensuring that each interview covered comparable topics (Bernard 2017).

4.3.3.2 Sampling

My aim was to speak to chain executives at all the chains included in the SP survey. Within those chains, I hoped to interview staff at some of the specific branches included in the survey (sampling described above). Two of the eight chains represented in the SP sample refused to participate in the qualitative research altogether. In two different chains, whilst a chain executive agreed to speak to us, they refused access to branch staff. This meant that we were denied access to the branch staff of four chains. However, many of the staff working in the branches of the four chains who did agree to participate in this part of the research had previously worked in the chains which denied us access. I interviewed these individuals about their experiences as ex-employees and through this mechanism ensured staff who had experience within all eight chains were interviewed. Two chains allowed me to choose the branches in which I wished to interview their staff, and the other two only approved interviews with employees in specified outlets. Independent owners were purposively chosen, from within the SP sample, to represent a geographical range across the city.

4.3.3.3 Data collection

Prior to commencing the interviews, a number of months were spent conducting the quantitative work within the research site, allowing for the development of understanding and familiarity with the research context (Malterud 2001, Reynolds et al. 2011). Interview questions were piloted with independent owners and the questions were updated accordingly. The interview guide was not piloted on chain staff due to the difficulty of recruiting chain participants (it was necessary to utilise all of the data collected). However, the questions were refined over the course of the research. Between 2014 and 2015 I conducted 38 in-depth interviews with pharmacy employees and other relevant stakeholders in Bengaluru. These comprised 9 chain senior executives; 14 staff working within chain pharmacy branches; 12 independent pharmacy owners; and 3 key informants including the drug control department and pharmacy associations. Interviews were conducted by myself, with the help of a local research assistant, in English, Kannada or Hindi, depending on the interviewee's preference. Where consent was given, interviews were tape-recorded to ensure an accurate record of the information collected from informants. In the instances where informants were not happy to be recorded, detailed notes were taken and written up shortly after.

Interviews with chain senior executives explored the underlying business model, ethos and structure of different firms, with particular scrutiny of staff recruitment, salaries and incentives. I also sought to understand mechanisms employed for controlling quality, performance management, and relationships with drug control bodies. The interviews with staff working in chain branches focused on the incentives faced and motivations for working

in such a setting; their relationship with head office; and factors affecting their treatment behaviour. Several chain interviewees had previously owned their own shop and I questioned them about their experiences working in both environments. Interviews with independent pharmacy owners served as a comparison.

4.3.3.4   Data analysis

NVivo was used to aid the logistical aspects of analysis, and coding was completed using this package. The hypotheses presented in chapter 3 were used to generate an initial set of pre-defined coding categories. In an iterative process, these codes were applied to the data, with data-generated codes added as they arose. Within the analysis, patterns of convergence were considered between differently situated interviewees and particular attention was paid to the interpretations of staff of different levels who worked at the same branches. Understanding that there is a difference between what people say and what people do, specific attention was paid to interviewees' descriptions of their practices through specific examples. However, when discussing sensitive issues it was found to be helpful to ask about how other pharmacies acted because interviewees were sometimes reluctant to admit themselves to practices that would be frowned upon.

The role of prior assumptions and the influence of personal characteristics, in particular being a Westerner and a pharmacist, on the data generated were considered throughout the research process (Reynolds et al. 2011). From the outset of data collection, I was aware of the need to reflect on aspects of my own position and perceived identity in the field. Over time I came to realise that this would also shape the way I presented myself, and perhaps more crucially, how my data was constructed with research participants. Ryan encourages a move away from the 'insider' 'outsider' dichotomy to focus on dynamic positionalities which enable a move beyond the ethnic lens, showing that gender, age and professional status, as well as nationality or ethnicity, serve as the basis for commonality (Ryan 2015). On reflection, I adopted multi-positionalities, which were informed by my everyday experiences in the field. Being a researcher from a London university appeared to aid access to some of the chain executives who may not have otherwise agreed to an interview. Similarly, the association SOCHARA reassured participants that I was not linked to any regulatory bodies or planning to set up a foreign chain- something several interviewees were initially concerned about. I introduced myself as a researcher, and did not highlight my training as a pharmacist, thinking this may reduce the likelihood of social desirability bias although, if asked, I happily shared the details of my academic background.

The study tools and consent forms used for all the data collection methods are provided in Appendix 3.

4.3.4 Ethical approval

Ethical approval was obtained from SOCHARA Institutional Scientific and Ethics Committee in Bengaluru, India and the London School of Hygiene and Tropical Medicine Ethics Committee, UK (see Appendix 4 for approval letters). For the SP study, approval from both institutions was received in order to waive obtaining informed consent from the pharmacies prior to the SP visits. The main ethical concern with this method is that providers are essentially given false information. Madden and colleagues reflect on The Council for International Organizations of Medical Sciences (CIOMS) ethical guidelines which are supported by the WHO: (Council for International Organizations of Medical Sciences (CIOMS) 2011), (Madden et al. 1997). CIOMS state that in instances where obtaining consent would frustrate the purpose of the study, researchers may be justified in abstaining from doing so. It is likely that obtaining consent for a particular SP encounter would introduce observation bias into the study. Further, the subject of the research is considered important enough to warrant such an approach. CIOMS also acknowledges that in the case of publicly available information consent is not required. Drug shop encounters lie somewhere on the continuum of public private behaviour but this is a grey area because the definition of 'public' used by CIOMS is unclear. Madden et al go on to examine the effects of the method (Madden et al. 1997). They acknowledge that, if made public, the data would be defamatory to the providers and income may suffer. As such, it was critically important to ensure anonymity. The opportunity cost of taking up staff time is another consideration, although the purchasing of medicines could be seen as a form of compensation for their time. Harm to the standardised patients themselves was deemed to be minimal. Visiting pharmacies, as opposed to physicians, removed the risk of them being offered invasive procedures or having medicines administered. There was, however, the possibility of an SP facing the hostility of a provider who believed the encounter to be a simulation. Although this did not occur, SPs were advised to remain non-confrontational at all times and to leave the premises were they to feel uncomfortable. Research assistants travelled in pairs for safety; one conducted the SP visit and the other waited nearby and administered the debrief questionnaire following the encounter.

For the exit interviews with customers, each participant was given an information sheet in Kannada and English which covered the objectives of the research and explicitly stated that participation was voluntary and anonymous. Written consent was obtained from all participants in advance of administering the questionnaire. Research assistants were trained to ensure that potential interviewees leaving the pharmacy were not too unwell/in pain to participate or taking medicines to a critically ill patient. For the qualitative interviews, interviewees were also given an information sheet and then verbal consent, witnessed by a

fieldworker, was obtained prior to all interviews. Verbal, as opposed to written, consent was obtained because providers in many drug outlets (or chain headquarters) tend to be very cautious of inspectors and suspicious of having to sign documents that may be used to identify them or their outlet/company. Interviews were not expected to cause any harm or distress to participants but it was made clear to interviewees that they were not obligated to answer any questions and could end the interview at any time.

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PART III: RESULTS

5 Quality of case management

5.1 Introduction

This chapter presents the first results paper entitled "Do chain pharmacies perform better than independent pharmacies? Evidence from a standardised patient study of the management of childhood diarrhoea and suspected tuberculosis in urban India". It utilises standardised patient methodology to address objective A (comparing the quality of case management at chain and independent pharmacies). The paper was published in *BMJ Global Health* in September 2017. The Supplementary material for this paper can be found in Appendix 5.

The first 3 pages describe the rationale for the research and the methods, as was covered in the previous chapters. The results, which have not yet been addressed in this document, begin on page 4 of the paper.

5.2 Research paper 2

(Cover sheet on next page).

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Student	Rosalind Miller
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Thesis Title	The rise of chain pharmacies in India: implications for public health

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Do chain pharmacies perform better than independent pharmacies? Evidence from a standardised patient study of the management of childhood diarrhoea and suspected tuberculosis in urban India

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ABSTRACT

Introduction Pharmacies and drug stores are frequently patients' first point of care in many low-income and middle-income countries, but their practice is often poor. Pharmacy retailing in India has traditionally been dominated by local, individually owned shops, but recent years have seen the growth of pharmacy chains. In theory, lower-powered profit incentives and self-regulation to preserve brand identity may lead to higher quality in chain stores. In practice, this has been little studied.

Methods We randomly selected a stratified sample of chain and independent pharmacies in urban Bengaluru. Standardised patients (SPs) visited pharmacies and presented a scripted case of diarrhoea for a child and suspected tuberculosis (TB). SPs were debriefed immediately after the visit using a structured questionnaire. We measured the quality of history taking, therapeutic management and advice giving against national (Government of India) and international (WHO) guidelines. We used Pearson's χ^2 tests to examine associations between pharmacy type and case management.

Findings Management of childhood diarrhoea and suspected TB was woefully substandard. History taking of the SP was limited; unnecessary and harmful medicines, including antibiotics, were commonly sold; and advice giving was near non-existent. The performance of chains and independent shops was strikingly similar for most areas of assessment. We observed no significant differences between the management of suspected TB in chains and independents. 43% of chains and 45% of independents managed the TB case correctly; 17% and 16% of chains and independents, respectively, sold antibiotics. We found that chains sold significantly fewer harmful antibiotics and antidiarrhoeals (35% vs 48%, p=0.029) and prescription-only medicines (37% vs 49%, p=0.048) for the patient with diarrhoea compared with independent shops. Not a single shop managed the patient with diarrhoea correctly according to guidelines.

Conclusion Our results from Bengaluru suggest that it is unlikely that chains alone can solve persisting quality challenges. However, they may offer a potential vehicle

Key questions

What is already known about this topic?
► It is widely reported that pharmacy practice in many low-income and middle-income countries (LMICs) is substandard.
► Chain pharmacies are expanding in India and other LMICs.
► Economic theory predicts that chains may positively affect quality, but very little is known about this in practice in pharmacy markets.

What are the new findings?
► Quality of care for childhood diarrhoea and suspected tuberculosis, as measured by ideal case management of standardised patients and adherence to recommended history-taking and advice-giving lists, was found to be equally poor in chains and independent pharmacies in Bengaluru, India.
► Chains sold significantly fewer prescription-only medicines and those deemed 'harmful' for the patient with diarrhoea, compared with independent shops.

Recommendations for policy
► Introduction of chains alone is unlikely to address quality challenges in this context.
► Interventions to improve effectivess should be delivered through chains to see whether they yield different results compared to individual shops.

through which to deliver interventions. Future intervention research should consider recruiting chains to see whether effectiveness of interventions differ among chains compared with independents.

INTRODUCTION
It has been widely established that the care received from pharmacies in many low-income

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and middle-income countries (LMICs) is inadequate, despite frequently being patients' first point of contact with the healthcare system.[1–3] All too often, medicine use in these settings is 'irrational'. That is, patients do not receive the appropriate medicines, in doses that meet their individual requirements, for an adequate duration, and at the lowest cost.[4] Irrational medicine use is a major public health concern, which contributes to unnecessary morbidity and mortality; fuels the growing threat of antimicrobial resistance (AMR); and leads to needless spending.[5] AMR has garnered particular interest of late. WHO has declared it a 'global health security emergency', and 193 heads of states and governments have pledged to address the concern through a UN declaration.[6 7] In approaches to prevent the situation worsening, pharmacies should arguably be a key focus.

In recent years, there has been a growing interest in pharmacy chains in LMIC contexts.[8–10] India, in particular, has seen prolific expansion of the corporate pharmacy retail sector.[9] In theory, there are reasons to believe that chains may positively influence key determinants of treatment behaviour, notably the regulatory environment and profit incentives faced by staff.[3] The fragmented nature of retail pharmacy in India makes enforcing regulation costly and logistically difficult. Through consolidation, chains could improve regulation in two ways. State regulation can be concentrated on central management structures; essentially, the regulator can make firms take responsibility for local branches. Second, firms may self-regulate in order to preserve brand identity.[11] Another reason why quality may improve in a chain situation concerns incentive structures. Financial incentives faced by pharmacy-level personnel working in chains are low powered compared with those who own their own pharmacy and directly receive the profits of transactions.[12] Independent shopkeepers may therefore face stronger incentives to engage in irrational medicine use, such as selling unnecessary or prescription-only medicines (POMs) without a prescription, where this increases their profits.

The question of whether this organisational structure of the pharmacy firm affects quality of care remains largely untouched by empirical research studies in LMIC. Studies from high-income countries report on a wide range of outcomes,[13–15] but given the strength of regulation in high-income contexts, the findings are likely to have limited applicability in LMICs. Two studies from Mexico report on the sale of misoprostol (to induce abortion). One found that chains were less likely to sell misoprostol compared with independent shops,[16] while the other found no significant differences.[17] Others examined the effect of chain store entry on prices and drug quality in the retail pharmacy market in Hyderabad, India, but did not assess therapeutic management of patients.[18]

To address this gap in the literature, this paper reports on a study from Bengaluru, South India, which used standardised patients (SPs), often considered the 'gold standard' for quality of care measurement,[19] to assess the case management of two conditions, in a representative sample of chain and independent pharmacies. Symptoms of these conditions are commonly presented in pharmacies, represent a high burden of disease and are subject to key quality concerns in relation to underprovision and overprovision of treatment.

METHODS

Study setting and design

Pharmacy chains are concentrated in populous cities, with the greatest concentration in South India. This guided the selection of Bengaluru, the capital of Karnataka State and India's third most populous city, as the study site.

We used a cross-sectional SP survey to investigate the management of suspected tuberculosis (TB) in an adult and acute watery diarrhoea in a 2 year old (who was not present). WHO recommends non-bacterial diarrhoea in children under age 5 as a tracer condition for measuring quality of care. Other health problems that are either frequently presented or of particular clinical or economic importance are also deemed appropriate provided that there are clear treatment guidelines.[20 21] In India, TB meets these criteria.[22 23] These conditions also represent contrasting examples of recommended management—pharmacies should refer a suspected TB case, whereas diarrhoea is commonly wholly treatable in the pharmacy environment.

We trained six research assistants (one female and five males) as SPs to visit chain and independent pharmacies. SPs were recruited from Bengaluru where the study was undertaken. The average age was 31, the youngest being 20 and the oldest 45. The individuals were trained (in a group) by RM (with input from a local researcher) over a period of 1 week. Training included learning the cases, including much role play, and running through the debrief questionnaire in the classroom. All SPs also ran through the details of their back-story and practised answering questions relating to their personal situation, as well as the presentation of the medical case. Each SP completed a number of pilot presentations in the field, under the supervision of a senior research assistant, until we were confident that the cases were being presented in a standardised, convincing manner. It was discussed among the research team how they should dress to ensure their social background appeared similar to a typical customer who might present such cases.

The SPs presented a rehearsed, scripted scenario, in Kannada (the local language), of both conditions, during a single visit, at a random sample of pharmacies. SPs purchased any recommended medications. Immediately after each pharmacy visit, they were debriefed using a structured questionnaire. We measured the quality of case management based on national and international guidelines. For the TB case, we used Government of India (GOI) and the Indian Pharmaceutical Association guidelines for community pharmacists.[23] In the absence

Table 1 Standardised patient case details and expected management

Case details		Expected management		
Case description	Details of scenario	History	Treatment	Advice
Acute watery diarrhoea in a child	"I need to buy something for my niece who has diarrhoea. She is 2 years old?" Further questioning would reveal: ▶ Four episodes during the last day; ▶ More thirsty than usual; ▶ May have had a slight fever; ▶ No blood in the stool, abdominal pain or vomiting; ▶ No medication had been taken.	Pharmacy server to ask: ▶ Blood in stool? ▶ Duration of diarrhoea? ▶ Number of stools per day? ▶ Number of episodes of vomiting? ▶ Presence of fever? ▶ Preillness feeding practices? ▶ Type of fluids and foods during illness? ▶ Child passing urine? ▶ Tried any medication?	▶ Oral rehydration therapy using ORS solution; ▶ Zinc supplementation; ▶ No sale of antidiarrhoeals, antibiotics or antispasmodics.	▶ Explain how to use ORS; ▶ Importance of more fluids; ▶ Usual diet should be continued (including milk); ▶ Take to health worker if signs of dehydration or other problems, for example, blood in stool.
Suspected pulmonary tuberculosis in an adult	On completion of diarrhoea advice: "Also for myself… I have had cough and some fever for 3–4 weeks. We have had a relative staying with us who has TB. Can you suggest something?" Further questioning would reveal: ▶ Sputum in the cough; ▶ Sweating at night; ▶ Loss of appetite; ▶ No medication had been taken.	Pharmacy server to ask: ▶ Consulted doctor? ▶ Chest pain? ▶ Sputum or blood in cough? ▶ Weakness or fatigue? ▶ Weight loss? ▶ Loss of appetite? ▶ Chills? ▶ Night sweats? ▶ Any other symptoms? ▶ Tried any medication?	▶ Referral to TB clinic or other healthcare provider for sputum examination; ▶ No sale of antibiotics (including anti-TB medication) or steroids.	▶ Advise that treatment is available free of charge from government hospitals.

ORS, oral rehydration salts; TB, tuberculosis.

of any pharmacy-specific Indian or international guidelines for the management of diarrhoea, we based our assessment on WHO guidelines (also adopted by GOI) aimed at 'physicians and other senior health workers'.[24 25] These can be argued to be appropriate for pharmacy staff as India's 'Pharmacy Practice Regulations' include as responsibilities of community pharmacists 'selling over-the-counter medicines; counselling and advising the public on the treatment of minor ailments',[26] and the diarrhoea case presented here can be considered a minor ailment.

Cases
Table 1 provides an overview of the cases, how the SPs presented them and the expected course of action against which we measured their management. According to the guidelines, community pharmacists should refer patients with symptoms suggestive of TB for sputum examination. They should not sell medicines that require a prescription. The sale of medicines from Indian pharmacies is

governed by the Drugs and Cosmetic Rules 1945. Under this act, medicines are categorised as over-the-counter (OTC) (no schedule) or prescription-only. There are three levels of POMs: H, H1 and X. Schedule H medicines require a prescription from a qualified practitioner. Schedule H1 was introduced in 2013 to curb OTC use of certain POM medicines (mainly antibiotics). The 46 H1 medicines are subject to an extra set of conditions on dispensing (identity of the patient, contact details of the prescriber and the name and dispensed quantity of the drug must be recorded in a separate register). Schedule X is the most restrictive list, comprising a small number of narcotics, for which the pharmacy is required to retain the prescription for 2 years.

We considered provision of antibiotics (including anti-TB medicines) and/or steroids as 'harmful', in line with Satyanarayana and colleagues; incomplete and unneeded courses of antibiotics could lead to emergence of resistant strains and steroids could mask the

Outlets (n)	Chains (n)	Chains in our sample (n)	Outlets in our sample (n)
2–5	6	1	1
6–10	2	2	4
11–50	2	2	6
51–100	1	1	14
101+	2	2	78

Table 2 Size of pharmacy chains in Bengaluru and in sample

symptoms leading to delayed diagnosis.[27] A 2-year-old child with diarrhoea should be managed with oral rehydration therapy (ORT), supplemental zinc and continued feeding of energy-rich foods and breast feeding. Again, POMs should not be sold, and in this case, antibiotics, antidiarrhoeals and antispasmodics are categorised as 'harmful'.[25 28] We term medicines not listed in the guidelines yet not deemed 'harmful' as 'not recommended'. For both cases, we expect pharmacy staff to ask questions to confirm the diagnosis and determine appropriate treatment and to provide advice.

Selection of pharmacies and sample size
We obtained a list of all pharmacies registered in the Bengaluru urban district from the Karnataka State Drug Control Department. To check the comprehensiveness and validity of this list, we completed censuses in three neighbourhoods with differing wealth profiles (according to local informants). This exercise confirmed that the list provided a comprehensive sampling frame (97% accurate). From the list, we then categorised pharmacies as either 'independent' or 'chain'. We defined chains as organisations where two or more pharmacies were operating under the same name and the business used distinctive branding across all pharmacies. We excluded pharmacies operating inside hospitals or clinics, which customers could not access from the street. The resulting list contained 5135 independents and 529 chains shops deriving from 13 chains (table 2). Subsequently, we selected a random sample of pharmacies, stratified by type: chain or independent. Our sample included shops from eight chains: the largest seven and one chain of the 2–5 outlet size (details in table 2).

Between May and June 2015, SPs visited 333 pharmacies across Bengaluru (103 chains and 230 independents) and presented both cases at each pharmacy. These figures satisfy sample size calculations based on a level of significance of 0.05, 80% power, effect size of 0.2 (ie, can detect a 20% difference in quality measurements between pharmacy types) and a proportion of interest of 0.5 for the outcome of correct case management.

Statistical analysis
We used STATA 14 to analyse the two disease cases separately. The unit of analysis was the pharmacy. We used Pearson's χ^2 tests to examine the effects of pharmacy type (chain vs independent) on history taking, treatment recommendations and advice.

Ethical approval
The London School of Hygiene and Tropical Medicine Ethics Committee in London, England, and the Society of Community Health Awareness Research and Action Institutional Scientific and Ethics Committee in Bengaluru, India, approved the study. We specifically sought and received approval to waive obtaining informed consent from the pharmacies prior to the SP visits.

RESULTS
We present the results of the SP survey according to the three key aspects of case management specified in table 1.

History taking
Questioning of SPs by pharmacy staff was generally poor (table 3), with no significant differences in history taking at chain and independent pharmacies. Less than 10% of chains and independents asked a single recommended question regarding the diarrhoea case. This figure was slightly higher for suspected TB with 17% of chains and 23% of independents asking at least one relevant question.

Recommended questions for the suspected TB case are primarily to confirm the diagnosis. The most commonly asked question was regarding the presence of blood or sputum on coughing, asked by 12% of chains and 13% of independents. Less than 5% of chains and independents asked about action already taken or other questions to determine diagnosis including the presence of night sweats, pain in the chest, fatigue or any other symptoms. No shops asked about weight loss, loss of appetite or chills.

Correct questioning of the diarrhoea case would rule out a more serious underlying condition warranting referral for medical attention. No more than 5% of chains or independents asked any recommended questions. Not a single shop made enquiries regarding remedies already taken, fluid and food intake of the child either before or since falling ill or the presence of blood in the stool.

Therapeutic management
Figure 1 (and online supplementary appendix A1 for corresponding table) shows that SPs received correct management of the suspected TB case in 43% and 45% of chain and independent shops, respectively. We observed no significant differences between the therapeutic management of suspected TB in chains and independents. In terms of harmful medicines, shops rarely gave steroids, but 16% of chains and independents sold antibiotics[i]. A large proportion of chains and independents sold medicines that are not recommended for the treatment of TB: 63% and 62%, respectively. Over 50%

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[i] Top five antibiotics sold for suspected TB case: (1) amoxicillin; (2) azithromycin; (3) ciprofloxacin; (4) levofloxacin; (5) erythromycin.

Table 3 History taking in chain and independent pharmacies when presented with cases of suspected TB and diarrhoea

Case	Recommended questions	Chain (n=103) % (95% CI)	Independent (n=230) % (95% CI)	p Value*
Suspected TB	Consulted a doctor?	1.9 (0.5 to 7.5)	3.5 (1.7 to 6.8)	0.448
	Chest pain?	1.0 (0.13 to 0.67)	2.6 (1.2 to 5.7)	0.336
	Sputum or blood in cough?	11.7 (6.7 to 19.5)	13.5 (9.6 to 18.6)	0.646
	Weakness or fatigue?	0	0.9 (0.2 to 3.4)	0.342
	Weight loss?	0	0	
	Loss of appetite?	0	0	
	Chills?	0	0	
	Night sweats?	1.0 (0.1 to 0. 7)	1.7 (0.7 to 4.6)	0.594
	Any other symptoms?	4.9 (2.0 to 11.2)	1.7 (0.7 to 4.6)	0.105
	Tried any medication?	0	1.7 (0.7 to 4.6)	0.178
	Asked any recommended questions?	16.5 (10.5 to 25.0)	22.6 (17.7 to 28.5)	0.204
Diarrhoea	Blood in stool?	0	0	
	Duration of diarrhoea?	3.9 (1.5 to 10.0)	4.4 (2.4 to 7.9)	0.845
	Number of stools per day?	4.9 (2.0 to 11.2)	2.2 (0.90 to 5.1)	0.185
	Number of episodes of vomiting?	1.9 (0.5 to 7.5)	3.9 (2.0 to 7.4)	0.352
	Presence of fever?	0	0.9 (0.2 to 3.4)	0.342
	Preillness feeding practices?	0	0	
	Type of fluids and foods during illness?	0	0	
	Child passing urine?	0	0.4 (0.1 to 3.1)	0.503
	Tried any medication?	0	0	
	Asked any recommended questions?	9.7 (5.3 to 17.2)	9.1 (6.0 to 13.6)	0.867

*Estimated by Pearson's χ^2 test.

of both shop types sold a schedule H medicine, although chains did not sell any of the more restricted H1 drugs. Seven independent shops (3%) sold H1 medicines (all of which were antibiotics). It is notable that not a single shop sold first-line anti-TB medicine. Figure 2 shows, of medicine sales, the proportion accounted for by each medicine category. The results are strikingly similar for chains and independents. Almost two-thirds of medicines sold were cold and/or cough preparations. The second and third most commonly sold medicines were antibiotics and antiasthma drugs, respectively.

No shops managed the case of childhood diarrhoea according to current guidelines (figure 3 and online supplementary appendix A2 for corresponding table). Further, no shops sold oral rehydration salts (ORS) and zinc together. The sale of zinc was extremely rare, recommended by only two chain shops (2%) and no independents (p=0.034). Only 12% of chains and 10% of independents sold ORT and in exactly half of these sales; this was alongside harmful medicines. A total of 33% of chains and 42% of independents sold antibiotics. Antidiarrhoeal use was also higher in independents, 7% vs 2% for chains. Both antibiotics and antidiarrhoeals

are considered harmful in the management of this case, and chains were found to sell significantly fewer of this combined category of harmful medicines (35% vs 48%, p=0.029). Antibiotics[ii] or antidiarrhoeals accounted for nearly all the schedule H medicines sold; thus, we see significantly fewer chains selling schedule H medicines (37% vs 49%, p=0.045). H1 category medicine was sold by one independent pharmacy and no chains. A quarter of chains and 22% of independents sold treatments that are not recommended for diarrhoea. Although non-bacterial diarrhoea can be managed in the pharmacy, 41% of chains and 37% of independents referred the child to a doctor.

Of medicines sold for the patient with diarrhoea, worryingly, antibiotics made up the largest proportion for both chains and independents, 45% and 52%, respectively (figure 4). Prebiotics and probiotics were popular, accounting for 32% of sales in chains and 26% in

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[ii] Top five antibiotics sold for diarrhoea case: (1) metronidazole+norfloxacin; (2) ofloxacin; (3) ofloxacin+ornidazole; (4) ofloxacin+metronidazole; (5) metronidazole.
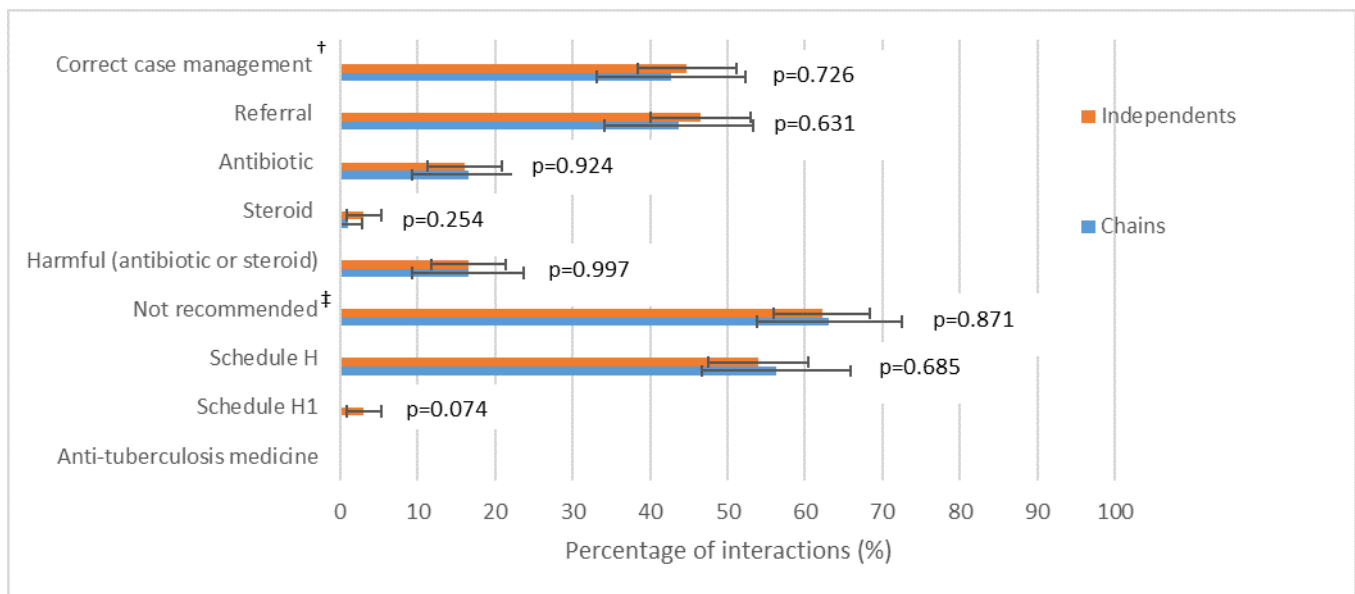
Figure 1 Therapeutic management of suspected TB case by independent and chain pharmacies (see online supplementary appendix A1 for corresponding table). p Values were estimated using Pearson's χ^2 test. †Correct case management defined as referral without sale of any 'harmful' medicines (antibiotic or steroids). ‡We define 'not recommended' medicines as those not listed in the guidelines yet not deemed 'harmful'. They include cough and/or cold medicines, analgesics and antiacid.
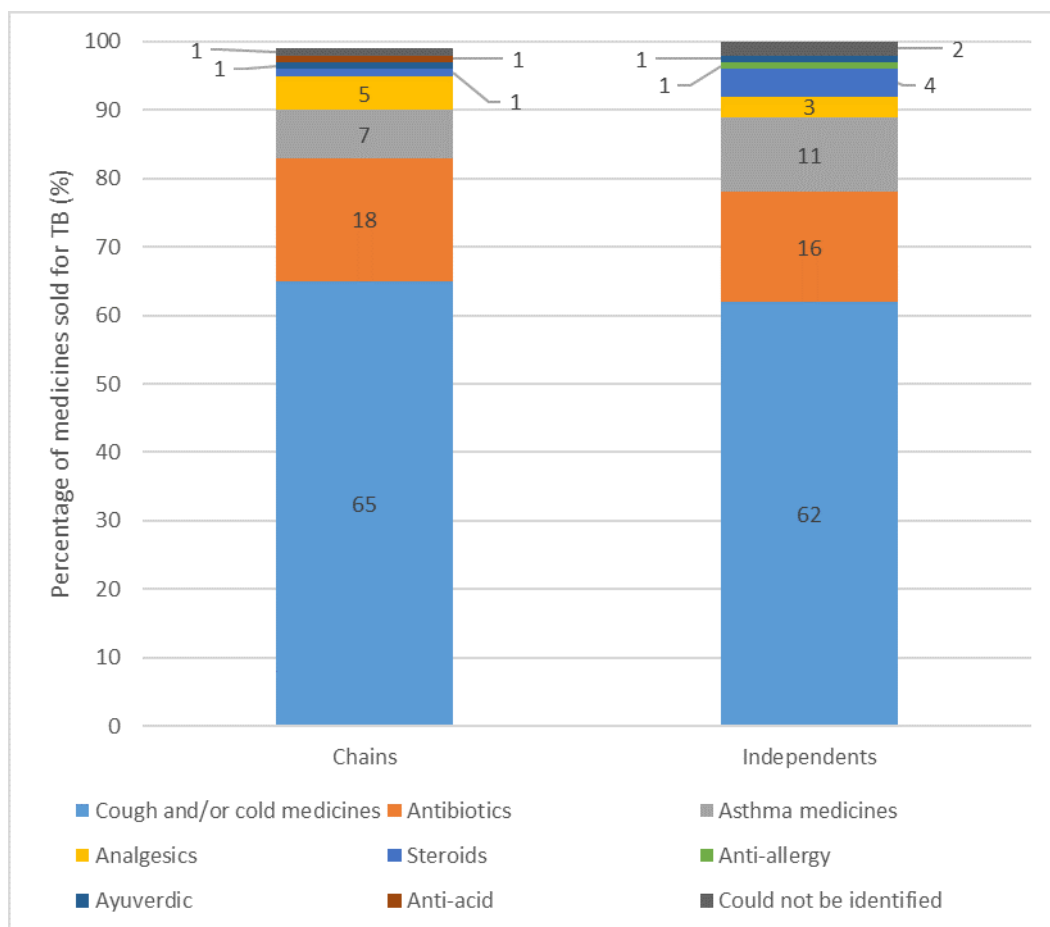
Figure 2 Breakdown of medicines sold for suspected TB case by outlet type. May not add to 100% due to rounding. TB, tuberculosis.
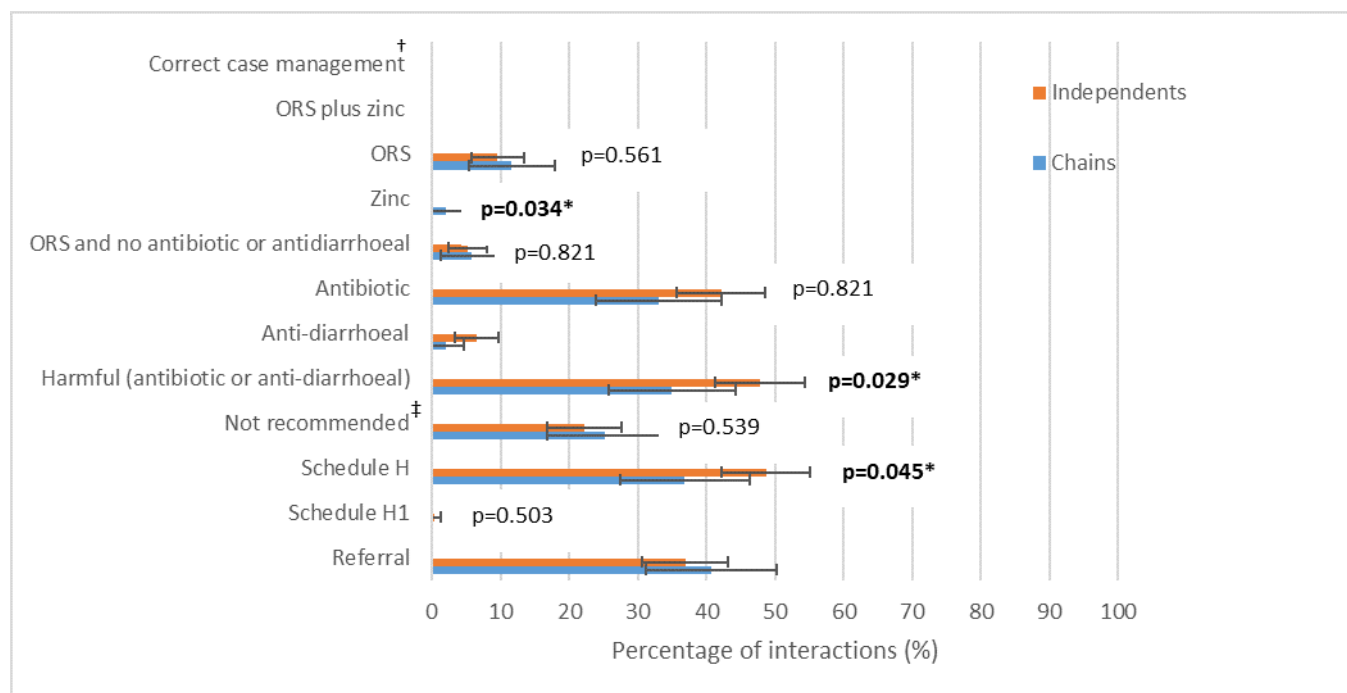
Figure 3 Therapeutic management of diarrhoea case by independent and chain pharmacies (see supplementary appendix A2 for corresponding table). p Values were estimated using Pearson's χ^2 test. †Correct case management defined as provision of ORS and zinc and no 'harmful' medicines (antibiotics, antidiarrhoeals or antispasmodics). ‡'Not recommended' medicines include prebiotics and probiotics, analgesics, antihelminitic and antiallergy. *Statistically significant at the 5% level. ORS, oral rehydration salts.

independents. ORT only accounted for 16% and 12% of sales in chains and independents, respectively.

We also demonstrated that the findings for treatment were unaffected after adjusting for any SP-specific effects (online supplementary appendix A3, 4).

Advice giving

Advice giving was uniformly limited. Only a handful of shops advised patients that TB treatment was available free of charge from the government (table 4). General advice for the fictitious child with diarrhoea was close to non-existent. While 41% of chains and 37% of independents referred the childhood diarrhoea case in the first instance, of the remaining shops, less than 1% of both shop types advised the SP to seek medical attention if they noticed any warning signs. One independent and no chains explained the importance of giving the child extra fluids to prevent dehydration. Advice regarding diet was similarly poor, given by 0.95% of chains and 1.75% of independents. We only observed one significant difference in terms of advice giving. Of shops that did sell ORS, chains were found to offer an explanation of how to make up and use the solution in a larger proportion of interactions, 56% vs 10% for independents. The absolute numbers that provided ORS were, however, low.

DISCUSSION

To our knowledge, this is the first study to compare the quality of all aspects of case management at chain and independent pharmacies for any condition in an LMIC

setting. Using SPs provides an accurate picture of how pharmacy staff manage these conditions in everyday life, and the standardised presentation allows for direct comparison across pharmacies.[29] Our results showed that the management of both cases did not live up to national or international standards, in either chains or independents. In terms of history taking, there were no significant differences between pharmacy types for either condition, and the level of questioning by pharmacy staff would not have elicited the required information to manage the SPs appropriately. We observed no significant differences in therapeutic management of the patient with suspected TB. Fewer than half of both shop types managed the case correctly by referring without selling any harmful medicines. The one other SP study that has investigated how pharmacies respond to TB in India showed that antibiotic use substantially decreased when SPs presented with a known diagnosis, as opposed to just symptoms.[27] In our scenario, while SPs did not present with a medically confirmed diagnosis, they mentioned contact with an infected individual and hence a suggestion that they might have TB. This is more in line with a known diagnosis and our results are therefore likely presenting pharmacy behaviour at the more positive end of the spectrum. As with all SP studies, our results reflect how pharmacies manage an unknown individual, and we cannot be sure this is the same as for regular customers.

Therapeutic management of the diarrhoea case was even worse than that of suspected TB. No pharmacies managed the case correctly. Chains did, however, sell

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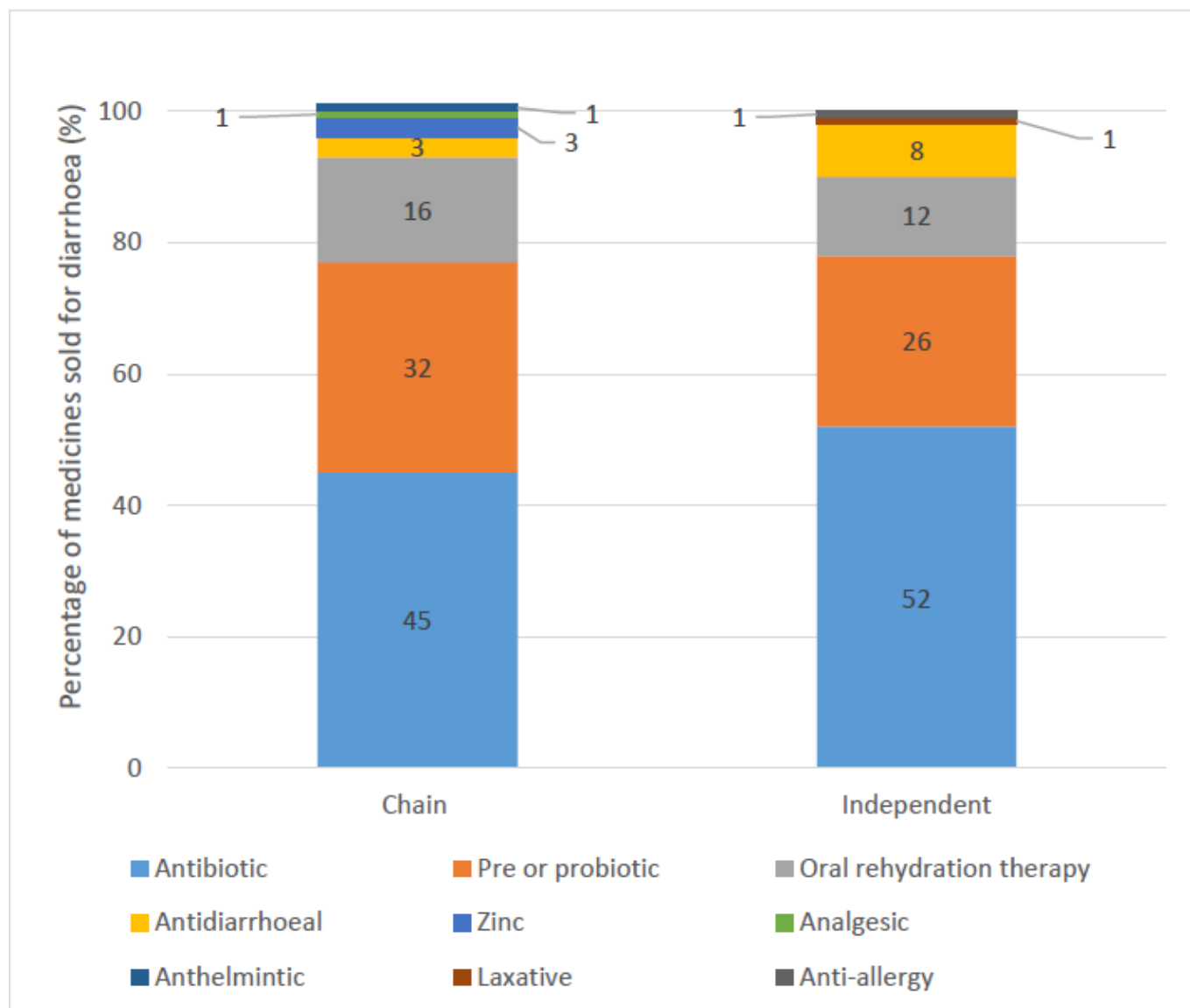
Figure 4 Breakdown of medicines sold for diarrhoea case by outlet type.

Case	Advice	Chain (n=103) % (95% CI)	Independent (n=230) % (95% CI)	p Value*
Table 4 Advice giving by chain and independent pharmacies				
Suspected TB	Treatment available free of charge from government hospital	1.0 (0.1 to 6.7)	1.7 (0.7 to 4.6)	p=0.594
Diarrhoea	Advised to visit doctor if any warning signs†	1.0 (0.1 to 6.7)	0.9 (0.2 to 3.4)	p=0.928
	Explained importance of giving extra fluids	0	0.5 (0.1 to 3.1)	p=0.503
	Gave advice regarding diet	1.0 (0.1 to 6.7)	1.8 (0.7 to 4.6)	p=0.594
		Chain (n=9)	Independent (n=20)	
	Explain how to make up and use ORS? (of those providing)	55.6 (22.5 to 84.3)	10.0 (2.3 to 34.7)	p=0.008*

*Estimated by Pearson's χ^2 test.

†This indicator excludes pharmacies that referred the patient to a medical practitioner as an initial course of action (see figure 2 for these data).

ORS, oral rehydration salts.

significantly more zinc and fewer medicines categorised as harmful. This translated into chains selling significantly fewer schedule H medicines. Advice giving was almost non-existent in both types of pharmacies. The lower sales of POMs for the patient with diarrhoea translated into significantly reduced cost of the diarrhoea consultation in chains compared with independent shops (draft in preparation). Further, given that patients are paying for their medicines out of pocket when seeking care at the pharmacy, we must note the unnecessary spending on both 'not recommended' and 'harmful' medicines.

The use of H1 medicines was scarce for both cases, but it is worth highlighting that not a single chain sold a medicine of this category (compared with eight independents). This is an important finding, which corroborates the research of Satyanarayana and colleagues who report that pharmacies in other Indian cities (Mumbai, Patna and Delhi) also did not sell any first-line anti-TB medicines when presented with an SP.[27] Adherence to restrictions on the prescription of H1 medicines appears to be a positive finding for TB control efforts.

This study also brings to our attention the lack of guidance for the treatment of minor ailments in the Indian (and other LMIC) pharmacy setting and highlights the grey area of how the management of conditions such as diarrhoea should be assessed. Considering the high proportion of childhood deaths accounted for by diarrhoea in India and the high utilisation of pharmacies, the development of pharmacy-specific treatment guidelines seems long overdue.

We report results from one city, raising the question of whether the findings are generalisable to other urban centres where chains operate. While other research has not focused on chains, our results add to a growing body of research in other areas of India that has used SP to assess quality of care for both pharmacies and other primary healthcare providers, including for childhood diarrhoea and TB. These other studies have shown quality of case management to be ubiquitously poor, regardless of whether patient first contact is with a pharmacy, a medically qualified practitioner or an unqualified, informal provider.[27 30–32] Many of the chains in Bengaluru also operate in other Indian cities, where they would be likely to face similar incentives. Pharmacies across India operate under the same regulatory controls, and despite potential state-level variations in regulatory implementation, regulatory failure has been reported to be widespread across the country.[33–37] Moreover, reviews have found striking similarities in the determinants of pharmacy provider behaviour in LMIC across countries and even continents,[3 38 39] meaning that these results are potentially applicable to other LMIC settings with similar regulatory challenges. Other LMICs that have either an established or growing corporate pharmacy retail sector include Mexico, South Africa, Nigeria, Kenya, Uganda and the Philippines.[8–10] Further study would be worthwhile to determine whether differences exist in other settings, where the business models for chains may differ.

While we report the results from the suspected TB and diarrhoea scenarios separately, SPs presented the details of the cases in a single encounter at each pharmacy, rather than the more common approach of using separate interactions. Treatment results are in keeping with other studies that presented one of these conditions as a standalone case at pharmacies in India.[27 40] We, therefore, have no reason to believe that pharmacy staff acted differently because SPs presented both cases in a single client interaction.

While no other studies have compared chain and independent pharmacies in terms of quality of care in an LMIC setting, Bennet and Yin examined the effect of chain store entry on prices and drug quality in Hyderabad, India.[18] Through collaboration with a pharmacy chain, they gathered baseline data in markets the firm wished to enter and later resurveyed markets 1 year after market entry. The paper reported that, compared with independent retailers, chain prices were 6% lower and pharmacopoeia compliance (drug quality) was 6% higher. The resulting effect of chain entry on the market was a relative 5% improvement in drug quality and a 2% decrease in prices at existing retailers. If chain entry had led to similar spill over quality improvement effects in our study site, this would imply that our measured effect of a chain on quality would be biased towards zero. We do not have sufficient geographical data in order to determine whether the presence of a chain shop nearby alters the behaviour of independents, though this would be an interesting area for future research. However, a review of pharmacy practice in Asia reported similar management for various presentations of childhood diarrhoea going back 30 years, that is, before the advent of chains, indicating that major changes in the behaviour of independents do not appear to have occurred in recent times.[3]

The main difference between pharmacy types observed was the lower use by chains of harmful POMs for the patient with diarrhoea. There is evidence that some of these POMs, such as antibiotics, are high profit generators.[41–43] Lower-powered financial incentives faced by chain staff may explain a reduction in their use. Through in-depth interviews with chain and independent staff that we completed as a complement to this SP survey, we have been able to gain a more in-depth understanding of the behaviour of chains and independents (draft in preparation). We found that chain staff were heavily incentivised through a combination of sales targets and pressure from head-office and hence the incentives they faced were, in fact, not low powered. Additionally, these interviews revealed that profit-maximising strategies of chain employees tended to focus on improving customer experience, whereas independent owners focused on medicines sales. In addition to profit concerns, knowledge and regulation have also been shown to be important determinants of pharmacy practice. Our qualitative work showed that stronger penalties for the provision of the more restricted medicine schedules have been effective

and some chains have instigated processes to ensure these rules are not broken (ibid). Chains use a number of methods to self-regulate and are able to control staff practices, but their main area of concern is customer satisfaction, rather than rational medicine use. Only a minority of chains had measures to monitor the sale of POMs at their outlets. In terms of knowledge, there appears to be little difference between knowledge of those working in chain and independent pharmacies. Even were there to be differences, it is well established that there is a large gap between what providers know and what they do in India, indicating that knowledge is necessary but not sufficient to ensure best practice.[27 30–32 44]

Our results provide a starting point for investigating how the organisation of the pharmacy firm affects provider behaviour in an LMIC setting. We did find small differences between the behaviour of chain staff and independent pharmacy owners. However, chains were far from fully addressing the quality deficiencies observed in the retail pharmacy sector, and it is unlikely that chains alone are going to solve persisting quality challenges. However, they may offer a potential vehicle through which to deliver interventions. Intervention initiatives reported in the literature include training, intensification of regulatory controls, peer review and accreditation.[45–47] Some strategies, such as peer review and performance management, may have more impact within the structure of a chain. 'League tables' and 'naming and shaming' have been used in high-income settings to influence prescribing behaviour of doctors working within a common organisation.[48]

CONCLUSION

The performance of chains and independent shops was equally poor for most areas of assessment. Our results indicate that, while in theory chains have the potential to improve treatment behaviour, in practice, they are unlikely to offer a magic bullet solution. However, importantly, we found that chains sold fewer prescription-only and harmful medicines to the patient with diarrhoea and successfully self-regulated the sale of H1 medicines. Future intervention research should consider recruiting chains to see whether intervention effectiveness differs among chains compared with independents.

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Do chain pharmacies perform better than independent pharmacies? Evidence from a standardised patient study of the management of childhood diarrhoea and suspected tuberculosis in urban India

Rosalind Miller and Catherine Goodman

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Notes

6 Price and socioeconomic status of clients

6.1 Introduction

This chapter presents the second results paper entitled "Cheaper medicines for the better off? A mixed methods study of medicine price and socioeconomic status of clients in chain and independent retail pharmacies in urban India". It draws on both the standardised patient survey and the key informant interviews to address objective B (to compare the price of consultations at chain and independent pharmacies) and the price component of objective D (to explore how and why the organisational structure of pharmacy chains may affect prices of medicines). This paper has not yet been submitted to a journal.

6.2 Research paper 3

(Cover sheet on next page)

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Principal Supervisor	Professor Catherine Goodman
Thesis Title	The rise of chain pharmacies in India: implications for public health

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Stage of publication	**Not yet submitted**

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For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	Designed study, conducted data collection and analysis, drafted manuscript with supervisory support from CG.

Student Signature: _____   Date: _5/11/18_

Supervisor Signature: _____ **Date:** 5 / 11 / 18

Cheaper medicines for the better off? A mixed methods study of medicine price and socioeconomic status of clients in chain and independent retail pharmacies in urban India

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Abstract

The growth of chain pharmacies in India, and other low and middle-income countries, is challenging the status quo of pharmacy retail markets which have historically been dominated by independent pharmacies in these settings. There is a need to understand the effects of different organisational arrangements on the functioning of pharmacies in these countries, including the prices of the medicines they sell and the populations that they serve. This paper draws on a standardised patient survey to measure the prices of consultations for two tracer conditions (suspected tuberculosis in an adult and diarrhoea in an absent child) at a random sample of chain and independent pharmacies. In addition, in-depth interviews were conducted with chain executives, branch staff and independent pharmacy owners to understand how organisational type affects price; and asset and education data were collected from exit interviews with pharmacy customers to determine socioeconomic profiles of clients. We found no difference between chains and independents in the price of medicines for the tuberculosis case. However, chains were cheaper for the diarrhoea case, undercutting the maximum retail price significantly more than independent pharmacies. Additionally, chains were found to realise efficiencies in the supply chain and exploit their buying power to offer fixed discounts, thus likely further reducing prices for regular customers compared to independent shops. Despite the availability of cheaper medicines, the potential to serve poorer groups has not yet been realised. Chains served wealthier and more educated clients, compared to independent pharmacies. Any attempt to leverage this organisational model for public health good would need to take account of the current reach of these pharmacies. Great care would be required to ensure that appropriate regulatory constraints and incentives were in place in order to realise the potential benefits for all groups, especially the poor.

Introduction

Pharmacy retail markets in low and middle-income countries (LMIC) have traditionally been dominated by local, independently owned pharmacies. These pharmacies are widely used by populations but their practice has been judged to be poor. Insufficient history taking, a lack of adherence to treatment guidelines, and inappropriate supply of medicines have been shown to be commonplace (Miller and Goodman 2016, Smith 2009, Wafula, Miriti, and Goodman 2012). Insufficient knowledge, strong profit motives, and regulatory failures go some way to explaining these shortcomings (Goel et al. 1996, Miller and Goodman 2016). Economic growth has spurred the entry of pharmacy chains into these retail markets in Africa, Asia and South America, with a particular presence noted in countries such as India, The Philippines, Mexico, Brazil, Chile, South Africa, Nigeria, Kenya and Uganda (IMS consulting group 2014, Lowe and Montagu 2009).

Chains could be argued to have the potential to both improve quality and reduce price in comparison to independent pharmacies, and therefore be a welcome addition to these markets, from a public health perspective. First, consolidation through pharmacy chains may enable regulators to concentrate on central management structures and thus alleviate some of the difficulties and high costs associated with enforcing regulation in a highly fragmented market. Secondly, firms may self-regulate quality in their branches in order to preserve brand identity or image (Bishai et al. 2008, Bloom, Standing, and Lloyd 2008). Thirdly, the profit motives of branch staff may be lower-powered compared to those of pharmacy owners, who directly receive the profits of medicine sales, which may mean there are weaker incentives for chain staff to engage in irrational medicine use (Frant 1996).

Turning to the potential impact on price, chains may be able to take advantage of scale economies to invest in cost-reducing and quality-enhancing technologies (Bennett and Yin 2014). They may buy directly from manufacturers, thus by-passing wholesalers and the serial mark-ups associated with a complex supply chain. Firms may also partner with manufacturers to offer 'private label' products. Not only would these actions increase margins and reduce prices, but they would also give the firm more control over medicine quality. Further, additional savings could be made if firms became large enough to experience buying power in the market. Such cost savings may be passed onto patients in the form of cheaper medicines, though firms may use their brand power to raise prices.

To date, research on this evolving segment of the pharmacy retail market has been limited. The chain that has, perhaps, received most attention is the Mexican giant, Farmacia Similares- the brain child of 'physician-pharmacist-industrialist' Victor Gonzalez Torres (Shadlen 2009). Farmacia Similares is the channel used to distribute generics produced by

Laboratorios Best, also owned by Torres. Laboratorios Best saw an opportunity to enhance their business following a Mexican health reform in 1998 that required public sector doctors to prescribe using the active ingredient ie generics, as opposed to the brand name. However, existing distribution channels refused to sell their products, due to a campaign to discredit generics, and private doctors continued to prescribe branded products. This led Laboratorios Best to create Farmacia Similares- a low cost, doctor-pharmacy chain offering cheap generics to the bottom of the pyramid (adjacent to each outlet is a medical clinic offering consultations for $2) (Peng 2016). This innovative model, coupled with successful marketing of the products as 'The Same But Cheaper' (Lo mismo pero mas barata) and a portrayal of the Mexican-owned company as taking a stand against 'transnational greed' has led to the rapid expansion of the chain in Mexico and in 2005 it registered revenues of over $400 million (Hayden et al. 2007). The chain has now entered markets in Costa Rica, El Salvador, Honduras, Nicaragua, Chile, Ecuador and Peru (Centre for Health Market Innovations 2017). Farmacia Similares's success has drawn the attention of policy makers and global health organisations to the possibilities of pharmacy chains.

Farmacia Similares's business model of selling low cost generics to the bottom of the pyramid is, however, unique, and we are unaware of other chains, elsewhere in LMICs with a similar offering. Instead, pharmacy chains in other settings tend to follow the traditional model of selling both generics and branded medicines, the latter being favoured by both doctors and patients (Nguyen et al. 2008). The only published work looking at the impact of these traditional chains in LMICs, is from a study in Hyderabad, India, which investigated the effect of chain entry on quality and prices of medicines in local markets. Researchers worked with a leading Indian pharmacy chain, MedPlus, and collected data on medicine price and pharmacopoeia compliance of two antibiotics (through a SP survey) in independent pharmacies in control and treatment markets (a MedPlus shop opened), before and after chain entry. They reported that, compared to independent pharmacies in control markets (ie no chain presence) chain pharmacy prices were 6% lower (p=0.02) and pharmacopoeia compliance was 6 percentage points higher (p=0.46) (Bennett and Yin 2014). The same study comments that MedPlus initially entered the city's most affluent neighbourhoods, suggesting that some chains may be targeting wealthier populations but this evidence is anecdotal (ibid).

This paper aims to build on this limited evidence base on the performance of chain pharmacies. In earlier papers we explored the impact of organisational structure on quality of care, as measured by adherence to treatment guidelines, using standardised patients (SPs) to present fictitious scenarios, and found that the potential for quality improvement does not currently appear to have been realised in the Indian context (Miller and Goodman 2017,

Miller, Hutchinson, and Goodman 2017). We found that quality of care, for a child with diarrhoea and an adult with suspected tuberculosis (TB), was equally poor in chain and independent pharmacies. Fewer than half of the pharmacies managed the TB case according to the current guidelines, and not a single pharmacy treated the child in accordance with guidelines. However, chains sold significantly fewer harmful and prescription-only medicines (POMs) for the diarrhoea patient compared to independent shops. In this paper we turn to the question of the impact on price and the associated question of the socioeconomic groups served by the chains. Using exit interviews from a random sample of pharmacy chains in Bengaluru, India, we present the first data on socioeconomic profiles of customers shopping at chain pharmacies in a LMIC, compared to independent pharmacies, and of the general population. We also present price data from our SP survey completed at chain and independent pharmacies in the same setting. Additionally, we draw on insights from in-depth interviews with pharmacy owners, chain executives and in-store staff and other key informants to learn more about how and why the organisational structure of pharmacy chains may affect medicine prices, compared to independents.

Methods

The data presented in this paper are drawn from three distinct sources: a SP survey, exit interviews with pharmacy customers, and in-depth interviews with key informants. We begin this section with some background on the retail pharmacy market in Bengaluru, and then describe the collection and analysis of each dataset in turn.

Study site and Bengaluru's retail pharmacy market

Chains currently account for around 4% of India's 800,000 odd pharmacies but their rate of growth is rapid (IMS consulting group 2014). These chains are concentrated in India's big cities, with a larger presence in the South. This guided the choice of Bengaluru, the capital of the Southern Indian state of Karnataka and India's third most populous city, as the site for this work. At the time of data collection (November 2014-June 2015) there were 13 chains operating in the city, accounting for 529 (9%) of Bengaluru's 5664 registered retail pharmacies (Miller and Goodman 2017) (these figures exclude pharmacies operating within hospitals or clinics, which could not be accessed from the street). Chain size varied from two to two hundred - plus outlets and five chains also owned pharmacies outside of Karnataka.

Both chains and independent pharmacies stock a mix of branded and generic products. In India a distinction is made between 'national' and 'local' medicine manufacturers. 'Branded' products are produced by national manufacturers, who advertise their products heavily in order to establish a reputation and improve market power (Bennett and Yin 2014). These manufacturers tend to comply with Indian and international quality standards. Local

manufacturers produce generics and are difficult to regulate due to their vast numbers. Retail pharmacies stock a high number of national and generic brands for common medicines in order to accommodate a wide range of doctor and customer preferences. Each manufacturer dictates a maximum retail price (MRP) for their product but the MRP for a particular compound can vary across brands. There is therefore some scope for price variation through brand substitution. The National Pharmaceutical Pricing Authority (NPPA), an independent body, also stipulates a ceiling price for some essential medicines listed in a 'schedule' and found in the Drugs Prices Control Order (NPPA).

Standardised patient survey: price data

Data on price were collected through a SP survey of chain and independent pharmacies in the city. A stratified sample of chain (103) and independent (230) pharmacies were chosen, at random, from a verified list of all licensed pharmacies in Bengaluru (see (Miller and Goodman 2017) for more details). The sample included eight of Bengaluru's 13 chains- the largest seven and one of the six chains with 2-5 outlets (see Table 1). Six research assistants were trained to visit pharmacies and present standardised cases of diarrhoea in an (absent) child and suspected TB in an adult. A substantial component of the training involved role play to practice both the presentation of the cases and personal back stories. SPs completed a number of pilots under the supervision of a senior research assistant, until we were confident that the presentations and associated dialogue would be perceived as authentic. The scenarios were presented in Kannada (the local language) and it was discussed how researchers should dress to ensure they appeared similar to a typical customer who may present with such cases. At each pharmacy the SPs purchased any medicines that were recommended during the consultation and recorded the price of each individual medicine sold in a debrief questionnaire, completed immediately after each visit.

Table 1: Size of pharmacy chains in Bengaluru and in SP sample

Number of outlets in chain	Number of chains	Number of chains in our sample	Number of outlets in our sample
2 to 5	6	1	1
6 to 10	2	2	4
11 to 50	2	2	6
51 to 100	1	1	14
101+	2	2	78

Price data from the SP survey were analysed using Stata 15. We present the difference in both mean (accompanied by standard deviations and t test) and median price, interquartile range (IQR), and p value from the Wilcoxon rank sum test of the hypothesis of equal medians in chains and independents.

Exit interviews with patients: SES indices and education

We conducted exit interviews with customers at the same random sample of pharmacies used for the SP survey. During a second visit to the pharmacies, researchers approached each customer that left the pharmacy and, if they agreed to take part, administered the exit interview. This process was repeated until 3 exit interviews were completed at each outlet. A total of 808 exit interviews were completed. Whilst researchers were supposed to record the number of clients who refused to participate, this was not recorded satisfactorily and, as a result, we cannot calculate the response rate. The exit interview collected data on personal characteristics, reasons for visiting the pharmacy, and ownership of a number of assets.

Due to the difficulty of collecting accurate income or expenditure data in LMICs, it has become common practice to measure wealth by collecting data on variables that capture living standards, including assets (eg TV or motorbike) and housing characteristics (eg water source or roof material) (Vyas and Kumaranayake 2006). We have employed this approach to measure the wealth of pharmacy customers in our sample. In order to compare the customers in our sample with the general population, we used asset data from the national District Level Health Survey (DLHS), a household survey powered at the district level. Using these assets allowed for comparison with the general population. These comparative wealth data were downloaded from the International Institute for Population Studies (IIPS) website. Our sample was taken from Bengaluru urban district, within Karnataka. As such, we used the data from the corresponding district in the DLHS. We collected data on assets used in the most recent DLHS-4 (2012-13). In order to limit the time needed to collect these data during the exit interviews (and hence improve participation), we did not ask about all assets in the DLHS-4, rather a subset of assets relevant to the Bengaluru city context[8]. For example, we did not ask about ownership of a tractor or cart driven by an animal as these are more applicable for rural areas. Others have shown this to be a valid approach in both India and elsewhere (Bassani et al. 2014, Chakraborty et al. 2016).

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[8] Refrigerator, telephone (landline) only, mobile phone only, sewing machine, tap/running water, radio, scooter/motorcycle, washing machine, car/jeep/van, watch/clock, computer without internet, computer with internet, cooler/AC, number of bedrooms

We derived our socioeconomic status (SES) indices using principal components analysis (PCA) in Stata 15. First, we completed the PCA on a merged dataset (data from the DLHS-4 and our exit interview data), using a common set of assets, to assign standardised wealth scores to each individual (Vyas and Kumaranayake 2006). We then created quintile cut-offs, as described by Filmer and Pritchett (Filmer and Pritchett 2001), using only the DLHS-4 data. These cut-offs were then applied to our exit interview customers and this enabled us to examine the relative economic status of clients patronising chains and independents compared to the general population of Bengaluru.

We also used the DLHS to compare the education level of pharmacy customers in our sample by pharmacy type and also with the general population. It was not possible to use the DLHS-4 data for this analysis as educational classification for around a quarter of the data set was unclear, so instead we used the earlier DLHS-3 (2007-8), acknowledging the limitation that the DLHS-3 is less up-to-date.

<u>Key informant interviews: understanding how organisational type affects price</u>

38 in-depth interviews were completed with pharmacy employees and other stakeholders in Bengaluru. We selected interviewees from a sub-sample of the pharmacies in our SP survey. Interviewees comprised 9 chain senior executives working in 8 chains (all the major chains bar one agreed to an interview). Additionally, we interviewed 14 chain in-store staff; 12 independent pharmacy owners (representing a geographical range across Bengaluru); and 3 key informants including staff from the drug control department and pharmacy associations. Interviews were conducted in English, Kannada or Hindi (depending on the interviewee's preference) by RM with the help of a local research assistant. Two chains refused to allow us to interview their in-store staff; however, we were able to learn about the experiences of ex-employees of those chains who were currently employed at other chains. Through the interviews we sought to explore some of the hypotheses laid out in the introduction concerning how the organisation of pharmacies within a chain structure might influence medicine prices. We focused our questions on the supply chain for both chains and independents; the extent of purchasing power realised by chains in the market; pricing procedures for both pharmacy types; and factors influencing the location of new chain stores.

Interview transcripts were coded by RM in NVivo 11. We used the predefined hypotheses on the effects of chain organisation to generate an initial set of pre-defined coding categories. These codes were then applied to the data in an iterative process and the final coding frame was agreed by the authors. Where similar topics were covered, we sought to triangulate the data collected from both chain executives and branch staff.

Ethical approval was obtained from The London School of Hygiene and Tropical Medicine Ethics Committee, London, UK, and the Society of Community Health Awareness Research and Action Institutional Scientific and Ethics Committee in Bengaluru, India. For the SP study, approval from both institutions was received in order to waive obtaining informed consent from the pharmacies prior to the SP visits. For the exit interviews with customers, written consent was obtained and for the interviews with chain and independent staff we gained verbal consent. This is due to reluctance of providers to signs documents that could be used to identify their chain or outlet.

Results

We first present price data from the SP survey at chain and independent pharmacies, followed by insights on price from our qualitative data. Subsequently, we look at SES and education of customers shopping at chain and independent pharmacies, compared to the general population.

Price

Data from our SP survey enables us to compare the price of medicines sold at chain and independent pharmacies based on a standardised presentation of symptoms. Further, it allows us to understand how recommendations on number and type of medicines by pharmacy staff affect the overall cost to the customer. SP consultations for childhood diarrhoea and suspected TB were analysed separately. Of the 333 shops visited by the SPs (103 chains and 230 independents), 65% of chains and 66% of independents sold medicine(s) to the patient with suspected TB. For the diarrhoea patient, these figures were 61% and 67% for chains and independents respectively. The subsequent analyses of price data were conducted only on those shops who did sell medicines.

Figure 1: Histogram of price of diarrhoea encounter with kernel density
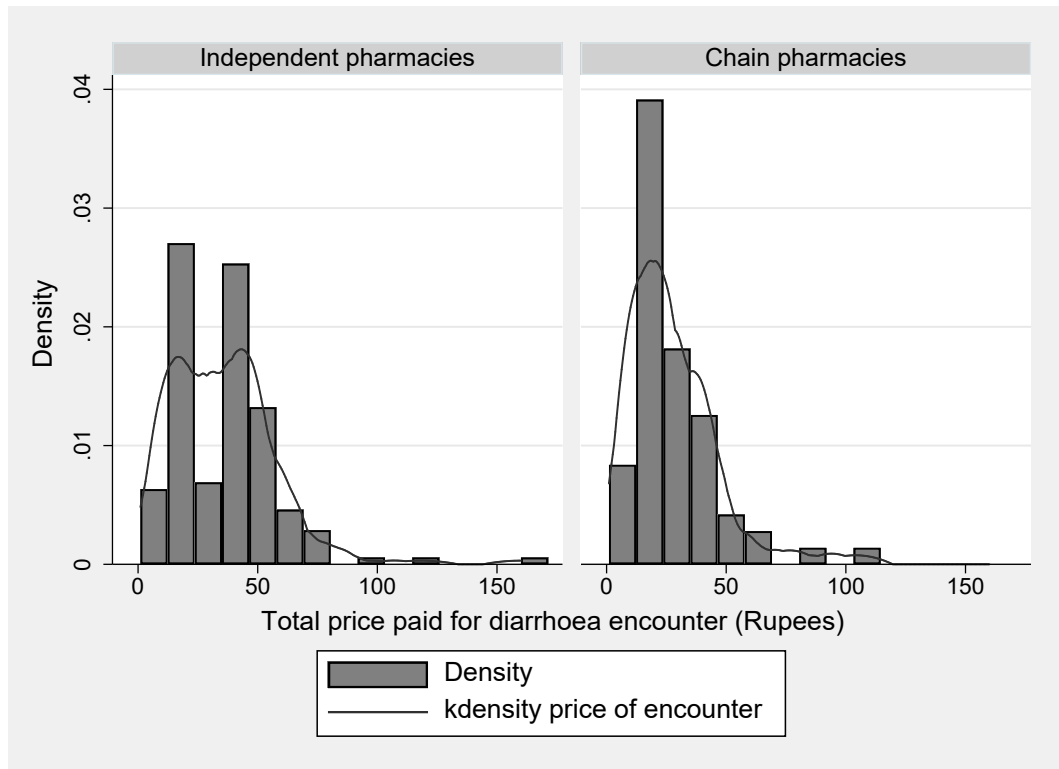
Figure 2: Histogram of price of TB encounter with kernel density
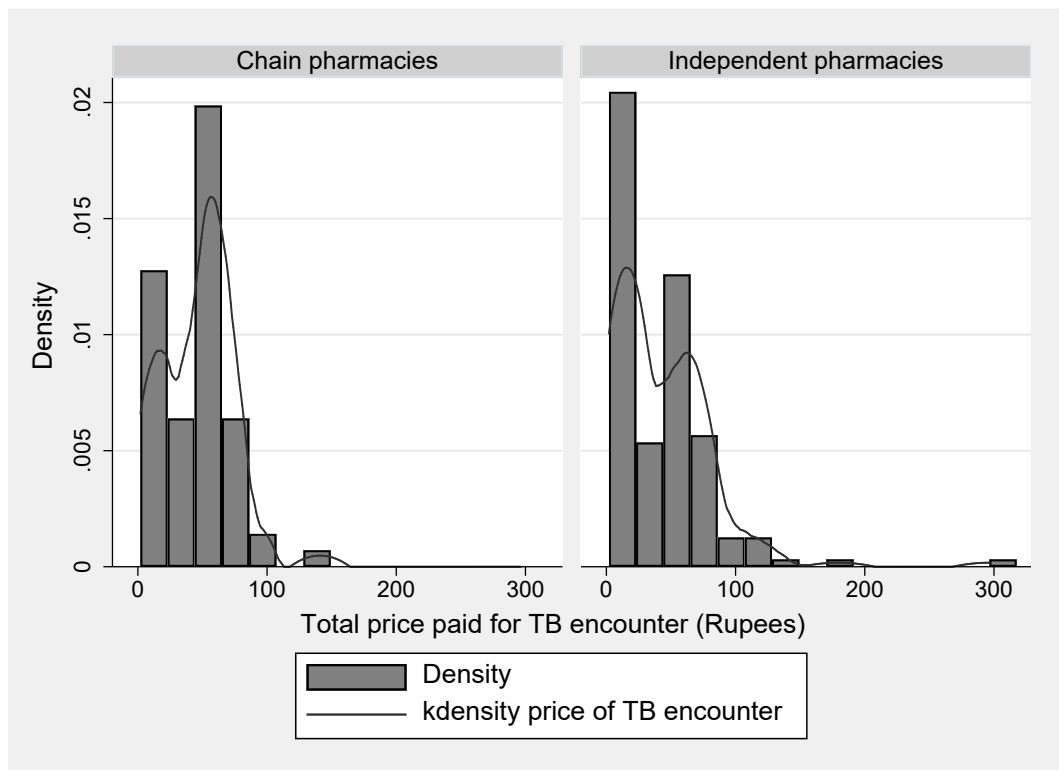
Figures 1 and 2 show histograms of prices for the diarrhoea and TB encounter respectively, with kernel densities. Table 2 shows that there was no significant difference between chains

and independents in terms of the price of the TB encounter. For the diarrhoea case, the mean and median price paid for all purchased medicines was significantly less for chains- 27.5 and 19 Rupees (Rs) respectively, compared to 35.6 and 38 Rs for independent shops (p=0.01 and p=0.002). The mean number of medicines sold does not offer an explanation for the observed price difference between chains and independents for this case (1.2 for both pharmacy types).

Table 2: Descriptive statistics for diarrhoea and TB encounter

	Chains		Independents		
Encounters (n)	103		230		**Statistical tests**
Diarrhoea encounter					
Number of encounters where SPs received any medicine	63 (61%)		153 (67%)		**Chi^2**
					P=0.344
Mean number of medicines received	1.21		1.22		**t test**
					p=0.886
Total price paid (of encounters where medicines were sold) (Rs)	**Mean**	**SD**	**Mean**	**SD**	**t test**
	27.5	18.3	35.6	22.1	p=0.01
	Median	**IQR**	**Median**	**IQR**	**Wilcoxon rank sum test**
	19	13-37	38	18-47	p=0.002
Price per medicine (Rs)	**Mean**	**SD**	**Mean**	**SD**	**t test**
	22.8	13.8	29.3	20.4	p=0.012
	Median	**IQR**	**Median**	**IQR**	**Wilcoxon rank sum**
	18.8	13-30	24	13-41	p=0.008
Tuberculosis encounter					
Number of encounters where SPs received any medicine	67 (65%)		151 (66%)		**Chi^2**
					p=0.915
Mean number of medicines received	1.37		1.51		**t test**
					P=0.171
Total price paid (of encounters where medicines were sold) (Rs)	**Mean**	**SD**	**Mean**	**SD**	**t test**
	46.4	26.8	42.7	38.5	p=0.473
	Median	**IQR**	**Median**	**IQR**	**Wilcoxon rank sum test**
	49.5	20-64	29	11-64	p=0.191
Price per medicine (Rs)	**Mean**	**SD**	**Mean**	**SD**	**t test**
	33.8	24.5	28.3	26.2	p=0.082
	Median	**IQR**	**Median**	**IQR**	**Wilcoxon rank sum test**
	26.58	10-55	13.5	8-55.7	p=0.064

Further analysis looked at price deviation from the MRP in both chains and independents (Table 3). This shows that, on average, the diarrhoea encounter was 1.09 Rs less than the

MRP at chains, compared to 0.17 Rs less at independents (p=0.005). Chains therefore appear to be offering medicines at cheaper prices than independents for this case. For the TB case, chains were found be following the MRP (0.04 rupee deviation per encounter), whereas independent shop encounters were, on average, 1.79 Rs more expensive than the MRP (although this result is not significant at the 5% or 10% level). For the TB case, whilst independents were charging more than the MRP and selling more medicines on average (1.51 Rs vs 1.37 Rs for chains), the medicines that they did sell were cheaper (mean price per medicine was 28 Rs at independent and 34 Rs in chains). This resulted in no price difference between chains and independents for the overall consultation.

Table 3: Price deviation of standardised patient (SP) encounters from the maximum retail price (MRP) for chain and independent pharmacies

		Diarrhoea case			
	Chains		**Independents**		
	Mean	**SD**	**Mean**	**SD**	**t test**
	-1.09	2.78	-0.17	1.86	p=0.005
Price difference of encounter (MRP - price paid)	**Median**	**IQR**	**Median**	**IQR**	**Wilcoxon rank sum test**
	0	-2 - 0.46	0	0 - 0.46	p=0.28
		Tuberculosis case			
	Chains		**Independents**		
	Mean	**SD**	**Mean**	**SD**	**t test**
	0.04	6.67	1.79	8.27	p=0.129
Price difference of encounter (MRP - price paid)	**Median**	**IQR**	**Median**	**IQR**	**Wilcoxon rank sum test**
	0	-1.83 - 1.23	0	0 - 1.2	p=0.226

A regression analysis was conducted to further explore the effect of outlet type on price (Table 4). The first model shows the raw correlation between log price of the diarrhoea encounter and pharmacy type, while the second also controls for SP fixed effects. Model 2 shows that chains were 23% cheaper[9] than independent pharmacies, after controlling for SP fixed effects (p=0.014). Model 3 explores the hypothesis that chains are cheaper due to selling fewer antibiotics, a class of medicines that are known to be expensive. The binary independent variable 'antibiotic' (whether an antibiotic was sold) is added to the model. The

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[9] $(e^{-0.2578} - 1)*100 = -22.7$

coefficient on the chain dummy is reduced, but does not disappear, indicating this may explain part but not all of the observed price difference.

Table 4: Effect of pharmacy type on price: diarrhoea encounter

Dependent variable	ln (price)		
	Model 1	Model 2	Model 3
Chain pharmacy	-0.2531*	-0.2578*	-0.2269*
	(0.103)	(0.104)	(0.094)
SP fixed effects	No	Yes	Yes
Antibiotics	_	_	0.3761**
			(0.094)
Observations	216	216	216
R2	0.03	0.04	0.11

Standard errors in parentheses
* p <0.05, **p<0.01

Table 5 analyses the effect of the same independent variables on the log price of the TB encounter. In line with the descriptive statistics, after controlling for SP fixed effects, there was shown to be no significant difference between the price of chain and independent pharmacies.

Table 5: Effect of pharmacy type on price: TB encounter

Dependent variable	ln (price)	
	Model 1	Model 2
Chain pharmacy	0.2371	0.2478
	(0.127)	(0.133)
SP fixed effects	No	Yes
Observations	218	218
R2	0.01	0.09

Standard errors in parentheses
* p<0.05, **p<0.01

Table 6 explores the effect of selling 'private label' medicines on log price of the TB encounter. Qualitative work from this study (see below) revealed that chains offer private label products and these products were reportedly cheaper for patients and yielded higher margins for the chain. 43% of the chain pharmacies in this analysis were found to sell a private label medicine in the TB encounter[10]. Model 2 shows that the after controlling for SP fixed effects, there is no significant difference between independent pharmacies and either

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[10] A similar analysis is not shown for the diarrhoea encounter because the share of chain pharmacies selling a private label medicine for diarrhoea was only 6%.

chains that sold a private label medicine and those that did not. This indicates that private label medicines do not appear to be driving down prices.

Table 6: Price of TB encounter, investigating the effect of 'private label' medicines on price

Dependent variable	ln (price)	
	Model 1	Model 2
Chain pharmacy (sold private label)	0.2324	0.2290
	(0.190)	(0.185)
Chain pharmacy (did not sell private label)	0.2407	0.2622
	(0.170)	(0.166)
SP fixed effects	No	Yes
Observations	218	218
R2	0.01	0.08

Standard errors in parentheses
* p <0.05, **p<0.01

Qualitative insights on price

In order to better explain how and why price variations exist between chain and independent pharmacies in Bengaluru, we have drawn on a set of in-depth interviews with key informants, concentrating on two key themes of retail discounts and wholesale purchasing.

As with all SP studies, our results reflect how pharmacies manage a client not already known to the pharmacy. From in-depth interviews with chain executives and in-store staff we learned that many of the chains offer customers a fixed discount on medicines, and this apparently reflected aggressive price competition on the part of chains. One of the market leaders introduced a 10% discount on the MRP for all medicines and other chains have since followed suit. Discounts ranged from 5-10% and only a couple of the smaller chains did not offer this price reduction to their customers. One large chain recorded the phone number of new customers and then applied a 10% discount to purchases (using the phone number as an identifier), whereas other chains reserved discounts for senior citizens or 'loyalty card' customers only. Discounts offered by independent shops appeared to be less fixed and were usually only offered if requested by a customer. Some independents refused to apply discounts, stating that they could not survive if their margins were reduced further; others offered 2-3% and some matched the 10% given by the bigger chains. Given that our SPs were not regular clients, it is likely that the price data from our SP study does not capture the full extent of these discounts and it is likely that regular customers would face cheaper

encounters. Independent shop owners cited this discount culture as the single largest grievance regarding the advent of chains. One owner explains:

'Chain medical shops are disturbing a lot. It's like polluting our Ganges River. Giving 10% discounts, and making the customers to change their route.' #29 independent pharmacy owner

Whilst our qualitative work revealed grievances from independent pharmacy owners regarding the growth of pharmacy chains, we found no concrete evidence of independent store closures, as yet.

Interviews revealed that chains realise cost savings through central purchasing for all of their Bengaluru stores that would not be available to independents, giving them the potential to apply these discounts. As one chain executive says:

Respondent: 'Our purchase power will increase no…If you purchase in bulk, definitely your purchase power will increase.'

Interviewer: 'What kind of discounts do they offer?'

Respondent: 'It depends on the brands and distributors. From 3 to 6, 7% discounts will be there.' #4 chain executive

Further, some describe how chains are able to cut one or more layers out of the supply chain by purchasing directly from manufacturers and carry and forwarding (C&F) agencies, rather than from local distributors, as independents do (figure 1). It is such supply chain efficiencies that enable the larger chains to offer substantial discounts on medicines. A chain executive describes:

'Procurement, we have a contract with most of the vendors so that is done centralised from Delhi major companies like J&J [Johnson and Johnson], Cipla they have their C&F [carry and forwarding] delivering the stocks directly to us… They are the stockist for that particular products, so they get directly from their company and they sell it directly to us, so there is no, very few distributors in between so we are able to offer that margin what we are saving there to the customers…For a single shop [ie independent pharmacy] *he will not get a direct buy from a C&F, C&F has a minimum order of value for that particular product, so I being a small timer I go and approach and they'll not deliver products to me. If I represent a company who has 10 stores or 20 stores then they will, so that's the difference what we make.' #18 chain executive*

Figure 3: Typical supply chain for independent and chain pharmacies purchasing medicines, as told by informants
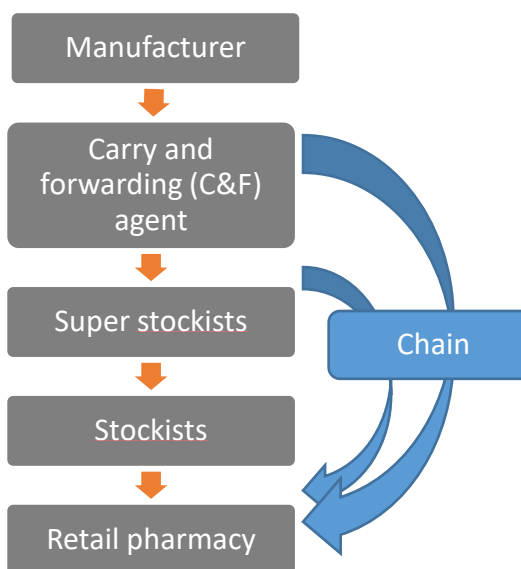
Additionally, some of the larger chains offer their own line of 'private label' medicines. These are generic medicines purchased directly from the manufacturer, branded, and sold under the chain name. Margins on these generic products are much higher for the chain than on national brands because they are obtained at much lower cost and, as such, chains heavily incentivise their staff to sell these products. The chain is also able to have more control over the quality of such products. Customers are said to be suspicious of generics in general, and prefer national brands, but where they do substitute for these pharmacy-branded medicines, they will pay less for the same compound, benefiting both company and customer.

Socioeconomic profile of clients

We explored the SES of pharmacy customers compared to the general population of Bengaluru in terms of both wealth and education.

Figure 2 shows the distribution across wealth quintiles (based on our asset index) of customers visiting chain and independent shops in our sample, compared to that of the general population. The figure shows a clear pattern of higher wealth of independent customers compared to the general population. Chain customers appear to be relatively wealthier than both the general population and independent customers. The clearest difference can be seen in the highest wealth category (quintile 5) which comprises 20% of the general population, compared to nearly half (45%) of independent customers and the

majority (67%) of chain customers. Chi^2 tests showed that differences in Q5 between all groups were significant (p<0.001 for all tests).

Figure 4: Wealth of customers patronising chain and independent pharmacies relative to the general population of Bengaluru
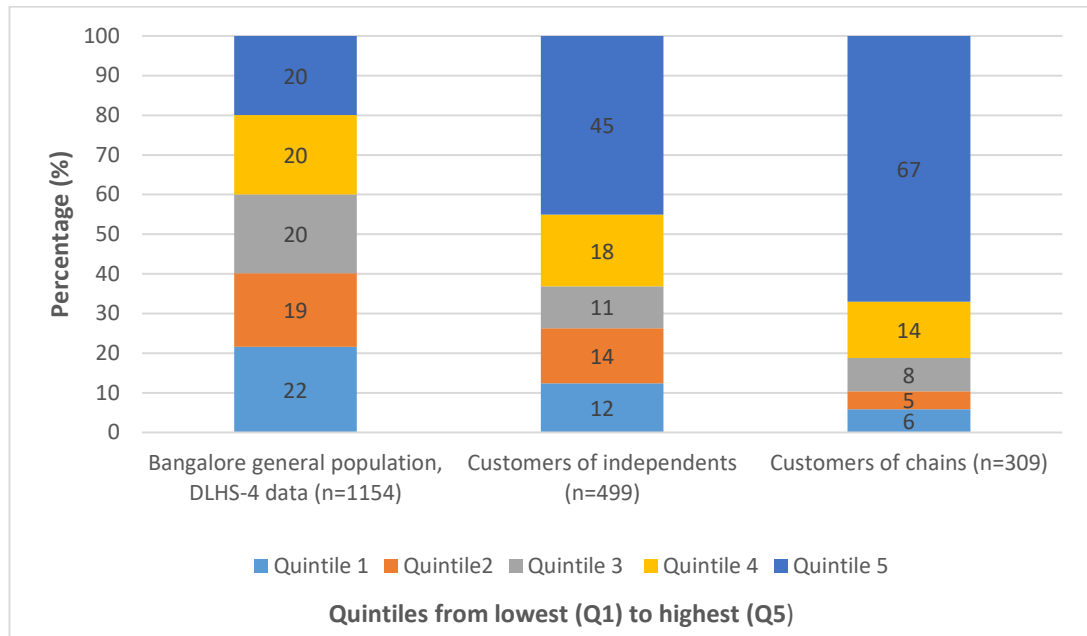
Secondly, we present educational attainment of customers patronising chain and independent pharmacies, relative to the general population (Figure 4). Educational attainment of independent customers was similar to that of the general population. Those visiting chain pharmacies had a higher proportion (79%) of customers in the highest two educational categories (secondary school and above) and fewer (21%) in the lowest two (no schooling and primary education) compared to independents and the general population. These differences between the education of chain and independent customers (p<0.001), and chain and the general population customers in the top two educational categories were found to be significant (p<0.001).

Figure 5: Educational attainment of customers patronising chain and independent pharmacies relative to the general population of Bengaluru
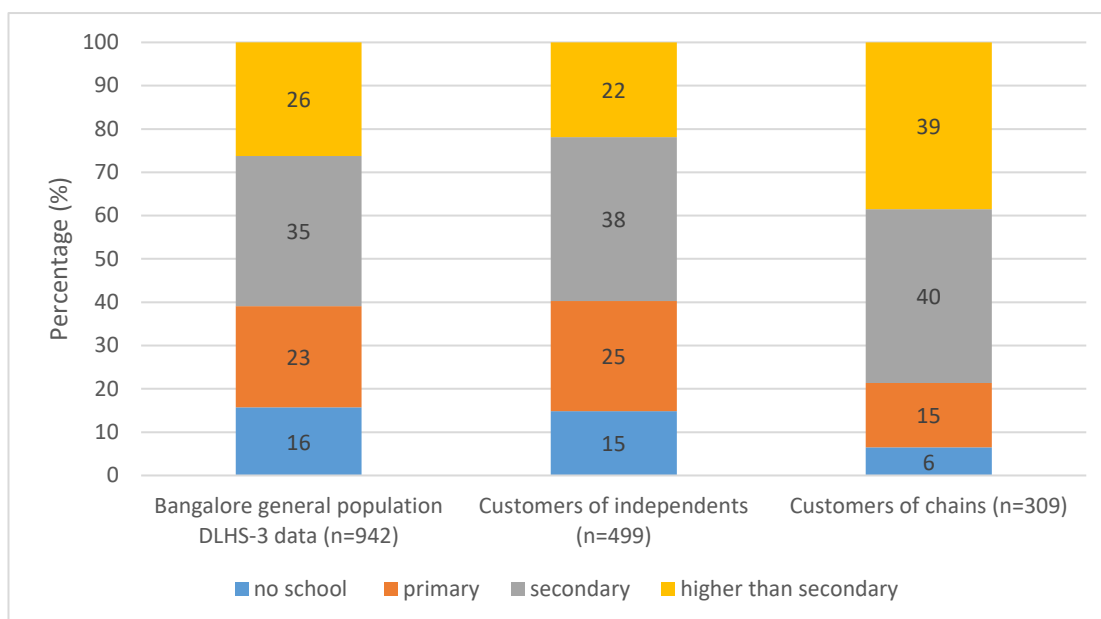
We conducted further analysis to investigate whether the above results (customers patronising chain pharmacies being both more educated and relatively wealthier than those using independent pharmacies) were driven by the location of chains (potentially in wealthier areas). Using Arc GIS the GPS locations of all pharmacies in our sample were plotted. A 1km radius was applied to each chain pharmacy. In an attempt to match pharmacies by area, all chains that had an independent within the 1km radius were included, as were the independents within that geographical area. Conversely, any independents not within 1km of a chain and chains that did not have an independent within 1km were excluded. We repeated the same analyses on this matched dataset (see supplementary material) which included 264 exit interviews from 90 independents and 237 exit interviews from 79 chains.

The results from the geographically matched data were very similar to our original results in terms of customer wealth. The percentage of independent customers in the top quintile increased by 1 percentage point to 46% and decreased to 66% (1% point) for chain customers. The difference between the two was still significant ($p < 0.001$). In terms of education, the change in results was more marked. The percentage of independent customers with secondary education or higher increased from 60% in the original dataset to 68% in the geographically matched data. For chain customers there was a slight decrease in this figure from 79% to 75%. However, the difference between the percentage of chain and independent customers educated to secondary level and above was still significant ($p = 0.019$).

Discussion

The data presented in this paper on relative pricing and client SES can be combined with other published evidence from this study on relative quality of care (Miller and Goodman 2017, Miller, Hutchinson, and Goodman 2017) to provide a wider picture of the comparative performance of chain and independent pharmacies. Medicine quality may be a third key mechanism through which chains could be hypothesised to differ from independents. Our qualitative work found that chains do enjoy shorter supply chains and buy directly from manufacturers, which may enable greater control over quality. Further, the storage capabilities of chains may be superior to those of independent retailers and this could safeguard medicines against the high temperatures and humidity that are commonplace in India. In their study of the independent pharmacy market in Hyderabad and the effect of chain (MedPlus) entry, Bennet and Yin reported that chain medicine quality was initially 6% points higher but over time the pharmacopoeial quality of independent medicines improved to match that of chains, but at a higher cost than the chains (Bennett and Yin 2014).

This paper set out to investigate the impact of pharmacy type on price and to scrutinise the socioeconomic groups served by these pharmacies. It was unclear whether chains would take advantage of scale economies to offer cheaper medicines or whether they would exert brand power to raise prices. From our SP survey, we found that there was no significant price difference between chains and independents for the management of the TB case. The consultation for the child with diarrhoea was, however, significantly cheaper at chains compared to independents. Regression analyses which explored the relationship between the log price of encounters and pharmacy type, controlling for SP fixed effects showed that this encounter was 23% cheaper in chains, compared to independents (p=0.014). This difference appears to be driven mainly by chains undercutting the MRP price significantly more than independent pharmacies.

There are two reasons why our price data may actually be underestimating the price-cutting impact of chains. Firstly, our qualitative data revealed that most chains offer up to 10% discount on medicines to repeat customers which is not entirely captured by our SP patients who are unknown, first-time visitors to the pharmacy. These discounts are made possible by discounts on wholesale prices through bulk purchasing and realising efficiencies in the supply chain. Secondly, there are possible price spill over effects to independents, who may have decreased their prices in response to price competition from chains. Bennet and Yin's (2014) study of the effect of chain entry on medicine quality and price showed that after the entry of a chain into a local pharmacy retail market, the price at independent shops fell by a non-significant 2-4%. However, for non-national brands alone they found a significant 12-

15% price reduction. This phenomenon of retail prices falling in markets following the entry of a low-cost chain has also been observed in other industries (Basker 2005, Jia 2008).

No prior research had investigated the type of customers served by pharmacy chains in India. Given that chains may be cheaper (undercutting MRP for diarrhoea medicines, and discounts for regulars), one might have expected them to serve poorer groups on average, but in fact the reverse was true. We found that customers patronising chain pharmacies were both more educated and relatively wealthier than those using independent pharmacies. These results held after restricting the analysis only to chain and independent pharmacies situated within 1km of each other, thus ruling out the explanation that the observed results were purely driven by the location of chains.

Our accompanying qualitative work offers some explanation for the self-selection of independents by poorer clients and chains by wealthier ones. This work reported that independent pharmacies offer credit facilities to those who cannot afford to buy medicines and this may be an important consideration of such clients. Additionally, given that chains have a more high-end feel in terms of appearance, it may be that they are off-putting or intimidating to lower income groups. Whilst most independent stores had an open, on-the-street shop frontage, chains were often enclosed. In addition, most chain branches had air conditioning, were neatly organised, and some chain executives described their aim to create a more 'international' experience compared to independent shops. The apparent self-selection also suggests that the rich maybe more sensitive to quality. Both quality of care, given that chains were found to sell fewer prescription only and harmful medicines to the diarrhoea patient; and quality of medicines, given that other work has found the medicines sold by chains to be of superior pharmacopeial quality to those sold at independents (Bennett and Yin 2014). It is feasible that these groups perceive that a chain with air conditioning will offer better quality medicines.

It is also noteworthy that the profile of independent customers in our sample was considerably wealthier than that of the general population. A growing body of work focusses on the role and space that informal providers occupy in India (Bloom et al. 2011, Gautham et al. 2014, George and Iyer 2013), and it may be that this cadre of providers are the preferred channel for medical advice and medicine purchasing for the urban poor in Bengaluru.

This paper also touches on the expansion of private label products into the retail pharmacy market. Steiner argues that when private label products compete in the market, the competition with national brands is welfare-enhancing. Due to their 'unique form of rivalry' they are able to constrain the market power of national brands (Steiner 2004). Despite the welfare gain from lower retail prices, some argue that this is offset against the feeling of

reassurance customers get from purchasing a trusted (national) brand. However, in the US large, well established retailers have developed their own reputation and it has been shown that consumers experience the same feeling of reassurance from purchasing a leading retailer's private label aspirin that years earlier could only have been experienced by purchasing a leading national brand (ibid). Retailers also have more control over the quality of private label products (compared to non-national brands), due to sourcing directly from the manufacturer.

In the long run, transaction cost economics would predict that chains will become the dominant organisational model due to their superior efficiency (Douma and Schreuder 2008). Moreover, other industries have seen diffusion of retail chains in LMICs from big to smaller cities, and from upper to middle to poorer classes (Reardon, Timmer, and Minten 2012). However, one could argue that the costs of monitoring chain branches in more dispersed areas would be much higher and such operational costs may not be feasible (Milgrom and Roberts 1992). For this reason, chains may restrict their operations to urban areas.

The set of hypotheses about the potential positive impact on affordability and quality of chain entry might lead some national or international bodies to consider investing in chains to accelerate this process in order to improve public health outcomes, perhaps to some degree inspired by the Farmacia Similares experience. However, although we found chains to offer lower cost medicines for their urban Indian clientele, the potential to serve poorer groups has not yet been realised, and the impact on quality of care was very limited. Any attempt to leverage this organisational model for public health goals would therefore need to be carefully designed to ensure that appropriate regulatory constraints and conditions were incentives were in place to ensure that the potential benefits were reaped.

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Supplementary material

Figure S1: Wealth of customers patronising chain and independent pharmacies relative to the general population of Bengaluru (pharmacies within 1km radius only):
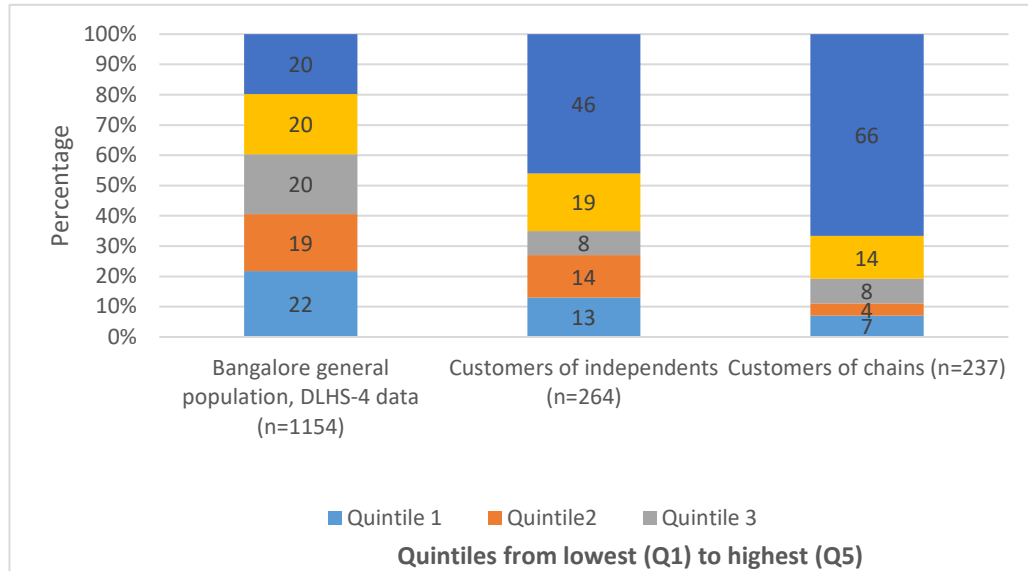
Figure S2: Educational attainment of customers patronising chain and independent pharmacies relative to the general population of Bengaluru (pharmacies within 1km radius only)
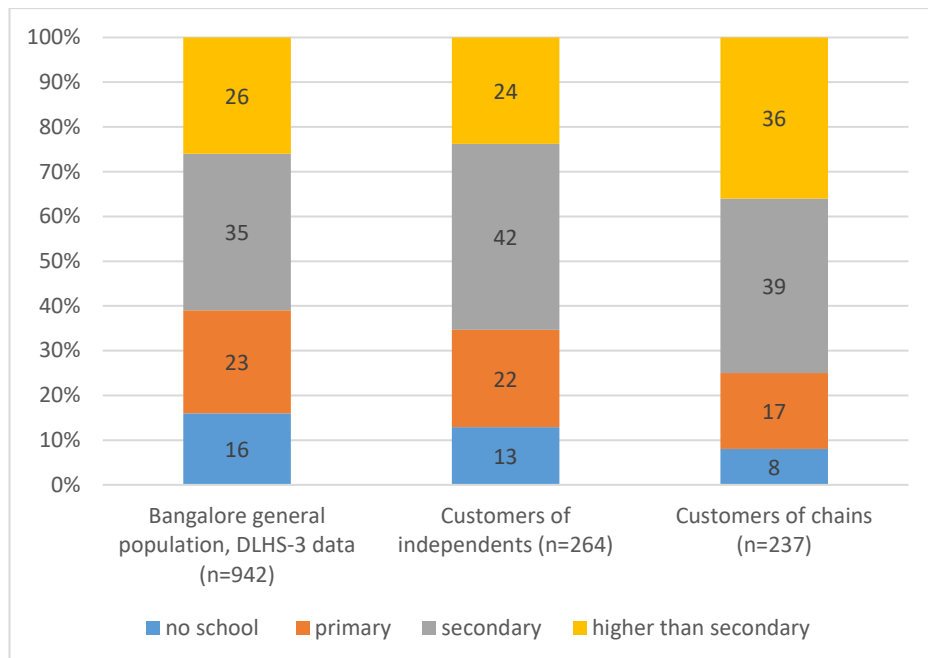
7 Understanding chain business models and their implications

7.1 Introduction

This chapter presents the third results paper entitled "'A smile is most important.' Why chains are not currently the answer to quality concerns in the Indian retail pharmacy sector." It draws on the key informant interviews to address the quality component of objective D (to explore how and why the organisational structure of pharmacy chains may affect the quality of service provision). A version of this paper was published in Social Science and Medicine in July 2018.

7.2 Research paper 4

(Cover sheet on next page).

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SECTION A – Student Details

Student	Rosalind Miller
Principal Supervisor	Professor Catherine Goodman
Thesis Title	The rise of chain pharmacies in India: implications for public health

If the Research Paper has previously been published please complete Section B, if not please move to Section C

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Where is the work intended to be published?	Social Science and Medicine
Please list the paper's authors in the intended authorship order:	Rosalind Miller. Eleanor Hutchinson, Catherine Goodman
Stage of publication	**Undergoing revision**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	Designed study; conducted data collection; conducted analysis; drafted manuscript with supervisory support from CG and EH.

Student Signature: _____   Date: 22/3/18

Supervisor Signature: _CAlder_   **Date:** _22/3/18_

'A smile is most important.' Why chains are not currently the answer to quality concerns in the Indian retail pharmacy sector.

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Abstract

Chain pharmacies are expanding in many low and middle-income countries (LMICs). Historically practices of independent pharmacies in these settings have been poor, and there is a need to understand how these new organisational arrangements are affecting the functioning of pharmacies, and the implications for public health. Drawing on economics literature, we develop a set of hypotheses as to how chains could address the quality failures that typify LMIC retail pharmacy markets, and explore these hypotheses using a set of 38 in-depth interviews, conducted in Bengaluru, India. We look specifically at how being organised in a chain affects several key behaviours: employment of qualified staff; the ability of government authorities to concentrate regulation on central management structures; the propensity for firms to self-regulate; and the impact of the potentially lower-powered incentives faced by chain employees compared to independent owners. In practice, few differences were identified between chain and independent organisations in these areas. Not all chains were operating with a qualified pharmacist (akin to independent shops). Drug control authorities did not take advantage of the existing chain architecture to enforce regulation. Chains did heavily self-regulate but their priority was customer service, rather than aspects of quality relevant to health outcomes. Additionally, widespread bribery in the sector was a barrier to effective drug control. Finally, the incentives faced by chain employees were not low-powered due to rewarding sales targets and pressure to increase sales. We observed that chains exerted strong influence over their staff but the potential to exploit this to improve quality of care is not currently being realised. If clinical accountability within these organisations were improved and regulatory bodies made chains take responsibility for their outlets by using tough sanctions for illegal practices, chains may hold promise for quality improvement.

Introduction

Pharmacies and drug stores are the first point of care in many low and middle-income countries (LMICs) for a range of medical conditions, including respiratory infections, fever, malaria, injury, body and dental pains, skin infections, diarrhoea and sexually transmitted infections (Igun 1987, Kamat and Nichter 1998, Saradamma, Higginbotham, and Nichter 2000, Smith 2009b, Wafula, Miriti, and Goodman 2012). Practice in these outlets is often characterised by deficient knowledge, poor adherence to treatment guidelines, inappropriate supply of medicines, and insufficient counselling (Smith 2009b, Wafula, Miriti, and Goodman 2012, Miller and Goodman 2016). In most LMICs, pharmacy retailing has traditionally been dominated by owner-run shops, but chain pharmacies are now a growing organisational arrangement for delivering pharmacy services in these settings. Given the limited evidence-based policy options to improve pharmacy practice in LMICs (Miller and Goodman 2016, Smith 2009a, Wafula and Goodman 2010), chain pharmacies may have potential to address quality challenges. Despite emerging interest amongst the global health community, empirical research on pharmacy chains in LMICs is scant (Lowe and Montagu 2009). Work from high-income countries has explored the effect of pharmacy type on various outcomes (eg Fritsch and Lamp 1997, Kalsekar, Sheehan, and Peak 2007) but is of limited applicability to LMICs given the strength of regulatory frameworks in these settings. With either established or growing corporate pharmacy retail sector in Mexico, Brazil, South Africa, Nigeria, Kenya, Uganda, India and The Philippines (Center for Health Market Innovations 2014 , IMS consulting group 2014, Lowe and Montagu 2009) , there is a need to understand the effects of these new organisational forms on the functioning of pharmacies and the implications for public health.

This paper is concerned with practices in pharmacy chains in urban Bengaluru, the capital of the State of Karnataka, South India. Recent years have seen the steady growth of pharmacy chains in India. There are estimated to be around 800,000 medicine retailers in India, with chains accounting for 4% of these but growing at a rate of 25% per annum (Northbridge Capital 2011, IMS consulting group 2014).

The research presented in this paper is nested within a broader mixed-methods study of Bengaluru's chain pharmacies, which included a standardised patient (SP) study comparing the quality of management of two tracer conditions at chain and independent pharmacies (diarrhoea and suspected TB) (Miller and Goodman 2017). The SP study showed that quality of care, as measured by adherence to treatment guidelines, was equally poor in chain and independent pharmacies. No shops managed the diarrhoea patient according to current guidelines and fewer than half for the tuberculosis (TB) case. However, chains sold

significantly fewer harmful and prescription-only medicines (POMs) for the diarrhoea patient compared to independent shops (ibid). The survey also revealed that whilst overall sales of POMs were high, sales of the more restricted H1[11] subcategory were low, with chains not selling any of these medicines.

Drawing on insights from economics literature, this paper uses a set of in-depth interviews to explore how and why the organisational structure of pharmacy chains may affect the quality of service provision, compared to independent pharmacies. Qualitative work focusing on what drives patterns of pharmaceutical use and the poor behaviours characteristic of pharmacy practice in India has been illuminating, but rare (Kamat and Nichter 1998, Das and Das 2006, Seeberg 2012), and has not explored the role of chains in this setting. To our knowledge, this is the first study of its kind in a LMIC.

Theoretical approach

Various bodies of theory provide insights into the study of pharmacy arrangements, such as those from neo-classical economics, industrial organisation and regulatory theory. Conventional economic analysis of pharmacy markets in LMIC typically focuses on the high likelihood of various market failures. Inappropriate prescribing of medicines can be associated with negative externalities (Laxminarayan 2003) and information is highly imperfect (Mushkin 1958). Further, the nature of information in health markets is asymmetric (Arrow 1963). Within the agency relationship that results, it has been suggested that providers do not always act as perfect agents; rather they influence demand for their own self-interest, trading off income against patient welfare (McGuire 2000, Morris, Devlin, and Parkin 2007). Fee for service (as in a pharmacy) is the provider payment system most associated with the resulting 'overserving' patients (Hennig-Schmidt, Selten, and Wiesen 2011, McGuire 2000).

Drawing on theoretical insights, we develop a set of hypotheses as to how chains could address some of these market failures. A prior literature review of pharmacy practice in low-middle income Asian settings identified regulation, knowledge and profit motive as three key determinants of pharmacy provider behaviour (Miller and Goodman 2016). Figure 1 presents

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[11] In India POMs are classified as either H, H1 or X. Under the Drugs and Cosmetic Rules 1945, Schedule H medicines should only be sold with a valid prescription from a doctor. In light of the high sales of these medicines in India without a prescription, Schedule H1 was introduced in 2013. The H1 list comprises of 46 medicines (mainly 3rd and 4th generation antibiotics and anti-tuberculosis medicines) and require that the identity of the patient, contact details of the prescriber and the name and dispensed quantity of the drug be recorded in a designated register. Schedule X comprises of a small number of narcotics and requires the pharmacy to retain the prescription for 2 years after dispensing.

these hypotheses detailing how being organised as a chain may influence these determinants. Enforcing regulation is costly and logistically difficult due to the fragmented nature of pharmacy retail in India. Through consolidation (in chains) regulation could be improved. First, state regulation could be aimed at central management structures; essentially, the regulator could make firms take responsibility for their branches. Second, firms may self-regulate in order to preserve brand identity and image. This may, for example, lead to greater presence of qualified pharmacists at the point of service delivery, who are currently often absent (Basak, van Mil, and Sathyanarayana 2009, Kamat and Nichter 1998). Several authors have alluded to the potential of such 'market-based' regulatory mechanisms within pluralised, unregulated markets where traditional approaches have failed (eg Ensor and Weinzierl 2006, Bloom, Standing, and Lloyd 2008). These reputation-based ways of delivering health care are argued to build trust and can, in theory, help to overcome the information asymmetry that characterises transactions in healthcare (ibid).

Another reason why quality may improve in a chain situation arises from the different incentive structures in place for pharmacy owners as opposed to managers. High-powered incentives exist when the profits of transactions flow directly to the parties involved (Frant 1996). In the case of independent pharmacy owners, the potential for higher profits provides incentives to behave opportunistically. A hierarchical structure (as in a chain) can attenuate opportunism because the incentives faced by the personnel working in the pharmacy are low-powered (if salaried). While chain owners themselves will have incentives to maximise profits, these incentives may not be transmitted directly to their frontline staff. This could improve some aspects of treatment in public health terms, as a number of poor practices have been found to be linked to profit maximising strategies (which require effort), for example, the sale of medicines with high profit margins (Miller and Goodman 2016). Other aspects of good practice, such as counselling, are effort intensive and these practices may worsen among employees of chain pharmacies with a tendency to shirk. Some economists suggest that incentive schemes are the key to overcoming these moral hazard problems (Hölmstrom 1979, Harris and Raviv 1979). Others argue that whilst incentives can improve efficiency, they do not necessarily maximise profits- the bonus required to induce high effort can be substantial and yield a lower expected profit than using a flat wage (Miller and Whitford 2007).

Figure 1: Hypothesised effects of pharmacy chains on quality of care provision
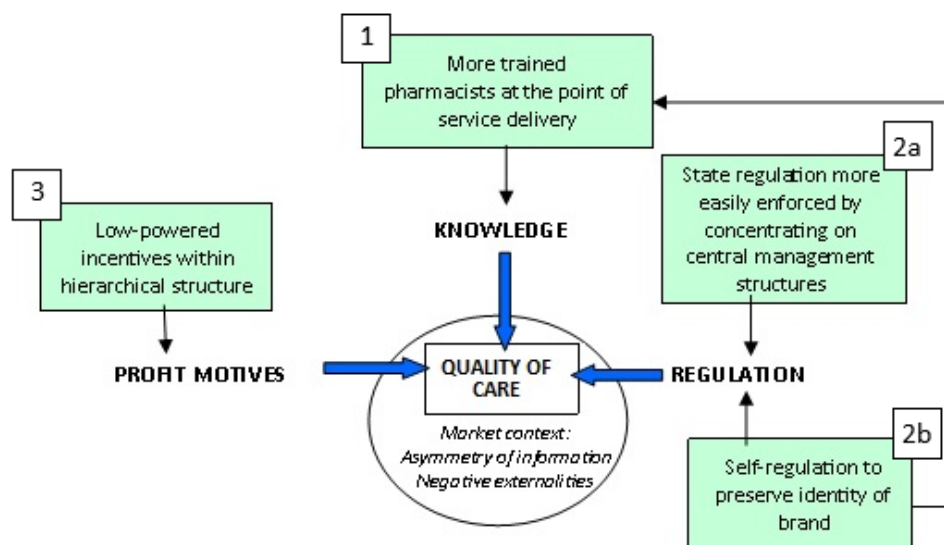
Methods

Between 2014 and 2015 we conducted 38 in-depth interviews with pharmacy employees and other stakeholders in Bengaluru, India. Bengaluru presents an appropriate setting for this research as a number of pharmacy chains are well established. We have used the interviews as a tool to test the hypotheses laid out above, an approach advocated by Miles and Huberman (1994). The framework informed both the development of the interview guides and the analysis, although we were open to any new ideas or issues that arose.

The interviewees were selected as a sub-sample from the pharmacies in our SP survey (see Miller and Goodman (2017) for full details). We used a list of all pharmacies in Bengaluru urban district, obtained from the Karnataka State Drug Control Department, as a sampling frame (we validated the list through three neighbourhood censuses which found it to be 97% accurate). The list contained 5135 independents and 529 chain shops deriving from 13 chains. For the SP survey we then selected a random sample of pharmacies, stratified as either 'chain' or 'independent', including shops from 8 chains- the largest 7 and one chain of the 2-5 outlet size.

We completed in-depth interviews with 9 chain senior executives working in these 8 chains. Additionally, we interviewed 14 staff working within chain pharmacy branches; 12 independent pharmacy owners (representing a geographical range across the city); and 3 key informants including the drug control department and pharmacy associations. Interviews were conducted by RM, with the help of a local research assistant, in English, Kannada or,

Hindi, depending on the interviewee's preference. Two chains did not give permission for us to speak with their branch staff. However, many of the staff we interviewed had previously worked in other chains so we asked them about their experiences as ex-employees. A few of the chain interviewees had previously owned their own shop and we questioned them about their experiences working in both environments.

Interviews with chain senior executives explored the underlying business model, ethos and structure of different firms, with a particular focus on staff recruitment, salaries and incentives. We also sought to understand mechanisms employed for controlling quality, performance management, and relationships with drug control bodies. The interviews with staff working in chain branches concentrated on the incentives faced and motivations for working in such a setting; their relationship with head office; and factors affecting their treatment behaviour. Interviews with independent pharmacy owners served as a comparison.

Coding of the interview transcripts was completed by RM in NVivo 11. The hypotheses in figure 1 were used to generate an initial set of pre-defined coding categories. In an iterative process, these codes were applied to the data, with data-generated codes added as they arose, and then the final coding frame was agreed by all authors. Deviant cases can be particularly useful for hypothesis testing and, as such, particular care was taken to look for these (Silverman 2010). As some of the same topics were discussed with both chain executives and branch staff, we sought to triangulate the data collected from both sources, particularly for those working within the same chain. Care was taken to focus on what interviewees did (ie through specific examples) rather than just broad statements about an issue; although when discussing sensitive issues it was found to be helpful to ask about how other pharmacies acted because interviewees were sometimes reluctant to admit themselves to practices that would be frowned upon.

Ethical approval was obtained from the London School of Hygiene and Tropical Medicine Ethics Committee, UK and the SOCHARA Institutional Scientific and Ethics Committee in Bengaluru, India. Verbal consent, witnessed by a fieldworker, was obtained prior to all interviews. Verbal, as opposed to written consent was obtained as providers in many drug outlets (or chain headquarters) tend to be very cautious of inspectors and suspicious of having to sign documents that may be used to identify them or their outlet/company.

Findings

Considering the lack of literature on pharmacy chains in LMIC, we begin this section with a description of the pharmacies studied and the context in which they operate. The findings that follow are then organised under the three determinants of practice - knowledge, regulation and profit motive. We visit each of the hypotheses (numbered in figure 1)

regarding how chains may affect these determinants and present the supporting or refuting evidence from our data.

<u>Knowledge</u>

Hypothesis 1: More trained pharmacists at point of service delivery?

Whilst we were not able to verify the proportion of chains and independent stores staffed by qualified pharmacists, senior management amongst all chains claimed that they employed a qualified pharmacist to work in each store. However, several of these informants later admitted that recruitment of pharmacists was a major challenge and this was not always possible. Some commented on a scarcity of qualified personnel in the labour market. Many pharmacy graduates were said to open their own store, find a position in the pharmaceutical industry, or pursue careers unrelated to pharmacy. Poor salaries and low social status reportedly drove people out of the profession.

Both chain and independent shop staff talked about renting the certificate of a qualified pharmacist, whilst the certificate holder worked elsewhere. Where a pharmacist was present, due to long opening hours, this was only for a portion of the day. Further, cover was seldom provided for pharmacist's day off and holidays.

"No, in some shops they will be there and in some shops they are not there. If the staff shortage is there, only Pharma Aide and experienced person will be there. Pharmacist will not be there." KI#20 chain pharmacy aide

"No, we don't have [DPharm or BPharm], we have taken licence of some other person…yearly we have to pay 30 thousand." KI#31 independent owner

Many interviewees talked about 'experience' and saw this to some degree as a substitute for formal qualifications. In fact, individuals with several years' experience working in independent shops were viewed by some as more knowledgeable than qualified pharmacists. A few interviewees cast doubt over the quality and appropriateness of pharmacy education. The syllabus was described as outdated, with an emphasis on subjects such as extemporaneous preparations that are no longer relevant to pharmacy practice today and missing others such as 'therapeutics'. The reality was that pharmacy personnel learn on-the-job. Experience was acquired through various means, including learning from the shop seniors or pharmacist, doctors' prescriptions and customer requests for medicine. It appears that knowledge accumulated from these avenues was not always in line with treatment guidelines but, once learned, these practices were enacted, reinforced, and passed on to the

next 'trainee'. Some chains provided training for new staff members but the focus of this was on interaction with customers and company procedures, rather than anything medicine-related (described in more detail below). As one chain in-charge said:

"Every day some problems some problem like somebody came and say me that give me Taxim-O 200mg [3rd generation cephalosporin]. Just I don't know what is the use of it. Ask the sir [pharmacist], after customer went off, 'Sir it's for what.' He says it's for fever, antibiotic. Just he is explaining and we are learning from that only." KI#8 chain pharmacy aide

Another employee describes how he came to learn about the medicines he sells:

"I am zero knowledge person in the beginning. I was in checking for one year in [large pharmacy chain] for audit department. We will go morning by 8, we check cash, and total A-Z stock will be checked. Morning 8 to 6 we do that. If any shortage is there, we have to inform to manager…When I started getting to know about medicine knowledge, in this audit we got to know the medicine name and what is the molecule. After that I could do in outlets. Then I worked for 2 years as normal employee. After I got promotion as in-charge and worked for 1 year.

RM: Did you get any training while joining?

Respondent: No training. That audit was training.

RM: After auditing when you joined the pharmacy store, was there any training at that time?

Respondent: No. I will observe and learn.

RM: What did you study?

Respondent: BCom in computers. It's a degree." KI#19 chain pharmacy aide

Interviewees in chains reported no legal requirement for a member of the senior management team to possess pharmacy qualifications and take responsibility for maintaining safety standards. As such, the clinical aspect of running a pharmacy within a chain was left to the pharmacist or in-charge and not a matter concerning senior management.

The overall picture we gained of staff working in chain pharmacies, and the knowledge they possessed did not appear to be any different to those working in independent pharmacies, where the narrative around qualifications and experience was similar to that in chains.

Regulation

This section examines hypotheses 2a and 2b, before turning to a data-generated theme around bribery.

Hypothesis 2a: State regulation is more easily enforced by concentrating on central management structures

We found that drug inspectors did not enforce regulation through chain headquarters. Within Karnataka state, areas are divided into 'circles' (geographical areas comprising of several postcode zones). Bengaluru has 6 circles with an assistant drug controller (ADC) assigned to each. Under the ADC are 2-3 drug inspectors. ADCs and drug inspectors each take responsibility for a number of postcodes within the circle and are required to inspect each pharmacy in their designated postcodes at least once a year. Staff working in shops most commonly reported that they were visited by drug control once every 6 months, although the range was from 3-monthly to annually. Several chains had shops in multiple circles and therefore interacted with numerous inspectors. The level of control in each area appeared to differ due to the individuals responsible for enforcement.

Most chains and the drug control department reported that there were no differences between the regulation of chain shops and independents. However, one chain executive felt that drug controllers came down more harshly on chains compared to independent pharmacies in event of a violation of the rules. Chains, he described, were treated with less leniency due to the processes and operating procedures in place.

Hypothesis 2b: Chains self-regulation to preserve the identity of their brand?

A host of methods were employed by chains in order to keep constant track of day-to-day operations in each store. The main strategies included regular shop visits from supervisors, area managers and more senior managers. Sales reports were usually sent daily, although some chains had information systems that enabled monitoring of real time sales. CCTV cameras were used to monitor the behaviour of shop staff and several chains sent mystery shoppers to their stores (and their competitors). The impression given was one of relentless monitoring. Chains that utilised CCTV claimed to watch their staff closely and staff corroborated that they were informed immediately of any sub-par performance.

While this initially might imply quality was being monitored, the overarching theme across all chain interviews, both with management and shop staff, was that ensuring a positive customer experience was the highest priority. Key areas of concern included customer service, ambience of the pharmacy, appearance of the staff, and ensuring availability of medicines. Management went to great lengths to guarantee that in-store staff were friendly and polite to their customers. On joining a chain, staff undergo training (ranging from half a

day to a few weeks). The majority of this concerned how to treat and interact with customers. Chain executives described how independent shop owners have excellent rapport with their customers and chains felt it was essential for their staff to match this, in order to attract and maintain customers. During shop visits, managers also checked that the store was neat and tidy and staff members were presentable.

Whilst there is irrefutable evidence that chains do self-regulate, the aspects of practice that they strived to control were not the same as those that concern the public health community ie sale of appropriate medicines and advice provision. We know from our SP survey that case management was poor in both independents and chains, which is not surprising given the lack of self-regulation of quality of care in chains. One chain Chief Executive Officer (CEO) explained what the training in his company involved:

"Yes, they need to dress well, they need to be able to communicate well so then their level of English needs to be good. Their level of Hindi needs to be good. So we employ people who can speak all the three languages because Bangalore is like a melting point right now. So you have people from all kinds of various cultures coming…Of course they need to follow the SOPs [standard operating procedures] *again. So that stresses on how well you treat customer, how you make the sale. How you finish the sale. So those are the things we train them before they start."* KI#24 chain executive.

Another chain executive vented his frustration regarding the lack of customer care he commonly observed on CCTV:

"Sometimes they will be seeing that Facebook and all, will be telling to them don't see that, then if the customer comes, they won't stand up and they won't greet the customers. They won't be any smile, they will be standing like a robot and they will be doing. We will be telling you have to do like this and all that. Because a smile is most important whenever a customer comes." KI#2 chain executive.

Alongside customer interaction, chains reported stock availability as the other crucial concern. Both headquarter and in-store chain staff explained that filling all items on a customer's prescription without any 'bounce' products (items on a prescription that are not available) was essential for customer satisfaction. In instances where required items are not available, there runs a risk that the customer will go elsewhere and not patronise the store for future transactions. Due to the large number of brands in the Indian market and the illegal nature of brand substitution (a different brand with the same active ingredient cannot be dispensed in place of the brand prescribed), this was cited as a key challenge. Some chains report sending mystery shoppers with prescriptions to monitor the 'bounce ratio'.

We observed that employees often appeared to buy into the goals and mission of the chain in which they worked. In interviews with in-store employees they used a lot of the same language and talked about the same issues as being important as the headquarter staff. These comments from a chain employee echo the concerns of the management:

*"**RM**: Why are people coming to [pharmacy chain], in what way are you keeping them happy?*

***Respondent:** Availability of medicines, and we used to welcome them with a smile, I used to check the order list of their medicines and if that medicine is not available I used to tell them will get that evening, we used to take their mobile numbers and call them after it."* KI#16 pharmacy aide.

There was little evidence of chains regulating the clinical aspects of pharmacy practice in their stores- for example, the accuracy of advice given or the appropriateness of medicines sold. A small proportion of chains did mention that they monitored sales of POMs without a prescription. One ex-staff member of a leading chain explained that staff were told explicitly not to make such sales. Another working in a smaller chain described how their head office sent mystery shoppers to purchase POMs in order to determine whether there was mis-selling in their pharmacies. These strategies may explain the relatively lower sales of POMs for diarrhoea patients in chains compared to independent shops in our SP survey (although this was still common in both shop types). However, only a minority of chains touched upon this issue and it was clear that clinical governance was not an area of interest to most chains, as shown by this conversation with one pharmacist:

*"**RM**: Do they monitor the medicines that you are selling or the advice you are giving?*

***Respondent:** Medicines?*

***RM:** In the sense, if somebody comes and says can we have something for diarrhoea or fever - do they check what medicines you give?*

***Respondent:** Yeah, yeah we will give common medicines for diarrhoea.*

***RM:** But do head office check?*

***Respondent:** No, no they won't. They don't know about this thing what to do –only I have knowledge. They don't know about that."* KI#25, chain pharmacist.

In our SP survey, we found that the more highly restricted H1 medicines were rarely sold, by either chains or independents. We were keen to understand how pharmacy staff understood and interpreted these regulations and how drug control authorities had achieved success in the control of these medicines. We found that around two-thirds of both chain staff and

independent interviewees were aware of the difference between H and H1 medicines. Most interviewees spoke about H1 medicines with an aura of seriousness. They did not give a great amount of detail but there was a general understanding that you simply did not sell these medicines. Several informants (from both chains and independents) confused schedule H1 and X. Interviewees reported that drug control are stricter on restricted schedules. Regulatory authorities confirmed that they were more aggressive in the control of these schedules and that they typically would suspend or even cancel the licence of a shop found to be selling such medicines. Sale of H medicines, however, was only punishable by a fine or brief shop closure. One chain pharmacy had a list of these prohibited H1 medicines on the wall for staff to refer to and another reported that there was a SOP in place for dispensing them. Asides from these two examples we did not find any major differences between the attitudes of chains and independents towards the more regulated medicine schedules.

Practices of bribery undermining regulatory system

Several interviewees talked about the bribing of drug controllers. Most of these reports came from independent shop owners, who talked candidly about this. One CEO of a chain touched upon this but his comments related to the industry in general, rather than any specific practices that occurred within his organisation. The impression given by these informants was that bribery was commonplace and organised in nature. One interviewee described how all pharmacies in his area were required to give a fixed amount (4000 Rs/$62) every 6 months and this was collected and passed on to the authorities by a local coordinator. In another area, fixed amounts were said to be collected monthly. Shopkeepers described how pharmacies that ran without a pharmacist had to pay a higher rate than those where a pharmacist was present. Interviewees explained that if bribes were not paid then drug controllers would be sure to find something they could penalise for during their next inspection visit. Payment of the bribe would ensure inspections were uneventful.

*"**RM**: How come so many medicines are sold without a prescription then?*

Interviewee: They get bribed. It's easy to bribe a drug controller. As long as you pay them they will not complain.

RM: So they don't regulate POM well?

Interviewee: They say they do but they don't. The entire supply chain pays the drug controller. Retail market is unorganised but bribing is very organised. There is a package you keep paying them and they don't come." KI#7 chain MD

Chain staff working in pharmacy branches did not talk about such practices. However, as employees, they would not have the status to authorise any bribes on behalf of the chain and

it is unknown whether such practices occurred at a higher level. Even if such practices were commonplace, it is unlikely that this information would be shared freely. We cannot be sure whether the practices are just hidden in chain organisations or whether it is a phenomenon restricted to independents.

Some independent shop owners said that they had never encountered any requests for payment from drug controllers. This may be because they did not wish to acknowledge this, being a sensitive issue; or because such practices are area dependent, based on where a pharmacy is located and who is responsible for enforcement. The workload of the drug control department was also mentioned. With so many shops to visit, one pharmacy owner explained how it would not be possible for them to check everything in one day.

<u>Profit motive</u>

Hypothesis 3: Low-powered incentives will arise within the hierarchical structure of a chain?

Independent pharmacy owners came across as more business-oriented than chain employees; and it was evident that their livelihood was closely linked to sales. Whilst in theory, we expected chain staff to be less invested in sales and profit, in practice they were incentivised by numerous targets and relentless pressure from head office. Most chains set monthly sales targets for each of their shops and some had other specific targets. These included the sale of 'private label' products (generic medicines or toiletries that are branded for that particular chain), number of home deliveries and 'customer related' targets. Chain staff reported that they were motivated to work hard to meet these targets, because the bonuses associated with reaching them were worth it; it gave them job satisfaction to feel they were performing well; and it showed they were fulfilling their customers' needs. In addition, some chains offered a monthly award for the branch with the highest sales and employees were keen to win this for 'name and fame'. Monthly sales bonuses were reported to be between 2,000 ($31) and 20,000 ($311) Rs, most commonly 10,000 Rs ($156) (divided between all store staff of which there were usually 4-5). In light of staff salaries, this was relatively substantial (around 25% of pharmacy aide and 10% of pharmacist salary) and hence motivating. Private label incentives were particularly strong with the bigger chains offering staff 10-12% of sales profits. The margins on these products were said to be 200-300%, which was very high compared with usual margins on branded products (which are preferred by customers) of around 15-40%.

When scrutinising the strategies of profit maximisation identified from our data, there appeared to be some differences between chain and independent shops. Independent shop owners reported selling POMs without a prescription because they did not want to lose

business. They admitted selling antibiotics because they had a good margin. Finally, they stated that they gave priority to products which they had purchased on offer e.g. on a buy X strips get Y strips free basis (these were said to commonly be antibiotics and combination cold and flu medicines). In terms of medicine sale choices amongst chain employees, there were several reports of trying to sell private label products in the first instance, which is not surprising considering the strong financial incentives associated with these products. Only one chain staff member talked about deliberately choosing items based on their profit margin. When pushed on how they achieved their sales targets, the strategies reported by chain staff tended to be more customer orientated. For example, if any prescription items were not in stock, they ensured those items were ordered and delivered to the customer's home that same day; they made lists of regular customers and called them to see if they needed to replenish their stock; and they talked to their customers 'like family members'. This is not to say that independent staff were not also mindful of their customers. In addition to offering a friendly, timely service, independent shops offered credit to customers who could not afford medicines and cut medicine strips into smaller quantities for poor clients. Both chain and independent pharmacy interviewees reported selling medicines that they believed would 'cure faster'- though medicine sales based on perceived efficacy is often not in line with standard treatment guidelines.

Discussion

We generated several hypotheses regarding how the chain structure might influence the knowledge of pharmacy staff; the way in which they are regulated; and the profit motives faced by employees, in comparison to independent pharmacy owners. In-depth interviews with a range of individuals working in chain headquarters and pharmacy stores, independent shop owners and key informants allowed us to explore these hypotheses. We have presented our results under distinct headings but, in practice, these three areas intertwine and influence one another. For example, most aspects of chain self-regulation relate to customer satisfaction. In turn, happy customers become repeat customers and this is therefore related to profit maximisation. Business strategies are inextricably linked to survival in the market, which is shaped by the intense nature of competition. Similarly, pharmacy staff understanding and interpretation of the different medicine schedules straddles the themes of knowledge and regulation. While our hypothesis driven approach allowed for a focused investigation of specific issues and we allowed for data generated themes to emerge, a more inductive approach could have led to a closer examination of these interconnections

A further limitation of this work was the selection of chain interviewees. In some instances, chain headquarters only approved us to interview employees in specified outlets. We assume

that in these cases, chain executives sent us to stores they deemed to have the most competent and qualified staff, which may not have been typical. Additionally, most chain executives dismissed any claims of bribery in the industry. This needs to be explored further to determine whether it is only a concern for independent pharmacies.

Our findings revealed that most of the theoretical mechanisms for quality improvement did not hold true in practice. An apparent shortage of pharmacists willing to work in the retail sector and the legitimising of 'experience' as a substitute for qualifications, meant that not all chains were operating with a qualified pharmacist (akin to independent shops). Regulation of chains differed little compared to independent shops, and the authorities did not direct their efforts towards chains' central management structures. Further, chains did not self-regulate aspects of quality that concern public health advocates. A small subset of chains took action towards monitoring the illegal sale of POMs without a prescription but as one chain managing director explained, "bringing ethical standards to corporates- that is lacking currently" KI#7. In terms of self-regulation, chains were myopically preoccupied with customer service and satisfaction. Additionally, the pervasive nature of bribery in the sector was a barrier to effective drug control. Whilst we hypothesised that chain employees face low-powered incentives, in fact this was not the case because in addition to salaries there were lucrative sales targets and unyielding pressure to improve sales figures. Profit maximisation, in itself, is not necessarily a problem, but it has previously been linked to poor and harmful practices in the pharmacy context (Miller and Goodman 2016). Profit maximising strategies of chains seemed to be more customer centirc compared to independent pharmacies- which tended to focus on medicine sales. The latter is more of a concern from a public health perspective because when medicine sale choices are driven by profit considerations, patient safety and clinical needs can be compromised.

Policy implications and potential of chains

It was evident from our study that pharmacy chains are primarily business entities and their main concern is increasing sales and turnover. Perhaps unsurprisingly, the aspects of quality that chains focussed on were those that are observable to customers- the friendliness of staff, cleanliness of the shop and the availability of medicines ie perceived quality. Asymmetric information about the technical quality of care (from a health perspective) disincentivises chains to monitor and improve it. Patients are, in most cases, lacking perfect information regarding the treatment and advice they require, and therefore judge 'quality' based on what they can see and chains are sensitive to this.

Whilst the current emphasis of chains is on customer experience, the methods in place to control staff behaviour on the shop floor are undeniably extensive and effective. One could

therefore argue that chain pharmacies have the potential to use this established strong influence over staff behaviour to engender health improvement. However, this is likely to require outside engagement in this principal-agent relationship- for example, by external regulation. Others have written extensively about the disconnect between government aspirations to enforce regulation through administrative and bureaucratic controls and the realities of highly unregulated private health markets in LMICs, including India (eg Bloom, Henson, and Peters 2014, Sheikh, Saligram, and Hort 2013, Bloom, Standing, and Lloyd 2008, Ensor and Weinzierl 2007, Peters and Muraleedharan 2008). Some propose a more active role for civil society, the media and provider organisations in order to realise the potential of consumer and market-oriented regulatory approaches in a context of government regulatory failure (Peters and Muraleedharan 2008). Yet our SP survey showed that not a single chain shop sold H1 medicines and our interviews confirmed that penalties from drug control for this offence were harsh. This indicates that external regulation can be effective in certain circumstances, and relatively more effective through chains that can successfully control treatment behaviours of their staff. There may therefore be potential to extend tighter regulatory control to other elements of care provision, by harnessing chain management structures.

However, currently there remains a distinct lack of clinical accountability among chains. Pharmacists or in-charges were not answerable to any senior management figure regarding their clinical actions. The presence of a pharmacist on the senior management team to take responsibility for patient safety and hold staff to account for their actions (as in some other countries), in a clinical sense, was absent. Pharmacy legislation does not appear to have kept pace with organisational change, and clinical governance in the sector warrants attention. Further, interviewees did not appear to possess a sense of professional identity. Others have noted that professional standards are lacking in India and suggest that state pharmacy councils could do more to improve the situation with continuing professional development (CPD) activities and guidelines for practice (Adepu and Nagavi 2009). Chains would be in a position to oversee and enforce CPD activities of its staff, or even provide clinical training.

Conclusion

Chains are expanding rapidly in India and elsewhere in Asia, South America and Africa. Going forward, there is interest in the potential of pharmacy chains in LMIC as a solution to the substandard practices that typify retail pharmacy in these settings. Up until now, there has been no empirical evidence of whether and how these chains do enable quality improvements. We have found that, in their current state, expectations for quality improvement were not in evidence. However, the existing architecture and the influence they

exert over their staff offers opportunity for intervention and a potential focal point for regulatory bodies, meaning that chains could prove to be a vehicle through which to affect change in the sector in future. However, this requires a realistic attitude to the company goals and incentives such private sector organisations face, which are not usually aligned with public health needs.

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PART IV: DISCUSSION AND CONCLUSION

8 Discussion

8.1 Introduction

This PhD set out to better understand the effects of chain pharmacies on the functioning of Indian pharmacies, compared to independent pharmacies, and the implications for public health. To inform this work, I conducted an up-to-date, systematic literature review examining the performance of independent pharmacies in low and middle income Asian settings (Miller and Goodman 2016). This provided a comprehensive overview of the status quo. The review included over 50 papers from 14 countries, with the most research coming from India and Vietnam. I found that history taking was insufficient; of particular concern was the lack of enquiry about danger signs that would indicate a more serious underlying condition. Whilst minor ailments can be managed in the pharmacy environment, some conditions (or symptoms of conditions) presented at the pharmacy require examination, diagnostic testing, or POMs and therefore their management is outside the remit of a pharmacist's expertise. In these cases, clients should be referred for medical attention, yet many patients were reportedly 'treated', rather than referred. The sale of POMs without a prescription was a common phenomenon in all 14 LMI Asian countries included in the review. Worryingly, antibiotics were reported to make up between a fifth and a third of all purchases. In addition, medicine sales were commonly clinically inappropriate and frequently sold unlabelled, outside their original packaging. Finally, medicine sales were reportedly accompanied with limited counselling and advice provision.

As part of the same review, I also sought to understand what the key determinants driving these poor practices were. From the literature, I was able to identify three important factors, namely profit motives which may influence pharmacy personnel, knowledge, and the regulatory environment. Drawing on economics literature I then generated a set of hypotheses regarding how being organised as a chain may influence these determinants, and hence performance. I hypothesised that the following key behaviours may differ within the chain structure and lead to potential quality improvements: (i) employment of qualified staff; (ii) ability of government authorities to concentrate regulation on central management structures; (iii) propensity for self-regulation; and (iv) potentially lower-powered incentives for chain employees, compared to independent owners. I then extended this thinking to the potential effects on other public health concerns, including the price, quality of medicines,

and access. Chains could be argued to have the potential to reduce prices by exploiting scale economies and enjoying buying power in the market; and improve drug quality through shortened supply chains and improved medicine storage capabilities. In terms of geographical access, I hypothesised that chains were unlikely to expand out of urban centres. I used these insights to create a set of hypotheses (figure 1, chapter 3), which provided the theoretical underpinning for the programme of work that followed.

In this discussion, first I provide a summary of the results and situate my results within the existing literature; I then explore the limitations of the work, examining the scope of the research and methodologies utilised; I reflect on the generalisability of the findings and then highlight the contribution of this thesis. Finally, I consider the policy implications of this work and present concluding remarks.

8.2 Summary of findings and comparison with the literature

This section provides a summary of the empirical research findings, in light of the specific objectives initially laid out; it also situates the findings within the context of previous relevant research.

8.2.1 Objective A: To compare the quality of case management (of two tracer conditions) at chain and independent pharmacies

As shown in chapter 5, my SP survey revealed that the management of suspected tuberculosis and childhood diarrhoea was equally poor at both chain and independent pharmacies. I found no significant differences in terms of history taking between chains and independents for either case. Fewer than 10% of both pharmacy types asked a single question to the parent of the child with diarrhoea; and for the suspected TB case this figure was around one fifth for chains and independents. Advice provision was similarly limited, again with little difference between pharmacy types. For example, only 1% of chains and 1.7% of independents advised the SP that TB treatment was available free of charge from the hospital. Similarly, for the diarrhoea case, of pharmacies which did not initially refer the SP (59% of chains and 63% of independents), less than 1% advised to visit a doctor in case of any danger signs.

In terms of treatment recommendations, there were no significant differences between pharmacy types for the suspected TB case. 43% of chains and 45% of independents managed the case correctly (referral without selling antibiotics or steroids); antibiotics were sold by 17% and 16% of chains and independents respectively. Overall, management of the diarrhoea case was of poorer quality. Not a single pharmacy managed the SP according to national and international guidelines (sale of ORS and zinc in the absence of antibiotics,

antidiarrhoeals or antispasmodics). Disappointingly, rehydration therapy was only recommended by 12% of chains and 10% of independents. Chains did, however, compare favourably to independent pharmacies in terms of harmful medicine (antibiotics and antidiarrhoeal) sales (35% vs 48%, p=0.029) and sale of POMs without a prescription (37% vs 49%, p=0.048).

These findings paint a depressing picture of the management of both a minor ailment and a more serious condition requiring referral in the pharmacy setting. There is a growing body of work that has used SPs to assess the quality of medical care in India's private sector (eg Das et al. 2012, Das et al. 2015, Mohanan et al. 2015, Satyanarayana S et al. 2016). These studies have covered a range of conditions, including diarrhoea, TB, angina and pneumonia, but the results are unanimous: regardless of type of practitioner, facility, or qualifications, management appears to be poor. Of the aforementioned SP studies, only Satyanarayana and colleagues studied quality of care at pharmacies; they assessed the management of TB in three urban areas (Delhi, Mumbai, and Patna). The results of their study across the three cities are in line with my findings from Bengaluru - overall history taking was poor with patients not being asked relevant questions, and referral for medical attention was inadequate.

Following the publishing of my SP results, I was invited to write an editorial piece, together with investigators from the Satyanarayana et al study, examining the results from both papers (this paper can be found in Appendix 6). From this work, it emerged that management of the SP varied according to the certainty of the diagnosis. The more apparent it was to the pharmacist that the patient had TB, the higher the proportion of shops that referred the SP. Where the SP presented only with cough and fever (and no explicit mention of TB), the referral proportion was 16%; in my study where the SP presented with symptoms and a suggestion of TB (as indicated by the relative with confirmed TB) 46% were referred; and in Satyanarayana et al's other case where SPs presented with a positive sputum report, the proportion was 67%. This showed that pharmacists did deviate from accepted norms when diagnosis was unknown or uncertain, but their management dramatically improved when diagnoses were clearer. One can conclude from these findings that a pure profit motive, whereby pharmacists wanted to sell medicines to clients at all costs, is a poor explanation of observed behaviour (Miller, Das, and Pai 2018). The other important finding from both studies is that pharmacists did not sell first-line anti-TB drugs OTC, and sale of the more tightly controlled H1 medicines was rare (for all the TB cases and my diarrhoea case). This indicates that the enforcement of the H1 schedule has been effective in these urban settings.

8.2.2 Objective B: To compare the price of consultations (for two tracer conditions) at chain and independent pharmacies

On examining the prices of medicines purchased for each case (chapter 6), I observed that after controlling for auditor effects chains were 23% cheaper for the diarrhoea case (p=0.01). Chains were found to undercut the MRP of the diarrhoea encounter, on average, by 1 Rupee, compared to -0.17 rupee for independents (p=0.005). Further, chains sold fewer antibiotics, which were associated with higher encounter prices.

Bennet and Yin (2014) also studied the effect of chain entry on price and found that independents reduced their prices in response to increased price competition from chains. Chain prices were initially 6% lower for two antibiotics (ciprofloxacin and amoxicillin), but prices at independents fell by a non-significant 2-4% after chain entry; further analysis revealed that for non-national brands the reduction was a significant 12-15%. The lack of consideration of such spillover effects in this thesis is discussed under methodological limitations in section 8.4.2 below. If chains are able to achieve a given medicine quality at a lower cost than independents, it is likely that, in the long run, they will dominate pharmacy markets in India (Douma and Schreuder 2008).

8.2.3 Objective C: To assess the socioeconomic status of clients shopping at chain and independent pharmacies

Using an asset index to assign exit interviewees to wealth quintiles, in chapter 6 I showed that the chain clients in my sample were significantly wealthier than independent pharmacy clients. Comparing the clients in my sample with the general population revealed that both groups (chain and independent customers) were wealthier relative to the general population. This was evidenced by the proportion of clients in the top wealth quintile- 20%, 45%, and 67% for the general population, independent clients, and chain clients respectively (Chi^2 tests showed differences between each of these groups to be significant (p<0.001 for all tests)). In terms of educational attainment, independent clients had a similar profile to the general population, and chain clients had a higher educational status. 79% of chain customers had reached 'secondary school' or 'higher than secondary', compared with 60% of independent customers and 61% of the general population. These differences in education between chains and independents, and chains and the general population, were both significant, p<0.001. Differences in the wealth and education profile of chain and independent clients remained after conducting the same analysis on a set of pharmacies matched by area (only including chains and independents within 1km of each other). This suggests that wealthier and poorer clients are self-selecting chains and independents respectively.

Given that pharmacies are private service providers, it is perhaps not surprising that the customers in our sample were wealthier relative to the general population. Whilst there is no specific literature on SES of chain customers in LMICs to compare my findings to, there is some research on the effect of social franchises (which use the principles of commercial franchising to fulfil social rather than financial goals) on equity of access. A number of evaluations have found these services to favour the better-off. (Shah, Wang, and Bishai 2011, Hennink and Clements 2005, Haemmerli et al. 2018, Viswanathan, Behl, and Seefeld 2016). However, these services are not comparable with chain pharmacies because joining a social franchise is dependent on both the goals of the NGO running it, and how franchisees believe they can benefit. Further they tend to be donor led in terms of standards and equity. It is therefore hard to draw parallels between these two very different business models. It may be that the urban poor in Bengaluru favour informal providers over registered pharmacies and physicians. There is evidence for this in other parts of India (Bloom et al. 2011, Gautham et al. 2014, George and Iyer 2013).

There is the possibility that chains or franchises are in some ways off putting to poorer groups. In terms of appearance, chains in my study were more likely to have a more high-end, sterile feel including closed shop fronts, air conditioning, bright lighting and neatly organised shelving units. This is in comparison with independent pharmacies, most of which had an open on-the-street frontage and were less organised. Further poorer clients may choose independents based on their willingness to offer credit facilities; and there is the possibility that wealthier clients are more sensitive to quality (processes of care and medicine quality). Alternatively, there may be other explanations for the differences observed in client mix, such as familiarity with staff, and this would be an interesting area for further research.

8.2.4 Objective D: To explore how and why the organisational structure of pharmacy chains may affect the quality of service provision and prices of medicines, compared to independent pharmacies

8.2.4.1 Quality of service provision

As presented in chapter 7, through a set of in-depth interviews with key informants, I found that most of the theoretical mechanisms for quality improvement laid out in chapter 3 did not hold true in practice. Few differences were identified between chain and independent organisations in terms of qualifications of staff, regulation enforcement, and financial incentives. It was reported that, akin to independent shops, a number of chain branches operated without a pharmacist. Drug control authorities did not regulate chains any differently, despite the possibilities of utilising the hierarchical structure in place. Further, reportedly widespread bribery undermined the drug control process. In the face of profitable

sales targets and constant head office pressure to increase revenue, chain employees did not appear to face significantly lower-powered incentives than their independent pharmacy counterparts. However, I did find differences in the profit maximising strategies of chains and independents, the former being more customer focused, and the latter more profit driven. I had also anticipated that chains may self-regulate to preserve brand identity and image. Whilst I observed that chains exerted strong influence over behaviour of their staff, they did not control aspects of quality that are of public health concern. Rather, their main concern was customer service and satisfaction.

It is unlikely that a change in the priority of self-regulation will occur without external regulation. Chains are first and foremost business entities, and in order to increase business and maintain a healthy customer base, they concentrate their attentions on aspects of quality that customers can observe (eg friendliness of staff and availability of medicines). Chains have no incentive to self-regulate technical quality because, due to information asymmetries, this is not something most customers can observe. In some countries, regulation of medical practitioners is delegated to professional organisations. I found that the interviewees did not appear to have a strong professional identity and others have noted that professional standards are lacking in pharmacy services in India (Adepu and Nagavi 2009). Dua and White reported that pharmacists interviewed in their study of antimicrobial use (in India) saw themselves as businessmen rather than professionals (Dua, Kunin, and White 1994). This view is reportedly shared by the public, other healthcare professionals, and even the government (Basak, Arunkumar, and Masilamani 2002, Sachan, Sachan, and Gangwar 2012).

Others have reflected on the disconnect between regulatory strategies and the realities of health markets in India and LMICs more generally (Bloom, Henson, and Peters 2014, Peters and Muraleedharan 2008, Bloom, Kanjilal, and Peters 2008, Ensor and Weinzierl 2007, Sheikh, Saligram, and Hort 2013). In their study of the architecture of health regulation in two Indian states, Sheikh and colleagues (2013) highlighted widespread gaps in both policy design and implementation with this mixed (public and private) health system. They found that implementation shortcomings were underpinned by inadequacy of human and financial resources; ambivalence of regulatory staff regarding the roles of their agencies; and infiltration and dominance of private sector interests within regulatory institutions leading to concerns of regulatory capture.

8.2.4.2   *Price*

Through the qualitative work, it was reported that the majority of chains offered discounts on medicines of up to 10%. These discounts were not fully captured by the SP survey, because

the SPs were unknown, first-time customers. Chains tended to apply discounts to the medicine bills of regular customers (or in some cases just those who signed up to a loyalty scheme). Discounting at independent stores was reportedly not the norm and was said to be ad hoc; usually owners only agreed to discounts in situations where customers pushed for one. The discounts on medicines offered by chains were made possible due to bulk purchasing and realising efficiencies in the supply chain. As a result of the fixed MRP, aside from discounts, the only other way for pharmacies to reduce medicine prices was to substitute cheaper brands (ie non national brands). It was not possible to tell from my quantitative analysis the extent to which this occurred. I learned from the interviewees that some of the larger chains offered their own line of 'private label' medicines (essentially generics branded for a particular pharmacy). These medicines were reportedly cheaper for customers than national brands and also yielded a greater profit for the pharmacies, hence staff were incentivised to sell such products.

In Bennet and Yin's (2014) study of chain entry into local pharmacy markets in Hyderabad, they found that customer traffic in control markets (where no chain entered) initially increased by 25%, yet it stagnated in markets with chain entry (treatment markets). Further, two years following chain entry, 96% of independents remained in control markets, compared with 91% in treatment markets (both results were significant). These results are in line with the grievances of independent owner interviewees who took part in the study. They expressed profound concern over the advent of chains, in particular the discounts they offered and many relayed how their customer traffic had reduced.

8.3   Contribution to knowledge

To date, research on the effect of chain pharmacies in LMICs has been limited. My literature review found only 5 prior studies in this area; two covering the sale of abortifacients in Mexico, looking at pharmacy type as a potential characteristic of selling such medicines (Billings et al. 2009, Lara et al. 2011); one using a quality indicator tool to assess five dimensions of quality in Thailand at both chains and independents (Arkaravichien, Wongpratat, and Lertsinudom 2016); one looking at equity of pharmacy distribution in South Africa (Ward et al. 2014); and a final study investigating the effect of chain entry on the price and quality of medicines sold at independent pharmacies in India (Bennett and Yin 2014). This thesis adds substantially to this small body of literature and is the first piece of work to consider comprehensively the overall public health implications of chain pharmacies in LMIC settings.

The thesis presents the first results from a LMIC for a number of outcomes relating to chain pharmacies. Whilst the work from Mexico used SPs to ask for misoprostol over-the-counter,

my SP work compares the quality of all aspects of case management at chain and independent pharmacies, including history taking, treatment choices, and advice provision. I also provide data on the prices of these encounters, where Bennet and Yin's work only collected prices for individual medicines. My exit interviews shed light on the type of customers (in a socioeconomic sense) served by pharmacy chains in India, an area no prior research has investigated in India or other LMICs. Finally, this is the first study to employ qualitative research methods to attempt to gain an understanding of how and why chains might affect public health outcomes of interest, specifically quality of care and prices of medicines.

8.4 Limitations

8.4.1 Scope of outcomes investigated

Whilst the hypotheses presented in chapter 3 laid out the potential mechanisms by which chains may affect quality of care, price of medicines, quality of medicines and access, some of these outcomes were explored in more detail than others. The following section discusses the scope of what this thesis did, and did not cover in relation to those four outcomes.

8.4.1.1 *Quality of care*

The main focus of this thesis was on quality of care, as measured using standardised patients. Essentially this captured the quality of case management of an unknown individual for my two tracer conditions, childhood diarrhoea and suspected tuberculosis. SPs were chosen because they are considered the gold standard in terms of quality measurement and they overcome a number of methodological problems associated with other methods (Das et al. 2012). SPs provide accurate data on how these conditions are managed in everyday life and the standardised nature of the cases allows for direct comparison (Madden et al. 1997). Quality of care is, of course, a multidimensional concept and there have been several attempts to measure it in the community pharmacy setting (mainly for high income contexts), using various instruments (Halsall, Ashcroft, and Noyce 2008). These instruments have had varied intentions, measuring clinical governance systems, organisational culture and maturity, safety climate and systems, effectiveness of pharmacy services, or patient feedback (ibid). Akin to these other instruments, I acknowledge that this research does not measure quality comprehensively, rather it concentrates on aspects related to safety and effectiveness. Further, there are important aspects of these dimensions that the research does not capture, for example, accuracy of prescription dispensing; communication; drug labelling, packaging and nomenclature. I also recognise that customers seek care at Indian pharmacies for a number of conditions (Evans and Lambert 1997, Lalchhuanawma and

Murhekar 2012, Nisula 2006, Seeberg 2012), and the results of this thesis only shed light on the management of two of these. However, similar patterns, such as limited history taking and advice provision, are likely to be consistent across consultations for various ailments.

As discussed in chapter 2, the SPs captured the quality of the process of care, as opposed to the other dimensions (structure and outcomes) discussed by Donabedian (Donabedian 2005). Initially, I also planned to collect data on inputs of care (number of personnel, qualifications of staff, presence of refrigerator and power backup etc) through a survey of pharmacies. Unfortunately, this was not possible due to the unwillingness of chains to participate in such a study.

8.4.1.2   Price

Using the SPs I was able to measure the price of encounters for suspected TB and childhood diarrhoea at both chains and independents. Due to the heterogeneity of medicines recommended for these conditions, this work did not compare the prices of like-for-like medicines across pharmacy types. I was able to show, however, that pharmacies adhered to MRPs, indicating that there was limited scope for price variation. Measuring the price of whole encounters, as opposed to the prices of specific medicines, provided a holistic and realistic picture of the effect of chains on medicine price. Additionally, I was able to collect detailed information around discounting from my qualitative work that would be missed in any purely quantitative study.

8.4.1.3   Quality of medicines

The presence of substandard and counterfeit medicines, particularly in LMICs such as India, is an area of growing concern (World Health Organization 2017a). Counterfeit drugs are the result of deliberate criminal activity and have been defined as those 'deliberately and fraudulently mislabelled with respect to identity and/or source' (World Health Organization 1999). Substandard drugs are essentially those that do not meet the pharmacopoeial standards set for them, in terms of quality, purity, strength or packaging (Newton et al. 2006). Such products are an inevitable consequence of inadequate local regulatory controls and lack of good manufacturing practices (ibid). This is a particular challenge in India, where there are around 8000 local manufacturers. A number of studies have highlighted the presence of substandard medicines both circulating in and originating from India (Atemnkeng, De Cock, and Plaizier-Vercammen 2007, Laserson et al. 2001, Minzi et al. 2003). Substandard medicines pose a greater public health risk than counterfeits (because they are much more common) yet most efforts to address these issues have focused on the latter; this is in part because pharmaceutical companies, threatened by such products, have invested energy in tackling the problem (Caudron et al. 2008). The same incentive does not

apply to substandard medicines, hence the problem remains both poorly quantified and ill addressed (ibid).

Whilst the qualitative work in this thesis touched on the ability of chains to have greater control over their supply chains and hence potential for improved drug quality, it was beyond the scope of this thesis to study this in detail. I was unable to sufficiently verify how storage of medicines differed for chains and independents. It would have been valuable to compare the pharmacopoeial quality of medicines sold at chains and independents but unfortunately this was outside the scope of this research in terms of both time and funds available). However, others have collected such data elsewhere in South India and found that the pharmacopoeial quality of MedPlus' (one of India's leading pharmacy chains) medicines were initially (when a chain first entered a local market) 6% points higher compared to medicines sold at independents. However, over time the quality of medicines at independents improved until there were no differences between pharmacy types, although this higher quality came at a greater cost to the independents (Bennett and Yin 2014).

8.4.1.4   Access

Definitions of access are plentiful and varied, but there is consensus that it is related to the timely use of services according to need. Peters and colleagues present a comprehensive framework for assessing access to health services, which is based on established descriptions of access and takes into consideration both supply and demand elements (Peters et al. 2008). The framework includes geographic accessibility - the physical distance that must be travelled to reach care; availability - appropriate care available for those who need it, for example a pharmacy having a qualified staff member or the required medicines in stock; financial accessibility- the relationship between the price of services and clients' willingness and ability to pay for them; and finally, acceptability- the extent to which providers are responsive to users' cultural expectations.

Whilst I proposed that there was potential for chain pharmacies to affect access, this was not tested. I hypothesised that chains may restrict their business to urban areas. However, my study site only included an urban area so this is not something I was able to measure. I enquired about company expansion plans in the in-depth interviews and some chains were already operating in or had plans to move into tier II and tier III settings[12]. I posited that an interesting geographical analysis would be to look at chain pharmacy concentration by wealth of areas (at the ward or postcode level). Using the GPS location of chains I was able

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[12] India's cities are categorised according to their development, population and infrastructure. India's tier I cities include the major metropolises- Delhi, Bengaluru, Chennai, Kolkata, Mumbai, and Hyderabad. Tier II cities include smaller hubs, such as Surat, Jaipur, and Pune. Tier III cities include Madurai and Coimbatore.

to see that they appeared to have a presence across most areas of the city, rather than being limited to specific areas but I was not able to identify a suitable proxy measurement for wealth at the ward or postcode level.

8.4.2 Methodological limitations

8.4.2.1 Standardised patient survey

Whilst standardised patients are seen as the gold standard in terms of measuring quality of medical care, they still raise a number of methodological issues. The SP method provides details on how an unknown, first-time client is managed but it is unclear the extent to which this may differ from the management of regular customers. It is also hard to know whether the SP presentations were representative of typical pharmacy encounters. The exit interviews collected data on the reason interviewees were visiting the pharmacy that day. The most common reason was to fill a prescription (57% of chain and 42% of independent clients). 37% of chain clients and 36% independent clients reported that they were purchasing medicines without a prescription; 10% and 9% of chain and independent clients respectively had visited to obtain health advice; and these figures were 13% (chain clients) and 16% (independent clients) for purchasing fast moving consumer good (eg toiletries). It is unclear whether those purchasing medicines without a prescription sought the recommendation of the pharmacist or whether they knew a priori which medicines they wanted. Other studies, which have used observation to learn more about pharmacy practice in India, have reported that patients commonly request POMs by name, by showing a scrap of paper, or by bringing in an old sample (Greenhalgh 1987, Kamat and Nichter 1998, Saradamma, Higginbotham, and Nichter 2000). It would be interesting for future work to investigate how chains fare in terms of managing direct requests for medicines and filling prescriptions (accuracy and counselling).

In terms of the data collection, due to financial constraints the SPs presented both cases in a single encounter. They initially presented the details of the diarrhoea case (for an absent child) and on the completion of advice for this case they moved on to describing their own symptoms that were suggestive of TB. I am not aware of any other studies that have presented two cases simultaneously; usually SPs will present one case per pharmacy encounter. However, my results are in line with other studies that have presented either diarrhoea (Diwan et al. 2015) or TB (Satyanarayana S et al. 2016) as a standalone case in India and I therefore have no reason to believe that staff managed the two cases together any differently than they would have managed them in separate encounters. My work also shows different results for the diarrhoea and the TB case (there were fewer differences between

pharmacy types for the TB case compared to the diarrhoea one). This highlights the importance of including a range of conditions, where possible.

Whilst I used standardised guidelines against which to measure the quality of case management, there are still many potential ways to present the results. For the TB case, for example, the guidelines for pharmacists clearly stipulate that any client with suspected TB should be referred. Therefore, whilst referral or non-referral is an easily determined measure, the guidelines are of no help in categorising some of the other treatment strategies I observed. There is no universal agreement or guidance on which medicines should be categorised as 'harmful' or 'unnecessary'. For this I have drawn on the work of others (informed by expert panels) (eg Satyanarayana S et al. 2016) and my own clinical knowledge having previously trained and worked as a pharmacist. For the diarrhoea case, no pharmacy-specific guidelines were available and I had to adapt those aimed at 'physicians and other senior health professionals' by the WHO (World Health Organization 2005). Pharmacies in India, and elsewhere in LMICs, are widely used for a host of conditions of public health importance, including childhood diarrhoea which is a leading cause of under-5 mortality (Indian Council of Medical Research 2017, Kosek, Bern, and Guerrant 2003). It would arguably be useful to develop a set of pharmacy- specific guidelines for management of key conditions, not only to help improve the management of such ailments but also to provide researchers with a clear (and agreed) benchmark against which to measure practice.

The work of Bennet and Yin suggests that chain entry into a local pharmacy market leads to existing independent retailers lowering their prices and increasing their medicine (pharmacopoeial) quality (Bennett and Yin 2014). If a similar trend occurred in Bengaluru, with regard to spill over treatment quality improvements, this would imply that the measured effect of a chain on quality would be biased towards zero. Further, the price differences presented in this paper may underestimate the impact of chain entry on market prices. I did not have sufficient geographical data in order to determine whether the presence of a chain shop alters the behaviour or prices of nearby independents, but this would be an interesting area for future research. However, my review of pharmacy practice in Asia reported similarly poor management of childhood diarrhoea dating back three decades, ie before the advent of chains, indicating that the behaviour of independents has not seen any dramatic improvements in recent times (Miller and Goodman 2017).

8.4.2.2   Exit interviews

The exit interviews were relatively straightforward, methodologically; however, I have identified two potential weaknesses: uncertainties surrounding the response rate and the potential for responder or sampling bias, and the reliability of using an asset index to

measure wealth. With regard to the sampling of clients for the exit interview, researchers approached each client leaving the pharmacy with the aim of enrolling them in the study. Whilst researchers were supposed to record the number of clients who refused to participate, this was not recorded satisfactorily and, as a result, we cannot calculate the response rate. I found that customers in my survey were wealthier compared to the general population. I cannot rule out the possibility of non-responder bias if poorer customers were more likely to refuse to take part in the survey. There is also the possibility that, in busy pharmacies where a number of customers left simultaneously, researchers subconsciously approached richer looking customers for participation in the study, although there is no evidence to support this.

With regard to wealth measurement, the asset-based approach I have adopted is one alternative to using income and expenditure data, which are difficult to capture. Whilst this method has been widely adopted for the measurement of SES in a number of contexts, it has also been criticised. Howe and colleagues discuss the limitations of this approach, citing that PCA is not appropriate for use with discrete data and that the first principal component often only explains a small proportion of the total variation in asset data (only the first principal component is used to define the asset index given the aim is to construct a single wealth measure) (Howe, Hargreaves, and Huttly 2008). I acknowledge that this method may have its limitations, but it provided a rapid, simple and feasible way of collecting SES data. It also allowed for comparison with the general population given assets data are collected in the open-access DLHS.

8.4.2.3   In-depth interviews

One of the key limitations of my qualitative work was the selection of branch staff interviewees. Whilst I intended to speak to the staff working in the chain branches included in the SP survey, in practice, some chain executives did not allow us this choice; rather, they specified which branches I was allowed to visit. In these instances, I assume that I was directed to the stores where the staff were most competent and qualified. As such, these interviewees may not have been typical. However, this was not the case for all branch interviews and, as described in the methods, I also spoke to a number of ex-employees about their experiences in their previous companies. I assume that ex-employees would have spoken relatively candidly about their experiences in past roles, considering they were no longer affiliated with the companies.

Reflecting on the hypothesis-driven approach used, both strengths and weaknesses emerge. It arguably provided fruitful lines of enquiry and allowed for targeted investigation of specific issues. However, whilst my results are presented under distinct headings, in practice, the

issues of regulation, profit motives and knowledge both intertwine and influence one another. A more inductive approach may have led to a closer examination of these interconnections. Finally, whilst independent pharmacies spoke freely about practices of bribery, most chain executives dismissed such claims. Greater exploration of this topic is required in order to uncover whether this phenomenon is restricted to independent pharmacies, or whether it is also widespread amongst chains. It would likely occur at a high-up level between chain executives and senior drug control officials, rather than at the shop level. Through one-off interviews it was not possible to develop progressive informality over time which may have allowed for the collection of richer data on such a sensitive topic.

8.4.2.4   Data Gaps

Researching the private sector comes with unique methodological challenges. One of the major hurdles of this research was that chains did not allow us permission to conduct a general survey of chain branches. The purpose of this outlet survey was to collect representative quantitative data on characteristics of the outlets, their staff and prices and availability of key medicines (at both chain and independent pharmacies to allow for comparison). Had I been able to collect such data, I would have been able to investigate the association between pharmacy type and treatment behaviour whilst adjusting for potential confounders (eg regulatory inspection in the last year, provider experience, and qualifications). It would also have provided me with more general descriptive data on the two pharmacy types.

My results have sought to compare chains and independent pharmacies. A further area of interest would be the variation within the chain sector (as measured by size of chain). I explored the data with regard to chain size and no clear patterns emerged for key outcomes but my study was not sufficiently powered for sub-group analysis. This would be an interesting area for future research.

The focus of this body of work has solely been on providers, with little account for patient demand. It is important to acknowledge that the pharmacy interaction is two-sided and that the demand for medicines is an important determinant of pharmacy provider behaviour. For example, there is evidence that clients attribute quality to the mode of medicine delivery (Williams et al. 1999). Thus far, this thesis has not considered the impact of patient demand on pharmacy staff behaviour and quality of care. The SP method ensures that we have measured the quality of management of standardised case presentation. In real life encounters, however, providers may make treatment decisions based on what patients ask for, or based on what they believe patients want. In investigating supply and demand side factors influencing antibiotic use in China, Currie and colleagues (2011) conclude that, in

this setting, antibiotic abuse is 'largely a supply-side phenomenon'. Their work suggests that antibiotic misuse is mainly driven by financial incentives (Currie, Lin, and Meng 2014). There is scope for future work to investigate whether chain and independent staff respond similarly or differently to client demands.

Another facet of provider behaviour that has been shown to be important for physician behaviour is altruism. There is empirical evidence that doctors take patient benefit into their decision making, rather than simply maximising income at all costs (Kolstad 2013, Lagarde and Blaauw 2014). There is no clear hypothesis as to why pro-social motivation of chain employees and independent pharmacy workers would differ but this would be an interesting area for investigation.

8.5   Generalisability of the findings

This study was conducted in a single Indian city which raises questions over the extent to which the findings are generalizable to other metropolises where chains are concentrated. The findings are consistent with other studies that have used SP methodology to investigate quality of care for TB and diarrhoea in the private sector in India; although others have not included chains (Das et al. 2012, Mohanan et al. 2015, Das et al. 2015, Satyanarayana S et al. 2016). In terms of price and SES the literature offers little for comparison. Whilst some of the chains studied operate only in Bengaluru, others have presence in South India and even across the country. Chain staff in other cities likely face similar incentives and monitoring procedures. The regulatory controls governing the functioning of pharmacies are the same throughout India, and despite likely variation in state-level implementation, regulatory failure is reportedly widespread (Bloom, Kanjilal, and Peters 2008, Greenhalgh 1987, Kamat and Nichter 1998, Peters and Muraleedharan 2008, Seeberg 2012, Sheikh, Saligram, and Hort 2013). Given these likely similarities, I believe that my findings are likely to have relevance beyond Bengaluru and Karnataka. Further, the determinants of good and poor pharmacy practice have been found to be comparable across LMICs in Asia, Africa and South America indicating that my findings may potentially be applicable in these settings too (Goel et al. 1996, Miller and Goodman 2016, Ratanawijitrasin, Soumerai, and Weerasuriya 2001). Additional study is warranted in other LMIC settings where chain pharmacies are flourishing, to determine if and how their functioning differs to the Indian context.

8.6   Policy implications

Pharmacists have historically been absent from health policy discussions in India and the concept of engaging this cadre of health professionals for public health improvement has not

gained traction (Basak and Sathyanarayana 2009). Schemes to improve pharmacy practice in India have been limited to disease-specific initiatives and evaluation of such schemes has been limited (cf Gharat et al. 2007). Even within disease specific initiatives efforts to engage pharmacies in LMICs have been limited. For example, even after more than 10 years of public-private mix efforts for TB control, only 5-9% of pharmacies have been successfully engaged in promoting such efforts (Konduri, Delmotte, and Rutta 2017). Globally, the role of the pharmacist is undergoing a transformation from product and task centric (dispensing) to patient centric (advice, counselling, and provision of care), yet this shift is not yet underway in India. The latter is arguably more appropriate, given the extensive training pharmacists undergo, and their level of expertise. Mossialos and colleagues outline this change in paradigm in three stages: retailing of products; safety monitoring; and finally a public health role (Mossialos, Naci, and Courtin 2013). They cite that no country has reached the final stage, which involves a 'comprehensive role, including health promotion, prevention and disease management' but that some high-income countries are moving in this direction. They also acknowledge that the evidence base for the expansion of the role of pharmacists is limited and there is a need for research to evaluate any future developments in this arena. In light of demographic, economic and public health challenges, it is hard to ignore the potential that community pharmacists may hold in low- middle- and high-income settings.

8.6.1 Addressing pharmacy practice

This thesis revealed that the quality of management of two tracer conditions was poor at both chain and independent pharmacies, echoing the findings of the original literature review I conducted on performance of pharmacies in low and middle income Asian countries. The delivery of poor quality care at pharmacies is a health system issue that warrants attention. Diarrhoea and TB are both major public health concerns in India. Over a quarter of the 1.8 million deaths caused by TB in 2015 were in India (World Health Organization 2016). Early symptoms of pulmonary TB are vague, common, and persistent, leading those infected with the disease to seek care at local primary care providers (Kapoor et al. 2012). A study which tracked patient pathways to care in 13 countries reported that over 60% of the study population first sought care in the private or informal sectors, including pharmacies (Chin DP and Hanson C 2017). Improving the management of patients who present at pharmacies with TB symptoms could greatly contribute to control efforts, the success of which hinges on early diagnosis and appropriate treatment. The widespread mismanagement of diarrhoea is also a huge concern. Diarrhoea accounts for 23% of all deaths in children under 5 in South Asia, yet correct treatment with ORS could prevent up to 93% of such tragedies (Morris, Black, and Tomaskovic 2003, Munos, Walker, and Black 2010). Further the pervasive selling of antibiotics without a prescription is a major driver for the development of

antibiotic resistance, a problem that has been dubbed a 'global health security emergency' by the WHO (World Health Organization 2014). A study which tracked antibiotic consumption over a 10 year period (2000-2010) in 63 countries reported that use during this time has increased by 35% and that 76% of this increase was attributable to 5 countries, one of them being India (Van Boeckel et al.). In 2010, India was the world's largest consumer of antibiotics for human health (Laxminarayan and Chaudhury 2016). Tackling the irrational use of these medicines in pharmacies is paramount among efforts to tackle the global threat of antibiotic resistance

There are also a number of positive findings resulting from this work that I wish to highlight. Firstly, Bengaluru enjoys a well-developed network of pharmacy outlets, providing good geographical coverage and hence access to medicines for the city's residents. Moreover, the registration system appears to be effective, with nearly all outlets being registered and the drug control department holding up-to-date and accurate records of the city's pharmacy outlets. This is in contrast with many other LMIC settings where routine health information systems have poor coverage of the private sector and provider registration data are limited (Conteh and Hanson 2003). However, perhaps the most promising finding was the limited use of H1 medicines and the apparent effective regulation of this more recently introduced schedule. The OTC sale of antibiotics from pharmacies is an ingrained norm in so many LMICs that it may take considerable time and effort to bring the sale of such medicines under control. In the meanwhile, India's apparent success in introducing a hierarchy of drug control could hold lessons for other countries and prove to be a key component in the fight against antibiotic resistance. 24 antibiotics have been moved from the H to H1 schedule, including third and fourth generation cephalosporins, carbapenems, first- and second-line anti-tuberculosis drugs. and newer fluoroquinolones (Hazra 2014); and moreover, the penalties for flouting the regulations with regards to these medicines are more severe. SP work from this thesis and other studies has showed that H1 medicines were very rarely sold OTC in Bengaluru, Patna, Mumbai, or Delhi (Miller, Das, and Pai 2018). My qualitative work revealed that pharmacy staff were tightly bound by the implicit norms that restrict the sale of these medicines. Further, Laxminariyan and Chaudhury (2016) note that a number of retail pharmacy licences have been revoked following non-compliance with the regulations concerning the H1 schedule. However, they also caution that several important antibiotics, such as gentamicin and tigecycline, are not included in the schedule and that pharmacies may substitute for such medicines still under the H classification. Future work should investigate whether this is the case.

Categorising medicines into tiers is a recent innovation in public health and ties in with the WHO's 20th Model List of Essential Medicines, in which they have introduced three

categories of antibiotics, representing the biggest update to the antibiotic section of the lists' 40 year history (World Health Organization 2017b). This move in a bid to develop stewardship of antibiotics at the local, national, and global level sees antibiotics categorised as either 'access', 'watch', or 'reserve'. 'Access' antibiotics should be available at all times to treat a wide range of common infections; 'watch' antibiotics are first and second line choices for a small group of infections; and those in the 'reserve' group are to be saved as a last resort where all other alternatives have failed. Using such categorisation to inform tiered drug schedules is a policy option that warrants greater attention in settings that struggle with the sale of POMs OTC.

Finally, it is acknowledged that while the emphasis of this work has been on strengthening service provision. However in thinking about rational medicine use, it is also prudent to consider the demand side of the equation. Examples of strategies to address this include social marketing to tackle consumer lack of information; and creation of new institutions that provide consumers with more authority to challenge poor quality care (Mills et al. 2002).

8.6.2 Implications for chains

Turning to the future for chain pharmacies, it is likely that, due to their ability to provide medicines at a lower price compared to independents (with discounts), they will continue to expand their presence across India. If policy makers were interested in encouraging the development of chains, there are a number of regulatory or fiscal levers that could be set in motion to allow for this. These include tax breaks, relaxing licensing procedures, or liberalisation of foreign direct investment (FDI) for multi-brand retail trading (into which category the selling of pharmaceuticals falls). In 2012 the Government permitted FDI up to 51% of the equity of Indian entities engaged in such retailing (Kumar 2012). However, these investors are subjected to a host of conditions, including a minimum investment of $100 million, 50% investment in backend infrastructure, and 30% compulsory procurement of products sourced locally from small industries. In addition, they can only trade in cities and towns with a population minimum of 1 million (ibid). In January of this year the Union Cabinet approved 100 per cent foreign direct investment in single-brand retail but such relaxation has not yet been extended to multi-brand retail (The Hindu 2018).

However, based on current evidence time there is little justification to utilise such levers to encourage the growth of chains, on public health grounds, in India. The SP survey showed the quality of pharmacy practice at chains to be similarly poor to that of independent pharmacies. However, given the tight control that chains have over their branch staff, one could argue that chains could be a vehicle for more efficient or more effective quality improvement in the future.

I now turn to look at the (albeit limited) menu of options for improving pharmacy services in LMICs and reflect on whether chains may serve as a more effective vehicle through which to deliver some of these interventions (compared to independent pharmacies). Across other LMICs pharmacy intervention strategies have included training, peer review, accreditation, performance management, and social franchising (Chalker et al. 2005; Wafula and Goodman 2010).

Improving knowledge through training is the aim of most pharmacy interventions in LMICs (Miller and Goodman 2016, Smith 2009, Wafula and Goodman 2010). Chains may be better placed to deliver training more efficiently. I found that some large chains provided training to staff upon joining, although currently this does not include any clinical training. Where such a setup is already in place, this presents an opportunity to improve knowledge of the management of key conditions that may present in the pharmacy. However, as found in chapter 2, knowledge is necessary but not sufficient to improve pharmacy practice; hence this would need to be delivered alongside other initiatives (Miller and Goodman 2016). The structure of a chain may lend itself well to interventions which benchmark branches against one another. Qualitative interviews with branch staff revealed that they worked hard to achieve sales targets and strived hard to win monthly competitions for 'name and fame'. Performance management using 'league tables' and 'naming and shaming' have been used effectively in high income settings to improve prescribing behaviour of doctors working within a common organisation (Checkland et al. 2013). If targets were based on public health outcomes eg sale of POMs without prescriptions and following guidelines for the management of key conditions, rather than sales figures, staff may improve their prescribing behaviours.

8.6.2.1 Financial incentives

Pay for performance (P4P) has received much attention as an innovative strategy to improve quality in LMICs (Eichler 2006). It has been defined as the 'transfer of money or material goods conditional on taking a measurable action or achieving a predetermined performance target' (ibid). Recognising competing objectives (such as treating patients and the desire to maximise profits) and introducing dynamics that align provider motivations is at the heart of P4P. Most empirical evidence on P4P in LMICs concerns nationwide payment reforms (cf Powell-Jackson, Yip, and Han 2015); there is also a sizeable body of literature on the use of P4P mechanisms to health facilities and providers to improve indicators relating to child and maternal health (mostly in African settings), eg to increase institutional deliveries and childhood vaccinations (Das, Gopalan, and Chandramohan 2016). A review of these schemes found weak evidence for P4P's positive effect on child and maternal health outcomes and noted some negative effects on structural quality. Additionally, there were

reportedly issues around constant monitoring and evaluation needs (Chimhutu 2011). Further, Ssengooba and colleagues warn that such interventions must be planned to match the institutional and technical capabilities of the implementers (Ssengooba, McPake, and Palmer 2012). Essentially, chains are already successfully implementing P4P schemes with sales targets as their performance measures.

There are no existing models to implement P4P at the chain level, although a number of high-income countries have initiated schemes that pay pharmacies to deliver patient-centred services (Mossialos, Naci, and Courtin 2013). The aims of such an initiative would be to help more closely align the objectives of chains with public health goals. In thinking about the context of pharmacies in India, a number of challenges present. Namely, which indicators could be used and how they would be measured. In settings such as GP surgeries in the UK (which are subject to one the world's largest P4P schemes- the quality and outcomes framework) the details of each consultation are recorded on an electronic database making it possible to measure and make payments based on a number of clinical (as well as organisational) performance indicators eg percentage of patients with coronary heart disease who are treated with a beta blocker; or the percentage of patients with diabetes, on the register, in whom the last blood pressure reading (measured in the preceding 12 months) is 140/80 mmHg or less (Roland M 2004). Such clinical details are not recorded in pharmacies in LMICs, making the possibility of monitoring problematic. Sale of medicines would be highly challenging to measure, given that regulatory agencies are already overburdened, but referrals could be tracked, especially within the public system. For example, payments could be made for each patient with symptoms suggestive of TB who is referred into the system and, resulting in a positive sputum test. Inputs can be more tangibly measured, such as qualified personnel along with clear plans for and records of continual professional development; and having standardised guidelines in place for the management of key conditions and minor ailments, guided by India's public health priorities. However, inputs are poor proxies of quality of care in terms of diagnoses and treatment. There may be scope for an external agency to take on a monitoring role of such a scheme but this raises questions over sustainability.

8.6.2.2 Regulation

Perhaps the most obvious response to current challenges within LMIC pharmacy markets would be to focus efforts on strengthening the regulatory environment. While the pharmacy market has evolved, it is striking that the regulatory response has lagged behind and no modifications have been introduced in the light of new organisational arrangements, such as chains. For example, within the structure of chains, I noted that senior management teams lacked a trained pharmacist to take responsibility for patient safety and hold branch staff to

account for their clinical actions. This is not currently a legal requirement, but arguably should be (as in some other countries). Moreover, encouraging peer review and fostering an ethos of professionalism amongst staff within chains may go some way to improving the current situation. There is arguably scope for pharmacy councils to take a more active role in improving pharmacy practice. For example, they could advance continuing professional development activities and issue guidelines for practice. As long as pharmacists lack a professional identity, however, it seems unlikely that oversight by a professional body would bring about significant change in practice.

Currently, enforcement is typified by 'command and control' mechanisms of universal inspection and sanction but these methods appear to be ill-suited given limited resources, overwhelming numbers of providers, and rent-seeking officials. It may be possible to streamline external regulation through utilising the hierarchical management structure of chains. Any such developments should take into account the latest thinking in regulatory design, which includes alternatives to administrative and bureaucratic approaches (Black 2005, Braithwaite 2006). In addition to 'market supply-oriented' approaches, such as incentive schemes (mentioned earlier), Bloom and colleagues (2014) identify 'consumer or citizen-oriented' strategies such as consumer education and empowerment; and 'collaboration-oriented' efforts, for example partnerships between government, civil society actors, providers and technical experts to agree and set locally measurable and enforceable standards for performance.

Thinking from high income countries has proposed the idea of responsive regulation, whereby a hierarchy of enforcement measures, ranging from persuasion to licence revocation, are enacted. Braithwaite argues that LMICs with limited capacity may benefit from such an approach were it to be conducted by a network of government and non-governmental actors (Braithwaite 2006). Risk-based regulation is another proposed technique that aims to target regulatory actions according to the risk associated with the parties' behaviour (Black 2005). However, complex systems such as regulatory and legislative arrangements exhibit features of path dependency, whereby current options are greatly constrained or directed by historical choices and expectations (Bloom, Henson, and Peters 2014). For this reason, regulatory success stories from one context may not have the same effect in another. It is unlikely that a single approach will be sufficient to bring about the required improvements in pharmacy or health markets more broadly. Rather, a package of context specific regulatory measures will likely be required.

8.6.2.3 Governance and corruption

Whilst improved regulatory strategies have the potential to transform pharmacy markets, it is necessary to be cognisant of the high level of corruption that is treated as normal in Karnataka. The in-depth interviews identified that bribery was reportedly widespread in the pharmacy sector and these practices represent a great hindrance to the effective implementation of regulations. For example, a Task Force on Health and Family Welfare of the State (Karnataka) Government reported that nearly half of all pharmacies in Karnataka lacked a qualified pharmacist. However, between 2008 and 2010 there were only 14 prosecutions (Sudarshan and Prashanth 2011). The same report saw corruption topping a list of 12 key issues of concern for the State's health system (ibid). Corruption in the health sector is increasingly being linked with poor outcomes in LMICs (Azfar and Gurgur 2008, Solberg 2008). The most recent India Corruption Study, showed that whilst perceived and experienced corruption had overall declined in the country, in Karnataka it had increased (Centre for Media Studies 2017). The proportion of households reporting experiencing corruption in public services was 77% (up 20% points from 57% in the 2005 survey); Karnataka fared the poorest (highest proportion) for this indicator amongst all 20 states surveyed (ibid). Corruption within the State's health service delivery reportedly has its roots in many areas and is pervasive at all hierarchical levels from low-paid workers to senior investigative officials (Sudarshan and Prashanth 2011).

Poor governance in the pharmaceutical sector is not restricted to Karnataka and exists across India. In their study of pharmaceutical distribution systems in India, Jeffrey and colleagues reported that both retailers and wholesalers viewed the process of obtaining their licence as a chore and that regulations pertaining to the pharmacy sector had 'no real intrinsic significance' (Jeffrey et al. 2007). They also commented that within India's 'licence Raj' (which was said to have flourished under the administration of Prime Minister Nehru), the function of protecting consumers is low down on the priority list; rather, those who issue licences are able to earn economic rents by exploiting their position of power. This is not unique to India, however, as many other LMICs also struggle with corruption in health (Vian 2008).

Anti-corruption advocates call for good governance, transparency, and zero tolerance as the basis of strategies to address the problem (Jain, Nundy, and Abbasi 2014). In Karnataka, a number of initiatives have been instigated which aim to increase people's participation in the planning, implementation and monitoring of health services (Sudarshan and Prashanth 2011). For example, it is a pilot state for community monitoring of health services under the National Rural Health Mission. Coupling good governance initiatives with increased community participation is hoped to make progress to address corruption. Jain describes the

payment of bribes and use of connections to get 'a little ahead, a little extra, a little quicker' as ingrained in people's attitudes (Jain, Nundy, and Abbasi 2014). Empowerment of citizens has been proposed as an important step to bring about changing cultural attitudes that have long been accepting of corruption, ultimately leading to a law-based society (Johnston 1998). However, there is obviously no overnight solution and social change is likely be incremental and slow.

8.6.3   Equity considerations

Any discussion of encouraging chains or designing interventions to capitalise on their potential for quality improvement must be accompanied by the recognition that they are currently serving a relatively wealthy subset of the population. If their quality were to significantly improve, then this would further compound existing health inequalities, before it improves them. Victora and colleagues (Victora et al. 2000) propose that those of higher SES benefit first from new health interventions. They term this the "inverse equity hypothesis". Initially the relatively wealthy have better outcomes than the relatively poor. This gap is further perpetuated as the wealthy benefit from new initiatives. Subsequently, the poor make up some (but not all) of the shortfall and relative social inequalities in health outcomes are hypothesised to diminish but not disappear. As such, an accompanying set of requirements maybe necessary to ensure, for example, that chains had presence in poorer areas.

8.7   Concluding remarks

Pharmacies in LMICs are widely utilised for filling prescriptions, purchasing medicines and seeking health advice for a number of conditions. The substandard quality of care that is received from these pharmacies is a cause for concern and a system-wide issue that needs to be addressed. Whilst the problem is relatively well defined, potential solutions are currently lacking. This PhD shines a light on a new development within pharmacy markets in these settings - retail chains. Chains are expanding across Asia, Africa and South America and this raises questions about their impact on the public health concerns of quality, access, and price.

The hypothesised potential positive impact on affordability and quality of chain entry might lead some national or international bodies to consider investing in chains to accelerate this process in order to improve public health outcomes. However, although I found chains in Southern India to offer lower cost medicines for their urban clientele, the potential to serve poorer groups has not yet been realised, and the impact on quality of care was very limited. This thesis also revealed that chains have the means to monitor and control branch staff

behaviour; but a shift in focus from customer satisfaction to outcomes of public health concern is unlikely without either financial incentives or external regulation. Therefore, any attempt to leverage this organisational model for public health improvement would need to be carefully designed to ensure that appropriate regulatory constraints and incentives were in place to ensure that the potential benefits were realised. Moreover, without good governance initiatives that aim to reduce corruption in the sector, it is likely that quality issues will persist.

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APPENDICES TO THESIS

Appendix 1: Supplementary data to Miller and Goodman 2016, Health Policy and Planning

Table 1: Key Characteristics of papers included in systematic literature review of pharmacy performance

Author & date, country	Number and type of shops	Study design	Data collection methods	Part of review
Al-Faham et al 2011, Syria	200 private pharmacies	Cross-sectional study	*Simulated client presenting as the sibling of a woman with sinusitis. *Questionnaire survey to ascertain information on pharmacy and staff characteristics and knowledge and practice regarding menstrual regulation.	1
Apisarnthanarak et al 2008, Thailand	280 1st class drug stores	Cross-sectional study	*Simulated clients presenting with various conditions (acute viral pharyngitis; influenza; acute viral sinusitis; acute gastroenteritis; non-infected skin abrasion; acute UTI).	1&2
Basak and Sathyanarayana 2010, India	24 private pharmacies	Cross-sectional study	*4 hours of observation per pharmacy *Structured interviews with pharmacy staff regarding medicines.	1

Bista et al 2002*, Nepal	37 private pharmacies	Cross-sectional study (unclear if baseline results for Khan 2006)	*Simulated client presenting with history of urethral or vaginal discharge. *Review of registry data kept on all STI clients by pharmacies.	1
Chalker et al 2000*, Vietnam	60 private pharmacies	Cross-sectional study	*Simulated client presenting on behalf of a friend suffering from pain on urinating and a urethral discharge for past 3-4 days (5 clients per shop- 300 encounters). *Semi-structured interview questionnaire to assess reported management of an STD client.	1&2
Chalker et al 2005*, Vietnam and Thailand	68 private pharmacies in Vietnam, 78 private pharmacies in Thailand	Multi-component intervention study (regulatory enforcement, training, peer influence) evaluated using a cluster randomised controlled trial with a time series design.	*Simulated client for 2 scenarios (request to purchase antibiotic without a prescription, request to purchase steroid without a prescription). *4 rounds (a baseline and after 1 month of each of the 3 interventions).	2
Chua et al 2013, Malaysia	10 (5 corporate, 5 independent)	Cross-sectional study	*Observation of interactions between pharmacist and customers for 4 days in each pharmacy. Data recorded according to structured data collection form.	1

Chuc and Tomson 1999, Vietnam	2 pharmacies	Case study	*Observation (observed all encounters for 2 weeks) and interviews with customers. *Inventory and observation of operation. *Informal chats and in-depth interviews with staff regarding economic issues and good pharmacy practice.	1&2
Chuc et al 2001*, Vietnam	60 private pharmacies	Cross-sectional study	*Simulated client presenting as the mother of a 3-5 year old at home with cough for 2 days (uncomplicated RTI). * Semi-structured interview questionnaire to assess reported management of RTI client.	1&2
Chuc et al 2002*, Vietnam	68 registered private pharmacies	Multi-component intervention study (regulatory enforcement, training, peer influence) evaluated using a RCT with a time series design.	*Simulated client for 4 tracer conditions (upper RTI in a child, a STD, request to purchase an antibiotic without a prescription, request to purchase a steroid without a prescription). 4 rounds (a baseline and after 1 month of each of the 3 interventions).	1&2

Cong et al 1998 , Vietnam	125 private sector drug vendors also known as alternative treatment providers (ATPs), including private doctors, private pharmacies, government and private drug outlets (breakdown not given)	Cross-sectional study	* Structured interviews with drug vendors. *Observation of storage, handling and sale of antimalarials. * Simulated patient presenting with 3-day long fever which subsides and keeps returning.	1
Dineshkumar et al 1995*, India	32 retail pharmacy outlets	Cross-sectional study	*Observation and record of all sales for 2 complete days per pharmacy. *Structured interviews with patients who purchased medicine.	1&2
Dua 1994, India	34 private pharmacies	Cross-sectional study	*Structured interview questionnaires for providers to elicit information on ownership and structure of business. *Structured interview questionnaires for clients to elicit demographic information and information concerning the pharmacy encounter. *Observation of sales (4-5 hrs per pharmacy).	1&2
Duong et al 1997b*, Vietnam	25 private pharmacies	Cross-sectional study	*Interviews with customers based on structured questionnaire.	1&2

Duong et al 1997a*, Vietnam	29 private pharmacies	Cross-sectional study	*Simulated client presenting as the mother of a child with diarrhoea.	1
Greenhalgh 1987, India	12 private pharmacies	Cross-sectional study	*Observation of interactions in the pharmacy.	1&2
Hadi et al 2010, Indonesia	75 pharmacies, 10 drug stores, 39 roadside kiosks	Cross-sectional study	*Simulated clients requesting first line antibiotics with and without a prescription.	1
Huda et al 2014, Bangaldesh	331 private pharmacies	Cross-sectional study	*Simulated clients presenting with various scenarios relating to menstrual regulation/medical abortion.	1
Hussain and Ibrahim 2011*, Pakistan	371 private pharmacies (96 type A, 186 type B and 66 type C)	Cross-sectional study	*Observation of 1113 patient-dispenser interactions (2 hours per pharmacy).	1&2
Hussain and Ibrahim 2012*, Pakistan	371 private pharmacies (96 type A, 186 type B and 66 type C)	Cross-sectional study	*Simulated client presenting as older sibling of a 5 year old with diarrhoea.	1
Kafle 1998*, Nepal	352 private pharmacies (baseline), 314 by second follow-up	Randomised controlled trial (combinations of training, mailed materials and audit feedback)	*Simulated clients presenting with various scenarios (parent of a child with diarrhoea, husband of a pregnant woman, parent of a child with a cough). *Structured interview questionnaire for retailers to assess socioeconomic indicators at baseline and changes in knowledge.	2

Kafle et al 2013*, Nepal	342 private pharmacies (baseline), 314 by second follow-up	Randomised controlled trial (combinations of training, mailed materials and audit feedback)	*Simulated clients presenting with various scenarios (parent of a child with diarrhoea, husband of a pregnant.woman, parent of a child with a cough). *Structured interview questionnaire for retailers to assess socioeconomic indicators at baseline and changes in knowledge.	2
Kafle et al 1996, Nepal	112 registered drug retailers	Cross-sectional study	*Simulated client presenting as the husband of a woman who 'is pale and looking weak'. *Structured interview questionnaire to assess knowledge of pregnancy problems. *Focus group discussions with drug retailers to explore motivations for current practice.	1&2
Kamat and Nichter 1998, India	75 pharmacies (interviews); 6 pharmacies (observation and sales data)	Ethnography	*Semi-structured interviews with pharmacy owners. *Participant observation for minimum of 10 days in 6 pharmacies. *Drug sales data for 3 full days in each of 6 pharmacies. *Exit interviews with customers who purchased a scheduled	1&2

			medicine without a prescription. *In-depth interviews with medical representatives.	
Khan et al 2006*, Nepal	37 private pharmacies	Cross-sectional study (presents 'after' results from a training programme)	*Simulated client presenting with history of urethral discharge (35 year old male) or vaginal discharge (inquiring for wife). *Structured interview questionnaire to assess knowledge and reported practice.	2
Kotwani et al 2012, India	40 pharmacists (retail, public sector, and office bearers of pharmacists' associations)	Exploratory single-site case study	*Focus group discussions.	2
Krishnaswamy et al 1985*, India	33 retail pharmaceutical shops	Cross-sectional study	*Observation and record of all sales for 4 complete days per pharmacy.	1
Lansang 1990, Phillipines	59 private drug stores	Cross-sectional study	*Observation of transactions (monitored sales of all drugs for 3 days in small, single owned shops and for 2 days in larger branches of chain stores). *Structured interview questionnaire with all customers who asked for or bought antibiotic.	1&2

Larsson et al 2006*, Vietnam	60 private pharmacies	Randomised control trial (baseline results only)	*Simulated patient requesting steroid tablets. *Semi-structured questionnaire interview (mainly multiple choice, few open-ended questions) to gain info on reported practice.	1&2
Mac et al 2006, Vietnam	33 public and private pharmacies (breakdown not given)	Cross-sectional study	*Simulated client requesting 10 units of the cheapest anti-epileptic drug (AED). *Structured survey questionnaire to establish a list of AEDs available and their prices.	1&2
Mamun et al 2006, Bangladesh	5 private medicine-dispensing shop (main focus of study on rural medical practitioners)	Cross-sectional study	*Interviews with drug sellers. *Interviews with customers. *Reviewed sale books of shops. *Observation of medicine sales.	1&2
Minh et al 2013*, Vietnam	220 private pharmacies	Before and after intervention study (training)	*Structured questionnaire with pharmacy staff (281) recording knowledge and reported practice for diarrhoea management. *Simulated client seeking advice for 14 month old child with diarrhoea (baseline and 6-months post intervention).	1&2

Mondal et al 1994, India	30 private pharmacies	Cross-sectional study	*Simulated client presenting as the father of a 2 year old boy with diarrhoea.	1
Nakajima et al 2010, Mongolia	250 private pharmacies	Cross-sectional study	*Structured interview questionnaire for pharmacy workers mainly focussed on antibiotic medicines. *Structured interview questionnaire customers to elicit demographic information and details of medicine purchases.	1
Nga et al 2014, Vietnam	30 private pharmacies	Cross-sectional study	*Observation of all drug sales at each pharmacy for 3 days. *Semi-structured questionnaire for pharmacy staff focussing on antibiotic sales. *In-depth interviews and focus group discussions with pharmacy staff regarding perceptions of factors affecting inappropriate antibiotic dispensing.	1&2
Ngo et al 2012, Vietnam	100 registered private pharmacies	Cross-sectional study	*Structured interview questionnaire with pharmacy staff to assess knowledge of medical abortion. *Simulated clients presenting as either a young female seeking medical abortion or a young male seeking	1

			abortifacients for his girlfriend.	
Pham et al 2013*, Vietnam	220 private pharmacies	Before and after intervention study (training)	*Structured questionnaire with pharmacy staff recording knowledge and reported practice for diarrhoea management. *Simulated client seeking advice for 14 month old child with diarrhoea (baseline and 6-months post intervention).	2
Podhipak et al 1993, Thailand	240 private pharmacies. 120 type I and 60 type II pharmacies in Intervention area. 60 of each type in control area	Before and after intervention study (training)	*Simulated clients presenting as mothers of children with watery diarrhoea and dysentery.	1&2
Puspitasari et al 2011,Indonesia	105 private pharmacies	Cross-sectional study	*Simulated clients presenting with various scenarios (request for 10 tablets of ciprofloxacin; request for 2 capsules of tetracycline; prescription for paediatric amoxicillin dry syrup).	1
Qidwai et al 2006, Pakistan	6 private drug sellers	Before and after intervention study (training)	*Structured questionnaire to obtain shop and drug seller characteristics. *Simulated clients	1&2

			presenting with various scenarios of diarrhoea.	
Rahman et al 2000, Bangladesh	157 private pharmacies	Cross-sectional study	*Self-administered questionnaires for medicine sellers exploring knowledge and reported practices relating to STD/AIDS management. *Simulated clients presenting with an STD.	1
Ratanajamit et al 2001*, Thailand	30 pharmacist-owned and 30 non-pharmacist owned drug stores	Baseline results of randomised controlled trial	*Structured interview questionnaire to measure knowledge of oral and emergency contraception. *Simulated clients requesting oral contraception and emergency contraception (on different occasions)	1&2
Ratanajamit et al 2002*, Thailand	30 pharmacist-owned and 30 non-pharmacist owned drug stores	Randomised controlled trial (educational intervention)	*Simulated client presenting as college student who experienced unprotected mid-cycle sex 24 hours earlier. *Structured interview questionnaire to assess knowledge.	1&2
Rathnakar et al 2012, India	60 private pharmacies	Cross-sectional study	*Simulated clients presenting with various scenarios (URTI, acute bronchitis, diarrhoea accompanied with pain and fever).	1

Ross-Degnan et al 1996, Indonesia	87 private pharmacies (43 intervention, 44 control)	Randomised control trial (educational intervention)	*Structured interview questionnaires to assess knowledge of diarrhoea management. *Simulated clients presenting as the mother of a child under 5 with diarrhoea (before and after intervention). *Focus group discussions with pharmacy staff to understand factors underlying treatment behaviours.	1&2
Roy J 1997, Bangladesh	Sample of village 'doctors' (pally chikitshak/pharmacy salespersons). Numbers not given.	Cross-sectional study	*Interviews. *Direct observation of practice.	1&2
Saencharoen and Lerkiatbundit 2013*, Thailand	142 private pharmacies	Cross-sectional study	*Simulated clients presenting with mild or moderate migraine. *Structured interview questionnaire to assess knowledge regarding migraine management.	1&2
Saengcharoen and Lerkiatbundit 2010*, Thailand	115 private pharmacies (96 type I and 29 type II)	Cross-sectional study	*Simulated client presenting as the aunt of a 4 year old with watery diarrhoea. *Written questionnaire collecting data on demographics and knowledge and attitudes towards diarrhoea management.	1&2
Saradamma et al, India	11 private pharmacies	Cross-sectional study	*4 hours of observation per pharmacy. *Structured interviews	1

			with customers who purchased antibiotics.	
Seeberg 2012, India	20 private practitioners and chemists	Ethnography	*In-depth interviews and clinical observations over an 18-month period.	1&2
Stenson et al 2001a*, Lao PDR	106 private pharmacies (mostly class 3)	Cross-sectional study	*Structured interviews with the drug sellers. *Facility-specific indicator survey of the pharmacies. *Semi-structured exit interviews with customers outside the pharmacies. *Inspection of drug purchases. *Recording of prices of sample drugs. *Structured interviews with district drug inspectors.	1
Stenson et al 2001b*, Lao PDR	92 private pharmacies - mostly class 3 (46 regular intervention, 46 active intervention)	Randomised controlled trial (regulatory intervention)	*Structured interview with drug seller and inspection of premises to assess facility-specific indicators. *Semi-structured exit interviews and review of medicines purchased to obtain dispensing indicators.	2
Syhakhang et al 2001*, Lao PDR	92 private pharmacies (mostly class 3) and 13 public pharmacies	Cross-sectional study	*Structured interviews with the drug sellers. *Facility-specific indicator survey of the pharmacies. *Semi-structured exit interviews with customers outside the	1

			pharmacies. *Inspection of drug purchases.	
Thamlikitkul 1988, Thailand	40 1st class drug stores	Cross-sectional study	*Simulated clients presenting with various conditions (urethral discharge in adult male; cut wound in 4 year old, impetigo in 2 year old; acute watery diarrhoea in 6 month old; acute watery diarrhoea in adult; fever with sore throat in adult; fever, rhinorrhoea and cough in a 2 month old; fever with rhinorrhoea in adult; acute dysuria in adult female.	1
Tomson and Sterky 1986, Bangladesh, Sri Lanka and Yemen Arab Republic	25 private pharmacies in each country setting	Cross-sectional study	*Simulated client (Caucasian man) presenting as the father of a 11 month old with diarrhoea of 3 days duration.	1&2
Tuladhar et al 1998, Nepal	160 private pharmacies	Before and after intervention study (training)	*Simulated clients reporting urethral discharge.	1&2
Van Sickle 2006, India	52 private pharmacies	Cross-sectional study	*Simulated client presenting with symptoms of asthma for preceding 2-3 weeks in themselves or a child (aged 10 or 14).	1&2

			*Simulated client presenting with symptoms of tuberculosis and request for anti-TB drugs.	
Vu et al 2012, Vietnam	138 private pharmacies	Cross-sectional study	*Structured interview questionnaire to record information on pharmacy, provider, management of a fictious case and knowledge of the national tuberculosis programme.	1&2
Wachter et al 1999, Nepal	100 private pharmacies listed in Nepal Chemists' and Druggists' Association	Cross-sectional study	*Simulated clients presented two scenarios (a case of cystitis in 25 year old male, 5 year old son with loose stools for 1 day).	1
Wolffers 1987, Sri Lanka	28 private pharmacies	Cross-sectional study	*Simulated clients requesting 2 tablets of tetracycline.	1

*One of several papers from the same research study. The following sets of papers appear to come from the same research projects:

- Stenson et al 2001a, Stenson et al 2001b, Syhakhang et al 2001

- Saencharoen and Lerkiatbundit 2013, Saencharoen and Lerkiatbundit 2010

- Ratanajamit et al 2001, Ratanajamit et al 2002

- Pham et al 2013, Minh et al 2013

- Krishnaswamy et al 1985, Dineshkumar et al 1995

- Khan et al 2006, Bista et al 2002

- Larsson et al 2006, Chalker et al 2000, Chalker et al 2005, Chuc et al 2001, Chuc et al 2002

- Kafle 1998, Kafle et al 2013

- Hussain and Ibrahim 2011, Hussain and Ibrahim 2012

- Duong et al 1997a, Duong et al 1997b

Appendix 2: Summary of literature on effects of pharmacy chains in high-income countries

Authors	Country of study	Outcomes investigated	Study Design and Methods	Summary of Relevant Findings
Arora et al 2017	America	-Drug price	-Collected prices for 2 generic antibiotics by telephone from 528 pharmacies in Los Angeles. -Compared prices at chain, grocery, big-box (large retail shops) and independent pharmacies.	- In low income postcodes, independents accounted for 65% of pharmacies, in high-income areas they only accounted for 37%. - The lowest average prices were found at independent pharmacies and chain drug stores charged the most. -There was little variation in price for chain drug stores, particularly in comparison with independent pharmacies and grocery stores.
Briesacher and Corey 1997	United states	-Patient satisfaction	-An interviewer administered the Pharmacy Encounter Survey (PES) face-to-face to 260 consecutive people immediately after their visits to randomly selected chain pharmacies (n = 10) or independent pharmacies (n = 16) in Philadelphia County, Pennsylvania. -The 15-item PES gathers demographic data and asks respondents to rate their satisfaction with the time it took for prescriptions to be filled, the technical skills and courtesy of pharmacy personnel, the convenience of the pharmacy's location, and other aspects of the experience.	-for each item rated, and for the overall visit, respondents rated independent pharmacies better than chain pharmacies.

| Clark and Mount 2006 | United States | -Pharmacy Service Orientation (PSO) | -Authors describe PSO as 'an ideational manifestation of what is valued by the organisation'
 -Attempts to measure the service-related culture of a pharmacy practice organization. In designing the PSO instrument authors considered attitudinal artefacts relating to pharmaceutical care provision. These were thought to indicate where its focus may lie (between quantity and quality), whether organisation leaned more towards patient or product, and whether pharmacists tend to be professional or technical. Each item was measured on a scale-orientation: patient (10)- product (1); focus: quality (10)-quantity (1); work: professional (10)- technical (1)
 -Schools of pharmacy were sampled and all graduates of 1999 eligible for inclusion. 24/30 schools approached participated.
 -Study participants were asked to provide ratings for recent work experiences
 -2041 surveys mailed. Of 1850 deliverable 259 returned (14% response rate)
 -Data reports on corporate community sites and non-corporate community sites | -Analysis of potential predictors of PSO showed that non corporate community sites had significantly greater pharmaceutical care-orientated cultures (mean PSOs 7.42 and 5.13, P<0.001) |
| Cochran et al 2014 | United States | -Screening and discussing | -Cross-sectional web based survey | -Chain pharmacists were most likely to report current screening. |

			-Survey items assessed whether pharmacists screened and discussed prescription opioid abuse with patients	
		prescription opioid abuse		
Dobson 2011 et al	Canada	-Perceived authority and autonomy	-Self-administered questionnaire to community pharmacy managers across Canada -Master list of 6342 managers drawn up, sample size of 2000 chosen to increase chance of receiving desired 600 replies. -646 responses (32.9% response rate). 288 were independent (44.6% of respondents), 119 were franchise (18.4% of respondents), and 229 were corporate chain (representing 35.4% of respondents)	- Significant differences among all 3 pharmacy types with respect to manager autonomy and decision-making (P,0.001 for both constructs). Corporate respondents reported the least amount of manager autonomy and decision-making ability, followed by franchise respondents, with independent pharmacy managers reporting the most autonomy and decision-making control. -No statistical differences were found for professional authority based on type of pharmacy ownership. -Comparative analysis of the employer authority construct resulted in a statistically significant difference between corporate pharmacy respondents and those in franchise and independent pharmacies (P<001).
Doucette et al 1997	United States	-Examination of the relationships between the availability of community pharmacies and various market factors	-Drawing on data from 3 databases, linked at the county level. -Looked at 2 dependent variables- total number of community pharmacies per 10,000 population in the county and the proportion of independently owned community pharmacies. -linear multiple regression containing market factor variables as independent variables was performed for each of the dependent variables.	- Factors significantly associated with the proportion of independently owned pharmacies in a county included: percentage of elderly people, percentage living in a rural setting, percentage earning less than the poverty level, and the average pay per employee.

Doucette et al 2017	United States	-Services provided by community pharmacies	- Cross-sectional national mailed survey - Collected data on frequency and availability of services including medication management, immunization, adjusting medication, medication reconciliation, disease state management, health screening, complex nonsterile compounding, and point-of-care testing. -Types of pharmacies included independents, chains, mass merchandisers and supermarkets	-Chains and supermarkets were found to offer the most services.
Evans et al 2009	Canada	-Degree of medication adherence	-Retrospective cohort study of all drug plan beneficiaries filling a new statin prescription between 2000-2005. -Pharmacy companies serving urban centres in Saskatchewan grouped into 3 categories (department-mass merchandise, chain-franchise, independent). -sampling of stores was not random (6 mass merchandise stores, 12 chain-franchise, 16 independent) -Subjects classified as adherent if exhibited at least 80% adherence over their observation period -Multivariate logistic regression to evaluate association between pharmacy categories and subject adherence	-pharmacy category type was significantly associated with overall statin adherence. -subjects in the chain-franchise and independent categories were more likely to be adherent to statin medication than the department-mass merchandise category (OR 1.36, 95% CI 1.23-1.50, P<0.0001). -No significant difference was observed when comparing chain-franchise with independents
Flynn et al 2003	United States	-Dispensing errors	-Pharmacies across 6 cities randomly selected. 50 in total	-Overall accuracy rate 98.3% -Accuracy rates did not differ significantly by pharmacy type

			-Sample included chain, independent, and health-system pharmacies (located in hospitals or managed care organizations) -Each pharmacist was observed for 1 day, being monitored for dispensing errors	
Fritsch and Lamp 1997	United states	-Percentage of patients counselled	-stage 1 of study involved 15-minute observational period of pharmacist counselling in 50 randomly selected pharmacies in the Kansas City metropolitan area - stage 2 was a mailed survey to the same pharmacies to obtain policies, self-reported rates of counselling, baseline workload, and personnel information, as well as perceived communication barriers	-Pharmacists in independent pharmacies were observed counselling a significantly higher percentage of patients than were pharmacists in chain pharmacies (44% vs. 11%; p = 0.014) -Pharmacists in chain pharmacies reported dispensing greater numbers of prescriptions than did pharmacists in independent pharmacies.
Gellad et al 2009	United states	-Variation in drug prices	-Using Florida's publicly available directory of drug prices charged by pharmacies drug prices were analysed (website represents 99% of pharmacies in the state) -Prices for 1 months supply of 3 commonly used medicines for chronic conditions and one acute course of antibiotic were collected -main focus of study was to collect data on disparities in price between neighbourhoods of various income classification but also collected data on chain vs independents	-poorer zip codes had lower shares of chain pharmacies -at each income level chain pharmacies were found to be less expensive and less variable in price than independent pharmacies. -the mean price of each of the four drugs was highest in the poorest ZIP codes. The majority of variation was due to prices in independent pharmacies; across the 4 medicines prices were 15% higher in the poorest areas compared with the statewide average. -Chain pharmacies showed little price variation across ZIP code income categories

			-Within each ZIP code, median household income from the 2000 Census was used as a measure of area wealth -pharmacies were classified as part of a large chain if they belonged to CVS,Wal-Mart, Walgreens, Winn-Dixie, Publix, Kmart, or Target (comprise 75% of pharmacies). All other pharmacies were classified as independent -Mean pharmacy prices were compared using analysis of variance	
Jacobs et al 2013	England	-Workplace stress	-Questionnaire to a random sample of 2000 pharmacies. -Instrument used to measure stress was A Shortened Stress Evaluation Tool (ASSET). - Chi squared tests and analysis of variance were used to compare characteristics across organisational types of pharmacy. -Response rate 47.8% (903/1890).	-Pharmacists working for large multiples were significantly more troubled by work place by most work place stressors than those working in independent and small chain pharmacies. Stress levels perceived by supermarket pharmacists were similarly raised.
Jacobs et al 2017; Hann et al 2017	England	- Clinical productivity (levels of service delivery and service quality) - Organisational factors associated with this variation	-All pharmacies in 9 socioeconomically diverse areas in England were invited to participate (bar those owned by four national chains who refused permission). -Sample included independent, chains (categorised as small, medium or large) and supermarket pharmacies.	-Initial survey response rate 35% (277/800). In terms of levels if service delivery, MUR volumes, and NMS interventions were related to ownership type (all highest in large chains and supermarkets). Higher annual dispensing volumes were not significantly associated with ownership type in the pharmacy survey, but looking at national datasets higher dispensing volumes were associated with larger chains/supermarket pharmacies.

			-Data on level of service delivery included monthly dispensing volumes, volume of medicine use reviews (MURs), and new medicines service (NMS). Also used national dataset (10k pharmacies to look at service quantity). -A community pharmacy survey collected data on ownership type, organisational culture, staffing and skill mix, working patterns, management structure, safety climate, pharmacy-GP integration. -In second stage of research 41 pharmacies from initial work were randomly selected to participate. 39 agreed. In these pharmacies patient questionnaires were distributed to collect data on self-reported measures of satisfaction with pharmacy visit, satisfaction with information about medicines, and adherence to medicines. -Also conducted 40 semi structured interviews with pharmacy and commissioning representatives.	-In terms of service quality, safety climate (Pharmacy Safety climate questionnaire) was significantly associated with pharmacy ownership (large chains and supermarkets had more favourable organisational learning scores but worse working conditions scores). -Satisfaction with pharmacy visit, SIMS (Satisfaction with Information about Medicines Scale), and MARS (medication adherence report scale) scores were not significantly associated with pharmacy ownership type. - Qualitative work revealed that the role, values and prioriites of pharmacy management were key, with some organisations exhibiting a target-focussed culture aimed at maximising service quantity. Cultures centring on skill-mix, team development and extended staffing models were thought to enable delivery of service quantity and quality.
Kalsekar et al 2007	United states	-Utilisation patterns and adherence to oral hypoglycaemic agents (OHAs)	-study used medical and prescription claims data from a State Medicaid program. -Patients with type 2 diabetes were identified by diagnosis codes. -Retrospective cohort design was employed. The first prescription for an OHA during a 4 year period (1998-2001) was treated as an index prescription.	-Univariate chi squared analysis did not show any difference between utilisation patterns between patients filling prescriptions at chain or independent pharmacies. -Multivariate analysis (controlling for age, gender, race, rural/urban location, year of index prescription, comorbidity index, complexity of regimen) showed patients filling at a chain were 1.3 times more likely to augment therapy (add another medication eg insulin or a different class of OHA) compared to those filling at independent

			-Utilisation (discontinuation, augmentation, switching, nonmodification) and adherence was measured for 12 months postindex prescription -Pharmacies were classified as chains or independents using the State Board of Pharmacy website	-Multivariate analysis showed that patients filling at an independent had 1.7% higher adherence to OHAs compared to patients filling at an independent (P=0.02)
Kennedy and Littenberg 2003	United States	-Error reporting	-All pharmacies in Vermont contacted via telephone -Survey questioned about United States Pharmacopeia Medication Errors Reporting (USP MER)	Significantly more pharmacists employed by independent pharmacies had submitted a report, compared with pharmacists from other pharmacy types (chain, supermarket, mass merchandiser; P = 0.03). Submitting reports through a corporate hierarchy or to a corporate program was the reason most frequently cited by pharmacists for not submitting reports directly to USP MER
Khan and Azhar 2013	Saudi Arabia	-Information on inhaler technique	-71 pharmacies approached in Al-Ahsa region 'keeping in view the population facts'. 31 were independents and 40 from the 2 main chains in the region. -Simulated patients presented in pharmacies and asked for advice on how to use inhaler for newly diagnosed asthma. Pharmacists counselling was scored against criteria from the 'Guidelines for the Diagnosis and Management of Asthma, National Asthma Education and Prevention Program'.	-pharmacists working in chain pharmacies were found to be more knowledgeable/give better advice than those working in independents. -Mean score for chains was 4.48 +/- 2.10 and for independents 3.88 +/- 2.04. This difference did not reach statistical significance P=0.226.
Munger et al 2003	United States	-Occupational job satisfaction and stress	- Online survey instrument of previously validated occupational stress and satisfaction. -303 independent and chain pharmacists	- Was a high level of reported dissatisfaction jobs, with more than 50% considering leaving current employment. -Dissatisfaction was higher amongst those employed by chains.

Perepelkin et al 2010	Canada	-Role orientation, role affinity, and role conflict	-Self-administered questionnaire to community pharmacy managers across Canada -Master list of 6342 managers drawn up, sample size of 2000 chosen to increase chance of receiving desired 600 replies. -646 responses (32.9% response rate). 288 were independent (44.6% of respondents), 119 were franchise (18.4% of respondents), and 229 were corporate chain (representing 35.4% of respondents)	Pharmacy managers and owners were on the whole oriented to their professional role; however, those working in a chain were less oriented to their business role when compared with those working in an independent or franchise pharmacy environment.
Qato et al 2017	America	-Pharmacy availability -Characteristics of pharmacy operations that can improve access to prescription medications e.g. home delivery	-Linked detailed information from the National Council for Prescription Drug Programs with publically available demographic data to examine the availability and characteristics of pharmacies -pharmacies classified as either chains, independent (up to three stores under the same organisation), mass retailers, food stores, government, or clinic-based. - pharmacies self-reported whether they "accept electronic prescriptions", "offer a home delivery service", "have one or more drive-up windows for prescriptions", and "offer 24-hour emergency access to a pharmacist with access to the location" Pharmacies reporting a language other than English were coded as having multilingual pharmacy staff.	-The number of pharmacies increased by 6.3%, from 63,752 pharmacies in 2007 to 67,753 pharmacies in 2015 -This trend varied across pharmacy type. Mass retailer pharmacies increased by 18%, compared to an 8.3% for chains and 3.8% for independents. The distribution of pharmacy types did changed little over this period, with chain and independent pharmacies more prevalent than other types. -the study reported large differences in pharmacy characteristics by pharmacy type -Of 26,789 chain pharmacies in 2015, 10.7% were open 24 hours and 23.9% reported having a drive-up window, which was a significantly higher proportion than all other pharmacy types. -Chain pharmacies were significantly less likely than independents to report offering a home-delivery service (6.2% vs. 64.2%) or multilingual staff (1.8% vs. 30.6%). P<0.001 for all these differences.

Rae et al 1992	United States	-Use of reference sources to answer drug information questions	-Sampling frame was mailing list of the Louisiana Board of Pharmacy. -15% of registered pharmacists obtained by stratifying by zip code and gender -pharmacists were sent an uncoded, pretested questionnaire and were asked to complete and return it if they were employed by an independent or chain pharmacy -91 independent pharmacists and 71 chain pharmacists included in study (54% response rate)	-Independent and chain pharmacists were found to receive the same types of drug information questions and also rely on the same references to answer such questions
Raisch 1993	United States	-Effect of payment type and pharmacy setting on patient counselling activities	-Pharmacies were randomly selected -Pharmacists collect self-reported data regarding counselling activities and an observer also collected data -Forty-seven pharmacists in national chain pharmacies and 26 in independent pharmacies collected data on 3766 counselling events	-Patient counselling rates, defined as percentage of patients counselled per prescription per pharmacist, were somewhat higher (p = 0.06) for chain (median 17.7 percent) than for independent pharmacists (10.7 percent). -Although there was no difference in terms of pharmacist-initiated counselling, chain pharmacists had higher rates of patient-initiated counseling per prescription (median 4.3 percent) than independent pharmacists (median 2.7 percent) (p < 0.01). -A strong correlation between observational data and self-reported data was found (Pearson r = 0.696, p < 0.001).
Segal et al 1987	United States	-Attitudes of pharmacists toward a set of attributes associated with professionalism	-A questionnaire that included the 40-item Shack and Hepler professionalism instrument was mailed to 1999 pharmacists in Ohio. -Responses from 617 pharmacists who worked in hospital, independent community, or chain community pharmacy practice were used.	-There were significant differences between the responses of pharmacists who worked in the different practice settings (multivariate analysis of variance, p < 0.01). -The practice setting accounted for less than 10% of the variance in the responses.

Winslade and Tamblyn 2017	Canada	-Patient adherence to antihypertensive medication	-A population based cohort study using community pharmacy claims data - Study population was all pharmacies in Canada. 1742 pharmacies dispensing 8,655,348 antihypertensive prescriptions to 760,700 patient -Non-adherence: If the previous days covered over the 90 days prior to the dispensing was less than 72 days (80%), then the dispensing was to a non-adherent patient.	-90% of pharmacies included in this study were chain pharmacies and 10% independents. - Odds of non-adherence were significantly higher for chains/ banners relative to independent pharmacies (OR: 1.02; 95%CI: 1.00 to 1.05).
Winterstein et al 2010	United States	-Provision of written consumer medication information (CMI) according to FDA guidelines	-pharmacies sampled from a national electronic list of 55,513. -CMI was collected by mystery shoppers presenting with prescriptions written by physicians. - After the pharmacy visit, shoppers submitted the prescription containers and any written materials provided along with notes about verbal counselling. - Shoppers filled prescriptions for lisinopril at 365 pharmacies and for metformin at 364 pharmacies in 41 states. -Of surveyed pharmacies, 87 were independent, 252 chain outlets, and 4 franchise stores.	-All instances where prescriptions were dispensed without any CMI occurred in independent pharmacies (22 pharmacies, 6%). -Chain pharmacies dispensed longer CMI leaflets, which met a larger percentage of the expert-required content, with a mean difference of 22.1% (95% CI, 15.8%-28.4%) for lisinopril and 21.1% (95% CI, 14.9%-27.3%) for metformin.

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Appendix 3: Study tools and consent forms

Appendix 3 provides the study tools and consent forms used for each method.

These include:

- 3a: Standardised patient debrief questionnaire
- 3b: Exit interview information sheet
- 3c: Exit interview survey (including consent form)
- 3d: Key informant information and consent form
- 3e: Topic guide for key informant interviews (chain executives)
- 3f: Topic guide for key informant interviews (chain branch staff)
- 3g: Topic guide for key informant interviews (independent pharmacies)

3a: Standardised Patient Debrief Questionnaire

Outlet ID	
B1. Today's date (dd/mm/yyyy)	[_|_]-[_|_]-[2|0|1|5]
B2. Standardised patient's code	[__|__]
B3. Debrief Interviewer's code	[__|__]

B4. Name of outlet *(if no name, record "no name" or owner's name)*	B4a. Outlet code
[_____]	[__|__|__|__]

B4. Type of Outlet:

        Chain......................1
        Independent 2

B5. Did this outlet agree to the general survey?

        Yes, general survey completed 1
        No, refused to participate 2
        Decision still pending 3

B7. Length of consultation

        [__|__] minutes

B8. Was it possible to complete the consultation for both conditions (adult TB and childhood diarrhoea)?

        Yes 1
        No ....0 (if no, give reason and details below)

....

....

B9. Latitude: [_|_] . [_|_|_|_|_|_]	B10. Longitude: [_|_] . [_|_|_|_|_|_|_]

Scenario:

'I need to buy something for my niece who has diarrhoea. She is 2 years old'

'Also for myself...I have had cough and some fever for 3-4 weeks. We have had a relative staying with us who has TB. Can you suggest something?'

TUBERCULOSIS CONSULTATION:

Questions Asked:

T1. Did the Shopkeeper ask about any additional signs or symptoms of the illness?	No .... 0 Yes .... 1 (tick all mentioned) Pain in the chest? [ ] Coughing up blood or sputum? [ ] Weakness or fatigue? [ ] Weight loss? [ ] No appetite? [ ] Chills? [ ] Night sweats [ ] Other _____ [ ] Other _____[ ] Other _____ [ ]
T2. Did the shopkeeper ask if you have already visited a doctor?	No .... 0 Yes 1
T3. Did the shopkeeper ask if you have a doctor's prescription?	No .... 0 Yes 1
T4. Did the shopkeeper ask if you have already tried any other medicines?	No .... 0 Yes 1
T5. Did the shopkeeper ask if you were taking any other medicines for other conditions?	No .... 0 Yes 1
T6. Did the Shopkeeper ask if you wanted a particular medicine?	No .... 0 Yes 1
T7. Write down any other questions asked by the shop keeper	_____ _____ _____

Management of standardised patient:

T8. How did the shopkeeper manage the condition? (tick all that apply)	Recommended medicines from the shop [ ] Referred to another health provider [ ] Consult a traditional healer/traditional medicine [ ] Did nothing [ ] Other [ ] (specify) _____
T9. If referred to another health provider, provide details e.g. 'see physician', 'go to DOTS centre', 'go to government hospital', 'go to private hospital', 'visit another chemist'	_____ _____
T10. Did the shopkeeper inform you that TB medicine was available free of charge from the government?	Yes .... 1 No 0
T11. Did the shopkeeper sell you any medicines?	Yes .... 1 No 0
T12. Did the shopkeeper refuse to sell you one or more medicines?	No .... 0 Yes, refused to sell any medicines .... 1 Yes, sold some but refused others .... 2 Specify which medicines were refused: _____
T13. If the shopkeeper refused to sell certain medicines, what was the reason?	Suitable medicines out of stock .... 1 Suitable medicines only available with prescription ....2 Referred to other health provider .... 3 Other (specify) _____ .... 4 Other (specify) _____ 5
If no medicine was sold skip ahead to T18 (page 5)	

T14. Recommended drugs	Strength	Formulation (tabs/caps/ powder etc)	Amount sold (e.g 3 tabs)	Cost (Rs)	Reason sold (as told by shopkeeper)	Recommended dose (eg. 1 tab twice a day after food) If not told how to take write 'no advice given'	Recommended duration (e.g. take for 3 days/take for 6 months)	Side-effects mentioned by shopkeeper
Drug 1 . Brand name: Generic name:								
Drug 2. Brand name: Generic name								
Drug 3. Brand name: Generic name:								
Drug 4. Brand name: Generic name:								
List any drugs recommended but not sold (e.g because out of stock)								

Advice given

T15. Were you sold TB medicine?	No .... 0 **Go to T18** Yes 1

T16. If sold TB medicines, did the shopkeeper advise you to visit a doctor if you develop any worrying symptoms?	No 0
	
	Yes .... 1 (tick all mentioned)
	
	Being sick (vomiting) [ ]
	Yellowing of skin and whites of eyes [ ]
	Unexplained high fever [ ]
	Tingling or numbness in hands or feet [ ]
	A rash or itchy skin [ ]
	Joint pain [ ]
	Changes to vision e.g. blurred vision [ ]
	Other
	   _____ [ ]
	
	   _____ [ ]
	
	   _____ [ ]

T17. If sold TB medicines, did the shopkeeper advise you about any tests or monitoring you would need whilst taking the medicines?	No .... 0 Yes .... 1 (describe) _____ _____
T18. Did the shopkeeper offer any other kind of advice?	No .... 0 Yes .... 1 (describe) _____ _____ _____

Make any extra notes here:

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END OF TB CONSULTATION

DIARRHOEA CONSULTATION

Questions Asked:

D1. Did the Shopkeeper ask questions/more details about the case?	No ………. 0 Yes ……… 1 (tick all mentioned) Duration of the diarrhoea? [ ] Number of stools per day? [ ] Presence of blood in the stool? [ ] Episodes of vomiting? [ ] Fever? [ ] Is the child passing urine regularly? [ ] Has the child been able to take in fluids/food whilst ill? [ ] What remedies has the child already taken? [ ] Other _____ [ ] Other _____ [ ] Other _____ [ ]
D2. Did the shopkeeper ask if the child has already visited a doctor?	No ………. 0 Yes ……… 1
D3. Did the shopkeeper ask if you have a doctor's prescription?	No ………. 0 Yes ……… 1
D4. Did the shopkeeper ask if the child was taking any other medicines for other conditions?	No ………. 0 Yes ……… 1
D5. Did the shopkeeper ask if you wanted a particular medicine?	No ………. 0 Yes ……… 1
D6. Write down any other questions asked by the shop keeper	_____ _____ _____ _____

D7. How did the shopkeeper manage the condition? (tick all that apply)	Recommended medicines from the shop [ ] Referred to another health provider [ ] Consult a traditional healer/traditional medicine [ ] Did nothing [ ] Other [ ] (specify) _____ _____
D8. If referred to another health provider, give details e.g. 'see physician', 'go to government hospital', 'go to private hospital', 'go to another chemist'	**_____** _____
D9. Did the shopkeeper sell you any medicines?	Yes .... 1 No 0
D10. Did the shopkeeper refuse to sell you one or more medicines?	No .... 0 Yes, refused to sell any medicines .... 1 Yes, sold some but refused others .... 2 **Specify which medicines were refused:** _____
D11. If the shopkeeper did not sell you any medicine, what was the reason?	Suitable medicines out of stock .... 1 Suitable medicines only available with prescription ....2 Referred to other health provider .... 3 Other (specify) _____ .... 4 Other (specify) _____ 5
If you were not sold any medicines skip to D15 (page 10)	

D12. Recommended drugs	Strength	Formulation (dispersible tabs/ syrup/ powder)	Amount sold (e.g 3 tabs, 1 sachet x 21.8g, 1 bottle x 60ml)	Cost (Rs)	Reason sold (as told by shopkeeper)	Recommended dose (eg. 1 sachet after each loose motion/ 5ml 3x day) If not told how to take write 'no advice given'	Recommended duration (e.g. take for 3 days)	Side-effects mentioned by shopkeeper
Drug 1. Brand name: Generic name:								
Drug 2. Brand name: Generic name:								
Drug 3. Brand name: Generic name:								
Drug 4. Brand name: Generic name:								
List any drugs recommended but not sold (e.g because out of stock)								

Advice given

D13. If ORS was sold, did the shopkeeper tell you how to prepare and use the solution? **Tick box if ORS was not sold [ ]**	No .... 0 Yes .... 1 (describe below) _____ _____

D14. Did the shopkeeper advise you to visit a doctor if the child develops any worrying symptoms?	No 0
	
	Yes .... 1 (tick all mentioned)
	
	Has repeated vomiting [ ]
	Becomes very thirsty [ ]
	Eating/drinking poorly [ ]
	Develops high fever [ ]
	Blood in stool [ ]
	Starts to pass many watery stools [ ]
	Does not improve in 3 days [ ]
	Other
	        _____ [ ]
	
	        _____ [ ]
	
	        _____ [ ]

D15. Did the shopkeeper explain the importance of giving the child more fluids than usual to prevent/treat dehydration?	No .... 0 Yes .... 1 (describe) _____ _____ _____
D16. Did the shopkeeper give any advice regarding diet? e.g. continue normal diet (and milk), withhold food, advise which types of food to eat?	No .... 0 Yes .... 1 (describe) _____ _____

D17. Did the shopkeeper offer any other advice?	No .... 0 Yes .... 1 (describe) _____ _____ _____
D18. Do you have any reason to believe the drug seller did not think you were a genuine customer?	No .... 0 Yes .... 1 (describe) _____ _____

Make any extra notes here:

END OF INTERVIEW

3b: Exit interview information sheet

Information Sheet

Organisational arrangements of pharmacy retail in Bangalore and public health

EXIT INTERVIEWS

(To be read to the interviewee)

What is Research?

The London School of Hygiene and Tropical Medicine (LSHTM), UK, is a university that carries out research in the name of improving health. Sometimes research only involves asking questions of patients, their parents, community members or health providers about what they know, feel or do. This is the type of research we are here to do today. All research at LSHTM, including those involving only interviews, is approved by the relevant authorities to ensure that participants' safety and rights are respected.

What is this research about?

In this research, we want to learn more about the people who use different pharmacies in Bangalore and the factors influencing this. We will be conducting this study in pharmacies across Bangalore. We will be interviewing around 900 customers.

Why do you want to talk to me and what does it involve?

We feel that your experiences can contribute much to our understanding and knowledge of how pharmacy services in India can be improved.

I would like to ask a number of questions about:
- Your visit to the pharmacy today
- Your basic personal details
- The home of the person for whom the pharmacy was visited

If you or any of the others to be interviewed do not want to answer any of the questions you may say so and the interviewer will move on to the next question. No-one else but the interviewer will be present unless any of you would like someone else there.

Are there any disadvantages or advantages involved in taking part?

The discussions should take approximately ___ minutes per person. There are no individual benefits to taking part, but in answering our questions you will help us improve our understanding of how improve pharmacy services for the benefit of all Indians in the future. Unfortunately we are not in a position to assist with financial or other family problems that we come across.

Who will have access to the information I give?

We will not share individual information about you or other participants with anyone beyond our research team.

The knowledge gained from this research will be shared in summary form, without revealing individuals' identities, with interested organisations or individuals who may find the information useful in improving pharmacy services.

What will happen if I refuse to participate?

All participation in research is voluntary. You are free to decide if you want to take part or not. If you do agree you can change your mind at any time.

What if I have any questions?
For information about this study, you can contact the researcher who is responsible:

Rosalind Miller
Society of Community Health Awareness Research and Action (SOCHARA), 359 1st main, 1st block, Koramangala, Bengaluru, 560034
Mobile: 9035163280
Email: rosalind.miller@lshtm.ac.uk

3c: Exit interview survey

PATIENT EXIT INTERVIEW
(Interviewer to fill in this information before proceeding with interview)

Outlet ID	Interviewer – postcode - Outlet Code: [| | |-[| | | |-[| | | |]
B1. Today's date (dd/mm/yyyy)	[| |-[| |-[2 | 0 | 1 | 5]
B2. Interviewer's name [ ]	B2a. Interviewer's code [| |]
B3. Area name [ ]	B3a. Post code [5 | 6 | 0 | | |]
B4. Name of outlet *(if no name, record "no name" or owner's name)* [ ]	B4a. Outlet code [| | | |]
B5. Type of Outlet:	Chain .... 1 Independent 2

CONSENT

- My name is _____. I work on a research project that is being conducted by researchers at The Society of Community Health Awareness Research and Action (SOCHARA), Bengaluru and The London School of Hygiene and Tropical Medicine (LSHTM), UK.

- We are conducting this study to learn more about pharmacies in Bangalore.
- We are visiting 300 pharmacies in Bangalore and are interviewing a few patients in each outlet.
- For each patient we are asking questions concerning their visit to the pharmacy, some basic personal information and also about assets in the home.
- The whole interview will take approximately 5 minutes.
- **READ OUT INFORMATION SHEET AND HAND TO CUSTOMER**

- Have you understood? Do you have any questions?

CONSENT **(customer)**: I have had the study explained to me. I have understood all that has been read and had my questions answered satisfactorily. I understand that I can change my mind at any stage and it will not affect the benefits due to me or the household members.	☐ *please tick* **I agree to be interviewed** Signature: ....

CONSENT **(interviewer)**: I certify that I have explained this study to the interviewee and that s/he understands the nature and purpose of the study and consents to participate. S/he has been given an opportunity to ask questions which have been answered satisfactorily.	YES .... 1 NO .... 2 Signature: ....
Time Interview Started (24 hour clock)	HOUR[ ][ ] MINUTE[ ][ ]

Pharmacy visit

I would like to ask some questions about your visit to this pharmacy today	

G1. How many times have you visited this pharmacy before?	Never, this is the first time…….1 Between 1 and 5 times…………2 More than 5 times…………….. 3
G2. Why did you visit the pharmacy today? **Read out all options and record yes/no**	YES NO To fill a prescription ……………………………………1 0 To purchase medicines over the counter ……………..1 0 To ask for some health-related advice……………..…1 0 To purchase beauty/cosmetic/toiletry products …….1 0 Other 1 (specify) _____ Other 2 (specify) _____ Other 3 (specify) _____
G3. Are you visiting the pharmacy for yourself ?	Yes……………..1 **Got to G5** No…………...….0
G4. What is your relationship to the person whom you are visiting the pharmacy for?	Parent/spouse/partner/ child…………….. 1 Other relative……………………………. 2 Friend…………………………………….3 Employer……………………………….... 4 Other (specify)……………………….... 5 _____
G5. Was the pharmacist present in the pharmacy today?	Yes……………………… 1 No ……………………… 0 Don't know ……………9

Personal Charactersitics

I would like to ask some questions about yourself	
P1. Male or female	Male................1 Female 2
P2. Age (in years)	[____]
P3. What is the highest level of education you have completed?	No education............................. 1 Some primary............................2 Primary (to 8th standard)................3 Secondary (to 10thth standard).........4 Higher secondary (to 12th standard)/diploma.......................5 Graduate ....6 Post-graduate.............................7 Declined to answer 9
P4. **ONLY if interviewee purchasing medicines for someone else…** What is the highest level of education attained by the person for whom medicines were purchased? (if medicines purchased on behalf of minor- under 18- record details of head of household)	No education............................. 1 Some primary............................2 Primary (to 8th standard)................3 Secondary (to 10thth standard).........4 Higher secondary (to 12th standard)/diploma.......................5 Graduate ....6 Post-graduate.............................7 Declined to answer 9
P5. Can you read a letter in Kannada?	Yes.........................1 No.......................... 0
P6. Can you read a letter in English?	Yes.........................1 No.......................... 0

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Asset index

Ask if the household of person for whom the medicine is purchased has the following:	YES	NO
A1. Refrigerator	1	0
A2. Telephone (landline) only	1	0
A3. Mobile phone only	1	0
A4. Both telephone and mobile phone	1	0
A5. Electric fan	1	0
A6. Chair	1	0
A7. Pressure cooker	1	0
A8. Table	1	0
A9. Sewing machine	1	0
A10. Matress	1	0
A.11 Tap/running water in the house	1	0
A12. Television	1	0
A13. Bed	1	0
A14. Electricity	1	0
A15. Radio or transistor	1	0
A16. A sofa set	1	0
A17. Scooter/motorcycle	1	0
A.18. A washing machine	1	0
A.19. A car/jeep/van	1	0
A.20. A watch or clock	1	0
A.21 A computer/laptop without internet	1	0
A.22. A computer/laptop with internet	1	0
A23. Cooler/AC	1	0
A24. Number of bedrooms	1.....................1 2.....................2 3.....................3 4+....................4	

A25. Does your household have a below poverty line (BPL) card (green colour)?	Yes …………………1 No …………………2 Don't know…………9

Ending the interview	
Field worker to enter any comments/ observations about this interview	

Thank you very much for your participation in this interview. Do have any questions?

INTERVIEW ENDED AT (24 hr)   HR [__][__] MIN [__][__]

CHECKED BY:
INTERVIEWER CODE   [__][__]   DATE _____

3d: Information sheet and consent form for key informant interviews

Information Sheet for Key Informants

Study: Organisational arrangements of pharmacy retail in Bangalore and public health

Key informant interviews

What is Research?
The London School of Hygiene and Tropical Medicine (LSHTM) is a university that carries out research in the name of improving health. The Society for Community Health Awareness Research and Action (SOCHARA) is a local research organisation concerned with community health. Sometimes research only involves asking questions of patients, their parents, community members or health providers about what they know, feel or do. This is the type of research we are here to do today. All research at LSHTM and SOCHARA, including those involving only interviews, is approved by the relevant authorities to ensure that participants' safety and rights are respected.

What is this research about?
In this research, we want to learn more about how pharmacies in Bangalore operate.

Why do you want to talk to me and what does it involve?
We feel that your experience of working within a pharmacy firm can contribute much to our understanding and knowledge of how pharmacy services can be improved.

We would like you to take part in an interview with a researcher. The researcher will ask questions about your experiences of working in this firm. You do not need to discuss any information you are not comfortable in sharing.

If you agree, the interview will be tape-recorded to assist later in fully writing up the information.

Are there any disadvantages or advantages involved in taking part?
The discussions should take approximately 1 hour. There are no individual benefits to taking part, but in answering our questions you will help us improve our understanding of how to improve pharmacy services for the benefit of all Indians in the future. Unfortunately we are not in a position to assist with financial or other problems that we come across.

Who will have access to the information I give?
We are not here to inspect aspects of your business and no information about individual comments will be passed on to the regulatory authority. We will not share individual information about you or other participants with anyone beyond our research team.

The tapes will be destroyed after completion of the research.

The knowledge gained from this research will be shared in summary form, without revealing individuals' identities, with interested organisations or individuals who may find the information useful in improving pharmacy services.

What will happen if I refuse to participate?
All participation in research is voluntary. You are free to decide if you want to take part or not. If you do agree you can change your mind at any time.

What if I have any questions?
For information about this study, you can contact the researcher who is responsible:
Rosalind Miller
Society of Community Health Awareness Research and Action (SOCHARA), 359 1st main, 1st block, Koramangala, Bengaluru, 560034
Mobile: 9035163280
Email: rosalind.miller@lshtm.ac.uk

3e: Key informant interviewee consent form

CONSENT FORM

Study: Organisational arrangements of pharmacy retail in Bangalore and public health

Key informant interviews

(To be read to interviewee)

I certify that I have followed the information sheet to explain this study to
_____(name of participant) and that they understand the nature and the purpose of the study and consent to the participation in the study. They have been given an opportunity to ask questions which have been answered satisfactorily.

☐ *please tick* **Agree to be interviewed**

☐ *please tick* **Agree for the interview to be tape-recorded**

☐ *please tick* **Agree for verbatim quotes to be used in reports**

Signature: _____ Date _____

Designee/investigator's
Name _____ Time: _____
     (please print name)

EACH INTERVIEWEE SHOULD NOW BE GIVEN AN INFORMATION SHEET TO KEEP

3e: Key informant interview topic guide (chain executives)

General functioning and ethos of company

Can you tell me a little bit about 'company name' and your role within it?
Prompts
- Can you explain the structure of the company to me?
    -e.g. management structure
    -e.g. format of business (attached to doctor/stand alone pharmacy)
    -Check how many stores in Bangalore/India
- What are the underlying principles of 'company name'?

Did 'company' ever consider a franchise model or consider franchising some units? Why?

Can you tell me about some of the challenges of surviving in the pharmacy market in Bangalore?

Access
What factors influence where branches are opened?
Prompts
- Minimum population density?

Can you describe your target customer?
Does the company have any plans to expand further?
Prompts
- Which areas and why?
- Ie how choose an area to open a store?

Medicine prices/quality

Can you tell me about the process by which medicines are procured?
Prompts
- Where do you buy from? (manufacturers, super stockists, stockists).
- How many do you deal with?
- How much do you need to spend before receiving discounts? What sort of discounts do they offer?
- Ask about promotional offers from manufacturers/wholesalers.
- How is procurement process different to how an independent would purchase?

Who determines the prices at which medicines are sold in shops?
How would you say your prices compared with competitors?
Does the company find counterfeit medicines to be a problem?
Prompts
- Is there any difference between quality of medicines from manufactueres, super stockists, stockists.
- Which ones are more reliable/key players in Bangalore?
- Which ones don't you trust and why?

How is quality of medicines assured?

Staffing (knowledge and incentives)

What staffing arrangements do you have in your stores?

How do you recruit the store staff?

What do you look for in prospective employees?

Is it a challenge to find qualified pharmacists (DPharm, BPharm).

Prompts
- Is it always logistically possible to have a pharmacist in store?
- If not what do you do?
- What about other chains do they always have pharmacists?

How are staff paid?

Prompts
- Do you run any bonus schemes
- Do staff receive any financial incentives? Details?
- Private label incentives? Promotions? Exact details of any schemes

Do staff receive training?

Prompts

How long?

What exactly does training program consist of?

Is training the same for pharmacists and pharma aides and managers?

How does it vary?

Do you over any clinical material e.g. treating minor ailments?

Performance management/self-regulation

Can you tell me about your best performing branches? Prompt: What is good about them?

Have you had any problems with any of your branches? If so, explain what problems

Do you collect regular information from branches? How often? What?

Do you visit branches? If so, how often?

What is the purpose of these visits?

How do you evaluate the performance of staff?

Prompts

Do you monitor quality at branches? How?

What happens if a branch does not meet minimum requirements?

Use of mystery shopper? What exactly do they look for? MS scenarios?

Use of CCTV?

Any other methods?

Regulation/sensitive

What contact does the company have with regulatory bodies?

Prompts
- Does head office have direct contact with the drug control department?
-

What are they concerned with when they visit (either head office or branches)?
- Enquire about schedule H1- when was introduced? Why so strict? Is this different to regulation in the past? What happens when shops break the regulations?

Have you ever experienced bribery in the sector?

Appendix 3f: Key informant topic guide (chain branch staff)

Individual information

Can you tell me a little bit about this pharmacy and your role?

Prompts

- What is your qualification and how long have you worked here?
- What year did this shop open?
- Can you tell me a little bit about the company which you are a part of?
- How were you recruited for this position?
- Why did you decide to join a chain?
- What did you do before you worked here?
- Have you worked for any independent shops or other chains? (if so can ask about practices in that environment)

Shop information

What are the opening hours of this shop? Is this the same for all X company?

Asides from allopathic (Western) medicines do you sell any other types? (prompt Ayurveda, homeopathy, Unnani, Siddha). Ask if know about other chains.

Can you tell me about who else works in the pharmacy?

Who is responsible for doing what in the shop?

Did you receive any training when you joined X company?

Prompts

- Can you explain to me what the training involved?
- How long training was the training?
- What did the training cover?
- Is training the same for all staff (eg pharmacists and pharma aides /managers)
- Did you receive any training on how to manage different conditions in the pharmacy (eg diarrhoea) questioning patients and giving advice or? And when to refer to the doctor ?
- Are training programs the same in other chains?

Access

How would you describe this area?

Can you describe your typical clients?

Do you target any particular types of customers?

What about other chains do they have different target customers?

Motivations and Incentives

What do you like about working in a chain?

What don't you like about it?

(if applicable) is it different from running an independent pharmacy/working in another chain? If so, how?

Does the company have any incentive schemes in addition to your salary?

Prompt

- What about bonus schemes (prompt promotional offers, private labels, sales targets etc)?

- Can you explain to me how these work?

How much effort do you put into reaching the targets set? Is it worth your while?

Are these similar to schemes in other chains?

Performance management (self-regulation)

Is you progress/performance monitored by the head office? How?

Prompts

- Does anyone from the company HQ visit you? Who? How often? What do they do when here?

- Ask more about CCTV (are you watched, how much- do they give you feedback from this)

- Mystery shoppers (again ask re feedback and also what sort of scenarios do they use), and how they feel about this monitoring.

- Do you have to provide the company with regular information about the shop? How often? What?

Competitive strategies

Why do customers choose to visit your pharmacy?

How do you keep your customers happy?

Prompts

- Do you do anything to attract new customers?

- Do you have a loyalty card program- how does it work?

- Do you offer any services asides from dispensing (eg BP, cholesterol testing, home delivery)

- Does the shop offer discounts to customers? Explain

When customers come for advice OTC how do you decide which medicines to give them?

How do you choose between the many different brands?

Price/quality of medicines

Can you tell me about how you purchase medicines? Same for other chains?

Prompts

- Are there any company procedures that need to be followed?

- Ask about own brand products.

- Who decides the price of medicines?

- How is price decided upon?

- How would you say your prices compared with competitors?

Do you notice any difference in quality from manufacturers, super stockists, stockists?

Regulation/sensitive

What contact do you have with government regulatory officials?

What do they look for when coming for an inspection?

Prompts

- What is their position on schedule H drugs?

- Is this something they are monitoring a lot?

- Enquire about schedule H1- when was introduced? Why so strict? Is this different to regulation in the past? What happens when shops break the regulations?

- Have you had any experience of bribes?

Do you have a refrigerator in the store? And power backup? Would this be in all stores?

Is there a qualified pharmacist in the shop- what qualification?

Is the DPharm (or equivalent) always in the shop?

What about in other shops- Apollo, MedPlus, Trust- do they have a qualified person at all times?

Query about shortage of pharmacists. Why are they so difficult to find?

Ask about ORS for diarrhoea. Is it promoted by anyone? Is it popular medicine. If not, why?

Appendix 3g: Key Informant topic guide (independent pharmacies)

Individual information
Can you tell me a little bit about this pharmacy and your role?
Prompts
- What is your qualification and how long have you worked here?
- Can you tell me about the staffing arrangements in the pharmacy?
- Who is responsible for doing what?

Motivations
Why did you decide to setup your own shop?
Prompts
- What do you like about running a medical shop?
- What don't you like about it?
Can you tell me what you did before running this shop?

Views on chains
What do you think about chain/corporate pharmacies?
Prompts
- Do you think they operate in a fair way?
- How do they affect your business? If business affected (how much- % decrease in sales)?
- Do you think you will be able to continue your business in the long run?
- Do you know any other pharmacy owners affected by this? Know of any shops going out of business?
- Does the Chemist and Druggist association (or any other groups) offer any kind of support? How?
- What kind of staff do they have in chain shops (Apollo, Medplus, Trust). Query about qualified person eg DPharm.
- What strategies do they use to increase their business?
- Have you started running your business any differently since the chains became established? Have you added any new services? E.g. home delivery- or were already doing that?

Staff
If any other staff asides from owner....Do your staff undergo training?
Prompts
- What sort of training- describe?
- Anything on advice to customers/how to manage minor ailments in the pharmacy?
- Does owner attend any training courses? CPD?

How do you motivate/manage staff
Prompt
- Do you have any incentive/bonus schemes?

Access
Why did you decide to open your store in this area?
How would you describe this area?
Can you describe your typical clients?
Do you target any particular kind of customer?
Do chains target the same kinds of customers as you?

Competitive strategies

Why do customers choose to visit your pharmacy?

How do you keep your customers happy?

Prompt

- Do you do anything to attract new customers?
- When customers come for advice OTC how do you decide which medicines to give them? How do you choose between the many different brands?

Price/quality of medicines

Can you tell me about how you purchase medicines?

Prompts

- Who do you purchase from (manufacturers, super stockists, stockists)?
- Who are the main wholesalers in Bangalore?
- Does this differ to how chains purchase their medicines?

How is price decided upon?

How would you say your prices compared with competitors?

Does the company find counterfeit medicines to be a problem?

Prompts

- Is there any difference between quality of medicines from manufactueres, super stockists, stockists.
- Which ones are more reliable/key players in Bangalore?
- Which ones don't you trust and why?

How is quality of medicines assured?

Regulation/sensitive

What contact do you have with government regulatory officials/drug control office?

What do they look for when coming for an inspection?

Prompts

- What is their position on schedule H drugs?
- Is this something they are monitoring a lot?
- Enquire about schedule H1- when was introduced? Why so strict? Is this different to regulation in the past? What happens when shops break the regulations?
- What do they do if no qualified person?
- Have you had any experience of bribes?

Do you have a refrigerator in the store? And power backup?

Is there a qualified pharmacist in the shop- what qualification?

Is the DPharm (or equivalent) always in the shop?

What about in other shops - do they have a qualified person at all times?

Query about shortage of pharmacists?

Ask about ORS for diarrhoea. Is it promoted by anyone? Is it a popular medicine. If not, why?

Appendix 4: Ethical Clearances

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Observational / Interventions Research Ethics Committee

Ms. Rosalind Miller
Research Degree Student
PHP
LSHTM

7 October 2014

Dear Ms. Miller,

Study Title: Organisational arrangements of pharmacy retail in India and implications for public health

LSHTM Ethics Ref: 8543

Thank you for your letter of 25 September 2014, responding to the Observational Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

| Document Type	File Name	Date	Version
Information Sheet	Exit interview info and consent.docx	22/08/2014	1
Information Sheet	General survey information and consent form.docx	22/08/2014	1
Information Sheet	Mystery Shopper Survey info and consent.docx	22/08/2014	1
Protocol / Proposal	Rosalind Miller Upgrading Document July 2014.pdf	22/08/2014	1
Protocol / Proposal	Exit interview.docx	22/08/2014	1
Protocol / Proposal	General provider survey.docx	22/08/2014	1
Protocol / Proposal	Key informant interview Topic guide.docx	22/08/2014	1
Protocol / Proposal	Standardised patient scenarios.docx	22/08/2014	1
Protocol / Proposal	Key informant interviews info and consent.docx	25/09/2014	2

After ethical review

Any subsequent changes to the application must be submitted to the Committee via an Amendment form on the ethics online applications website. The Principal Investigator is reminded that all studies are also required to notify the ethics committee of any serious adverse events which occur during the project via an Adverse Event form on the ethics online applications website. At the end of the study, please notify the committee via an End of Study form on the ethics online applications website. Ethics online applications website link: http://leo.lshtm.ac.uk

Yours sincerely,

Professor John DH Porter
Chair

ethics@lshtm.ac.uk
http://www.lshtm.ac.uk/ethics/
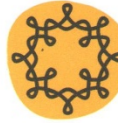
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SOCHARA Institutional Scientific and ethics Committee (SISEC)

Mr. Abhijit Sengupta, IAS (Retd)
Chairperon

Members

1. *Fr. Clement Campos* (Ethics)
2. *Dr. Arvind Kasturi* (Community Health Research)
3. *Dr. Maya Mascarenhas* (Community Health Practitioner)
4. *Dr. D K Srinivas* *(Public Health, Academic)*
5. *Ms. Manjulika Vaz* (Social Science)
6. *Ms. Kathiyani Chamraj* (Civil Society)
7. *Mr. Lawrence Liang* (Law)
8. *Mr. As Mohammad* (Demography and Statistics)
9. *S J Chander* (Member Secretary)

19th September, 2014

Dear Ms. Rosalind Miller

Greetings from SOCHARA Institutional Scientific and Ethics Committee (SISEC)!

The SOCHARA Institutional Scientific and Ethics Committee (SISEC) has reviewed all the necessary documents submitted to SISEC for clearance on scientific and ethical aspect of the PhD study titled 'Effects of different organizational form on the functioning of the Indian Pharmacies and the implications for public health'

I would like to inform you that your PhD proposal is approved by the SISEC. However you have been advised to take note of the following areas observed by the committee:

1. To review the sampling method and size
2. Translation of participant information sheet and consent forms into Tamil, Kannada, Telugu and Hindi needs to be considered.
3. To consider taking witnessed informed consent and standardizing the words used
4. To meet government authorities concerned for your study
5. To submit a six monthly progress report to the committee

With Best Wishes

S J Chander

Member Secretary

Appendix 5: Supplementary material to Miller and Goodman 2017, BMJ Global Health

Table A1: Therapeutic management of suspected TB in chain and independent pharmacies

Variable	Chain (n=103) % (95% CI)	Independent (n=230) % (95% CI)	P-value[†]
Correct case management	42.7 (33.5-52.5)	44.8 (38.4-51.3)	p=0.726
Referral	43.7 (34.4-53.5)	46.5 (40.1-53.0)	p=0.631
Antibiotic	16.5 (10.5-25.0)	16.1 (11.9-21.5)	p=0.924
Steroid	1.0 (0.1-6.7)	3.0 (1.5-6.3)	p=0.254
Harmful (antibiotic or steroid)	16.5 (10.5-25.0)	16.5 (12.2-21.9)	p=0.997
Not recommended	63.1 (53.3-71.9)	62.2 (55.7-68.2)	p=0.871
Schedule H	56.3 (46.5-65.6)	53.9 (47.4-60.3)	p=0.685
Schedule H1	0	3.0 (1.5-6.3)	p=0.074
Anti-tuberculosis medicine	0	0	

†estimated by Pearson Chi ^{2} test

Table A2: Therapeutic management of childhood diarrhoea in chain and independent pharmacies

Variable	Chain (n=103) % (95% CI)	Independent (n=230) % (95% CI)	P-value[†]
Correct case management	0	0	
ORS plus zinc	0	0	
ORS	11.7 (6.7-19.5)	9.6 (6.3-19.5)	p=0.561
Zinc	1.9 (0.5-7.1)	0	p=0.034*
ORS and no AB or AD	5.8 (2.6-12.4)	5.2 (3.0-9.0)	p=0.821
Antibiotic (AB)	33.0 (24.6-41.7)	42.2 (35.9-48.7)	p=0.114
Antidiarrhoeal (AD)	1.9 (0.5-7.5)	6.5 (4.0-10.6)	p=0.079
Harmful (AB or AD)	35.0 (26.3-44.7)	47.8 (41.4-54.3)	p=0.029*
Not recommended	25.2 (17.7-34.6)	22.2 (17.2-28.0)	p=0.539
Schedule H	36.9 (28.1-46.7)	48.7 (42.3-55.2)	p=0.045*
Schedule H1	0	0.43 (0.1-3.0)	p=0.503
Referral	40.8 (31.7-50.6)	37.0 (30.9-43.4)	p=0.507

†estimated by Pearson Chi ^{2} test
*significant at 5% level

We used a logistic regression model to assess the association between pharmacy type and components of therapeutic management for both tracer conditions. In this model we include standardised patient (SP) fixed effects in order to eliminate any SP-specific effects from the estimates. The adjusted odds ratios (for both the diarrhoea and suspected TB case) do not significantly differ from the unadjusted data, showing that inter-rater reliability is not what is driving our results.

Table A3: Impact of pharmacy type on therapeutic management of diarrhoea case, with and without SP fixed-effects

Variable	Unadjusted Odds Ratio	95% Lower Bound	95% Upper Bound	P-value	Adjusted Odds Ratio	95% Lower Bound	95% Upper Bound	P-value
Correct case management	n/a				n/a			
ORS plus zinc	n/a				n/a			
ORS	0.8	0.38	1.69	0.562	0.71	0.33	1.54	0.388
Zinc	1†				1			
ORS and no antibiotic or antidiarrhoeal	0.89	0.32	2.44	0.821	0.79	0.28	2.24	0.661
Antibiotic	1.48	0.91	2.41	0.115	1.49	0.91	2.45	0.115
Antidiarrhoeal	3.52	0.79	15.7	0.099	3.38	0.75	15.21	0.112
Harmful (antibiotic or antidiarrhoeal)	1.71	1.1	2.76	**0.029***	1.72	1.1	2.82	**0.030***
Not recommended	0.84	0.49	1.45	0.54	0.87	0.5	1.52	0.629
Schedule H	1.62	1.01	2.61	**0.046***	1.62	1	2.65	**0.052***
Schedule H1	1†				1			
Referral	0.85	0.53	1.37	0.507	0.82	0.51	1.34	0.431

*significant at 5% level

† standard error omitted (very few observations)

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Table A4: Impact of pharmacy type on therapeutic management of suspected TB case, with and without SP fixed-effects

Variable	Unadjusted Odds Ratio	95% Lower Bound	95% Upper Bound	P-value	Adjusted Odds Ratio	95% Lower Bound	95% Upper Bound	P-value
Correct case management	1.09	0.68	1.74	0.726	1.06	0.65	1.73	0.822
Referral	1.12	0.7	1.79	0.632	1.1	0.67	1.8	0.711
Antibiotic	0.97	0.52	1.82	0.924	1.03	0.54	1.95	0.933
Steroid	3.2	0.39	26.37	0.279	3.36	0.41	27.8	0.261
Harmful (antibiotic or steroid)	1	0.54	1.87	0.997	1.06	0.56	2.01	0.852
Not recommended	0.96	0.59	1.55	0.871	0.96	0.58	1.59	0.882
Schedule H	0.91	0.57	1.45	0.685	0.93	0.58	1.51	0.782
Schedule H1	1[†]							
Anti-tuberculosis medicine	n/a							

† standard error omitted (very few observations)

Appendix 6: Editorial for Journal of Clinical Tuberculosis and Other Mycobacterial Diseases

Research paper 5

(Cover sheet on next page).

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RESEARCH PAPER COVER SHEET

PLEASE NOTE THAT A COVER SHEET MUST BE COMPLETED __FOR EACH__ RESEARCH PAPER INCLUDED IN A THESIS.

SECTION A – Student Details

Student	Rosalind Miller
Principal Supervisor	Professor Catherine Goodman
Thesis Title	The rise of chain pharmacies in India: implications for public health

If the Research Paper has previously been published please complete Section B, if not please move to Section C

SECTION B – Paper already published

Where was the work published?	Journal of Clinical TB and Other Mycobacterial Diseases
When was the work published?	January 2018
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	

Have you retained the copyright for the work?*	No	OPEN ACCESS CC-BY	Was the work subject to academic peer review?	Yes

*If yes, please attach evidence of retention. If no, or if the work is being included in its published format, please attach evidence of permission from the copyright holder (publisher or other author) to include this work.

SECTION C – Prepared for publication, but not yet published

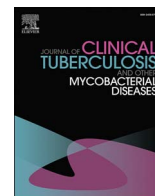|	
Where is the work intended to be published?	
Please list the paper's authors in the intended authorship order:	
Stage of publication	Choose an item.

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	Drafted editorial with critical input and comments from JD and MP.

Student Signature: _____   Date: 22/3/18

Supervisor Signature: _____   Date: 22/3/18

Contents lists available at ScienceDirect

J Clin Tuberc Other Mycobact Dis

journal homepage: www.elsevier.com/locate/jctube

Quality of tuberculosis care by Indian pharmacies: Mystery clients offer new insights

ABSTRACT

For many patients in India, pharmacies are their first point of contact, where most drugs, including antibiotics, can be purchased over-the-counter (OTC). Recent standardised (simulated) patient studies, covering four Indian cities, provide new insights on how Indian pharmacies manage patients with suspected or known tuberculosis. Correct management of the simulated patients ranged from 13% to 62%, increasing with the certainty of the TB diagnosis. Antibiotics were frequently dispensed OTC to patients, with 16% to 37% receiving such drugs across the cases. On a positive note, these studies showed that no pharmacy dispensed first-line anti-TB drugs. Engagement of pharmacies is important to not only improve TB detection and care, but also limit the abuse of antibiotics.

Tuberculosis (TB) is the world's top infectious disease killer, accounting for an estimated 1.8 million deaths in 2015 [1]. Over a quarter of those deaths were in India, which carries the largest burden of the disease, with worryingly high rates of MDR-TB. Early symptoms of pulmonary TB are common, vague and persistent, leading infected individuals to seek care from a variety of local primary care providers [2]. A study of patient pathways to care in 13 countries showed that nearly 60% of TB patients begin their care seeking in the private or informal sectors, including pharmacies [3].

Pharmacies are highly accessible in India due to their vast numbers (around 800,000 nationally) [4], long opening hours and absence of user fees [5]. For many patients, pharmacies may be their first point of contact, where most drugs, including antibiotics, can be purchased over-the-counter (OTC).

What exactly do pharmacists do when they encounter patients with suspected TB, or confirmed TB? We now have reliable, consistent data from two standardised (simulated) patient studies, across 4 Indian cities, on how Indian pharmacies manage such patients [6,7]. Standardised patients (SPs), also called mystery clients, are widely considered to be the gold standard when it comes to measurement of actual practice [8], and SPs have been effectively used to assess quality of TB care in India, Kenya and China [9–11].

Together, the two SP studies of pharmacies in India presented three different presentations of TB to multiple pharmacies (Table 1). Management of the patients was benchmarked against guidelines for pharmacists from the Government of India and the Indian Pharmaceutical Association [12]. Referral to a healthcare provider without selling antibiotics or steroids was deemed 'correct' management (Table 1). Correct management that is evidence-based is a core element of quality of care. There are, of course, other elements such as user experience and patient outcomes. But these were not captured in the SP studies.

Fig. 1 shows that correct management of the SPs ranged from 13% to 62%, increasing with the certainty of the TB diagnosis. Those presenting with non-specific symptoms of cough and fever, consistent with many differential diagnoses, were correctly managed only in 13% of the SP interactions. However, the suggestion of TB, due to close contact with a relative with TB, increased this figure to 45%. Further still, a confirmed positive sputum test ensured that almost two-thirds of SPs were managed correctly.

Antibiotics were frequently dispensed OTC to patients, with 16%–37% receiving such drugs across the cases. However, three positive findings emerged. First, antibiotic use more than halved when SPs explained they had been in contact with an infected individual or had a confirmed diagnosis, compared to those only presenting symptoms suggestive of TB. Second, the use of restricted Schedule H1 medicines was low in all cities. Third, out of 1533 SP encounters across 4 cities, not a single pharmacy dispensed first-line anti-TB medications without a prescription.

Successful TB control efforts hinge on early diagnosis and appropriate treatment. The results of these recent SP studies are consistent across 4 cities, and show that urban pharmacists do a poor job of asking patients with TB symptoms relevant questions, and referring them for TB testing. These practices likely delay TB diagnosis. However, a pure profit motive whereby pharmacists want to sell drugs to patients at all costs is also a poor explanation of observed behavior. Management varied with the certainty of the diagnosis and pharmacists were willing to forego sales in favor of referring patients with a stronger suggestion of TB. Therefore, training pharmacy staff to recognise the symptoms of TB could improve on the current situation.

In terms of treatment, these studies demonstrate that pharmacists do not give OTC first-line anti-TB drugs and are likely not a major driver of drug resistant TB in the country. The limited use of H1 medicines (a restricted category of medicines, mainly comprising third and fourth generation

Table 1

Specific case presentations of tuberculosis by standardised patients in Satyanarayana et al. [7] and Miller and Goodman [6].

|	Satyanarayana et al 2016 (Lancet case 1)	Miller and Goodman 2017 (BMJGH case)	Satyanarayana et al 2016 (Lancet case 2)
Case presentation (opening statement by the simulated patient)	`I have cough and fever that is not getting better. Please give me some medicine'	`I have had cough and some fever for 3–4 weeks. We have had a relative staying with us who has TB. Can you suggest something?'	`I am having cough for nearly a month now and also have fever.' While showing a positive sputum report to the chemist, the patient continues, 'I went to the government dispensary and they asked me to get my sputum tested. I have this report. Can you please give me some medicine?'
Definition of 'correct' management	Verbal or written referral to a DOTS centre or a health-care provider without dispensing any antibiotics (including anti-tuberculosis drugs and fluoroquinolones) or steroids	Referral to TB clinic or other healthcare provider for sputum examination. No sale of antibiotics (including anti-TB medication) or steroids	Verbal or written referral to a DOTS centre or a health-care provider without dispensing any antibiotics (including anti-tuberculosis drugs and fluoroquinolones) or steroids
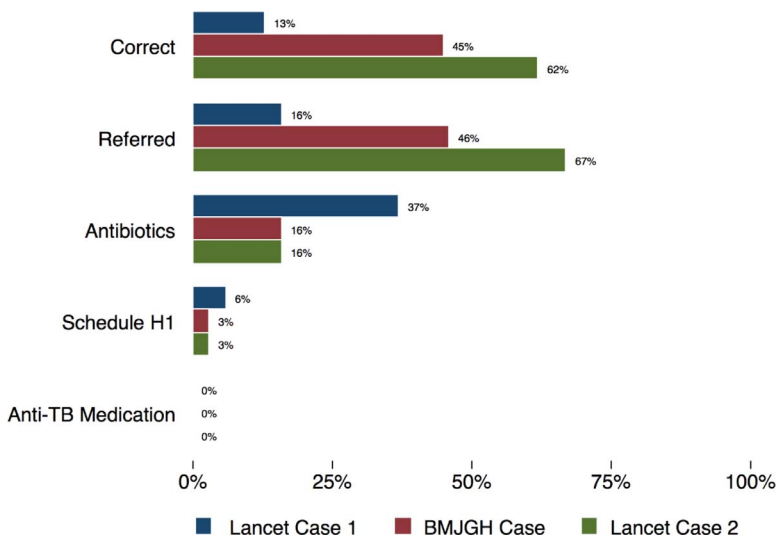
Fig. 1. Management of 3 different case presentations of tuberculosis by pharmacies in urban India. For definition of 'correct management' see Table 1.

cephalosporins, carbapenems, newer fluoroquinolones and first- and second-line anti-tuberculosis drugs) also suggests that the introduction of this regulation has had an effect.

Historically, community pharmacists have not been engaged in national policy discussions around TB control. However, recent years have seen some progress in this area culminating in the memorandum of understanding between the Central TB Division and the Indian Pharmaceutical Association, the All India Organisation of Chemists and Druggists, the Pharmacy Council of India and the SEARPharm forum to ``engage pharmacists in RNTCP for TB Care and Control in India''. Over the past decade, there have been projects focused on engaging pharmacists in India [13]. But such public-private mix (PPM) partnerships are yet to reach scale [14]. In the most recent draft of the National Strategic Plan for Tuberculosis Elimination 2017–2025, there are no budgets for engaging retail pharmacists, but mapping of pharmacies and their engagement is surveillance and social mobilization is envisioned [15].

It is widely believed that knowledge may not be sufficient to ensure good pharmacy practice as public health goals may not necessarily align with the financial interests of private sector pharmacists [16,17]. Our findings suggest that this view needs to be nuanced: pharmacists do deviate from accepted norms when diagnosis is unknown or uncertain. But their behavior improves markedly when diagnoses are more apparent. And their deviations are tightly bound by implicit norms that restrict the use of anti-TB medicines and Schedule H1 antibiotics.

In conclusion, we need to think beyond traditional models that expect pharmacists to be able to recognize who may have TB and passively refer TB patients to the public sector [18]. Pharmacists can be engaged for a variety of TB services across the cascade of care, and private pharmacies have been actively engaged in novel PPM models in India that have dramatically increased private sector TB case notifications in the country and improved quality of TB care in the private sector [19]. In addition, a supportive and effective regulatory environment may be as important to help curb the OTC sale of unnecessary antibiotics, and decrease diagnostic delays for millions of TB patients.

Conflicts of interest

None

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jctube.2017.11.002.

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