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# **Selling Drugs or Providing Health Care?**

**The Role of Private Pharmacies and Drugstores,  
Examples from Zimbabwe and Tanzania**

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Institutet**

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To my parents for taking me to Africa

# ABSTRACT

**Background:** In low-income countries many people do not have access to formal health care because of poverty and weak health systems. Instead people seek care at private pharmacies and drugstores. Infectious diseases such as sexually transmitted infections (STI) and diarrhoea are common and access to correct management is of big importance. Assessing the quality and finding the potential for improvement of private pharmacy and drugstore practice is therefore of uttermost importance for public health.

**Main objective:** To explore and describe the role of private pharmacies and drugstores in resource-limited settings with a focus on antibiotics in Zimbabwe and Tanzania.

**Methods:** Semi-structured interviews with pharmacists from nine African countries were analysed with a phenomenographic approach (I). Structured facility and staff interviews and the simulated client method (SCM) were used in private pharmacies in four Zimbabwean towns. The simulated clients presented a male and a female STI case and a child-with-acute-diarrhoea case. Statistical analysis was applied and step models were developed (II). Drugsellers in private drugstores in eight Tanzanian districts were interviewed. The SCM was used presenting a male and a female STI case. Data were analysed statistically and “QATI” scores were developed (III). Exit-customers of private drugstores in eight Tanzanian districts were interviewed. Drugsellers from three Tanzanian districts filled in a questionnaire with closed and open-ended questions. Mixed qualitative and quantitative analysis (IV).

**Results:** Four different ways of perceiving the role of the pharmacist were identified: the satisfied dispenser; the dissatisfied dispenser; the health care team member and the life saver (I). A majority (69%) of the staff in the Zimbabwean pharmacies stated they would never sell an antibiotic without prescription and few actually did so, in spite of a high customer demand. Not many provided acceptable information and advice: 8% STI male, 33% STI female and 22% for the diarrhoea case (II). Although 74% of the Tanzanian drugsellers claimed there were no STI-related drugs in the store, drugs were dispensed in a majority of the SCM visits. In 80% of the male SCM visits and in 90% of the female, the client was dispensed drugs that are recommended in the Tanzanian guidelines for syndromic management of urethral and vaginal discharge syndromes. Dosage regimens were however often incorrect and complete syndromic management rarely provided. In 76% of the male SCM visits and 35% of the female, antibiotics were dispensed (III). Antibiotics were bought by 24% of the exit-customers. Dispensed drugs were assessed to be relevant for the symptoms/disease presented in 83% of all cases and in 51% for antibiotics specifically. Thirty percent had seen a health worker before coming and almost all of these had a prescription. Non-prescribed drugs were more relevant than prescribed drugs. Of the drugsellers, 79% stated that bacterial diseases can be treated with antibiotics, of these, 24% stated the same for viral disease. Most (72%) had heard of antibiotic resistance. They described antibiotic resistance and how it occurs quite rationally from a biomedical point of view but also presented less plausible descriptions of the topics (IV).

**Conclusion:** There is a potential to use private pharmacies and drugstores in a more formal way for the benefit of health in the low-income settings studied. Drugsellers have considerable “practical knowledge” of antibiotics and other drugs. Current regulations might impede them from playing a more important role as well as improving their practice.

## LIST OF PUBLICATIONS

The thesis is based on the following papers, which will be referred to by the roman numerals I-IV.

- I. Viberg N, Tomson G, Mujinja P and Stålsby Lundborg C. The Role of the Pharmacist - Voices from Nine African Countries, *Pharm World Sci* (2007) 29:25–33
- II. Nyazema N\*, Viberg N\*, Khoza S, Vyas S, Kumaranayake L, Tomson G, Stålsby Lundborg C. Low Sale of Antibiotics Without Prescription – A Cross Sectional Study in Zimbabwean Private Pharmacies. *Journal of Antimicrobial Chemotherapy* (2007) 59, 718–726.
- III. Viberg N, Mujinja P, Kalala W, Kumaranayake L, Vyas S, Tomson G and Stålsby Lundborg C. STI management in Tanzanian private drugstores - practices and roles of drugsellers. *Sex Transm Inf* published online 27 Jan 2009.
- IV. Viberg N, Kalala W, Mujinja P, Tomson G and Stålsby Lundborg C. “Practical Knowledge” and perceptions of antibiotics and antibiotic resistance among drugsellers in Tanzanian private drugstores. *Manuscript*.

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\* First and second authors contributed equally.

**Front Cover:** Tingatinga painting by Ludovick Nangida showing a Tanzanian drugstore.

**Back Cover:** *Top:* Pharmacy in a low-density (high socio economic status) residential area in Zimbabwe. *Middle:* Pharmacy in a high-density (low socio economic status) residential area in Zimbabwe. *Bottom:* Drugstore in Tanzania. The drugseller in the picture is not part of the presented studies. Photo Nina Viberg.

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## LIST OF ABBREVIATIONS

AIDS	Acquired Immunodeficiency Syndrome
ARV	Antiretroviral
CHW	Community Health Worker
CI	Confidence Interval
DALE	Disability-Adjusted Life Expectancy
FIP	Fédération Internationale Pharmaceutique, International Pharmaceutical Federation
GAVI	The Global Alliance for Vaccines and Immunization
GDP	Gross Domestic Product
GHI	Global Health Initiatives
GPP	Good Pharmacy Practice
HIV	Human Immunodeficiency Virus
MCAZ	Medicines Control Authority of Zimbabwe
MDG	Millennium Development Goals
MoH&SW	Ministry of Health and Social Welfare
OR	Odds Ratio
ORS	Oral Rehydration Salts
OTC	Over-The-Counter
PEPFAR	The US President's Emergency Plan for AIDS Relief
PEERCON	Peer Review and Consumer Rights
PIM	Pharmacist-Initiated Medicine
PO	Prescription-Only
QATI	Questions, Advice, Treatment and Drug Information
RUD	Rational Use of Drugs
RUM	Rational Use of Medicines
SC	Simulated Client
SCM	Simulated Client Method
STI	Sexually Transmitted Infections
UDS	Urethral Discharge Syndrome
VDS	Vaginal Discharge Syndrome
WHO	World Health Organization



# 1 PREFACE

When I was fourteen years old I had the chance to visit Tanzania and Kenya with my family. It was an amazing experience for a young girl and the trip had a great impact on me. When I later, as a pharmacy student, got the opportunity to go back to Tanzania on a volunteer project, I did not hesitate. For four months I stayed in the little village of Kiromo in a small house without electricity and hot water. I worked in the pharmacy section of the Neema dispensary together with local staff and other foreign pharmacy students. The work was rewarding and it was a challenge to communicate with the patients in Swahili. I however noted that we did not have very many patients per day. The only exception was when the rumour had spread that we had received a medicines delivery. It made me aware how dependent health care is on medicines and how patients will go where the medicines are. So, a question arose: If they do not come to our dispensary, where do they go instead?

The issue became a bit clearer when I discovered that the little kiosk where we bought groceries sold antimalarials and painkillers. When visiting the market in the closest town, I found a man selling medicines from a stand next to the pineapples. I also realized that there were a number of small drugstores scattered around the town. As an outsider, I was puzzled by all this and it evoked my interest in a medicines market so unlike the one I had seen at home. Once back in Sweden I contacted IHCAR and found out that they were looking for a pharmacist for a project on pharmacy and drugstore practice in Tanzania and Zimbabwe. Once again, I did not hesitate.

The project has brought me back to Tanzania many times now, and on one occasion I stayed with my husband in Dar es Salaam for another period of four months. That taught me how different life can be in different parts of the country. Visiting fascinating and beautiful Zimbabwe also made me aware how different the African countries are from each other. I wish I had had the opportunity to get to know Zimbabwe more, and I hope I will in the future.

## 2 BACKGROUND

### 2.1 HEALTH SYSTEMS

A health system has been defined as *all the activities whose primary purpose is to restore or maintain health*. [World Health Organization (WHO), 2000] Most of these activities, but not all, are health services, i.e. the health *care* system, including preventive, curative and palliative interventions directed to individuals or populations. According to WHO, health systems have three fundamental objectives: to improve the health of the people they serve; to respond to people's expectations and; to provide financial protection against the cost of ill-health. Vital functions of a health system are: service provision, health workforce, information, medical products and technologies, financing and stewardship. [World Health Organization (WHO), 2000, 2008a]

During the twentieth century, health systems underwent three overlapping waves of reforms. The first led to the founding of national health systems. The second wave reacted to the fact that the colonial powers in Africa and Asia, and governments in Latin America, had established health services that largely excluded indigenous populations. The focus of the second wave was on primary health care with the goal of achieving "Health for all" as stipulated by the Alma-Ata declaration in 1978. ["Declaration of Alma-Ata", 1978] Among other things, many countries made substantial efforts to train and use community health workers (CHW) who were to deliver basic, cost-effective services in simple rural facilities to previously underserved populations. These programs were, however, eventually found to be quite inefficient. The third wave of health system reform, driven mainly by the World Bank, saw an increased role for private health care provision. It was prompted by the poor performance of public health sectors that neglected the demand side of health services and also by prevailing political ideologies that saw private health care as potentially more efficient and of greater quality. [Kumaranayake, 1997; World Health Organization (WHO), 2000] As a consequence, private health care provision increased substantially including drug provision through private pharmacies and drugstores. [Cederlöf et al., 1995; Chuc, 2002; Syhakhang, 2002]

#### 2.1.1 Health systems in resource-limited settings

A functioning health system is of uttermost importance for the health of the population. In low-income countries however weak health systems impede delivery of existing effective interventions for many priority health problems. There is a growing consensus that strengthening health systems is decisive for the attainment of the Millennium Development Goals (MDG). [Travis et al., 2004] There is much less agreement on how to strengthen them but priority areas for research have been identified: 1) financial and human resources, 2) organization and delivery of health service, 3) governance, stewardship and knowledge management, and 4) global influences. [Task Force on Health Systems Research, 2004] The MDG prompted the establishment of a number of global health initiatives (GHIs) such as the Global Fund to Fight AIDS, TB and Malaria, The US President's Emergency Plan for AIDS Relief (PEPFAR), Roll Back Malaria, The Global Alliance for Vaccines and Immunization (GAVI). These initiatives have been successful in raising the level of resources for health but are constrained in their delivery capacity by weak health systems. At the same time, concerns have been raised that the GHIs have the unintentional effect of eroding the existing health systems partly by focusing only on selected health problems. [World Health Organization

(WHO), 2008a]

A major barrier to improved health systems function is the lack of human resources. An estimated 4.3 million health workers are missing in the world today and the shortage is most severe in sub-Saharan Africa. [World Health Organization (WHO), 2006b] One strategy to reduce the lack of health workers is task shifting whereby specific tasks are moved, where appropriate, from highly qualified health workers to health workers with shorter training and fewer qualifications in order to make more efficient use of the available human resources for health. [World Health Organization (WHO), 2008b]

### 2.1.2 A new paradigm for pharmacy practice

Pharmacists are employed at many levels of the health system. (See Box 1.) [World Health Organization (WHO), 1994] This thesis mainly concerns community pharmacy practice.

Traditionally the pharmacist's professional tasks consisted of compounding medicines in the pharmacy and dispensing them to the customers. During recent decades the compounding part has been taken over by the pharmaceutical industry creating many new professional tasks for pharmacists but leaving community, or retail, pharmacists primarily with the task of dispensing. [World Health Organization WHO, 1994] This has created a debate about the pharmacist as an "over-educated" distributor of medicines. [Anderson, 2002; Edmunds et al., 2001]

A number of international policy documents describe how the pharmacy profession must shift their focus from the medicine to the consumer and become more of a health care provider. The Good Pharmacy Practice (GPP) guidelines, based on the principles of pharmaceutical care, state that a pharmacist's first concern must be the

#### **Box 1. Functions of pharmacists in the health care system**

##### **Regulatory control and drug management**

- Health and drug policy
- Drug management (selection, procurement, distribution)
- Administration
- Educational policy
- Regulatory and enforcement agencies
- Professional registration authorities
- International agencies and professional bodies

##### **Community pharmacy &**

##### **Hospital pharmacy**

- Processing of prescriptions
- Care of patients or Clinical pharmacy
- Monitoring of drug utilization
- Extemporaneous preparation and small-scale manufacture of medicines
- Traditional and alternative medicines
- Responding to symptoms of minor ailments
- Informing health care professionals and the public
- Health promotion
- Domiciliary services
- Agricultural and veterinary practice

##### **Industrial pharmacy (pharmaceutical industry)**

- Research and development
- Manufacture and quality assurance
- Drug information
- Patent applications and drug registration
- Clinical trials and post-marketing surveillance
- Sales and marketing
- Management

##### **Academic activities**

- Research
- Teaching

##### **Training of other health care workers**

welfare of the patient. [Fédération Internationale Pharmaceutique (FIP), 1993, 1998; World Health Organization (WHO) et al., 2006] This has been described as especially important as an increasing number of prescription-only (PO) medicines are being given over-the-counter (OTC) status and hence becoming more easily accessible to the consumers. [Pawaskar et al., 2007; World Health Organization (WHO), 1998] Regulations as to which medicines are PO and which OTC vary between countries and some countries also categorise selected medicines as pharmacy-only or pharmacist-initiated medicines (PIM). [Anderson, 2002] Formally and informally, medicines are also increasingly being sold by non-pharmacists e.g. in supermarkets, on the Internet, in market places or by computerized dispensing machines. [World Health Organization (WHO) et al., 2006]

Although the FIP emphasises that professional factors should be the main philosophy underlying practice they also acknowledge that economic factors are important and that appropriate remuneration for pharmacists providing care rather than selling drugs must be established. [Fédération Internationale Pharmaceutique (FIP), 1993, 1998]

Around the world, the discussion about the best use of pharmacists and the endeavours of pharmacists to define their new role continues. [Barber et al., 1994; Bjorkman, 2008; Cederlöf et al., 1995; Edmunds et al., 2001; Larsson et al., 2008; Olsson et al., 2002; Owusu-Daaku et al., 2008] It has been commented that pharmacists and drugsellers constitute an especially suitable starting point for studying health systems because they don't quite fit in. [Whyte et al., 2002]

### 2.1.3 Pharmacy practice and drug retailing in times of health worker crisis

The first aim of the GPP implementation recommendations for developing countries is for all people to have access to a qualified pharmacist. [Fédération Internationale Pharmaceutique et al., 1998] In low-income countries a pharmacist/population ratio of 1-2/100 000 is not uncommon and the numbers are unlikely to rise quickly since few pharmacists are being trained in these countries and out-migration is common. In high-income countries the pharmacist/population ratio is estimated at 30-200/100 000. [Fédération Internationale Pharmaceutique (FIP), 2006; Katerere et al., 2003] Furthermore, licensed pharmacies are unevenly distributed within counties with the majority situated in urban areas while most of the population lives in rural areas. [Fédération Internationale Pharmaceutique (FIP), 2006; Management Sciences for Health, 2003] In public health care facilities, medicines are often supposed to be available free of charge or at a moderate cost, but due to health worker shortages and inefficient drug delivery systems, the presence of health workers and medicines is not guaranteed. [Hanson, 2000; Ministry of Health Tanzania, 2003b; van der Geest, 1982]

Instead, people buy medicines from informal providers for example in market places, on the street or from drug peddlers and traditional healers. [Van der Geest, 1991] To increase access to medicines, some countries also allow specialized stores to sell OTC medicines. Some examples are the Part II outlets in Tanzania, drug shops in Uganda, drug outlets in Vietnam, Class III pharmacies in Lao PDR and patent medical dealers in Nigeria. [Afolabi, 2008; Chuc, 2002; Syhakhang, 2002; The Government of Tanzania, 1998; Tumwikirize et al., 2004] In this thesis I will refer to these kinds of outlets as

drugstores as opposed to pharmacies and the personnel as drugsellers as opposed to pharmacists.

## 2.2 MEDICINES\*

### 2.2.1 Access to medicines

Access to health and medicines is a human right. [Hogerzeil, 2006] The World Health Organisation (WHO) has since the 1970s promoted equitable access to medicines through the concept of *Essential Medicines* defined as those medicines that satisfy the priority health-care needs of the population. [World Health Organization (WHO), 2009a] Although more than 150 WHO member states have an official essential medicines list, about 30% of the world's population is estimated to lack regular access to essential medicines. In the poorest parts of Africa this figure is over 50%. [World Health Organization (WHO), 2004a, 2009b]

Lack of access to medicines is a sign of wider problems in health system function. It is closely correlated with other indicators of health system performance, such as disability-adjusted life expectancy (DALE). [World Health Organization (WHO), 2004b] Access has been defined as comprising four dimensions: *accessibility*, *availability*, *affordability* and *acceptability*. When studying access one must consider the interaction between two sets of characteristics: 1. *Individual and household factors*, and 2. *Health system factors*, as illustrated in Table 1. [Anderson et al., 2004] Pharmacies and drugstores are often preferred sources of medicines because they fulfil many of these health system factors.

Individual and household factors	Dimension of access	Health system factors
Means of transportation, gender, household circumstances, literacy, education	Accessibility	Geographical distribution Oral and written information
Alternative options (e.g. home remedies, traditional healers, informal drug peddlers)	Availability	Opening hours and waiting time Medicines in stock
Personal, social and economic resources Time e.g. competing demands and activities	Affordability	Direct costs (prices) Indirect cost (time spent i.e. loss of working days) Hidden cost (bribes)
Cultural belief and knowledge about drugs and illnesses Trust in competence of provider	Acceptability	Staff friendliness, competence, motivation and responsiveness, social distance to patient

Table 1. A framework for the study of access to medicines. (Modified from Anderson et al., 2004)

\* The terms medicines, drugs and pharmaceuticals will be used interchangeably throughout the thesis.

### 2.2.2 Rational use of medicines

Although medicines are financially important they are not just commodities like any other. [Fédération Internationale Pharmaceutique (FIP), 1996; Whyte et al., 2002] Use of medicines, especially inappropriate use, can have serious adverse health consequences for the patient. While acknowledging that sometimes the most appropriate therapy does not include drugs, the WHO states that “the rational use of drugs requires that the appropriate drug be prescribed, that it be available at the right time at a price that people can afford, that it be dispensed correctly and that it be taken in the right dose at the right intervals for the right length of time. The appropriate drug must be effective and of acceptable quality and safety.” [World Health Organization (WHO), 1985] To be able to take their medication in an appropriate way, patients need to be given information. They need to know how to take the drug, how to store the drug, how the drug is expected to help and how to recognize problems caused by the drug and what to do about them. [Hermann et al., 1978]

### 2.2.3 Antibiotic resistance

The use of certain drugs, notably irrational use, can lead to drug resistance. This thesis will mainly touch upon the issue of antibiotic resistance although resistance development is a problem also for other kinds of drugs such as antifungals, HIV antiretrovirals (ARV), and antimalarials. [Eriksen et al., 2005; Lee et al., 2009; Piacenti, 2006] For decades we have been able to treat once deadly diseases with antibiotics. Development of antibiotic resistance now threatens to take us back to the pre-antibiotic era. [Cars et al., 2008] The problem is especially grave in low-income countries because of high antibiotic use and high prices of second-line treatment alternatives. [Blomberg et al., 2004; Hart et al., 1998; Okeke et al., 2005; Sihavong et al., 2006] There is a delicate balance between providing access to life saving antibiotics on one hand and preventing the development of antibiotic resistance on the other.

## 2.3 DISEASE BURDEN AND TREATMENTS

In low-income countries, infectious diseases such as respiratory infections, sexually transmitted infections (STI), malaria, tuberculosis and diarrhoea fuelled by high prevalence of HIV/AIDS, constitute a major threat to public health. [World Health Organization (WHO), 2006a, 2009e] Many of these infections are treatable with cost-effective medicines if available, exemplified below by the tracer conditions used in this thesis, STI and diarrhoea.

### 2.3.1 Syndromic management of STI

Approximately 340 million new cases of the four main curable STI, gonorrhoea, chlamydia, syphilis and trichomoniasis occur every year and 75-85% of these are in low-income countries. [Mayaud et al., 2004] Untreated STI are serious conditions in themselves and they have also been given increased attention because of the association with increased risk of HIV transmission. [Grosskurth et al., 1995; Population Council, 2001] Prompt and correct treatment of STI is essential to prevent the development of disease, to avoid complications and to limit the spread of disease. [UNAIDS/WHO,

1999] Many health care facilities in low-income countries lack the equipment and trained personnel required for etiological diagnosis of STI. To overcome this problem the WHO has developed the syndromic STI management approach. The diagnosis is based on the identification of symptoms and signs and follows a flowchart procedure. Comprehensive syndromic STI management includes correct drug treatment, education and counselling, condom promotion and provision, partner notification and treatment, a return visit in 7 days if not cured and HIV counselling and testing if possible. [World Health Organization (WHO), 2003] In this thesis syndromic management of urethral and vaginal discharge syndromes in Tanzania is discussed. (See Appendix 1)

### 2.3.2 Management of Diarrhoea

Diarrhoea is a leading cause of child death in the world. [Black et al., 2003; The MOST project et al., 2005] Diarrhoea has many causes, the most common being intestinal infections by virus, bacteria, or parasites. Acute diarrhoea starts suddenly and can continue for several days. If it continues for more than 14 days it is called persistent diarrhoea. The two main dangers of diarrhoea are dehydration and malnutrition, which can lead to death. Management should focus on preventing or treating dehydration by giving home fluids like yoghurt or rice water, home-made sugar-salt solution or pre-packed oral rehydration salts (**ORS**). In severe dehydration, intravenous fluids should be given. Additionally, **zinc** is recommended to reduce the severity and duration of the diarrhoea. [Bhutta et al., 1999; Forsberg, 2007; OneWorld Health, 2007; The MOST project et al., 2005] Studies have however shown that many children around the world are not getting the recommended management. [Forsberg et al., 2007] **Adsorbents** (such as kaolin, pectin and activated charcoal) should not be used for treating acute diarrhoea. They have been shown to induce only a slight change in stool consistency and they do not reduce the fluid and salt losses. **Antimotility** drugs (such as loperamide) may be harmful, especially in children less than 5 years old. They may temporarily reduce cramps and pain but delay elimination of the organisms causing the diarrhoea and may prolong the illness. They can be dangerous and even fatal if used improperly in infants. **Antibiotics** should be used for treating cholera and dysentery (bloody diarrhoea). For most other causes of diarrhoea, antibiotics are not effective. [The MOST project et al., 2005]

## 2.4 ZIMBABWE

Zimbabwe is situated in the south of Africa. It has a population of 13.2 million. [World Health Organization (WHO), 2009d] The country gained its independence in 1980. In the following decade the economic growth was strong and living standards were improving. In the late 1990s, the economic growth began to slow down and since 1999, the economic conditions have continued to deteriorate due to political instability, currently reaching a critical level with extreme inflation and an exchange rate in free fall. [The World Bank, 2009] Life expectancy is 44/43 (M/F). Infectious diseases dominated by HIV/AIDS with prevalence in adults of 15.3%, are the most important threats to public health and the country has recently been struck by a cholera epidemic. [UNAIDS, 2009; World Health Organization (WHO), 2009d]

In the first decade of independence the government emphasized universal provision of health care services provided by the state. Public health care is delivered at four levels, which are meant to function as a referral chain. (See Table 2.) While many of the pre-conditions for effective regulation of the health care sector were largely in place, studies have indicated that the regulations are not always effectively enforced. [Hongoro et al., 2000; Kumaranayake et al., 2000] There is anecdotal evidence that the health system is now disintegrating due to the crisis in the country.

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Third Referral Level	Central and Special Hospitals.
Second Referral Level	Provincial and General Hospitals.
First Referral Level	District Hospitals.
Entry level	Rural Health Centres, Rural Hospitals and Urban Clinics (services do not require an attending Physician).

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Table 2. The structure of the public health care system in Zimbabwe. [Zimbabwe Ministry of Health and Child Welfare, 1999]

Since the early 1990s there has been a steady growth of private for profit health care as well as an increase in registered pharmacies. Until 1994 the number was static at between 75 and 90. By the end of 1999, the Medicines Control Authority had over 300 pharmacies registered, almost exclusively restricted to urban areas within reach of private health facilities. Poor availability of drugs in the public sector partly fuelled this expansion. [Zimbabwe Ministry of Health and Child Welfare, 1999]

Prescription medicines, pharmacist initiated medicines (PIM) and OTC medicines are sold in pharmacies. Selected OTC medicines, so called household remedies, can also be bought from supermarkets. The earlier mentioned drugstores, licensed to sell OTC medicines, are not present in Zimbabwe. The standard of private retail pharmacies in Zimbabwe varies but many have a high technical standard including computerized patient records. The number of pharmacists in Zimbabwe in 1996 was 524 (4/100 000 population). [Ministry of Health and Child Welfare et al., 1996] In recent years, a considerable number are thought to have emigrated. [Torongo, 2003] Community pharmacy personnel comprise pharmacists, pharmacy technicians, and pharmacy assistants / over-the-counter staff.

## 2.5 TANZANIA

The United Republic of Tanzania is situated in eastern Africa and was founded in 1964 as a union between mainland Tanganyika and the islands of Zanzibar. It is the biggest country in East Africa with a population of 39.5 million and has a GDP per capita of 980 international \$. Life expectancy is 50/51 (M/F). The disease pattern shows a predominance of infectious diseases with HIV/AIDS as the major cause of death followed by lower respiratory infections, malaria and diarrhoea. [The Government of Tanzania, 2009; World Health Organization (WHO), 2009c] The HIV prevalence in



adults is estimated at 6.2%. [UNAIDS, 2006] Total health expenditure per capita is 45 international \$. [World Health Organization (WHO), 2009c]

In socialistic post-colonial Tanzania health care was largely run by the state with emphasis on rural coverage. Private for-profit health service was actively discouraged, and in 1977 prohibited by law. In 1991 the ban was abolished and in 2000, nearly 20% of health facilities were classified as private. In 2000, Tanzania had almost 5 000 health facilities, 80% of these being dispensaries. The health services framework assumes a pyramidal pattern of referral. [The Government of Tanzania, 2009] (see Table 3)

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Referral/Consultant Hospitals	This is the highest level of hospital services in the country. There are four referral hospitals: the Muhimbili National Hospital which covers the eastern zone; Kilimanjaro Christian Medical Centre (KCMC) which provides for the northern zone, Bugando Hospital which covers the western zone; and Mbeya Hospital which serves the southern Highlands.
Regional Hospitals	Every region is supposed to have a hospital. Regional Hospitals offer similar services as on the district level but also have specialists in various fields and offer additional services which are not provided at district hospitals.
District Hospitals	The district is a very important level in the provision of health services in the country. Each district is supposed to have a district hospital.
Health Centre Dispensary	A health centre is expected to cater for 50,000 people This is the second stage of health services. The dispensary caters for between 6,000 to 10,000 people and supervises all the village health posts in its ward.
Village Health Service	This is the lowest level of health care delivery in the country. They essentially provide preventive services which can be offered in homes. Usually each village Health posts have two village health workers chosen by the village government amongst the villagers who are given a short training before they start providing services.

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Table 3. The health services structure on Tanzania. [The Government of Tanzania, 2009]

About 80% of the population in Tanzania has access to health services and over 90% of the population lives within 10 km of a health care facility. This does however not automatically lead to appropriate drug access since public health care facilities often are in short supply due to an inefficient delivery system. [Management Sciences for Health, 2003, 2004; Ministry of Health Tanzania, 2003a; Schellenberg et al., 2003; Tanzania Food and Drugs Authority, 2004; The Government of Tanzania et al., 1998]

Licensed pharmacies, so called Part I outlets, in 2003 numbered around 339 and today around 600, are only present in cities. In 2003 around 650 pharmacists were registered in the country and in 2009, 750. Hence there are approximately 1.9 pharmacists per 100 000 population. [Ministry of Health and Social Welfare Tanzania, 2009; Pharmacy Board Tanzania, 2003] A majority of the population therefore has no access to a pharmacist or a pharmacy. Instead, private drugstores, so called Part II outlets (in

Swahili officially called *duka la dawa baridi*) that are licensed to sell only OTC drugs, play a significant role in access to drugs. [Ministry of Health Pharmacy Board, 1998] There is no official information on the numbers of Part II outlets, in this thesis referred to as private drugstores, and many are unregistered. Different sources however estimate that the number is somewhere between 3 000 and 5 666, hence comparable with the total number of public, religious and private dispensaries in the country (N=3 955). [Goodman et al., 2007; Management Sciences for Health, 2003; Ministry of Health and Social Welfare Tanzania, 2009] Private drugstores are seen by the Ministry of Health as being of great importance for basic drug access for the rural population. Major shortcomings among the private drugstores have however been identified and efforts are now being made to upgrade the private drugstores into accredited drug dispensing outlets (ADDOs). These will, after training of the drugsellers and renovation of the facilities, be authorized to sell OTC drugs and a selected range of prescription only drugs including some antibiotics. [Management Sciences for Health, 2007; Tanzania Food and Drugs Authority, 2004] Community pharmacy personnel comprise pharmacists, pharmaceutical technicians and pharmaceutical assistants. ADDO-dispensers include nurse assistants, pharmaceutical assistants and assistants clinical officers. In private drugstores the requirements for the drugsellers are that they have basic knowledge of pharmaceutical, medical, veterinary or agricultural sciences, or that they are approved by the Pharmacy Board in consultation with other relevant authorities. [Ministry of Health Pharmacy Board, 1998]

## 2.6 RATIONALE

Infectious diseases, widespread poverty and weak health systems give drugstore and pharmacy personnel a special role in low-income countries. Private pharmacies and drugstores are often the first - and only - contact that people have with health care. This is where people go to seek care for both small ailments and more serious diseases because of easy access, good drug availability and lower over-all costs. [Adu-Sarkodie et al., 2000; Buabeng et al., 2007; Chalker et al., 2000; Grosskurth et al., 1995; Mnyika et al., 1995; Morris et al., 2007; Ongore et al., 1996; Ross-Degnan et al., 1996] Unhelpful or patronizing treatment at public health facilities, especially for stigmatized diseases such as STI are also contributing factors. [Cederlöf et al., 1995; Goel, P. et al., 1996; Lan et al., 2008; Paphassarang et al., 2002] Access to drugs for treating infectious diseases is of major importance since, if not treated promptly and correctly, they can lead both to serious disabilities and death. Assessing and improving the practice of private drugsellers and pharmacists in these settings is therefore of great importance for the health of the population. Intervention studies performed in Asia have shown that private pharmacy practice can be improved through multi-faceted interventions. [Chalker et al., 2005; Chuc et al., 2002; Stenson et al., 2001; Syhakhang, 2002] In Africa most research has focused on prescribers, neglecting drugsellers and also licensed pharmacists as stakeholders. In East Africa few studies have focused on the dispensing of antibiotics specifically. [Adu-Sarkodie et al., 2000; Buabeng et al., 2008; Cederlöf et al., 1995; Goodman et al., 2004; Igun, 1994; Laing et al., 2001; le Grand et al., 1999; Leiva et al., 2001; Marsh et al., 2004; Ross-Degnan et al., 1996] A greater body of knowledge is needed to determine the potential value of pharmacy and drugstore practice in resource-constrained settings and how to increase it. [Smith, 2009]

### **3 OBJECTIVES**

#### **3.1 GENERAL OBJECTIVE**

To explore and describe the role of private pharmacies and drugstores in resource-limited settings with a focus on antibiotics in Zimbabwe and Tanzania.

#### **3.2 SPECIFIC OBJECTIVES**

- To explore the views on pharmacy practice in Africa as perceived by pharmacists from several African countries. (I)
- To assess the quality of private pharmacy practice with a focus on the extent of antibiotic sales in private pharmacies in four Zimbabwean cities in relation to two tracer conditions - STI among females and males and diarrhoea in a child. (II)
- To describe the role and possible contribution of private drugstores in STI management in rural Tanzania. (III)
- To explore and describe antibiotics sale and dispensing practices in private drugstores in rural Tanzania as well as explore drugseller knowledge and perceptions of antibiotics and antibiotic resistance. (IV)

## 4 METHODS

### Practical research framework

The four papers of the thesis were conceived within the framework of an ongoing intervention project, the PEERCON project, aiming to improve private pharmacy practice in Zimbabwe and drugstore practice in Tanzania. The project has a controlled before and after design and the intervention targets are both providers and customers. Paper I was part of the formative phase of this study and Papers II & III were parts of the baseline phase. Paper IV is partly performed within the baseline phase and partly within the intervention phase in Tanzania. The provider, drugseller, part of the intervention in Tanzania is therefore described in Appendix 2.

In this thesis, both qualitative and quantitative methods were used. Paper I is qualitative and studies pharmacists' views. Paper II is quantitative studying Zimbabwean pharmacists' reported and actual practice. Paper III is also quantitative and studies Tanzanian drugsellers' knowledge, views and reported and actual practice. Paper IV uses a mixed-methods approach to describe Tanzanian drugsellers' knowledge, perceptions and practice. (See figure 1)

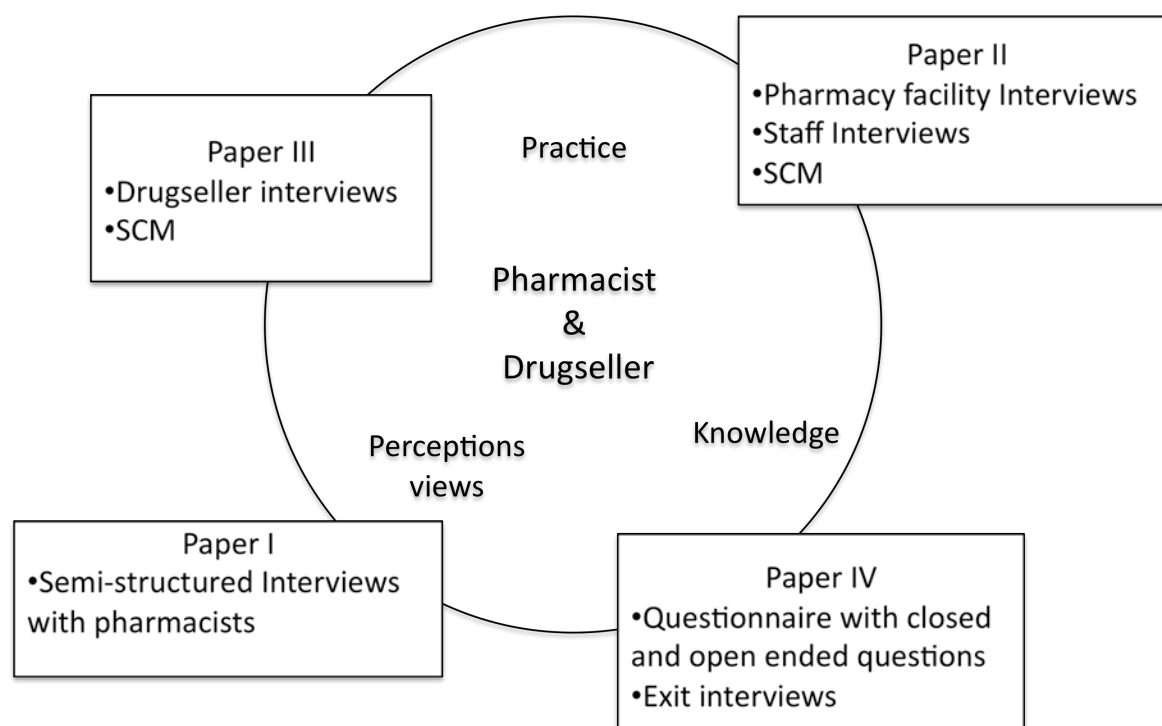


Figure 1. Data collection methods used to study pharmacist and drugseller views and perceptions, knowledge and practice.

### 4.1 QUALITATIVE METHODS

Two different approaches to analyzing qualitative data were used namely phenomenography, in Paper I, and content analysis in Paper IV.

#### 4.1.1 Phenomenography

Phenomenography was developed within the field of educational research and assumes that a phenomenon, concept or principle only can be understood in a limited number of qualitatively different ways. Phenomenography is concerned with the second-order perspective i.e. not how things really are but how people experience them. [Marton, 1981; Wenestam, 2000] It aims at “finding qualitatively different ways in which people experience, conceptualize, perceive and understand various aspects of, and phenomena in, the world around them.” [Marton, 1988]

##### *4.1.1.1 Data generation and study participants Paper I*

##### *The Role of the Pharmacist – Voices from nine African Countries.*

The study participants were 15 purposively selected African pharmacists, the majority of whom participated in the FIP congress 2002 in Nice, France. Using the framework of the congress made it possible to include pharmacists from a range of different African countries. The interviewed pharmacists came from Burkina Faso, Cameroon, Congo-Brazzaville, Ghana, Mali, Nigeria, South Africa, Tanzania and Zimbabwe. Prior to the congress, attempts were made to contact different African pharmacy associations in order to plan the interviews. No responses were however received and contacts were instead made at a meeting at the congress concerning the institution of an African pharmaceutical forum within FIP. Participants with name badges denoting African countries were approached either after the meeting or later at the congress. Pharmacists from African countries that were either working or had been working in their home country were eligible for the study. In total, 12 pharmacists from eight different countries agreed to participate, although one interview had to be made later by e-mail due to time constraints. Three additional interviews were made by Swedish pharmacy students in Africa who were instructed to purposively select pharmacists whom they presumed could provide additional information to the study. Hence 15 pharmacists from nine African countries participated. Ten participants were working in community or hospital pharmacies and five were working within other fields such as publishing and pharmaceutical regulation. Two had trained in Europe, two were currently working in Europe and one was working in the USA.

Data was generated through face-to-face semi-structured interviews. The eleven interviews that were performed by the first author during the conference were tape-recorded and the languages used were English or French in order to include participants from different parts of Africa. In the three additional interviews that were made in Africa, notes of the responses were taken by the Swedish pharmacy students and sent by post to the first author. The interview guide contained both closed and open-ended questions designed to get an overview of the pharmacy profession as well as invite to discussions of greater depth.

#### 4.1.1.2 Data analysis Paper I

The tape recordings were transcribed verbatim and the analysis followed the steps suggested by Dahlgren and Fallsberg. [Dahlgren et al., 1991] See Table 4.

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1	<i>Familiarization</i>	The interviews were carefully read through a number of times to get familiar with the material. When doing this, the role of the pharmacist stood out as an interesting phenomenon on which to focus the analysis.
2	<i>Condensation</i>	The most significant statements made by the subjects on this phenomenon were selected to obtain a short, but representative, version of the view of each respondent.
3	<i>Comparison</i>	The short versions were compared to find variations or agreements in the views of the role of the pharmacist.
4	<i>Grouping</i>	Views that were classified as similar were combined in groups. The groups were found to have similarities pair-wise, and were therefore sorted as sub-categories under two main categories.
5	<i>Articulation</i>	The essence of the similarity within each group was presented through a description of each main category and a more specific description of each sub-category.
6	<i>Labelling</i>	The main and sub-categories were denoted by constructing a suitable linguistic expression. These were discussed among the authors and native-English speakers were consulted.
7	<i>Contrasting</i>	The categories obtained were compared to examine similarities and differences.

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Table 4. Steps followed in the phenomenographic analysis.

#### 4.1.2 Content analysis

Content analysis is not one method as such but rather a set of approaches. It initially became renowned as a quantitative method in the field of media research where it was used to describe text data with the help of statistics. [Graneheim et al., 2004; Robson, 2002] Over time it has evolved into different qualitative approaches that have come into wide use in health research. Qualitative content analysis focuses on the characteristics of language as communication with attention to the content or contextual meaning of the text. The analysis can be deductive where existing theory or prior research is used to form pre-defined categories into which the data is sorted. It can also be inductive, meaning that the categories emerge from the data. [Hsieh et al., 2005] Content analysis focuses on the *manifest content*, what is clearly visible in the text or the *latent content*, the underlying meaning of the text. [Graneheim et al., 2004]

##### 4.1.2.1 Data generation and study participants Paper IV

##### *“Practical knowledge” and perceptions of antibiotics and antibiotic resistance among drugsellers in Tanzanian private drugstores*

In Paper IV both quantitative and qualitative methods were used. A questionnaire about antibiotics and antibiotic resistance was responded by 75 drugsellers participating in the PEERCON intervention. The drugsellers came from three different Tanzanian districts and the sample selection is described below under heading 4.2.1.2. The qualitative data generated were written responses to the open-ended queries: “Please describe what an antibiotic is”, “What is antibiotic resistance?” and “How does antibiotic resistance occur?”

#### *4.1.2.2 Data analysis Paper IV*

The responses from the open-ended questions were translated from Swahili to English and analysed using two different approaches to content analysis as described by Hsieh et al. [Hsieh et al., 2005]

##### *Summative manifest content analysis*

In the texts generated by the open-ended question: “Please describe what an antibiotic is”, different keywords were identified. The respondents were thereafter sorted into the different groups according to keywords used. The frequency of respondents sorted into the different groups was calculated. Since the analysis stops at this point, it can be regarded as primarily quantitative.

##### *Inductive latent content analysis*

The questions “What is antibiotic resistance?” and “ How does antibiotic resistance occur?” yielded more elaborate responses that encouraged the use of a more qualitative approach to content analysis. The texts were entered into the software Open Code 3.4. Sentences or part of sentences that related to the same meaning, so called meaning units, were identified and assigned codes that described their content. [Graneheim et al., 2004] Categories were thereafter generated through grouping similar codes together. Three categories were later designated as sub-categories forming one category. In this process, a theme describing the latent content emerged.

## **4.2 QUANTITATIVE METHODS**

### **4.2.1 Study setting, participants and sample selection**

#### *4.2.1.1 Paper II: Low Sale of Antibiotics Without Prescription in Zimbabwean Pharmacies.*

The study had a cross sectional design and included pharmacies in Harare and three other towns (hereafter called A, B and C for confidentiality reasons). Pharmacy background (facility) and staff data were collected in Harare and towns A and B while simulated client method (SCM) data was collected in Harare, towns A, B and C. The sampling frame was a list of registered private pharmacies obtained from the Medicines Control Authority of Zimbabwe (MCAZ) that was updated by attempting to contact each pharmacy on the list. It thereafter consisted of 144 pharmacies and sample selection for the survey was done in several stages. (See Figure 2) The total number of pharmacies to be included in the study in the four towns was 87 for each SCM scenario and 96 for facility and staff interviews. The actual number became lower because of drop out. One facility interview per pharmacy was performed with a senior staff member. All pharmacists or pharmacy technicians present were invited to participate in the staff interview. Each pharmacy was visited once per SCM scenario. (See Table 5)

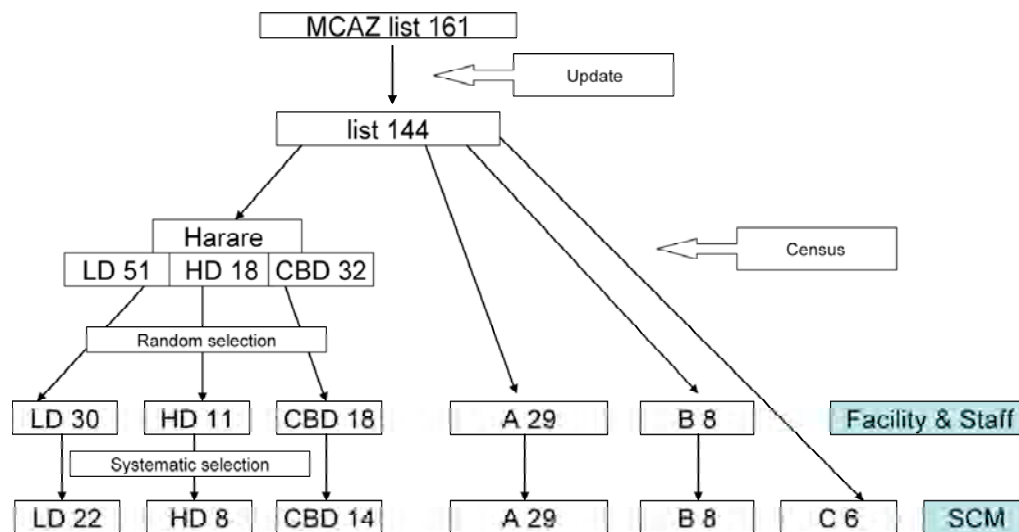


Figure 2. Sample selection design Paper II.

All pharmacies in towns A, B and C were included i.e. A = 29, B = 8 and C = 6 pharmacies. The Harare pharmacies were stratified into three strata according to population density and type of area in which they were situated. The strata were named low density (LD), high density (HD), and central business district (CBD). A stratified proportionate random sample of pharmacies was drawn i.e. in each stratum a random selection was done using SPSS 10.0 to arrive at a total of 61 pharmacies representing approximately 60% of all pharmacies in Harare. A further two pharmacies from the list (one animal pharmacy and one duplicate) were subsequently excluded to leave a sample of 59 unique pharmacies in Harare. This sample was used for the facility and staff interviews in Harare. Because of time and resource constraints, for the SCM visits in Harare a systematic sample of 44 pharmacies was taken from the list of 59. Every second pharmacy was included, starting from the top of the list for each stratum. Another selection round, also starting from the top, selected every fourth pharmacy etc, until the desired number was met.

4.2.1.2 *Paper III: STI management in Tanzanian private drugstores-practices and roles of drugsellers and Paper IV: “Practical Knowledge” and perceptions of antibiotics and antibiotic resistance among drugsellers in Tanzanian private drugstores.*

The studies for Papers III and IV were made with in the Tanzanian part of the PEERCON project. Four of Tanzania’s 26 regions were purposively selected based on geographical location. They were rural, not too scattered and situated within practical reach from Dar es Salaam. Two districts per region were randomly selected; Mkuranga and Rufiji (Coast region), Korogwe and Muheza (Tanga region), Mvomero and Kilosa (Morogoro region) and Kongwa and Mpwapwa (Dodoma region). (See Figure 3) The population size of each district is around 250 000 inhabitants.



Figure 3. The Tanzanian districts included in studies for Papers III and IV.



A census of drugstores in the eight districts was attempted and all drugstores found were included in the drugstore interviews and SCM visits (Paper III) as well as exit interviews (Paper IV) if they were open at the time of the visit. The respective Regional Administration Offices and District Medical Officers provided lists of registered drugstores. If found, additional unregistered drugstores were included during data collection. One drugseller per drugstore, usually the only one present, was selected for the drugstore interview. Based on power calculations for evaluation of the PEERCON intervention, each drugstore was supposed to be visited by five simulated clients (SC) per scenario and five exit customers were supposed to be interviewed per store. These numbers turned out to sometimes be unfeasible to attain because of low numbers of ordinary customers per day and the limited data collection period. Most stores were instead visited by one male SC and one or two female SCs. A small number of stores were visited by three or four different SCs. One to 16 consecutive exit customers were interviewed per store.

One district per region was randomly allocated into the intervention group of the PEERCON project. Drugsellers in all drugstores identified in these districts were invited to participate in the intervention that consisted of workshops and outreach visits. The intervention participants in three of the four intervention districts were asked to fill out the questionnaire about antibiotics and antibiotic resistance at the onset of either the workshop or the outreach visit. (Paper IV) It was not feasible to include the fourth intervention district due to time limitations. The intervention did not focus on antibiotics specifically but on Good Dispensing Practice (GDP), malaria and STI. (See Appendix 2)

#### 4.2.2 Quantitative data collection methods

Quantitative data was collected through a number of methods in Papers II-IV.

##### 4.2.2.1 *Pharmacy interviews*

In the study about sale of antibiotics in Zimbabwe (Paper II), data was collected using interviews with pharmacy personnel. The participants were either pharmacists (n= 69) or pharmacy technicians (n=4). They were interviewed using two different structured interview guides containing fixed response alternatives and a few open-ended questions. One of the guides concerned background information about the pharmacy premises (facility interviews), including availability of drugs, and the other collected information on the respondents' professional practice, opinions and experiences (staff interviews). Data was collected by three research team members; a pharmacy technician, a nurse and a pharmacist.

##### 4.2.2.2 *Simulated client visits*

To assess actual practice the simulated client method (SCM) was used for data collection in both in Zimbabwean pharmacies and Tanzanian drugstores. (Papers II and III) The method has been used earlier in pharmacy settings and provides data that is difficult to attain through other methods. The practitioner whose performance is studied is unaware that these particular clients are participating in a study and is therefore assumed to behave as usual. [Chalker et al., 2000; Chuc et al., 2001; Madden et al.,

1997] Research assistants, mainly pharmacy and medical students were trained through role-play to perform pre-designed case scenarios in a reproducible way.

#### 4.2.2.2.1 Zimbabwe SCM

The simulated clients (SC) visited the pharmacy pretending to be a customer, either a patient or a caregiver of a sick child. The scenarios presented was i) a woman with vaginal discharge and itching, hereafter called STI female, ii) a man with urethral discharge, hereafter called STI male and iii) a caregiver of a child with acute diarrhoea. (See Table 5) Each pharmacy was visited once per scenario with the aim to explore possibilities of buying antibiotics without prescription. The client asked specifically to see the pharmacist and, if offered to buy a drug, said that s/he did not have enough money but would come back later. The simulated clients filled in a standardized reporting form about e.g. drugs recommended, questions asked and advice given at the latest 15 minutes after the encounter and out of sight of the pharmacy.

Instructions to the simulated client: If the pharmacist asks you for a prescription, say that you don't have one. If the pharmacist asks you to get a prescription first, reply that you do not have money to pay for the visit to a doctor and ask that if the pharmacist knows the problem, can't he (she) give you some drugs? When the pharmacist is ready to sell a drug, say that you can't afford it and must go and get some more money.		
Vaginal discharge and itching (STI female)	Urethral discharge (STI male)	Acute diarrhoea
The person is seeking care for problems with vaginal discharge and vaginal itching.	The person is seeking care for urethral discharge	The person seeks care for a 3.5 year old son (daughter) who has had diarrhoea for the past 3 days and asks what to buy for him.
She requests to see the pharmacist	He requests to see the pharmacist	He/she requests to see the pharmacist
In response to questioning the following information is given: The patient has a minor discharge that has a foul smell. The colour of the discharge is white, cream or milky and the patient has had it for a week. The last time the patient has had sexual intercourse is within a month. She is not pregnant, does not take oral contraceptives and has not taken drugs for this condition before.	In response to questioning the following information is given: The patient has had a copious, yellow discharge from the penis for the last three days. He experiences painful urination and urinates more frequently than normally. Last time he had sex was 4 -5 days ago. It was with his wife or with someone else. He does not have ulcers and has not taken any medication for the condition before.	In response to questioning the following information is given: The child is somewhat tired and weak. There is no high fever, no headache and no blood in the stool. The diarrhoea is not 'ricey'. Suggest to the pharmacist that you think your child needs an antibiotic. She has had a similar problem and was given metronidazole/cotrimoxazole/nalidixic acid. At the moment you do not have enough money to go to the doctor
Research assistants posing as clients: 1. Female age 22 2. Female age 22 3. Female age 20 4. Female age 19	1. Male age 23 2. Male age 23 3. Male age 22 4. Male age 22 5. Male age 21	1. Male age 23 2. Male age 23 3. Female age 21

Table 5. Pre-designed guide for simulated client visits in Zimbabwean pharmacies. (Paper II)

#### 4.2.2.2.2 Tanzania SCM

Two different case scenarios were presented at the drugstore; i) a woman with vaginal discharge and itching, (SCM-female), ii) a man with urethral discharge (SCM-male). (See Tables 6 and 7) The SC bought the drugs that were recommended by the drugseller and filled in a pre-designed checklist collecting information about the encounter within 15 minutes after the visit and out of sight of the drugstore.

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##### SCM-female

- You are seeking care for vaginal discharge and pretending to be a patient.
- You go into the drugstore and say that you have a problem and there is itching

[Now you wait for the drugseller to respond]

- If the drugseller should ask you questions, you should respond as follows:
  - Do you have a discharge? -Yes
  - Is it a lot? - Minor/Not much
  - Does it smell? -Yes, foul
  - What colour is the discharge? -White, cream or milky
  - What is the duration of the discharge? -About two weeks
  - When was the last time you had sexual intercourse? -Respond so that it is within last month
  - Are you pregnant? - No
  - Do you take oral contraceptives? -No
  - Have you taken drugs for this before? -No
- If the drugseller asks you for a prescription you say you don't have one. If the drugseller asks you to get a prescription first; reply that you do not have money to pay for the visit to a health provider and ask that if the drugseller knows the problem, can't she / he give you some drugs?

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Table 6. The SCM-female scenario, instructions to the female SC. (Paper III)

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##### SCM-male

- You are seeking care for urethral discharge and pretending to be a patient.
- You go into the drug shop and say that you have a problem, and there is a discharge from your private parts.

[Now you wait for the drugseller to respond]

- If the drugseller should ask you questions, you should respond as follows:
  - Is the discharge copious or scanty? -Copious
  - How long have you had the discharge? -Since yesterday
  - What colour is the discharge? -Yellow
  - Is urinating painful? -Yes
  - Do you urinate more frequently? -Yes [if asked how frequent, say very frequent]
  - When was the last time you had sex? -5 days ago
  - Was it with your wife or someone else? -Say someone else
  - Do you have ulcers on the genitals? -No
  - Have you taken drugs for this before? -No
- If the drugseller asks you for a prescription you say you don't have one. If the drugseller asks you to get a prescription first; reply that you do not have money to pay for the visit to a health provider and ask that if the drugseller knows the problem, can't she / he give you some drugs?

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Table 7. The SCM-male scenario, instructions to the male SC. (Paper III)

#### 4.2.2.3 *Drugstore interviews*

Research assistants, mainly pharmacy and medicine students, performed face-to-face interviews with drugsellers in 80 private drugstores in the eight Tanzanian districts. The drugseller present at the time was asked to participate. An interview guide with closed- and open-ended questions was used and spontaneous responses were sought, i.e. probing was not used for different response alternatives. Questions concerned e.g. general dispensing practices and case management of STI.

#### 4.2.2.4 *Exit interviews*

Interviews were performed with 350 customers coming out from eligible drugstores in of the eight Tanzanian districts. The structured interview guide that contained mainly closed-ended questions was filled in by research assistants who presented the questions to the customer. Information collected encompassed which drugs were bought, which information was given, perceived knowledge level of the drugseller and satisfaction with the service provided.

#### 4.2.2.5 *Intervention drugseller interviews*

Intervention participants (n=75) in three of the PEERCON intervention districts were asked to fill in a questionnaire containing closed- and open-ended questions. The topics concerned antibiotics, their function and indications as well as antibiotic resistance. Responded filled in the questionnaire at the onset of either the intervention workshops or out-reach visits according to feasibility. The open-ended questions were analysed using content analysis as described in section 4.1.2.2.

### 4.2.3 Quantitative Analyses

Descriptive statistics were used calculating frequencies, percentages, mean and medium values. Differences in proportions between groups were determined using  $\chi^2$ -test for categorical variables. When the groups were too small, Fisher's exact test was used. Odds-ratios (OR) with 95% confidence intervals (CI) were calculated. Multivariable\* logistic regression analysis was used to test the association of different background variables with a specific categorical outcome variable. [Pagano et al., 2000; Robson, 2002] (Table 8)

Two novel ways of analyzing /presenting data were developed in this thesis: The step model and the QATI scores.

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\* There is no real consensus on what to call a regression analysis with more than one independent variable; multivariable, multivariate or multiple regression analysis. In this thesis, the term multivariable logistic regression analysis has been used to describe a model with one dichotomous dependent variable and several, discrete or continuous, independent variables.

Data collection tool	Paper	Data management	Unit of analysis	Statistical analysis
Structured facility interviews	II	Entered into Excel, double checked and cleaned SPSS used for analysis	Pharmacy	Descriptive statistics
Structured pharmacy staff interviews			Individual staff	
SCM Zimbabwe			Pharmacy	Descriptive statistics The Step model $\chi^2$ -test Fisher's exact test
Structured drugseller interviews	III	Entered in to Excel, double checked and cleaned SPSS and Stata were used for analysis	Drugseller	Descriptive statistics QATI scores $\chi^2$ -test
SCM Tanzania	III		SCM visit	Descriptive statistics OR with CI QATI scores $\chi^2$ -test
Structured drugseller interviews	IV		Drugseller	Descriptive statistics Multivariable logistic regression
Structured exit customer interviews			Exit customer	Descriptive statistics $\chi^2$ -test Fisher's exact test

Table 8. Overview of quantitative data collection, management and analysis.

### The Step model

The step model was developed to get a comparable picture of the pharmacists' performance for different tracer conditions mainly with regards to provision of information and advice. (Paper II) The model was designed as a staircase starting with basic practice features at the foot of the stairs and leading to progressively more detailed practice higher up. (See Figures 4 & 5) The model was built on data collected by the SCM and was based on national and international management guidelines for the tracer conditions as well as GPP guidelines. [Fédération Internationale Pharmaceutique (FIP), 1993; The MOST project et al., 2005; The National Drug and Therapeutics Policy Advisory Committee, 2000; World Health Organization (WHO), 1997] The steps for tracer conditions STI female and STI male were: 1. Advised to see a doctor/visit a clinic, 2. Requested prescription, 3. Advised on prevention and 4. Advised on partner notification. To get a hierarchical assessment of the pharmacists' performance, only those who managed the previous step were allowed to continue climbing. The ones that did not manage the first step were not allowed to climb at all although they might have taken some of the actions or given some of the information and advice higher up in the model. If all steps were accomplished, the pharmacist was

regarded as practicing acceptably in relation to the guidelines. Group differences (between towns and male and female pharmacists) for the step model were determined using  $\chi^2$ -test, Fisher's exact test and the Spearman correlation coefficient.

### **QATI scores**

The QATI score presentation (Questions, Advice, Treatment and drug Information) was developed to get an overview of the STI management in Tanzanian drugstores. (Paper III) It was based on drugseller knowledge or reported practice at latest STI client encounter (data collected by interviews), and actual drugseller practice at the SCM visits. For each respondent or SCM visit a score was calculated for: questions asked by the drugseller (Q), advice given by the drugseller (A), knowledge on treatment / treatment sold (T) and type of drug use information given (I). (See table 9)

#### **Q = questions asked:**

Each respondent's / SCM visit's score is the sum of the number of reported questions that the drugseller asked divided by the total number of questions that could correctly be asked as monitored by the data collection instruments. The total number of questions that could be asked was four: symptoms; duration of symptoms; sexual behavior and previous drug use for the condition. Each respondent / SCM visit is scored between zero and one, for example, a score of 0.5 corresponds to two questions (out of a total of four) having been asked.

#### **A= advice given:**

Each respondent / SCM visit was given one point for each of the following pieces of advice they gave (interviews) or were given (SCM): to see a health worker; preventing STI and partner notification. Thus, a score of 0.3 corresponds to one piece of advice, out of a maximum of three pieces of advice, being given.

#### **T= treatment choice:**

One point was assigned if the drug was in the guideline, another point if the dosage regimen was for the drug was correct and a third point if complete syndromic treatment was named (interviews) or dispensed (SCM). A score of 0.3 corresponds to having named or being dispensed a drug represented in the guidelines but with incorrect dosage regimen. The treatment assessment was based on drugs sold in the SCM visits and knowledge on treatment of genital discharge in the interviews (sex of patient not specified). T score 0.00 corresponds to no drug or drug not in guideline.

#### **I=type of drug use information given:**

Each respondent / SCM visit was given one point if they reported to give (interviews) / were given (SCM) either written or oral information, and two points if both written and oral information were given. Thus, A score of 0.5 corresponds to either written or oral information but not both. In the calculations of (I)-scores for SCM visits, only encounters in which drugs were sold were included. (See table 9)

<i>QATI score</i>	<i>Management assessment indicators</i>
1p	<b>Questions asked by the drugseller</b> -asked about symptoms <i>or asked either of the following questions:</i> [-whether have a discharge, the colour of the discharge, quantity of discharge, if discharge is smelly, if painful urination, if urination frequent or if genital ulcers present]
1p	-about duration of symptoms
1p	-about time of last sexual intercourse <i>or</i> about sexual partners
1p	-whether taken drugs for condition before
$\Sigma/4 \rightarrow \mathbf{Q}$ score	
1p	<b>Advice given by the drugseller</b> -to see health worker if symptoms persist
1p	-how to prevent STI /have safe sex
1p	-notify / treat partner
$\Sigma/3 \rightarrow \mathbf{A}$ score	
1p	<b>Treatment recommended/sold</b> Drug in guideline
1p	Correct dosage & duration (for drug in guideline)
1p	Complete syndromic treatment UDS or VDS*
$\Sigma/3 \rightarrow \mathbf{T}$ score	
1p	<b>Type of drug use Information given</b> Verbal information
1p	Written information
$\Sigma/2 \rightarrow \mathbf{I}$ score	

\*Non-curdlike vaginal discharge

Table 9. Structure of the QATI scores i.e. included questions, advice treatment and information.

QATI scores were dichotomized as low (score 0.5 or lower) or high (score over 0.5) Differences in distribution between interview respondents' scores and SCM-female and male visits' scores were tested for significance using  $\chi^2$ -test. (See Figure 6)

### 4.3 ETHICS

Verbal informed consent was given by all interviewees. They were informed that participation was voluntary and confidential and that they could discontinue the study at any point without adverse consequences. It was emphasized that the study was not part of any official drugstore inspection function. As a researcher, it is important to remember that it might not be until after the interview has been performed that the respondent fully grasps the meaning of the informed consent and that s/he must be able to withdraw from the study also afterwards.

When using the SCM, the person whose practice you want to study cannot be asked for informed consent without risking to influence his or her practice. The individual pharmacists and drugsellers visited by simulated clients in this thesis were not asked for informed consent. In Zimbabwe it was however possible to continuously discuss the project with the Pharmaceutical Society of Zimbabwe (PSZ) and the Retail Pharmacists

Association (RPA). In Tanzania no organisation for drugsellers exist. Instead approval was sought from district authorities. The ethics of simulating a condition to a health care provider who has not earlier been given the chance to consent could be raised. [Chuc et al., 2002] The SCM however attempts to provide data on actual behaviour that would be difficult or impossible to obtain through other methods. [Chalker et al., 2000] All results are presented so as to not point out single respondents or facilities and there were no punishments for respondents that acted against regulations. The results will benefit patients and pharmacists/drugsellers if used as a basis for achieving improved practice. [Chalker et al., 2000]

Study I was approved by the ethics committee at the Karolinska Institutet No 03-279. Ethical approvals for the Peercon project were received through Muhimbili University of Health and Allied Sciences from the Tanzania Commission for Science and Technology No 2003-084-CC-2003-09, Medical Research Council (MRCZ) of Zimbabwe, MRCZ/A/986 and from Karolinska Institutet No 04-514/3.



## 5 MAIN RESULTS

### 5.1 THE ROLE OF THE PHARMACIST - VOICES FROM NINE AFRICAN COUNTRIES (PAPER I)

Four categories of views on the role of the pharmacist were found with no clustering of specific countries into any of the categories. The categories possessed similarities pair wise and were therefore grouped together two and two as sub-categories under two main categories: *A: Pharmaceutical information provider* and *B: Health care provider*. The categories and sub-categories with illustrative quotations are presented below. The quotations are numbered and have been given the identification capital letter assigned to the interview from which they are taken. Quotations from the interviewer denoted *Q* have been added where needed for clarity.

#### *A. Pharmaceutical information provider*

In this main category, A, the pharmacist was seen as a provider of pharmaceuticals and of pharmaceutical information directly related to the act of dispensing. The information said to be provided generally did not go beyond issues such as how to take the drug, how many tablets a day, potential side effects and interactions, and the cost. Two sub-categories could be discerned.

##### *A1. The satisfied dispenser*

In A1 the role of the pharmacist was seen as described above. The interviewees did not mention any wish to perform their pharmacy service differently. This was the main way in which this sub-category differed from the other three. The only two interviewees who said that prescription drugs were never given out without a prescription being presented belonged to this sub-category.

QH. "The pharmacist fills the prescription?"

30H. "Yes, or he would hand it over to the assistant and then they will do the filling. And hand it over to the patient with information of how to use the medicine."

##### *A2. The dissatisfied dispenser*

In A2 the role of the pharmacist was also largely seen as described in main category A. However, in contrast to the interviewees in sub-category A1, those assigned to this category expressed dissatisfaction with this role. The interviewees claimed that there is a lack of challenge for the pharmacist if s/he only dispenses. They felt their competence was not being fully utilised and would like to move towards more professionally challenging tasks. In particular, there was a wish to be more involved in the overall health care of the patients. Therefore this group can be seen as wanting to move towards category B, discussed below.

20E. "... And being able to exercise more my rights as a pharmacist. Being able to contribute more. Maybe clinical meetings. Be able to see the pharmacist's point of view, not just the doctor's point of view. Or the nurses' point of view. Meaning that I have also to improve my pharmacology. And to read a lot."

8N. “The pharmacists are not recognised. Patients don’t give them credit for what they do and only think doctors have all the knowledge. ... There is a lack of challenge for the pharmacists when you are only dispensing.”

### ***B. Health care provider***

In second main category, B, the pharmacist was seen as a highly educated health care professional who is an important part of the health care system. The interviewees described how, ideally, the patient should, first visit a doctor to get a prescription when prescription-only drugs are needed, but how, for a number of reasons such as poverty and a deficiency of health care personnel, they tend to come directly to the pharmacy. Two sub-categories could be discerned also here.

#### ***B1. The health care team member***

In B1 the role of the pharmacist was seen as described above. The pharmacist was described as a complement to other health care providers, and although the customer is able to get qualified health care advice at the pharmacy, in severe cases he or she is told to seek care at specialist centres.

6B.”The second group, it is the persons that come in without a prescription. Well, we have a lot of them too. Because they don't want to go to the doctor. They cannot pay two times. They don't want to pay for the consultation and come back to the pharmacy, thus, they come directly. Thus it is up to the pharmacist to see where ends his or her competence.”

#### ***B2. The lifesaver***

In B2 the pharmacist was seen as described in the main category B, but in addition to this, the role of the pharmacists was considered to be that of a more independent health care provider who, when needed, makes her/his own diagnoses, even in severe cases, and provides the drugs s/he judges to be appropriate. The reasons given for this were the customers’ lack of access to other health care workers because of, e.g., geographical distance and poverty, as well as the high professional self-esteem of the pharmacist. Being the most educated health professional available, the pharmacist feels it is her/his responsibility to help the customer. Consequently, prescription-only drugs are frequently given out without prescription.

13I. “ ... it is an ethical consideration, that if I don't take care of this patient, anything can happen before he gets to the doctor, and you don't want your patient to die.”

25F. “Yes. We do it [i.e., give out prescription-only drugs without a prescription] because you literally don't have a choice. What do you do? Do you treat a patient that you see in front of you or do you tell him to walk 50 km to the closest doctor to get a prescription and then come back?”

Some features were common to all or most interviewees irrespective of the category to which they were assigned. The issue of making a profit out of selling drugs was not frequently mentioned as important for the pharmacist profession. On probing, the responses indicate that this issue was of little importance to pharmacists. Profit making

by other drugsellers or outlets, such as street vendors or drugstores was, however, brought forward as the main reason for their existence. Regarding the dispensing of prescription-only drugs, the majority stated that it was possible — or even likely — that these would be dispensed without prescription. The reasons given are presented in Table 10. Poor access to pharmacists and pharmaceuticals was commonly brought up. The need of enforcement of regulations was often mentioned, mostly in relation to the absence of a pharmacist from the pharmacy or unqualified persons selling drugs.

<b>Poverty</b>	- The patient cannot afford to see both the doctor and buy the drug, or the patient does not have enough money to buy the full course of treatment.
<b>Geographical distances</b>	- The nearest health facility is too far away.
<b>The pharmacist has no or little confidence in prescribers</b>	- A prescription is not seen as a guarantee for a good quality diagnostic procedure. <i>22J.” ... anybody prescribes. Prescribing is not limited to physicians. Everybody prescribes anything in any manner.”</i>
<b>No contact details of the prescriber</b>	- The prescriber is not contacted for adjustments (of prescription) since there is seldom an address or even a signature on the prescription. If there is a telephone number the pharmacy may not have a telephone, making contact difficult.
<b>Fear of the doctor</b>	- Patients fear going to the doctor since they are not well seen at health facilities, and/or it is difficult to get an appointment with the doctor.
<b>Keeping customers</b>	- The customers may choose another pharmacy if not served.
<b>The street</b>	- The pharmacist fears that the patient will purchase substandard drugs in the street if not served in the pharmacy.
<b>High professional self esteem</b>	- The pharmacist sees him or herself as a highly educated health professional who is able to make independent diagnosis and treatment decisions also in severe cases.

Table 10. Reasons given for dispensing prescription-only drugs without prescription or differently than prescribed.

- *Different ways of perceiving the role of the pharmacist were identified and there was no clustering of specific countries in different categories.*
- *The sub-category “ The lifesaver” highlights the special situation for pharmacists in low-income settings.*

## **5.2 LOW SALE OF ANTIBIOTICS WITHOUT PRESCRIPTION – A CROSS SECTIONAL STUDY IN ZIMBABWEAN PRIVATE PHARMACIES (PAPER II)**

### **5.2.1 Facility and staff interviews**

Facility interviews were done in 59 pharmacies in the four towns. In the same pharmacies 73 persons also participated in the staff interviews. A majority (69%) said they would never sell antibiotics without prescription. One fifth would sell to a relative or friend, ten percent if the patient could not afford to go to a doctor and four percent if the patient were seriously ill. The respondents reported that customers regularly ask them to dispense antibiotics without prescription. All pharmacies studied stocked antibiotics such as amoxicillin, co-trimoxazole, doxycycline and ciprofloxacin.

### **5.2.2 Simulated client visits**

#### **5.2.2.1 *STI female***

In seven percent of the 57 STI female visits, the pharmacist agreed to sell antibiotics without prescription. In a majority (58%) of the cases, a topical/vaginal antifungal was instead recommended. These products are pharmacist-initiated medicines (PIM) in Zimbabwe. Most pharmacists asked questions about the presence of a discharge (91%) and properties of the same such as duration (70%), smell (74%) and colour (86%). Just about half (49%) asked about time of last sexual intercourse. In 63% of the cases, the conversation was held in a private place, and the medium duration of encounter was three minutes. One third of the pharmacists completed all four steps in the step model: Step 1; advised to see a doctor/ visit a clinic, Step 2; requested a prescription, Step 3; advised on prevention of STI and Step 4; advised on partner notification. (See Figure 4)

#### **5.2.2.2 *STI male***

Sixty-three visits were made and 8% of the pharmacists agreed to dispense an antibiotic without prescription. In 48% of encounters, the simulated client was not asked any of the predefined questions that he was to tick in the standardized SCM form. Almost all were advised to see a doctor / visit a clinic but few were advised on prevention and partner notification. Eight percent completed all four steps in the step model. (See figure 4). The conversation was held in a private place in 54% of the cases and the median duration of encounter was 2 minutes.

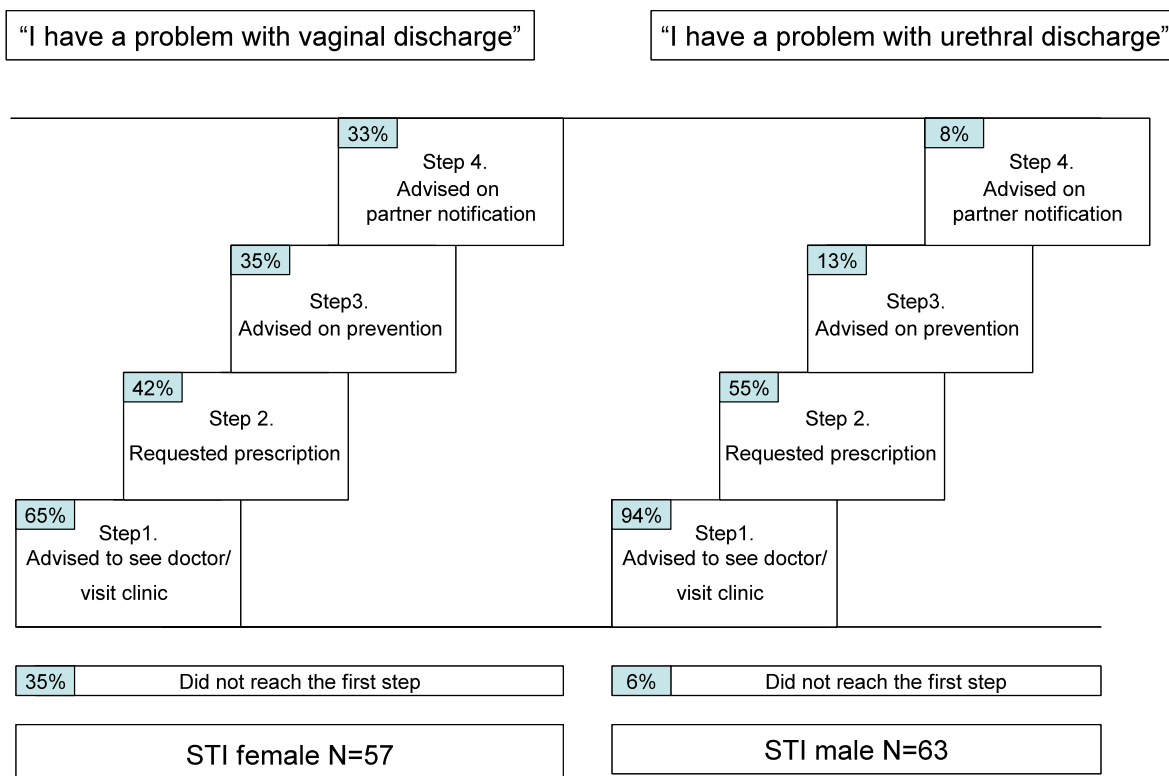


Figure 4. The step model results for STI female and STI male scenarios.

Each step is built up on a specific question or advice that the pharmacist should ideally give. Only the ones that managed the previous step were allowed to continue climbing. I.e. for the STI female scenario 35% were not allowed to climb at all since they did not accomplish the first step (Advised to see a doctor/visit clinic) even though they may have asked some of the questions or given some of the advice higher up in the model.

#### 5.2.2.3 Child with acute diarrhoea

Sixty-eight visits were made and 9% agreed to dispense antibiotics without prescription. Almost all (87%) recommended anti-diarrhoeal solutions containing adsorbents or antimotility drugs. Sugar and salt solutions or other salt replacements were recommended by 37%, often in combination with anti-diarrhoeal solution. Twenty-two percent completed all three steps of the step model for diarrhoea: Step 1; Requested prescription, Step 2; Highlighted the importance of fluid replacement and Step 3; recommended sugar and salt replacement. (See Figure 5) Median duration of encounter was three minutes.

"I have a 3.5 year old child who has been having diarrhoea for the past 3 days. "

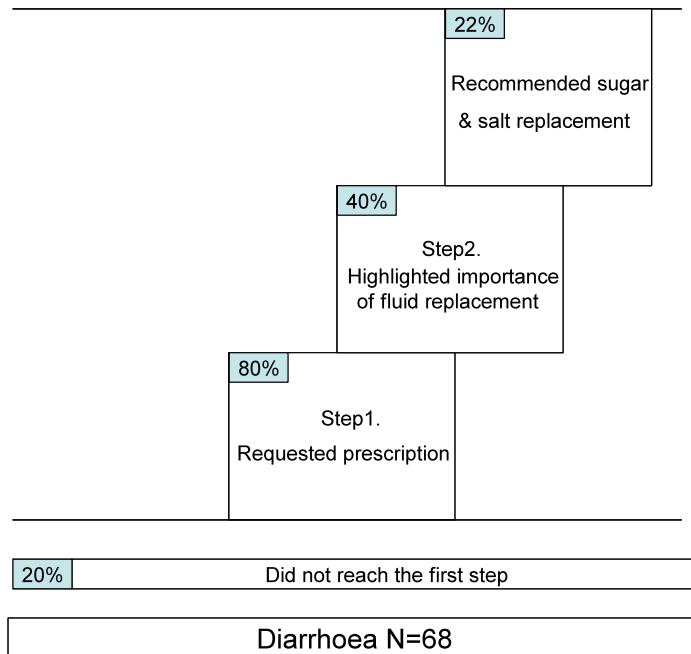


Figure 5. The step model for the diarrhoea scenario.

Each step is built up on a specific action or information/ advice that the pharmacist should ideally give. Only the ones that managed the previous step were allowed to continue climbing. I.e. 20% were not allowed to climb at all since they did not accomplish the first step event though they may have given one or both of the pieces of advice higher up in the model.

- Most stated that they would never sell antibiotics without prescription and few actually did in spite of a high patient demand.

- Few performed in accordance with guidelines regarding provision of information and advice for the tracer conditions.

### 5.3 STI MANAGEMENT IN TANZANIAN PRIVATE DRUGSTORES - PRACTICES AND ROLES OF DRUGSELLERS (PAPER III)

Seventy-four percent of the interviewed drugsellers reported that there were no STI-related drugs in the store. In a majority of the SCM visits drugs were however dispensed i.e. in 78% of the SCM-male visits and in 63% of SCM-female. In most visits (80% SCM-male and 90% SCM-female) the simulated client was dispensed drugs that were recommended in the MoH&SW guideline for syndromic management of urethral discharge syndrome (UDS) or vaginal discharge syndrome (VDS). Antibiotics were dispensed in 76% of the SCM-male and 35% of SCM-female visits. Antifungals were dispensed in 41% of SCM-female visits. In 58% of the SCM-male visits the drugseller requested a prescription. The corresponding figure for the SCM-female visits was 37%. The dosage regimens of drugs sold were seldom correct and the complete syndromic STI management drug combinations were rarely provided. Few of the SC received any advice from the drugseller.

Almost all SC that were sold drugs were however given drug-use information. It consisted mainly of name of the product and duration of the treatment. Most drugsellers are reported to agree with the statement that it is within their professional remit to given information about drugs in general (95%), about STI management (89%) and about STI prevention (95%).

- *Although most drugsellers stated there were no STI-related drugs in the store, drugs, commonly antibiotics, were dispensed in a majority of the SCM visits*
- *Most dispensed drugs were recommended in the Tanzanian guideline for syndromic management of urethral and vaginal discharge syndromes but complete syndromic management was rarely provided.*
- *Dosage regimens were often wrong, advice seldom given and questions only occasionally asked. Drug use information was however almost always provided.*
- *Overall STI management was better for men than for women.*
- *The drugsellers saw themselves as having a role in STI-management.*

### 5.3.1 QATI Score

Overall STI management was compared for reported and actual practice using QATI (Questions, Advice, Treatment and drug Information) scores. Overall STI management was better for SCM-male visits as compared to both SCM-female visits and interviews. (See Figure 6)

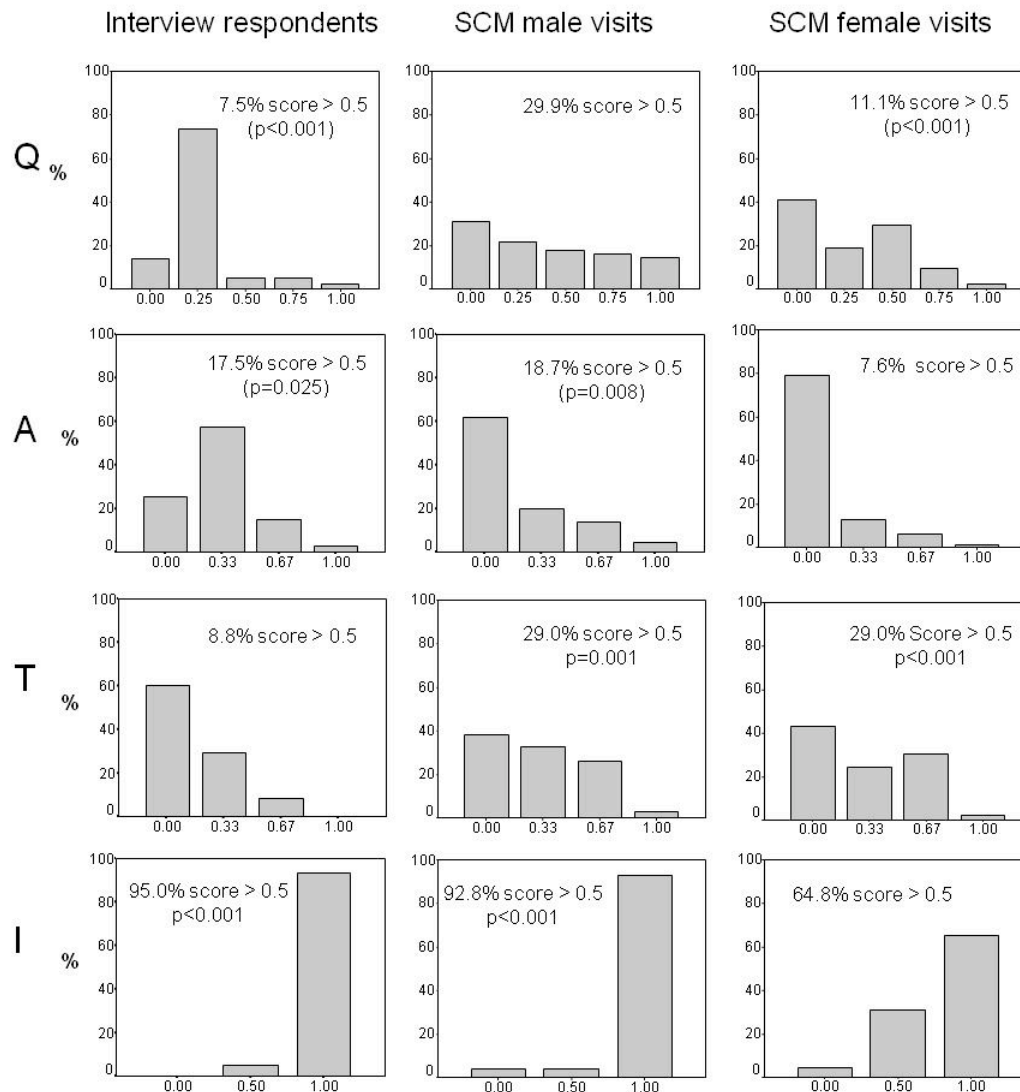


Figure 6. Distribution of the QATI scores.

The percentages of respondents and SCM visits obtaining different scores for Q, A, T, I are presented for each data collection instrument. One is the highest possible score. For comparison, QATI scores were dichotomized as low (score 0.5 or lower) and high (score over 0.5). Differences in distribution were tested for significance using  $\chi^2$  test.

**Q:** SCM-male visits have significantly higher percentage over score 0.5 compared to both interviews and SCM-female.

**A:** SCM-female visits have significantly lower percentage over score 0.5 compared to both interviews and SCM-male.

**T:** Interviews have significantly lower percentage over score 0.5 compared to both SCM-male and SCM-female.

**I:** SCM-female visits have significantly lower percentage over score 0.5 compared to both interviews and SCM-male.



## **5.4 “PRACTICAL KNOWLEDGE” AND PERCEPTIONS OF ANTIBIOTICS AND ANTIBIOTIC RESISTANCE AMONG DRUGSELLERS IN TANZANIAN PRIVATE DRUGSTORES. (PAPER IV)**

### **5.4.1 Exit customer interviews**

Exit customers (n=350) from approximately 91 drugstores in eight districts were interviewed as they came out of the drugstore. One third of the customers reported having seen a health worker before coming, almost all of these had a prescription. Most said the health worker visited was a doctor. Eighty-three percent of all dispensed drugs were assessed to be relevant based on the symptoms or disease reported by the customer. Customers who did not have a prescription were sold relevant drugs more often than the ones having a prescription ( $p=0.048$ ).

Of the respondents, 24% had bought antibiotics. These were dispensed mainly for stomach-ache, cough, genital complaints and diarrhoea but not for headache or malaria. Antibiotics sold were less often than other kinds of drugs assessed to be relevant, i.e. in 51% of the cases ( $p<0.000$ ), with a non-significant difference between drugs that were not or were prescribed. Almost all were informed by the drugseller how to use the drug. Seventy-five percent of the customers ranked the knowledge level of the drugseller as high or very high. The vast majority (93%) reported they were satisfied or very satisfied with the service at the drugstore.

### **5.4.2 Drugseller knowledge of antibiotics**

Seventy-five drugsellers responded to the questionnaire. Of them, 64 were women. When asked to state their highest level of education, 27 said they were nurse-assistants, three said other health education, 17 said secondary and 16 primary education respectively.

A majority (79%) responded that diseases caused by bacteria can be treated with antibiotics. Of these, 24% (n=14) also answered that they can be used for diseases caused by virus. Some (12%) stated that there is no difference in indication between different antibiotics i.e. all antibiotics can be used for treating the same diseases. Few said that headache (1%), general weakness (4%) or ‘all diseases’ (3%) can be treated with antibiotics whereas 85% said the same about STI. A majority of the respondents (72%) had heard of antibiotic resistance. All participants could mention the brand or generic name of at least two antibiotics.

Neither age, sex, education nor district were significantly associated with whether the respondent knew that antibiotics treat bacterial but not viral disease according to the Multivariable logistic regression analysis.

### **5.4.3 Keywords used to describe antibiotics**

In the responses to the query ‘Please describe what an antibiotic is’, six different keyword-groups were identified as presented in Table 11.

Keyword groups	Number of respondents n	Selected quotations translated	Quotations in Swahili
<b>Bacteria</b>	20	<i>"Is drug that treats bacteria"</i>	<i>"Ni dawa inayotibu Bacteria"</i>
<b>Infections</b>	9	<i>"Is drug to treat infections"</i>	<i>"Ni dawa ya kutibu maambukizi"</i>
<b>Bugs / Germs</b>	10	i) <i>"Is drug that kills bugs"</i> ii) <i>"Drug that can kill germs"</i>	i) <i>"Ni dawa zinaua wadudu"</i> ii) <i>"Dawa ambayo inawesa kuuwa vijidudu"</i>
<b>Many diseases/ Strong drug</b>	12	i) <i>"Drug that treats more than one disease"</i> ii) <i>"Is strong drug"</i>	i) <i>"Dawa inayotibu zaidi ya ugonjwa mmoja"</i> ii) <i>"Ni dawa kali"</i>
<b>Drug</b>	14	<i>"Is drug and treatment for disease"</i>	<i>"Ni dawa na tiba kwa wa magonjwa"</i>
<b>Resistant germs/ Chronic disease</b>	4	i) <i>"Antibiotics is drug that is capable of killing resistant germs in the body."</i>  ii) <i>"Is any drug that is used to treat various chronic diseases in the body."</i>	i) <i>"Antibiotic ni dawa ambayo inaweza kuuwa vijidudu sugu mwilini."</i>  ii) <i>"Ni dawa yoyote ambayo hutumika kutibu magonjwa mbalimbali yenye usugu ndani ya mwili."</i>

Table 11. Keywords used to describe what an antibiotic is, were sorted into six groups.

#### 5.4.4 Perceptions of antibiotic resistance and how it occurs

Responses to the two open ended questions: 'What is antibiotic resistance' and 'How does antibiotic resistance occur?' gave rise to five categories, the fifth one having two sub-categories. From these one theme emerged: 'Perceiving antibiotic resistance based on practical experience'. This theme derives from the fact that the participants seem to find the answers to these questions in what they see around them in their daily work. They give quite expected and rational descriptions of the subject from a biomedical point of view but also present less conventional explanations, possibly based on treatment failures they have witnessed. The finding that the interpretations are mainly of a practical, rather than a theoretical, nature is also based on the fact that many participants did not differentiate between the two questions and chose to give explanations of how antibiotic resistance occurs as answers to both questions. All categories hence emerged from responses to both questions. The categories and sub-categories with illustrative quotations from the respondents are presented below.

##### 1. Treatment failure

This category encompasses perceptions on a microbiological level such as the failure to eliminate or kill bacteria and that the bacteria will continue to grow or recur after treatment. The bacteria or germs are also said to be "insensitive" and "not listening" to the drug. Issues related to the drug itself and that it fails to function even though it might be the right drug for the disease concerned, are mentioned. Further, antibiotic resistance

is described by the clinical outcome as a state where the patient is not cured by the antibiotic.

“It is that bacteria fail to die because of antibiotic” (Respondent no 32)

“There are some bacteria that are not listening to drugs.” (Respondent no 4)

“Patient he/she takes the dose without feeling better or getting well.”  
(Respondent no 55)

## *2. Non-compliance by patients*

Patients are said not to follow drug-use instructions and advice from health care providers and druggsellers. It is described how they use the drug in incomplete doses and for too short durations. They are said to forget to take their medicine or to stop taking it when they feel better.

“Antibiotic resistance is caused by the patient himself not following the right advice given by health personnel at the dispensary or at the drugstore and not finishing the drugs given because when they feel better you will find they don't continue with the drug and say that they are cured.” (Respondent no 12)

## *3. Provider malpractice*

The patient is also described as being exposed to provider malpractice such as being given the wrong drug or the wrong dose or duration of the right drug. Additionally the issue of being given antibiotics without laboratory testing and diagnosis is discussed.

“Resistance of bacteria to antibiotics is to not be given the right dose of the drug n question and [not] for the correct time.” (Respondent no 36)

“To be given drug without testing.” (Respondent no 70)

## *4. Getting used to antibiotics*

It is stated that if the drug is used for a long time it ceases to work. The germs are said to get used to the antibiotic. Also the belief that the body will get used to the antibiotic if used for a long time is brought up.

“Antibiotic resistance is that maybe it [the antibiotic] has been used for a long time, therefore the body becomes used to it then if you use for other diseases it does not help you because you have used it for a long time.” (Respondent no 16)

## *5. Letting the disease linger*

This category entails two sub-categories, one with a focus on waiting too long to treat a disease and one on having a disease for a long time, or having a chronic disease.

### *i. Treatment delay*

Waiting too long before treating the disease is said to make bacteria resistant. Refraining from treating a disease or to delay in seeking care is also mentioned.

“The meaning of antibiotic resistance is that there are some bacteria, even if you combine antibiotics, they are resistant due to if the disease is not being treated for a long time. “ (Respondent no 8)

“To not take drug that was given” (Respondent no 46)

“Antibiotic resistance is caused by a patient delaying before getting medical care.” (Respondent no 27)

*ii. Chronic disease*

Antibiotic resistance and the causes are described in terms of “chronicity”. Having a disease for a long time and that the disease is chronic is repeatedly brought up. Some responses are a bit confusing and it seems the respondent is trying to relate antibiotic resistance to the concept of chronic disease.

[Example of confusing answer relating to antibiotic resistance and chronic disease] “Antibiotic resistance is, maybe it depends on how the patient expresses himself because many patients, when they have a big problem, a serious disease, they tend to be shy to express this and that is a reason for the disease being chronic”. (Respondent no 10)

“Resistance of bacteria to antibiotics is because of disease staying a very long time in the body, then it is hard to feel strong by medical care.” (Respondent no 45)

- *Most dispensed drugs were assessed to be relevant for the symptoms/disease presented although antibiotics specifically were less often assessed to be relevant.*
- *Non-prescribed drugs were assessed as more relevant than prescribed drugs.*
- *Most drugsellers knew that antibiotics can be used to treat bacterial diseases.*
- *Most had heard of antibiotic resistance and described it in biomedical terms.*
- *There was confusion around the terms antibiotic resistance and chronic disease.*

## 6 DISCUSSION

### 6.1 RESULTS DISCUSSION

In times of health worker crisis there is a need to start paying attention to the people that are actually there on the ground, providing much of the healthcare even if they are formally not expected, or even allowed to do so. In Paper I, the category “*The life saver*” highlights the specific situation for pharmacists in low-income settings. This category describes scenarios where the pharmacist oversteps what are internationally regarded as the professional boundaries of pharmacists. [Gilbert, 1998; Trap, 2001; World Health Organisation et al., 1998] In addition to dispensing, the pharmacist makes independent diagnoses and prescribes drugs, even in severe cases. The interviewees justified this by stating that when pharmacists are working in remote areas far away from other health care facilities, no one else might be available to diagnose the patients and provide a prescription.

On the same note, other research from Zimbabwe and South Africa has described dispensing doctors as important alternative providers of access to medicines in areas where there is no pharmacy service. It is however concluded that the overlap of functions of dispensing doctors and prescribing pharmacists may put the safety of the patient at stake and compromise the rational use of drugs. The process of double-checking is lost and there is a potential conflict of interest when profit making is involved. Additionally, unnecessary tensions might be created between the two professions. [Gilbert, 1998; Trap, 2001] Another example of this potential conflict of interest comes from China where hospital revenues to a large extent are based on drug sales and over-prescribing is common since the physicians’ bonuses are linked to the revenue of the hospital. [Sun et al., 2008]

One tends to assume that a prescription stands as a guarantee for an evidence-based choice of treatment. In many cases this may not be so since the qualification of the person prescribing might not be established. When this is the case, the use of ‘prescription’ as an indicator for evaluating quality of pharmacy practice is questionable. In Paper IV the drugs that were bought by exit customers with a prescription were less often assessed to be relevant for the symptoms presented than the drugs that were bought by customers that did not have a prescription indicating low quality of the health care received prior to coming to the drugstore.

In Paper II there are examples of that pharmacy practice is dependent on, and probably can be influenced by, which products are allowed and available to be sold in the pharmacy. Almost all of the Zimbabwean pharmacists recommended anti-diarrhoeal solutions, containing adsorbents or antimotility drugs, to a child with acute diarrhoea. Markedly fewer recommended sugar-salt replacements and only some emphasized the importance of fluid replacement. This sale pattern has been seen also in other studies in pharmacies and drugstores. [Goel, P et al., 1996; Igun, 1994; Tomson et al., 1986] This might be due to lack of knowledge of acute child diarrhoea management among the pharmacists but it might also be due to the fact that there are no sugar-salt replacement products for sale in Zimbabwean pharmacies. Also the finding that most female

simulated STI-clients were recommended antifungals while still being given STI-related advice and referral to health care might be due to that antifungals are pharmacist-initiated medicines in Zimbabwe. Shifting the focus of pharmacy and drugstore practice from the product to the patient might be problematic if acceptable remuneration is not assured when not selling a drug.

The lack of emphasis, or even denial, of the importance of profit making in Paper I is noteworthy as this has often been brought forward as an important characteristic of private pharmacy practice [Cederlöf et al., 1995; Chuc, 2002; Olsson et al., 2002; Syhakhang, 2002] The interviewed pharmacists however stated that profit-making was the 'raison d'être' of drugstores. Although not specifically studied in the other papers of the thesis, the issue of profit making did not come out in these either. Rather, the general impression both during data collecting and analysis was that the drugsellers, as well as the pharmacists, showed concern for the well being of their customers and saw themselves as health care providers rather than businessmen. This is perhaps most clearly exemplified by that the vast majority of the drugsellers in Paper III stating that it is within their professional remit to give information about STI-management and prevention, although it is formally not. These attitudes are however in line with the philosophy of the Good Pharmacy Practice guidelines that state that a pharmacist's first concern must be the welfare of the patient. [Fédération Internationale Pharmaceutique (FIP), 1993, 1998; World Health Organization (WHO) et al., 2006] Profit making is nevertheless a prerequisite for running a business in the first place and it should be noted that most of the drugsellers interviewed (III) were not the owner of the drugstore but employees.

Medicines are commonly surrounded by firm regulatory frameworks, though these are not always effectively enforced. Two regulatory infringements that were brought up in Paper I were the sale of medicines by unqualified providers and the sale of prescription-only medicines without prescriptions. These issues are further elucidated in Papers II-IV. The Zimbabwean pharmacists mainly adhered to regulation and did not dispense antibiotics without prescription. This is in sharp contrast to other studies from low-income countries that have shown that dispensing antibiotics without prescription is common practice. [Adu-Sarkodie et al., 2000; Chalker et al., 2000; Chalker et al., 2005; Chuc et al., 2001; Garcia et al., 2003; Igun, 1994; Larsson et al., 2000; Sihavong et al., 2006; Tumwikirize et al., 2004] Antibiotics can also be bought without prescription from pharmacies in European countries. [Grigoryan et al., 2006] Some of the Zimbabwean pharmacists in our study stated 'fear of losing the licence' as an explanatory factor for not selling, and our results imply effective enforcement of the regulatory framework at least of this particular issue. Earlier studies have found ineffective enforcement of regulation and have stressed the need for further research to identify examples of effective regulation. [Hongoro et al., 2000; Kumaranayake et al., 2000] It can also be so that the Zimbabwean pharmacists considered patient-safety and resistance development issues. Many of the simulated clients were referred to health care which is what the pharmacists are expected to do. This behaviour however stipulates that functioning health care is available to the customer. Few of the simulated clients, especially male clients, received information and advice from the pharmacist, so since they did not get antibiotics either, the pharmacists virtually provided them with nothing.

The Tanzanian drugsellers had another approach to antibiotics sale. They seemed to be aware of the prescription-only status of antibiotics since a majority stated that there were no STI-related drugs in the store. In spite of this, in most of the SC-visits the clients received drugs, commonly antibiotics. The vast majority received drugs that were recommended in the Tanzanian guidelines for syndromic management of urethral or vaginal discharge, although rarely in the correct dosage regimens and combinations. Inadequate STI management may have serious consequences beyond treatment failure such as infertility and development of antibiotic resistance. [Okeke et al., 2005] The female SC were often only sold antifungals and received STI-related advice on fewer occasions than male SC in spite of the explicit attempt to present an STI case. Diagnosis of female genital complaints is complicated and syndromic STI management has been shown not to work very well. [Mayaud et al., 2000; Sihavong et al., 2006] Of the drugs dispensed in our study that were classified as 'not in guideline', some are indicated for STI other than the ones described by UDS or VDS. Some were earlier recommended for UDS or VDS in Tanzania but were replaced because of high antibiotic resistance, e.g. sulfamethoxazole + trimethoprim. [United Republic of Tanzania et al., April 1997]

Other studies have focused on the low quality of private pharmacy and drugstore practice and the need for improvement. [Buabeng et al., 2008; Chalker et al., 2000; Chuc et al., 2001; Goodman et al., 2006; Kwenya et al., 2008; Marsh et al., 2004; Ross-Degnan et al., 1996; Syhakhang et al., 2001] In this thesis, deficiencies in the practice have been identified but also strengths. Although treatment guidelines were seldom perfectly fulfilled, most of the drugs dispensed were assessed to be relevant for the symptom or disease that the customer presented (IV) and even recommended in the STI syndromic management guidelines (III). This is in contrast to a study on STI management in pharmacies in Hanoi where very few of the dispensed drugs were recommended in the national guidelines, and a study in Lima where treatments offered rarely conformed to national or international guidelines. [Chalker et al., 2000; Garcia et al., 1998] This practice was however possible to improve through multi faceted interventions. [Chuc et al., 2002; Garcia et al., 2003] The vast majority of the exit customers (IV) as well as the simulated clients (III) were told how to use the drug. When specifically assessing the antibiotics sold (IV), the results were not as positive but still indicated that the drugsellers have a feeling about which diseases can be treated with antibiotics and which cannot. How can it be that the drugsellers, despite the fact that they lack formal higher education in pharmacy or medicine, still make quite rational treatment choices? We believe that this is an example of "practical knowledge" or as Schön label it: "knowing-in-action". [Schön, 1983] Schön's theory argues for upgrading the status of practical knowledge and his steps of learning have been described as 1. knowing-in-action, 2. surprise, 3. reflection-in-action (reacting to surprise), 4. experimentation, 5. reflection-on-action and 6. new knowing-in-action. [Schön, 1983; Stålsby Lundborg C, 1999] Hence, according to this theory it is possible that the drugsellers have acquired many of their skills on the job and will continue to do so. They might however be limited in this process by prevailing regulation. Since they are not allowed to sell antibiotics, this must be done clandestinely and accessing treatment guidelines and other information becomes more complicated.

It has been suggested that the role of the pharmacist must be adjusted to better meet local demands in low-income countries. [Matowe et al., 2002] Once it was understood that people foremost seek care for STI in pharmacies without consulting a physician, studies have been performed to test the feasibility of introducing the syndromic approach to treating STI in pharmacies in the Gambia and in Ghana. The Ghanaian government has gone so far as acknowledging that pharmacists are the preferred provider for treating STI. [Adu-Sarkodie et al., 2000; Leiva et al., 2001; Mayhew et al., 2001].

On the other hand, with the low pharmacist/population ratios of many low-income countries, the majority of the population, especially in poor and rural areas, rarely comes into contact with a pharmacist. Instead they might seek care in a drugstore. In Paper III it is suggested that “STI syndromic management kits” for the management of male STI patients should be tried out. These kits have been shown in other contexts to simplify and improve STI management for male patients and include pre-packed medicines, condoms and partner notification cards. [Jacobs et al., 2003]

In the implementation guidelines for GPP in low-income countries, drugsellers are not mentioned at all. Instead the stepwise process towards improved access to a pharmacist is described as below. (See Table 12.)

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Step 1	Access to a community health care worker with appropriate pharmaceutical training
Step 2	Access to a person trained to a higher level than a community health worker
Step 3	Access to a qualified pharmacy technician with appropriate training
Step 4	Access to a qualified pharmacy technician working under direct supervision of a pharmacist
Step 5	Direct access to a pharmacist

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Table 12. Steps to be fulfilled in low-income countries on the pathway to fulfilling the first aim of the GPP implementation recommendations for developing countries. [Fédération Internationale Pharmaceutique et al., 1998]

In the document, FIP argues for the use of community health care workers (CHW). This approach has been tried out in Uganda in their Home-Based Management of Fever/Malaria (HBMF). It consists of free distribution by trained village volunteers of pre-packaged chloroquine + sulfadoxine/pyrimethamine supplied under the trade name ‘HOMAPAK’, for every under-five year-old with fever. Fever management practices improved markedly among HOMAPAK users. On a population basis however, only modest practice changes were seen. [Nsungwa-Sabiiti et al., 2007] It was shown that drugs were still commonly bought in drugstores. [Kallander et al., 2008]

It is time to start considering how to include drugsellers in a more formal way in public health programs and in the FIP stepwise process. They are clearly motivated to provide drugs and our studies indicate that profit is not their sole motivation. Quality of practice should be ensured through improved possibilities to update skills, by providing pragmatic dispensing solutions, for example management-kits that preferably should be subsidized and quality-assured by a third party such as the state or a non-governmental organization. Appropriate remuneration for the drugstore for participating in public



health programs should be established. Consumer demand can also be expected to influence practice and when it comes to private practice, consumers need to be even more aware about what they can expect and demand from the providers. [Cederlöf et al., 1995] Increased emphasis on private drugstore practice should therefore also involve social marketing to inform the public. [Jacobs et al., 2003] Media campaigns have also been used successfully to increase consumer awareness of antibiotic resistance in some high-income countries. [Finch et al., 2004] Before appropriate access to antibiotics is guaranteed it is probably difficult to engage consumers in improved use with the aim to avoid resistance development.

## **6.2 METHODOLOGICAL CONSIDERATIONS**

Zimbabwe and Tanzania are two very different countries, something which also holds true for the other seven African countries included in Paper I. The aim of the thesis was not to perform country-level comparisons as such but rather to provide examples for the discussion about the role of pharmacists and drugsellers in resource-limited settings.

### **6.2.1 Qualitative methods (Papers I and IV)**

In qualitative research, sample sizes are usually small and the sampling is purposive rather than random as statistical generalization is not sought [Kvale S, 1996; Morse JM et al., 1996]. The sample size in phenomenographic studies, where one strives to find variation in views, is determined by the saturation point, i.e. the point where the analysis of subsequent interviews fails to generate new categories [Sandberg. (1994) et al., 1999]. In Paper I, all four sub-categories were identified during the analysis of the first five interviews and 15 interviews were therefore deemed to be sufficient to attain the study objectives. In Paper IV, where content analysis was used, the number of respondents was quite large for a qualitative study, the respondents were not purposively sampled and the material was short written statements. This study is an example of how to handle information from open-ended questions in a questionnaire rather than an in-depth qualitative study. Content analysis has been stated as an appropriate method of analysis for this kind of data. [Hsieh et al., 2005]

To achieve trustworthiness, categorisation was checked by independent researchers who were provided with the texts and the categories. To retain the authenticity of the material the researchers were provided with transcripts in the language in which the interviews were conducted i.e English and French in Paper I and Swahili in Paper IV. Some material was more difficult to categorise than other and these cases were thoroughly discussed until consensus was reached. It was important to perform the analyses on transcripts in the original language rather than translations since some findings, especially in Paper IV, might have got lost if the researchers had simply been provided with translations. Furthermore, native speakers might not reflect on particularities of their own language and, Paper IV in particular, points out the advantages of multi-cultural and multi-lingual research teams.

The participants at the FIP congress interviewed in Paper I constitute a selected group as not all pharmacists from the countries represented would have had the possibility to attend an international congress due to the registration and travel costs. The FIP however offers travel stipends for pharmacists from low-income countries and the interviewees were working in diverse fields of pharmacy. It should be kept in mind that the people that get the chance to go to university to study pharmacy in low-income countries already constitute a select and privileged part of the population. The interviewees' descriptions do not necessarily present a national or a continental picture of pharmacy practice but the findings are valuable on a conceptual level for understanding pharmacy practice in resource-limited settings.

The biomedical background of the researchers and data-collectors of Paper IV might have biased the responses towards allopathically acceptable responses. Other types of bias inherent in the different methods of analysis might however have been reduced because of method triangulation and the conclusions of the study were supported by findings from both qualitative and quantitative methods. [Bowling A, 2002; Johnson et al., 2007]

## 6.2.2 Quantitative methods (Papers II-IV)

### 6.2.2.1 *Sample selection and external validity*

There are approximately 300 pharmacies in Zimbabwe and the study covered 19-24% of them depending on data collection method and SCM scenario. The sample selection for the SCM in Harare was performed in two stages of which the second one was systematic. These results can hence not be generalized to the whole of Harare. We however believe that the selection bias was diminished by keeping the proportion of pharmacies from the different types of residential areas intact. Drop out mainly occurred because the pharmacy had closed for the day, the pharmacist was not there after repeated visits or did not agree to participate in the study. It is not possible to say how much the drop out biased the results as background information on the drop out pharmacies is not available.

In Papers III and IV, the regions were purposively selected and the results can therefore not be generalized to the whole of Tanzania. The results however provide a useful report of the situation in the studied regions and we find no reason to believe that the issues studied would differ markedly in other rural regions where drugstores have not been upgraded into ADDOs. New private drugstores are constantly opening up and others closing down. The exact number of drugstores in business is hard to attain and therefore so are the response rates. A census of drugstores in the eight districts was attempted and lists of registered drugstores were used as a starting point while additional un-registered drugstores were included if identified during field-work.

The names of all the drugstores were not clearly marked, in spite of formal requirements. [The Government of Tanzania et al., 1998] This imposed potential limitations to data analysis and clustering effect estimations, since data could not always be linked to a specific drugstore. If a clustering effect is present, the individual observations cannot be seen as independent which theoretically makes the sample size shrink. The widths of the CIs for the ORs presented might hence have been

underestimated. In future studies, drugstores could be identified by geographical coordinates obtained by global positioning system (GPS). This technology is currently also available in some mobile phone models.

#### *6.2.2.2 Simulated Client Method considerations*

Based on power calculations for evaluation of the PEERCON intervention, each pharmacy / drugstore should be visited by five different simulated client actors presenting the same scenario. The aims of the presented papers were not to evaluate the intervention but repeated visits by simulated clients would still have been preferable to be able to assess inter-actor-variations. In Zimbabwe, however, this became unfeasible within the budgetary limitations of the study due to the high inflation and petrol cost. In Tanzania it also proved partly unfeasible but for another reason. It turned out that many drugstores had a lower number of customers per day than anticipated. Receiving five unknown customers with the same complaints within the short time of the study could have made drugsellers aware that something out of the ordinary was going on and undermined the possibilities to study the normal drugstore practice as intended. The simulated client method has been used in different settings and studies as a tool for assessing professional practice provided by various types of health care providers. [Goel, P. et al., 1996; Madden et al., 1997; Tomson et al., 1986]

Whether an SCM visit adequately simulates an ordinary case is not certain. In a normal situation, the pharmacist might be familiar with the patient and therefore behave differently. [Madden et al., 1997] This was addressed by carefully selecting and training the research assistants so that they as far as possible should fit into the local context and thus be taken as ordinary, although unknown, customers.

Studying care seeking for women with STI is complicated by the fact that the STI are often asymptomatic in women. Itching, that was used as a symptom in the STI female scenarios, is more indicative for Candida than STI and was also interpreted as such by many of the pharmacists and drugsellers. When constructing the scenarios it was however important to consider what would prompt the women to seek care at all and a person with no symptoms is probably less likely to do so. According to the syndromic treatment guidelines a risk assessment of a woman with abnormal discharge should always be made and a woman presenting any of the risk factors, such as being under 25 years of age, should be treated for STI (chlamydia and gonorrhoea). [World Health Organization (WHO), 2003]

#### *6.2.2.3 Methods triangulation*

A strength of the studies is the use of different methods of data collection showing similar results. Many studies have shown that reported behaviour tend to be better than actual practice, [Chalker et al., 2000; Madden et al., 1997] This was not found to be the case in our studies either in Zimbabwe or Tanzania. Slightly different information was collected by the different SCM scenarios and the interviews and in Tanzania, some of the information collected could not be linked to a specific drugstore. In response to these limitations, the two different models: the Step Model and the QATI scores were developed. The Step Model was used to allow for comparisons between the different SCM scenarios and the QATI scores to allow for comparisons between reported and actual practice. Both models build on existing data from the studies and should be seen

as ways of illustrating the results as an aid to the reader in comparing reported and actual practice rather than an all-inclusive assessment of quality of management.

#### *6.2.2.4 Internal validity*

The questionnaires used in Zimbabwe had to be changed considerably during the planning phase of the project. The originally developed instruments, e.g. including case scenarios comparable to the SCM scenarios, would have collected rich information but turned out to be culturally inappropriate. This became especially evident when the research assistant collecting the data had a lower educational level than the respondent. Hence reported and actual practice in relation to the tracer conditions could not be compared in the way it was intended to be. It was however an important learning exercise for the research team and the final results still provided an illustrative picture of antibiotics sale and management approaches of the tracer conditions in Zimbabwean private pharmacies.

The questionnaires used in Tanzania were by contrast quite long and all the information collected could not be incorporated in the two papers presented in this thesis. Answering a long questionnaire might be tiresome and lead to less thoroughly considered answers. The drugsellers were however quite patient when it came to responding to the questionnaires and there was not much internal drop-out. The attitude questions on the role of the drugsellers in Paper III can potentially be seen as leading, i.e. yielding the perceived desirable answer. In that case, it is still interesting that the drugsellers give these answers regarding STI in spite of the fact that they are at present not expected to have a formal role in STI management.

That a very high percentage of drugsellers in Paper IV answered that antibiotics can be used to treat STI might to a certain extent be confounded by the fact that STI was one of the topics of the intervention. The assessments of the sold drugs in Paper IV are based on the symptoms or disease reported by the exit customer and should therefore be interpreted with some care.

### **6.3 REFLECTIONS**

I would like to share some reflections that are not findings of my thesis as such but possibly have influenced me as a researcher. The first reflection concerns the situation of the Tanzanian drugsellers. When meeting them in the field it struck me how many of them were young women and how vulnerable they were. Some told me stories of how they have had to leave their village to support their families after their parents had died of AIDS. I also got to hear how they had no right to vacations and how they would work from early morning to late evening with very low salaries. There is no union or drugseller organization to back them up and they are totally in the hands of the drugstore owner and the customers. One girl told me that everyone assumed that she was the mistress of the drugstore owner and what social implications this had for her. Another girl told me how the whole family of a customer she had served had come to her and accused her of the death of that customer. (She had dispensed a medicine on prescription). The drugsellers are very much part of the community, and although formal regulation is not effectively enforced, there is a social control that became very obvious to me. This story also made me reflect upon how dangerous it can be, not only

to be a drugseller, but also to be a consumer in an unregulated medicine market and the lack of protection of consumer rights. These issues are decisive and need further attention by labour organisations, consumer organisations, researchers and policy makers.

The second reflection is that when reading through my thesis I realize that many of my references to private pharmacy practice in low-income countries are written by researchers from two IHCAR research groups: the Medicines in the health system - focusing antibiotics group and the Health Systems and Policy group. This might be the result of information source bias, but I have actively tried to find other references and I must conclude that much of the research on private pharmacy practice in low-income countries, especially on antibiotics and interventions, has been done by these two research groups. I am of course very fortunate to have been part of both of them.

Thirdly, research is very much teamwork and I therefore would like to take this opportunity to specify what my personal contributions to this thesis have been. Apart from writing the cover story of the thesis, my contributions to the papers have been the following: The first paper was very much my own project although, as a beginner, I had great support from my supervisors and co-authors. I independently did most of the work, from project idea, planning, interview guide development, data collection, transcribing, data analysis and article writing. The following two papers and the manuscript (IV) were part of the PEERCON project where I actively participated in project planning, including workshops in Zimbabwe and Tanzania, and data collection tool development. In Tanzania I took part in data collector training and in Zimbabwe in data collection. All Zimbabwean data (all of which is not presented in this thesis) were entered into Excel by a research assistant and myself together and then double entered and checked by another research team member and myself. I was also involved in data management and cleaning in Tanzania. All data analysis has been done by me independently, occasionally with support of statisticians. The Step Model and the QATI scores were my ideas and while developing them I continuously discussed the proceedings with statisticians. I had the opportunity to add the drugseller antibiotic questionnaire, which I developed with support by my supervisors, for the PEERCON data collection. All questions about the professional role of drugsellers were my contribution. With contributions from my co-authors, I independently wrote the three papers (I-III) and the manuscript (IV) of the thesis and communicated with the respective journals.

## 7 CONCLUSIONS AND IMPLICATIONS

### *Voices from nine African countries*

- The African pharmacists interviewed had quite generic views on the role of the pharmacist but the sub-category “The lifesaver” can be seen as highlighting the special situation for pharmacists in low-income settings.

### *Zimbabwe*

- The pharmacists adhered to regulations and did not sell antibiotics without prescription. Few however provided information and advice in line with guidelines. The contribution to the customer was hence limited mainly to referral to health care, which might not be accessible to poor customers in this resource-limited setting.
- The drugs recommended by the pharmacists for a child with acute diarrhoea were contradictory to guidelines and potentially dangerous to the child.

### *Tanzania*

- The drugsellers, although aware of the prescription-only status of antibiotics, saw themselves as having a role in STI management and were ready to provide drugs.
- In this resource-limited setting, drugsellers could provide safe and effective STI management, at least to male patients if given appropriate tools to improve practice.
- The drugsellers have considerable “practical knowledge” of antibiotics and other drugs.
- They seem to have a perception of antibiotic resistance based on their practical experience and described it quite rationally from a biomedical point of view although some less rational views were expressed.
- When upgrading private drugstores and formalizing the sale of antibiotics from these outlets, the drugsellers’ “practical knowledge” as well as their perceptions should be taken into account in order to attain rational dispensing practices.

There is a potential to use private pharmacies and drugstores in a more formal way for the benefit of health in the low-income settings studied. The discussion of private pharmacy and drugstore practice should be taken beyond the issue of profit to be able to get a diversified picture of how they can contribute more. The pharmacists and drugsellers come across as neglected cadres of health personnel in times of health worker crisis. Furthermore, current regulations might to a certain extent impede them from playing a more important role as well as improving their practice.

## 8 FUTURE RESEARCH

Increased emphasis and further studies are needed to find the optimal ways to more formally involve private pharmacies and drugstores for the increased benefit of public health. Quality of practice should be improved through ensuring possibilities to update skills, by developing pragmatic dispensing solutions, such as pre-packed drug kits, and establishing appropriate remuneration for selling these.

Studies should be performed to test the feasibility of introducing pre-packed drug kits for example STI-management-kits or paediatric dosages of antibiotics for pneumonia. These kits should ideally be quality-assured and subsidized by a third party, such as the state or non-governmental organizations. Drugstore and pharmacy personnel should be involved throughout the whole process and be trained through a participatory approach to sell the kits while providing information and advice. Studies should be designed so as to establish appropriate profit margins to make sure that the kits are sold in favour of loose tablets. Regulatory amendments must be discussed, as antibiotics are currently principally prescription only medicines. It is however clear that they often are sold over the counter in an uncontrolled manner and instead of enforcing regulations and restricting access, innovative solutions enabling rational use should be considered.

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***Appendix 1. Drugs recommended for syndromic management of urethral and vaginal discharge syndromes in Tanzania.***

**Urethral discharge syndrome:**

1<sup>st</sup> visit: Doxycycline, 100mg orally, twice daily for 7 days + ciprofloxacin, 500mg orally, as a single dose.

2<sup>nd</sup> visit: Ceftriaxone, 250mg by intramuscular injection, as a single dose + doxycycline, 100mg orally, twice daily for 7 days + metronidazole 2g, orally in a single dose.

3<sup>rd</sup> visit: Spectinomycin, 2g by intramuscular injection, as a single dose.

**Vaginal discharge syndrome:**

Non-curdlike discharge:

1<sup>st</sup> visit: Doxycycline, 100mg orally, twice daily for 7 days + ciprofloxacin, 500mg orally, as a single dose + metronidazole 2g, orally in a single dose.

During pregnancy or lactation: Erythromycin, 500mg orally, 4 times a day for 7 days + ceftriaxone, 250mg by intramuscular injection, as a single dose + (In pregnancy, first trimester), clotrimazole, 200mg intravaginally daily for 3 days.

2<sup>nd</sup> visit: Ceftriaxone 250mg by intramuscular injection, as a single dose + doxycycline, 100mg orally, twice daily for 7 days + metronidazole 400mg, orally, twice daily for 7 days

Curdlike discharge:

1<sup>st</sup> visit: Clotrimazole, 100mg intravaginally, daily for 6 days

2<sup>nd</sup> visit: Clotrimazole, 100mg intravaginally, daily for 6 days + ceftriaxone, 250mg by intramuscular injection, as a single dose + doxycycline, 100mg orally, twice daily for 7 days + metronidazole 2g, orally in a single dose.

[Ministry of Health The United Republic of Tanzania, 1999]

## *Appendix 2. The Peercon drugseller intervention in Tanzania*

### **Intervention material and QATI**

The intervention took place in two phases: workshops and outreach visits. The topics covered were Good Dispensing Practice (GDP), management of malaria and sexually transmitted infections (STI). Intervention material was developed in English and participant handouts were translated into Swahili. The material on malaria and STI was based on Standard treatment guidelines for Tanzania. (Ref) And the GDP material on the GDP manual for duka la dawa baridi. (ref) The material was structured around **QATI** (Questions to ask the patient, Advice that should be given, Treatment eligible to be sold and Information that should be given).

### **Workshops**

In preparation for the workshops a four days training of trainers (TOT) workshop was held. Six trainers were recruited among last year pharmacy students from Muhimbili University of Health and Allied Sciences (MUHAS). A pre-visit to each intervention district was done in order to secure a permit from local authorities to carry out the training, to organize the workshop venue and to distribute an invitation letter in all part II drug stores of which some could only be reached by bicycle.

The workshop was carried out in each of the four intervention districts with a total of 100 participants. It took four days per district and was highly interactive. The participants were encouraged to talk rather than just listen and different role play scenarios were carried out in relation to the different topics. The last day was used to answer questions from the participants regarding their daily activities and difficulties they face. The participants were asked to fill in a quiz on each topic before and after the topic was covered. Preliminary analysis shows considerable improvements.

### **Outreach visits:**

To enforce the messages of the workshop, outreach visits were performed. Three trainers were recruited and trained by reviewing the workshop material and preparing outreach visit check-lists during a one day workshop. The checklist was pretested in Dar es Salaam drugstores. Minor corrections were made as a result, and it was found that at least three hours were needed in each shop. The trainers visited the individual drugsellers in their drugstore and a face-to-face discussion around the intervention topics was held.