EXPANDING PRESUMPTIVE MALE PARTNER MANAGEMENT OF SEXUALLY TRANSMITTED INFECTIONS (STIs) TO WESTERN CAPE, SOUTH AFRICAN COMMUNITY RETAIL PHARMACIES

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KEYWORDS

Western Cape

South Africa

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Pharmacists

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Scope of practice

Private sector

STI training

STI management

STI Information packets

HIV prevention

ABSTRACT

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The effect of industrialisation has thrust the pharmaceutical profession into a clinical paradigm where the approach to pharmaceutical decisions is more disease and patient orientated. Consequently, South African community pharmacies are inundated with requests from the public for advice and treatment on a wide range of medical conditions, including sexually transmitted infections (STIs). Although community pharmacies are often the first port of call for undiagnosed STI, limited diagnostic skills and legally-imposed prescribing restrictions preclude pharmacists from providing the necessary clinical management. The epidemiological approach to treating sexual partners, which is based on the diagnosis of the index case by a medical practitioner, presents an untapped opportunity for pharmacist-delivered treatment and counselling.

The overarching goal of this dissertation is to present objective arguments and evidences (new and existing) around an expanded role for pharmacists in STI partner management. Central to this thesis is a quantitative research undertaking with two primary goals, the first of which is to evaluate the effect of an STI distance learning course on the knowledge of pharmacists with respect to STI and secondly, to determine whether STI information packets

facilitate the provision of counselling and treatment to male sexual partners. A secondary goal, conceived out of noted poor participation in the main study, was to evaluate the resistance of pharmacists to expanded scopes of practice, which was operationalised in this study as resistance to change (RTC).

Eighty community retail pharmacies from a previous baseline, stratified (urban or rural), randomly sampled cross-sectional survey (Ward *et al.,* 2003) and 20 identically sampled and stratified additional pharmacies comprised the main study sample. Pharmacists completed a distance-learning course in STI syndromic management and completed pre- and post-training evaluations. Thereafter, six rounds of simulated partner visits were made to each pharmacy to assess pharmacists' proficiency with respect to counselling and recommending antimicrobial therapy for urethral discharge syndrome (UDS) and genital ulcerative syndrome (GUS).

Twenty pharmacists from the main study (participants) and an equal number of those declining the invitation to participate during the initial recruitment stage (non-participants) completed a telephonic interview to determine whether a lack of participation was linked to the pharmacist's inherent RTC, as established by pharmacists' responses (on scales of 1-6) to 18 statements.

Pharmacists' previous commitments to participate in the main study (Ward *et al.,* 2003) were not fulfilled (41% response rate). High levels of knowledge were reflected in the post-training evaluations and a significant improvement in test scores was achieved as a result of the training intervention (73.4% to 87.5% in urban pharmacies, $p<0.05$ and 75.4% to 86.3% in rural pharmacies, $p<0.05$). The overall level of counselling was deemed inadequate (an average of <7/13 messages were delivered). The actual utilisation of STI information packets, as opposed to mere assignment to pharmacies, which made no impact on outcomes, promoted more extensive counselling for urethral discharge

syndromes (p=0.01) only. Generally, rural pharmacists were significantly more likely than urban pharmacists to provide appropriate therapies for genital ulcer syndromes (p=0.03).

In the subsidiary study, RTC was marginally higher in the group of non-participants than participants (3.4 versus 3.1) although these differences failed to achieve statistical significance (p=0.08). A deep-seated resistance to change was therefore not attributable to poor participation in the main study.

Despite the poor levels of clinical management achieved in this study, the country's shift to primary health care, the continuing demand for STI services in the informal sector and the willingness of pharmacists to provide these services warrants the future involvement of pharmacists in presumptive STI partner management. Modifiable external factors, as opposed to deeply rooted internal resistance, are more likely to impede efforts geared toward expanding the role of community retail pharmacists.
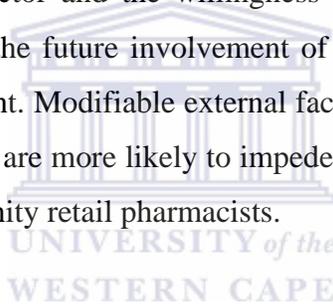
November 2007

DECLARATION

I declare that *Expanding Presumptive Male Partner Management Of Sexually Transmitted Infections (STIs) To Western Cape, South African Community Retail Pharmacies* is my own work, that it has not been submitted before for any degree or examination in any other university, and that all the sources I have used or quoted have been indicated and acknowledged as complete references.

Kim Lana Ward

November 2007

Signed……………………..

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academic journey and to the many friends who offered moral and prayer support through the most challenging and stressful stages of the research and writing process, I thank you from the bottom of my heart.

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AIDS	Acquired immunodeficiency syndrome
AOR	Adjusted odds ratio
ARR	Absolute risk reduction
ART	Antiretroviral therapy
ARV	Antiretroviral therapy
BV	Bacterial vaginosis
CHR	Committee on human research
CI	Confidence intervals
CPD	Continuous professional development
CR	Cognitive rigidity
CT	Chlamydia Trachomatis
DALE	Daily adjustment life expectancy
DOH	Department of health
E/R	Emotional reaction
FSW	Female sex worker
GP	General practitioners
GDS	Genital discharge syndrome
GUS	Genital ulcerative syndrome
HAART	Highly active antiretroviral therapy
HIV	Human immunodeficiency virus
HSV	Herpes Simplex virus
MOH	Minister of health
n.d.	No date
NDP	National drug policy
NG	Neisseria Gonorrhoea
NGU	Non-gonococcal urethritis
OR	Odds ratio

PHC	Primary health care
PID	Pelvic inflammatory disease
PPI	Public private interaction
PPV	Positive predictive value
RCT	Randomised controlled trials
RPR	Rapid plasma reagin
RR	Relative risk
R/S	Routine seeking
RCT	Randomised controlled trial
RTC	Resistance to change
RTI	Reproductive tract infection
STT	Short-term thinking
WC	Western Cape
SA	South Africa
SD	Standard deviation
SES	Socio-economic status
SM	Syndromic management
STI	Sexually transmitted infection
TV	Trichomoniasis vaginalis
UDS	Urethral discharge syndrome
UK	United Kingdom
UNAIDS	United Nations Joint Program on HIV/AIDS
USA	United States of America
VCT	Voluntary counselling and testing
VDS	Vaginal discharge syndrome
WC	Western Cape
WHO	World Health Organisation

TERMS AND DEFINITIONS

Community retail pharmacies

Privately owned independent or chain pharmacies consisting of a retail storefront and a dispensary for the regulated sale of scheduled drugs.

Head pharmacist

A qualified pharmacist who is either the owner or full-time manager of a community retail pharmacy.

Index patient

An index patient, in this study, refers to the initial/primary STI case, as contrasted with the appearance of subsequent cases.

Partners

For the purposes of this study, the term "partners" refers to contacts of patients who have recently been diagnosed with an STI in a health care facility.

Presumptive treatment

Within the context of this thesis, presumptive treatment refers to the treatment of suspected STIs without, or prior to any confirmatory laboratory tests. An example of presumptive treatment is epidemiological treatment whereby treatment is given to contacts of patients diagnosed with STI "after a history of exposure to disease but without or in advance of confirmatory pathological findings" (Carne, 1997, p.115).

Primary health care

Based on the World Health Organisation Alma Ata international conference definition, primary health care is:

"essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and the country can afford to maintain at every stage of their development in the spirit of self-determination" (World Health Organisation, 1978, p. 4)

Public private partnerships

According to the national treasury, PPP is defined as a:

"contract between a government institution and private party, where: the private party performs an institutional function and/or uses state property in terms of output specifications; substantial project risk (financial, technical and operational) is transferred to the private party; the private party benefits through: unitary payments from government budgets and/or user fees." (National Treasury, 2007, p.5)

Public private interactions

PPI, as defined in the South African health charter, is when:

"One or more persons or entities involved in health care within the public sector interact with one or more persons or entities involved in health care within the private sector or the NGO sector with the object of achieving a mutual benefit or goal and includes but is not limited to a PPP; PPIs include: public financing of health services provided by the private and/or NGO sectors; private financing of publicly provided health services; innovative healthcare delivery models and business models for health practices; delivery models aimed at skill retention and effective distribution and utilisation of skills; use of public assets for the provision of health services by the private sector; use of private assets for the provision of health services by the public sector." (Department of health, 2004, p.10).

Urban versus rural areas

An urban area, as defined by the Provincial Administration of the Western Cape, includes towns, cities and metropolitan areas. The main urban area in the Western Cape is the Cape Metropolis, whereas non-urban (peri-urban and rural) areas include commercial farms, small settlements, rural villages and other areas further away from towns and cities (Department of Health Western Cape, 2001).

Syndromic approach

The syndromic approach is based on classifying the causative organisms that give rise to a particular clinical picture/syndrome; treatment consists of multiple antimicrobials with known efficacy across the spectrum of organisms. Treatment encompasses a package of care including provision of information and education; counselling on completion on course of antimicrobials; contact tracing and counselling, voluntary counselling and testing (VCT) referral and condom promotion, distribution and instructions. This approach allows any health care worker to be trained in the use of algorithms to reach a diagnosis and prescribe suitable treatment (Ballard *et al.,* 2000).

CHAPTER 1

INTRODUCTION

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South Africa has one of the highest prevalences of HIV in the world (UNAIDS, 2006). Notwithstanding the recently publicized progress in national provision of antiretroviral therapy, prevention through various strategies, including management and control of sexually transmitted infections (STI) remains the cornerstone of South Africa's HIV/AIDS control strategy (Department of Health, 2007a). In a healthcare system fraught with human resource deficiencies (Dayi & Gray, 2006), the utilization of existing skills and the expansion of skills inherent to specific health professions at primary care level could facilitate the implementation of national HIV plans.

In South Africa, community retail pharmacies are often the first port of call for clients with medical problems; accessibility, after hour availability and prompt client assistance are among the reasons cited for this preference (Gilbert, 1998). Though often sought for curative services (Ward *et al.,* 2003), legislative restrictions bar pharmacists from diagnosing and treating medical problems, except for "minor ailments" (Republic of South Africa, 1997a). To determine the extent to which community pharmacists are called upon to treat patients with STI symptoms, the treatment practices of pharmacists, and their willingness to receive training on the syndromic management of STI, a survey of community pharmacists was conducted in the Western Cape region in 2001 (Ward *et al.,* 2003). This survey confirmed anecdotal reports that pharmacists are often sought for STI treatment, corroborating similar findings in Mexico, Nepal and Peru (Bista *et al.,* 2002; Garcia *et al.,* 2003; Turner *et al.,* 2003). The survey also noted that pharmacists were inadequately trained to provide syndromic treatment and that their level of willingness to receive training

and provide therapy was high. Conversely, pharmacists expressed a general reluctance to encroach on some of the more exclusive practices of nurses and doctors such as conducting a thorough physical examination of the genitalia, for which pharmacists do not traditionally receive training. Clinical skills in rational pharmacotherapy and chronic disease management already fall within the ambit of a pharmacist's professional artillery, and thus, if coupled with skill development in clinical diagnostic procedures, their capacity to be active role-players in HIV prevention strategies such as the syndromic management of STI index clients is strengthened. Alternatively, maximizing the existing skills of pharmacists for the presumptive treatment of STI contacts will certainly contribute much needed human resources toward the challenges presented in STI partner management and therewith potentially stem the continued spread of disease.

Community retail pharmacists in South Africa are moving away from customary business practices to a more service-oriented approach due in part to the country's move to limit the costs pharmacists may charge for medications (Republic of South Africa, 1997a). By providing direct patient care, as is done in the epidemiological treatment of STI contacts, pharmacists may charge for their services, thereby offsetting any possible loss of income from the change in pricing of medications. Providing specific STI syndromic training and provision of treatment packets combined with the changing role of community pharmacist has the potential to increase appropriate treatment of STIs in the private sector thereby decreasing the overall burden of these conditions.

The primary objective of this thesis was therefore to evaluate the impact of an STI training intervention on the general STI knowledge of pharmacists and to assess the impact of an STI management intervention on the counselling and treatment practices of pharmacists. Furthermore, a follow-on explorative study into the willingness of pharmacists to embrace the new roles defined in this thesis ensued in the wake of an unexpectedly poor response rate; quantification and measurement of the differences

in resistance to professional growth (operationalised as resistance to change) between a sub-sample of the study participants and pharmacists who declined the opportunity to enrol into the study was undertaken at the end of the data collection for the main study.

Chapter two sets the backdrop for proposed pharmacist role change initiatives within the South African health care system. An overview of selected health indicators depicts an immensely challenged health sector further subverted by human resource deficiencies. Private sector involvement in public health initiatives is explored with a view to demonstrate the need for private community pharmacists to engage more actively with the public sector in the provision of primary health care services.

In the third chapter, a summary and synthesis of relevant literature further substantiates the relevance of role expansion in human resource planning today and marries the proposed expanded role for pharmacists with global strategies for HIV prevention through STI management and control at primary care level. The literature review critically analyses published research study findings and reviews, borrows insights from treatises and examines pertinent local and international policy and legislative documents, with a view to develop the theoretical underpinnings for an advanced role pharmacist in primary care, more especially in syndromic sexually transmitted infection (STI) management. The review is divided into two subsections, the first of which seeks to elucidate obscurities surrounding the value of STI management in the fight against HIV and the effectiveness of various elements of the syndromic approach. The second instalment explores global trends in meeting human resource needs in primary healthcare settings.

The rationale for the main study as well as the main research objectives is outlined in chapter 4. A delineation of the design and methods employed in the training and management intervention study, as well as statistical and ethical issues are presented in chapter 5, followed by a description of the main results obtained from this

undertaking (chapter 6). Study findings are summarized in text, tables and figures according to the sequence in which the data was collected; firstly the results of the training interventions are described in the order of descriptive, bivariate and multivariate analyses and this is followed, in the same order, by STI management intervention findings.

The discussion in chapter seven explores plausible underpinnings for the results obtained within this thesis. The main findings, dictated by the primary hypotheses, will be central to the discussion, while subsidiary findings of statistical note will supplement this discussion by way of brief elucidation.

One of the more salient findings in chapter 6, i.e. the poor response rate, is dissected further through a subsidiary study in chapter 8, entitled, "Resistance to change: predictor of poor participation in STI training course by community pharmacists?" A review of literature, which culminated in the retrieval of a validated measurement scale for underlying resistance to change, independent of extraneous or circumstantial factors, will be described. This will be followed by an outline of the study objectives, methods, the results and a discussion of the main findings.

Finally, a distillation of the research findings, scholarly views and author opinions draws the thesis to a close in chapter 9.

CHAPTER 2

BACKGROUND

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This chapter serves to create a backdrop for the proposed advanced role for pharmacists in community pharmacy. Reflections on selected historical, political, legislative, social, economic and epidemiological forces impacting the current health system will contextualise the need for health care role innovation. More specifically, the overview will explore the efficiency of the South African health system in relation to other sub-Sahara African and developing nations, the progress of government in attaining the goals of health through the public health sector and private stewardship processes and the Department of Health's efficiency in dealing with the public health crisis of HIV/AIDS through various strategies including the management and control of STI at primary health care level. Furthermore, a synopsis of the contribution made by community pharmacy to primary health care in general will be given, with a view to highlight untapped opportunities for growth within this setting. Finally, a discussion around the plausible impact of recent legislative changes on a future primary health care role for pharmacists will conclude the background.

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2.1   THE SOUTH AFRICAN HEALTH SYSTEM

Although SA is regarded as an upper middle-income nation, wide income disparities and a dual economy relegates it to a developing-country status. The socio-economic inequalities within the population contribute towards the high private-public health expenditure differential, which undermines the performance of the national health system as a whole (World Health Organisation, 2000).

2.1.1 Relative efficiency

The South African health system is comprised of a sizeable public sector and a mushrooming private sector; fifteen percent of the population (~7 million) – invariably medical aid beneficiaries –patronize the latter, while nearly 85% (~40 million) of the population utilize the former. Funding disparities between the private and public sector are notably rife within the health system: the private sector, funded by medical aid scheme contributions and individual out-of-pocket expenses, is inordinately well resourced, accounting for over 60% of the total health expenditure, while less than 40% of expenditure, constituting taxation funding, caters for the health needs of the overwhelming majority (Dayi & Gray, 2006). The resultant poor segmentation of health funding between the private and public sector is a fundamental reason for the unfavourable placing of South Africa in a WHO ranking of world health systems. Although a relatively high proportion (8%) of the nation's gross domestic profit (GDP) is spent on health, SA ranks in the lower percentile of the world's nations. This, in stark contrast to other middle income-developing countries performing more favourably; Chile, Croatia and Argentina all rank in the top 80 while South Africa only managed a placing of 175th. Furthermore, failure to top the list of health systems in Sub-Saharan Africa countries belies the superiority of the South African economy relative to Ghana, Kenya, Uganda and Zimbabwe – all placed above South Africa (World Health Organisation, 2000). The said WHO report has, however, come under intense scrutiny by other development agencies and was subsequently criticised for the utilisation of an unsubstantiated index for the measurement of socioeconomic inequalities in mortality that does not correspond with international variations obtained from established indices (Houweling *et al.,* 2001).

In addition to the sectoral segmentation with respect to health care funding, selected health indicators are used in the evaluation of health systems, viz, the overall daily adjustment life expectancy (DALE)[1]; responsiveness to non-health needs (e.g. dignity and respect conferred by health providers and the right to client choice of provider etc.), and disparities in individual funding contributions towards health expenses as a percentage of total earnings (World Health Organisation, 2000). Poor outcomes with regards to these indicators have consequently attributed to the devaluation of the South African health system. This begs the question: is the South African health system, in its current state, poised to deal with public health crises, not least of all the colossal HIV pandemic?

The failure of the South African health system to be competitive on an international or even a continental level inspires poor confidence in its ability to deal with the myriad of public health issues currently facing this nation. While the responsibility for a poorly functioning health system does not wholly rest on the shoulders of government, their stewardship role in healthcare confers enormous influence on the functioning of the health system. In this regard, the government is deemed responsible for: 1) assuring the effective management of the public sector, 2) regulating the private sector, and 3) facilitating a co-operative relationship between the public and private sector (Leon & Mabope, 2005). The successes and failures of government with respect to these key roles will, in essence, determine the efficiency of the system.

2.1.2 Government's stewardship role

2.1.2.1 *Management of the public health sector*

Post-apartheid South Africa inherited a highly bureaucratic and vertically managed health system that was deliberately oblivious to the health needs of the

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[1] Measure of years lived minus an estimated percentage for each year lived in incomplete health.

masses. Under the old regime, health services were delivered in a fragmented and discriminatory manner, overtly favouring an elitist ethnic minority residing in urban areas. Furthermore, the government of the day placed greater pre-eminence upon curative, as opposed to preventative health, incurring enormous expenditure in the up-keep of secondary healthcare facilities (Department of Health, 2000a).

In a bid to enhance overall accessibility and affordability of essential health services, the 1994 elected government of national unity, in accordance with the White Paper for Transformation of Health Sector in 1997, decentralized the health administration to a local level of control by way of a district health system (DHS) (Department of Health, 1997). The unified district health system, underpinned by the philosophy of primary health care (PHC), was geographically aligned with local government jurisdictions within the nine provinces of South Africa (Eastern Cape (EC), Gauteng (GT), Kwazulu-Natal (KZN), Mpumalanga (MP), Northern Cape (NC), Limpopo Province (LP), North West (NW), Free State (FS) and Western Cape (WC)). Whilst provincial control over hospitals was retained, local authorities adopted the responsibility for administering primary health care services (Department of Health, 2000b).

To date, significant strides have been made in implementing the DHS in South Africa: 700 clinics have been upgraded or built; 2298 clinics have been supplied with new equipment and 125 new mobile clinics have been established. Overall, the public sector offers services from 3500 clinics across the country (Department of Health, 2000b), which translates to 10.5 PHC facilities per 100 000 population. The density disparities between provinces, ranging from 5.5 in GT to 19 in the NC per 100 000 people, correspond to the district expenditure differential between the 2 provinces (Dayi & Gray, 2006).

On a national level, the utilization of PHC facilities remains sub optimal, yielding annual rates of less than 3.5 (national target) visits per person[2]. Notwithstanding the national underperformance, the improvement in utilization rates in nearly 60%

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[2] Public-sector dependent population only

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of districts since 2003 inspires optimism for further progress (Dayi & Gray, 2006). Moreover, financial resources have been earmarked in the Medium Term Expenditure Framework for the DHS, and are expected to facilitate the attainment of this target within the next 3 years (Baron *et al*., 2006).

Human resource deficiencies, a key determinant of poor health service delivery and therefore an impediment to the attainment of positive health indicators, have become a point of notoriety within the revamped public health sector of South Africa. In recent years the national shortfall of health professionals in the public sector has hovered around the 30% mark, ranging from 16% in the Limpopo (LP) to 43% in Mpumalanga (MP) in 2006. Only a fraction of pharmacists (<20%) and doctors (<30%) are employed in the public sector, yielding national ratios of 4.3 and 23.7 to every 100 000 people respectively. A more equitable spread of professional nurses across the public and private sector has yielded ratios in excess of 100 state employed nurses per 100 000 people (Dayi & Gray, 2006). The unequal distribution of selected health personnel – overtly favouring the private sector – may be attributed to several factors, among others, more lucrative salaries (up to six times higher than public sector) and better working conditions as a result of higher staff to patient ratios (Paradath *et al*., 2003). The recent implementation of government policies to avert the human resource crisis has met with only marginal success: compulsory community service for graduates of selected health professions; obligatory tenures in public service for health professional students holding government bursaries; the introduction of racial quotas to ensure the enrolment of students representative of peripheral areas, and enhancement of student preparedness for public service through service training initiatives, have resulted in only nominal improvements in public sector staffing (Dayi & Gray, 2006). The aforementioned initiatives have, furthermore, achieved negligible strides in promoting staff retention at the end of obligatory public service, which has translated to high human resource turnover in public sector facilities and poor continuity of care.

The unbalanced distribution of human resources is aggravated by a problem of skill scarcity. Due to aggressive health professional recruitment from Western first world countries, the pool of human resources has dwindled quite dramatically. In a bid to avert the "brain drain", South Africa, in concert with other Southern African Development Community (SADC) countries, has successfully negotiated ethical international recruitment codes of conduct with countries such as the United Kingdom. Furthermore, national policy-driven training initiatives to increase the number of health professional graduates, coupled by skill-mix initiatives to enhance the capacity of available staff, should augment efforts to mitigate the skills dearth (Paradath *et al*., 2003).

In summary, the South African government faces enormous challenges in its plight to successfully manage the public heath sector, not least of all the human resource deficiencies, skills dearth and financial constraints. The fate of the public health sector ultimately hinges on vital decisions taken at governmental level, which may or may not involve the private sector.
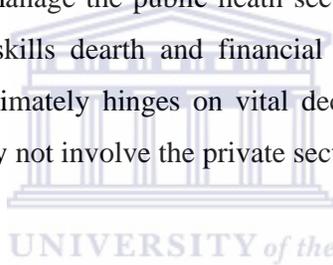
2.1.2.2 *Regulation of private sector and public-private partnerships*

Although the private sector generally meets the regulatory function of government with antipathy and cynicism, this stewardship role should perhaps be regarded as a necessary vice. Attesting to this view is the enactment of various pieces of legislation over the past 10 years, *inter alia* the Health Act No. 61 of 2003 (Republic of South Africa, 2003) and the Medical Schemes Act No. 131 of 1998 (Republic of South Africa, 1998) as amended, which have effectively enhanced general accessibility of healthcare facilities and medical schemes to previously marginalized segments of the population. Amendments to the Health Act have made provision for the equitable distribution of private health establishments in South Africa through the selective granting of certifications of need. Similarly, modifications to the Medical Schemes Act have paved the way for greater accessibility to health insurance by high-risk populations, the aged and less affluent, through minimum benefit packages (Republic of South Africa, 1998,

2003). Furthermore, the Medicines and Related Substances Control Act 2002 as amended – pending an appeal by pharmaceutical representative bodies – will enable the government to regulate the non-profit sale of medicines, thereby enhancing the affordability of essential drugs (Republic of South Africa, 1997a).

The prevailing acrimony between the Department of Health and private enterprise is antithetical to sentiments expressed by the health minister in the Health Act preamble with respect to the desired synergism between the two sectors, i.e. to:

"Promote a spirit of cooperation and shared responsibility among public and private health professionals and providers and other relevant sectors within the context of national, provincial and district health plans." (Republic of South Africa, 2003, p. 4).

By contrast, strategies promoting mutually beneficial partnerships between government and the private sector are more likely to foster the desired cooperation.

As strong proponents of public private interactions (PPIs), the government acknowledges the importance of private sector involvement in addressing public health priorities. The establishment of such interactions is predominantly based on a service delivery model (Leon & Mabope 2005), which allows the private sector to offer services on behalf of the public sector and/or the exchange of services or goods between the two sectors. Consequently, an abundance of resources in the private sector are tapped by the public sector without the incurrence of exorbitant cost and risk.

Regrettably, setbacks have abounded in the implementation of healthcare PPI in South Africa due to fundamental planning glitches. In the absence of a policy framework defining PPI and outlining the objectives and procedural establishment thereof, the process of developing sound and sustainable partnerships has been hampered. Discord in vision between various stakeholders prevails in consequence of these conceptual gaps, which further subverts a well-intended innovation. A further threat to successful PPI establishment has been the growing

mistrust emanating from the private sector in response to government's perceived regulatory encroachment on private enterprise (Leon & Mabope, 2005).

The fragmented approach to establishing PPIs without a guiding policy framework potentially undermines continuity of interactions between the public and private sector and widens the gulf of mistrust between the two sectors. In essence, the regulatory imperatives of government will not be adequately fulfilled unless the fundamental policies for PPI implementation are expressly delineated. With this in place, government will be well poised to exploit the leveraging effect of establishing partnerships with a richly resourced private sector.

In summary, the incumbent government has made significant strides in remodelling the foundation of public health, thereby closing some of the healthcare gaps induced by the apartheid regime. However, health indicators in general reflect poorly against national targets and residual interprovincial disparities remain a concern. Furthermore, the sustainability of supplementary funding to accommodate the escalating public health budgets is questionable, while human resource deficiencies and skill scarcity are, at this juncture, tantamount to a crisis. The best way forward remains ill-defined; however, attempts to develop cohesive strategies involving both the public and private sector are certainly at a premium in the face of immense public health challenges, not least of all a burdensome HIV epidemic.

2.2 THE HIV/AIDS PANDEMIC

2.2.1 A public health priority?

South Africa is currently plagued by one of the most devastating HIV pandemics in the world (UNAIDS, 2006); the magnitude and pervasiveness of disease is clearly demonstrated in the results of the 2006 national antenatal survey reflecting a prevalence of 29.1% (Department of Health, 2007b). The impact of deaths due to AIDS is far-reaching, adversely affecting the economic, social and welfare systems as well as overall population growth (Actuarial Society of South Africa, 2003); nearly 40% of deaths among the most economically viable age group (15-49 year olds) are attributed to HIV/AIDS (Dorrington *et al.,* 2001), overall life expectancy has plunged from 57 in 1998 to 50.7 in 2006 and the number of orphaned children as a result of HIV has escalated to a disconcertingly high 1.2 million (Dayi & Gray, 2006).

A gross failure by the Department of Health and other governmental ministries to promptly address the rising HIV levels in the early 1990s has contributed toward the rampant spread of infection from prevalence rates of 0.7% in 1990 to an astounding 22.8% in 1998. Furthermore, the dissident views held by leading politicians in the ruling governmental party at the turn of the 21st century, are thought to have further fuelled this epidemic. While the first HIV/AIDS and STI strategic plan for 2000-2005 (Department of Health, 2000c) was essentially prevention-based, vehement lobbying from advocacy groups successfully paved the way for the launch of an Operational Plan for Comprehensive HIV and AIDS Care encompassing strategies to roll out ARV therapy in selected public sector health facilities (Department of Health, 2003). By early 2006, national antiretroviral therapy (ART) coverage rates[3] in the public sector were 18.3%, ranging from 6.8% in MP to 43.2% in WC (Dayi & Gray, 2006).

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[3] ART coverage is the percentage of the population estimated to be in need of ART who are receiving ART.

In recent years infection rates have plateaued, although exhibiting no signs of tapering off. The provinces hit hardest by the epidemic are KZN (39.1%), MP (32.1%) and FS (31.1%), while the WC remains the province exhibiting the lowest HIV prevalence. The steady increase in WC infection rates from 3.1% to 15.2% from 1996 to 2006 is, however, a growing concern (Department of Health, 2007b).

2.2.2 Prevention through management and control of STI

Notwithstanding the significant strides made in terms of accessing ARV therapy, prevention remains the cornerstone of public health strategies, *inter alia*, improving the management and control of the estimated 11 million new STI episodes occurring in South Africa annually (Department of Health, 2007b; Sonko *et al*., 2003). Syndromic management was adopted as a national treatment approach in public primary healthcare facilities in the mid-1990s and by 2002, 50% of public sector professional nurses had received training in SM and nearly 95% of all public PHC clinics offered STI services (Health Systems Trust, n.d.). The advent of syndromic management in the public sector overlapped with plummeting syphilis prevalence rates (from 11.2% in 1999 to 2.7% in 2005) and a similar decline in the incidence of treated STI[4] (from 6.4% in 2000 to 4.8% in 2005) (Department of Health, 2007b; Health Systems Trust, n.d.). However, recent inclines in both syphilis prevalence (from 1.6% to 2.7% between 2004 and 2005) and new episodes of STI (from 4.8% to 5% between 2005 and 2006), warrants sustained efforts in the management and control of STI, with an emphasis on improving the dissemination of treatment guidelines, overall quality of care and partner management (Sonko *et al*., 2003). These figures are but a drop in the proverbial ocean of disease when considering the propensity for STI clients to seek treatment in the private sector (Wilkinson *et al*., 1998) and the unknown segment of the population practicing self-treatment or remaining untreated.

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[4] The percentage of people 15 years and older that have been treated for a new episode of a STI (annualised).

Contrastingly, syndromic STI training of private sector doctors and occupational nurses has been languid and riddled with problems. Research indicates that STI treatment protocols are seldom adhered to in the private sector, which has translated to relatively poor pharmacological treatment, counselling, provision of health education, promotion of voluntary counselling and testing and partner notification (Dartnall *et al*., 1997). Subsequently the Department of Health has developed strategies to standardize STI treatment across the various sectors of health through, among others, the development of public health-underpinned curricular for the training of health professionals at undergraduate and post-graduate level, and the development of PPI at primary levels of care (Sonko *et al*., 2003).

In summary, the languid governmental response to a threatening HIV epidemic in the early 1990s severely hampered future efforts to obliterate the disease. Consistent with natural disease phenomena, the prevalence of HIV has reached a plateau-level in South Africa. However, the high point at which the infection rates have settled has dire implications for an already overburdened public health sector. Private sector contributions to HIV prevention strategies through STI management have yielded relatively unfruitful interim outcomes among private doctors and nurses; however, perseverance with this sector is of paramount importance if the goal to standardize STI care through syndromic management is to be achieved.

2.3 PRIVATE COMMUNITY RETAIL PHARMACY: A POTENTIALLY UNDERUTILISED PRIMARY HEALTH CARE STRATEGY?

2.3.1 Primary healthcare roles for pharmacists

In the first half of the 20th century, pharmacy as a profession evolved from the pre-industrial era of apothecary towards a more technical role in the age of rapid burgeoning of the pharmaceutical industry. In the second half of the century the profession shifted paradigmatically towards a patient-oriented clinical role and at the close of the 20th century the philosophy of pharmaceutical care had become the bedrock of pharmacy (Pearson, 2007). In the various practice environments, pharmaceutical care refers to the provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life (Helper & Strand, 1989). Due to legislative restrictions allowing only limited diagnosing and prescribing by pharmacists (Republic of South Africa, 1997a)[5], this translates to the implementation and monitoring of pharmaceutical plans invariably designed by authorized health care professionals.
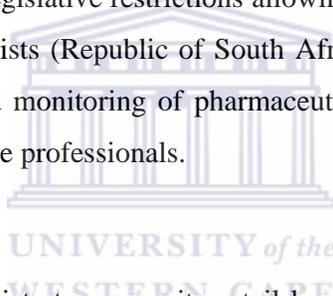
The "evolved" pharmacist at community retail level is often the first port of call for clients with medical problems; accessibility, after hour availability and prompt client assistance are among the reasons cited for this preference (Gilbert, 1998). Though often sought for curative services, including STI management (Ward *et al*., 2003), community pharmacists are restricted to performing the following primary health care functions: provision of essential clinical services including screening for various chronic diseases and prevention of childhood diseases via blood glucose, cholesterol and HIV testing, urine testing, peak-flow, blood pressure monitoring and immunizations respectively; referral services; provision of health care education and information at individual and community level and as alluded to earlier, the provision of pharmaceutical care. The restriction of pharmacist initiated therapy to the diagnosis and treatment of minor ailments

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[5] The Medicines and Related Substances Control Amendment Act of 1997 excludes pharmacists under the definition of "authorized prescriber" of medicines with a scheduling status of 3 and higher.

undermines the training of pharmacists in clinical decision-making and furthermore impedes the utilization of pharmacies in addressing public health priorities.

Allowing pharmacists to expand their range of curative services through wider scopes of practice may offer an alternative source of care to the public sector dependent population, provided that comparatively higher private costs are offset by government subsidies of various kinds. Evidence from a WC survey reflecting frequent requests for pharmacist initiated therapy by low to middle income groups, suggests that these facilities are already a preferred source of primary health care to a large segment of the public sector dependent population (Ward *et al*., 2003). The utilization of these existing facilities – 6.3 retail outlets for every 100 000 individuals[6] - potentially enhances accessibility to health services by the public sector dependent population by at least 50%. Unfortunately, the associated out-of-pocket expenditures by non-medical aid beneficiaries contribute toward the health-funding inequalities maiming the health system. This problem could be circumvented through the forging of private-public-partnerships, whereby private community pharmacies become conduits for government services and supplies. The aforementioned strategy is not a novel concept: the delivery of family planning services and immunization of children from these outlets by nurse practitioners on behalf of the state attests to the application of service delivery models in pharmacies. The consequent interface between pharmacists and nurses is in line with the concept of pharmaceutical care, which is premised on health professional teamwork.

2.3.2   Legislative context: a potential catalyst for role change?

The philosophy of pharmaceutical care, in congruence with the primary healthcare philosophy, is strongly patient centred and is supported by parallel pricing regulations that encourages the levying of a professional fee for services rendered

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[6] 2523 community pharmacies registered with the South African Pharmacy Council as per 2006 (South African Pharmacy Council, n.d.), divided by 40 263 557 (public sector dependent population as per 2006) (Health Systems Trust, n.d.)

to a client as opposed to being excessively product and sales driven (Gilbert, 1998; Republic of South Africa, 1997a).

With a view to correct gross health inequalities of the past, the government of national unity is committed to achieving the goals embedded in a National Drug Policy (Department of Health, 1996), which includes, among others, improved access to essential drugs within the context of good pharmaceutical care. Selected legislative amendments informed by this policy, viz, the Medicines and Related Substances Control Act and the Pharmacy Act, warrant further elaboration due to their impact on community pharmacy practice.

The Medicines and Related Substances Control amendment act No. 90 of 1997 (Republic of South Africa, 1997a) prescribes a transparent pricing system which fixes the price at which manufacturers shall sell medicines and Scheduled substances to any person other than the state . The final mark-up charged by pharmacies constitutes a tier-structured dispensing/professional fee in lieu of indiscriminate product mark-ups, thus affording end-users of medicine the ability to query exorbitant medicine pricing and to challenge disparate prices between various pharmacies. The consequent standardization of medicine pricing demands a level of service delivery that adds value to the product, thereby conferring competitive distinctiveness to a particular pharmacy.

In a bid to standardize the cost of numerous other professional services delivered by pharmacies, the South African Pharmacy Council, in accordance with the Pharmacy amendment act No. 88 of 1997 (Republic of South Africa, 1997b), has developed a schedule of services for which pharmacists may levy a fee. These services include, *inter alia*, the screening and testing of biological and physical parameters, the compounding of extemporaneous items and medical or pharmaceutical consultations, for which pharmacists may or may not require additional training (Republic of South Africa, 2007). The provision of financial incentives to perform professional services could potentially incite greater

willingness among pharmacists to upgrade their skills, and to challenge the professional boundaries imposed by official scopes of practice.

Furthermore, the enactment of pharmacy lay ownership – in accordance with the Pharmacy amendment Act No. 88 of 1997 (Republic of South Africa 1997b) – has seen major retail companies, leveraged with existing wholesale and distribution divisions, entering the market as strong competitors against smaller, independent pharmacies. Notwithstanding the institution of legislative safeguards to level the playing fields between independent and corporate pharmacies through the outlawing of perverse incentives such as discounting or rebates from pharmaceutical companies, the competitive edge conferred to large retailers due to the unregulated logistics fees (storage and distribution to retail outlets) added to medicines, is a threat to the continued existence of independent and small chain pharmacies. The viability of these smaller enterprises calls for innovative business models that will ensure consumer patronage.

In essence, the new reimbursement structures and service oriented approach to community pharmacy, coupled to the threat of corporate pharmacies, demands a reinvention in community pharmacy. The retention of traditional pharmacy business models has and will continue to spell the demise of many community pharmacies, whereas innovative approaches that incorporate needs-driven service models and partnerships forged with the public sector could signal the dawn of a new brand of primary health care community pharmacies.

2.4 CONCLUSION

The South African socio-political, economic and healthcare landscape is evidently primed for the proposed advanced roles for pharmacists in primary health care, *inter alia*, STI management. Moreover, the inauspicious state of the national health system demands an exploration into innovative public private interactions that will be mutually beneficial to all stakeholders, thereby boding well for improved healthcare in South Africa.

CHAPTER 3

LITERATURE REVIEW

This literature review critically analyses published research study findings and reviews, borrows insights from treatise and examines pertinent local and international policy and legislative documents, with a view to develop the theoretical underpinnings for an advanced role pharmacist in primary care, more especially in syndromic sexually transmitted infection (STI) management. The HIV/AIDS strategic document developed by the health ministry of South Africa contains a concretised plan for dishevelling the scourge that besets this nation. Prevention is the cornerstone of the said plan, and key priority areas such as STI management and control through syndromic treatment modality interventions are aimed at reducing the infection rate by 50% by 2011 (Department of Health, 2007a). In a healthcare system fraught with human resource deficiencies, the utilization of existing skills and the expansion of skills inherent to specific health professions at primary care level could facilitate implementation of the aforementioned interventions.

The opening segment of this review attempts to elucidate obscurities surrounding the value of STI management in the fight against HIV and the effectiveness of various elements of the syndromic approach and the second instalment explores global trends in meeting human resource needs in primary healthcare settings. The literature review culminates in the aims and objectives central to this thesis.

3.1   SYNDROMIC MANAGEMENT OF STI

In recent years the response of the South African government to the HIV crisis has shifted from gratuitous debates around the causal relationship between HIV and AIDS towards the implementation of a prevention-slanted HIV and AIDS and STI strategic plan (Department of Health, 2000c). This plan highlighted STI management and control as a primary goal, notwithstanding prevailing uncertainty around the true value of STI interventions in HIV prevention (Grosskurth *et al.*, 2000a; Kamali *et al.*, 2003; Wawer *et al.*, 1999).   Under the new dispensation of antiretroviral (ARV) therapy, prevention remains the cornerstone of strategic plans and STI related interventions are firmly embedded in syndromic treatment modalities (Department of Health, 2007a). Against a backdrop of uncertainty concerning impact, the point of departure for this review is to affirm the fundamental premise that STI management and control are indispensable to any HIV/AIDS strategic plans.

In an era of modern medicine where new medical interventions and technological innovations are rapidly burgeoning, the Spartan approach to treating STI syndromically has been the subject of wide debate. The effectiveness of World Health Organisation (WHO) syndrome algorithms has improved incrementally over the years through the incorporation of risk assessments, clinical examinations and diagnostic assays – composite algorithms are currently employed by public primary healthcare services in South Africa (World Health Organisation, 2003). However, in infrastructurally poor milieus such as community pharmacies, which are not conducive to performing invasive speculum examinations for microscopy and gram-stain analyses, and phlebotomies for syphilis serology, the basic algorithms, devoid of these augmentations may be required if pharmacists are allowed to perform these techniques in the future. The controversy around syndromic management therefore sets the background for the second review instalment in which the validity and efficacy of basic algorithms, incorporating confirmed entry point client complaint and

risk assessment, are evaluated independently and where possible against augmented algorithms.

One further aspect of syndromic STI management that has recently come under intense scrutiny is the expedient approach to treating sexual contacts presumptively, i.e. based on the diagnosis of the index client. In the face of poor partner treatment rates in South Africa and other developing countries, effective and innovative strategies, which enhance partner accessibility to treatment, are desperately needed. To this end, the simplicity of presumptive treatment certainly lends itself to a community pharmacy setting; however, the controversy shrouding this treatment modality warrants an exploration of literature into the scientific basis thereof.

WHO strongly advocates the training of all healthcare workers in the recognition and treatment of STI using simple syndrome algorithms. Furthermore, the South African Minister of Health (MOH) has been mandated to regulate education and training efforts targeted at nurses, doctors, dentists and pharmacists with a view to increasing manpower for the management of various communicable diseases, *inter alia*, STI (Republic of South Africa, 2003). In this regard, however, South Africa has taken a relatively conservative stance by overlooking healthcare workers outside the medical and nursing fraternity. This review instalment will explore the design and operational features of pharmacist-led STI control programmes in other countries and seek to demonstrate that pharmacists, undergirded with sufficient and appropriate training and support, exhibit the required competencies to provide quality STI care.

Finally, with a view to attain congruency between service provision and service utilization, there is a need for responsiveness to health seeking behaviour of target communities; to this end the attitudes and perceptions of STI clients are reviewed in the literature.

3.1.1 STI and HIV linkage

3.1.1.1   *Biological and clinical studies*

There is no shortage of scientific reviews centring on the biological link between STI and HIV (Galvin & Cohen, 2004; Flemming & Wasserheit, 1999; Rottingen *et al.,* 2001; Sangani *et al.,* 2004). A substantial body of evidence gives credence to the hypothesis that HIV shedding increases in the presence of a co-existing STI. Although risk estimates for ulcerative STI are slightly superior in relation to those for non-ulcerative STI, both infection types are recognized co-factors in HIV transmission. Risk estimates derived from a meta-analysis of reputable studies show that clients presenting with ulcerative STI are 2.7 times more likely to contract HIV after unprotected intercourse with an infected individual than a client without an STI, while for non-ulcerative STI the risk estimate is 1.7. Individually, ulcerative chancroid, syphilis and herpes simplex virus (HSV) yielded risk ratios of 2.1, 2.5 and 7.7 respectively while corresponding values for non-ulcerative Neisseria Gonorrhoea (NG), Chlamydia Trachomatis (CT), Trichomoniasis Vaginalis (TV) and Bacterial Vaginosis (BV) were 2.1, 2.2, 1.5 and 1.4 respectively (Dallabetta & Neilson, 2004). That STI are co-factors in the causal pathway of HIV transmission is therefore "no longer a hypothesis" (Cohen, 1998) and reinforces the empirical evidence underpinning the HIV prevention strategies advocated by WHO, *inter alia*, STI control.

Presumably, the biological association between STI and HIV gives leverage to the argument that the treatment of STI would reduce viral shedding relative to a viral set point. If we assume that reduced viral shedding mitigates infectiousness and thereby minimizes transmissibility, then the hypothesis that improved STI treatment at community level will reduce HIV incidence rings plausible. Experts in the field explore these two issues at a clinical and epidemiological level and their findings are summarized below.

In West and East Africa, Ghys *et al.* (1997), Wolday *et al.* (2004) and McCelland *et al.* (2001) sought to determine the impact of STI treatment on the viral shedding in genital secretions of HIV positive women. Generally, all curable STI were included in the evaluations, although the latter study targeted diseases causing cervicitis only. In Southern Africa, Cohen *et al.* (1997) investigated the association between viral shedding in HIV positive men and improved syndromic treatment of urethritis. All studies adopted a cross-sectional design spanning anywhere from 3 months to 3 years and a similar sequence of procedures was carried out: upon entry into the study, participants were clinically diagnosed for STI and treated presumptively, and at enrolment and follow-up 1 or 2 weeks later samples for pathogen-specific STI diagnosis and viral load quantification were elicited. Treatments for clinically missed diagnoses were offered within a few days subsequent to enrolment if necessary. Assays for STI diagnosis were all of comparable sensitivities, and polymerase chain reaction (PCR) analysis was performed across the board to quantify viral shedding. Only patients not receiving highly active antiretroviral therapy (HAART) were deemed eligible for participation so as to rule out the impact of HAART on viral shedding.

Ghys *et al.* (1997) enrolled 685 female sex workers (FSW) presenting with an STI to a local clinic in Abidgan, Cote d'Ivoire over an 8 month period and the samples collected for quantifying viral load were derived from cervical lavages and plasma sera. Among those cured of STI, detectable viral load was observed in 42% of participants at baseline, compared to 21% at follow-up (p<0.005). The prevalence of viral shedding among participants who experienced treatment failure was the same at baseline and follow-up. A logistic regression model fitted with ulcerative STI, non-ulcerative STI and HIV-1 cervical viral shedding reflected significant associations with NG (AOR 1.9, 95% CI 1.2-3.0), C. Trachomatis (AOR 2.5, 95% CI 1.1-5.8), cervical and vaginal ulcer (AOR 3.9, 95% CI 2.1-7.4) and immunosuppression/less than 14% CD4 percentage (AOR 6.3, 95%CI 3.4-11.9). An independent association between HIV-1 serum viral load and HIV shedding was not found leading authors to

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surmise that local factors, such as STI are the more likely determinants of HIV transmissibility than the circulating viral load.

Wolday *et al.* (2004) enrolled women from the general population, attending a health centre in Addis Ababa, Ethiopia, into a study evaluating the effect of improved syndromic treatment on viral shedding from the cervix as well as the impact of unsuccessful treatment outcomes on shedding. Of the 71 HIV positive individuals, 60 presented with symptoms of STI and the 11 who had no symptoms served as a control. As expected, cervical HIV-1 shedding was significantly higher among females with an STI in comparison to the controls, yielding median values of 3.15 and 1.9 $\log_{10}$RNA copies/swab respectively (p=0.02). Similarly, the prevalence of detectable cervical HIV-RNA was higher among STI carriers than controls (68% vs. 27%, p=0.02). Furthermore, cervical HIV-RNA load was significantly higher in females with genital ulcer syndrome (GUS) than genital discharge syndrome (GDS) (p=0.02). While the overall effect of syndromic treatment significantly reduced viral shedding (p=0.02), this was not the case for treatment of individual STI syndromes; genital shedding after syndromic treatment of GUD and GDS, taken separately, showed no appreciable decline from baseline (p>0.05). Authors ascribe this lack of significant effect to the poor treatment outcomes yielded by the syndromic approach (notably for GUS) as a result of missing and over diagnosing numerous infections. This line of reasoning is further corroborated by findings within the successfully treated subgroup: the median genital HIV load declined significantly only in the females exhibiting clinical improvement –a mean decrease of 0.43 $\log_{10}$ copies from baseline was achieved and more than 56% demonstrated a decrease in cervical HIV-RNA. The failure to cure GUS, as alluded to by the authors, could be attributed to the presence of HSV-2, which was not quantified in this study.

Between 1996 and 1999, McCelland *et al.* (2001) enrolled 70 HIV positive women with concurrent cervicitis from an STI clinic in Mombasa, Kenya, to evaluate the changes in cervical site specific shedding with syndromic treatment of cervicitis (due

to NG, CT or non-specific etiology). Among the successfully treated women, 72.2% demonstrated a decrease in cervical HIV-1 RNA with overall viral loads decreasing from a median of 4.05 at baseline to 3.24 $\log_{10}$copies/swab at follow-up (p=0.001), and median cervical HIV-1 RNA levels decreasing from 3.94 to 3.28$\log_{10}$ copies/swab (p=0.02) and 4.21 to 3.19 $\log_{10}$ copies/swab (p=0.02) for GC and CT respectively. These declining viral levels, as noted by authors, were comparable to values achieved after instituting highly active antiretroviral therapy (HAART) in a study conducted by Cu-Uvin *et al.* (2000).

In Malawi, Cohen *et al.* (1997) designed a prospective, sequence comparison study of 2 cohorts, one consisting of 206 HIV-1 infected men with concomitant urethritis, selected from an STI clinic and the control bearing 127 HIV-1 infected men without urethritis, recruited from a dermatological clinic. The main hypothesis was that antibacterial treatment of urethritis would reduce semen viral loads in HIV positive patients. The sequence comparison at baseline, week 1 and week 2 allowed for retreatment in the event of treatment failure and subsequently higher resolution of urethritis was attained by week 2. As expected, the HIV viral load (copies/ml) at baseline did not differ significantly from the follow-up group at week 2 in the control group. At baseline the median seminal plasma HIV-RNA concentrations were eight times higher in the STI group than in the control group (12.4 vs. $1.51x10^4$copies/ml; p=0.035), having similar CD4 counts and blood viral burdens. Furthermore, men with NG yielded higher concentrations of viral RNA in semen than those with non-gonococcal urethritis (NGU) (median 15.8 vs. $2.52 X10^4$ copies/ml; p=0.003). After initiating antibiotic therapy for urethritis a significant decrease in HIV-RNA concentration in seminal plasma was detected. Median concentrations of seminal plasma HIV-1 RNA with sequential samples at baseline, week 1 and week 2, decreased from $12.4x10^4$ copies/ml to $8.91 x 10^4$ copies/ml and $4.12x10^4$ copies/ml respectively (both p-values <0.05). The most considerable changes in viral load from baseline to week 1 and week 2 were observed in patients treated for NG,

although significant, albeit less dramatic changes were observed in patients treated for NGU at week 2.

An analysis of the few articles evaluating the correlation between the treatment of curable STI and viral shedding has led to two important observations: i) STI diagnoses (combining clinical and assay-derived findings) and treatment, especially of NG, in the general population (Cohen *et al.,* 1997; McCelland *et al.,* 2001; Wolday *et al.,* 2004) and among high risk groups (Ghys *et al.,* 1997; Woolday *et al.,* 2004), are associated with a decrease in genital HIV concentration – although only conjectured in the latter population – and in some cases are comparable to the decrease in viral load achieved through HAART (McCelland *et al.,* 2001), and ii) the impact of syndromic treatment on viral shedding is conditional upon treatment success rates achieved (Ghys *et al.,* 1997), which calls for, *inter alia*, stringent validation of syndrome algorithms. The untold impact of HSV-2 on the aforementioned findings should however be factored into the interpretation of results, especially in regions burdened with high HSV-2 prevalence (Woolday *et al.,* 2004). This notwithstanding, the encouraging clinical outcomes in this review beg the following question: could an STI treatment intervention at community level reduce HIV-1 incidence?

3.1.1.2. *Impact of STI on HIV: Community-level interventions*

Community based trials evaluating the implications of the discussed biological findings on HIV-1 incidence impose overwhelming financial and logistical burdens, which may explain the dearth of studies evaluating changes in HIV-1 trends. Three randomised control trials (RCTs) were conducted in rural Eastern Africa where STI control interventions were hypothesized to reduce incidence of HIV-1 in targeted populations.

Grosskurth *et al.* (1995) was a frontrunner in implementing a randomised matched control trial at a population level to evaluate the impact of an STI intervention on the HIV-1 incidence in a rural Tanzanian region between 1991 and 1994. The intervention consisted of 5 components, viz the establishment of an STI reference clinic; a 3 week STI training course for healthcare workers; a supplementary delivery system ensuring improved drug supply; periodic site visits by research personnel and community education with an emphasis on STI treatment. Over 12 000 adults in twelve communities were paired according to geographical delineations –so as to control for regional variations in HIV prevalence –and one in each pair was randomly assigned to the intervention group immediately after a baseline survey. The control group was not exposed to the intervention until the 2-year follow up. Surveys, syndromic diagnoses and laboratory tests for STI (including HIV) were conducted at baseline and follow-up. This open cohort study produced comparable follow-up coverage rates in the intervention and control group. Surveys encompassed issues such as sexual behaviours, demographics, history of STI, travel out of area, and male circumcision status. The aforementioned variables were fitted into a logistic regression model to control for individual differences between subjects. Results showed that the intervention proved to be protective against HIV-1 acquisition; the intervention group exhibited a lower seroconversion rate (1.2%) in comparison with the control group (1.9%), (ARR 0.58; 95%CI 0.42-0.79), translating to a 40% reduction in HIV-1 infections. The reductions were consistent in all matched pairs and were observed in both sexes. Although the intervention group reflected a slightly lower STI prevalence than the control for symptomatic and etiological STI, the differences were not significant. Since the intervention focused on enhancing STI treatment only and was devoid of any behavioural interventions, the subsequent absence of sexual behaviour change as reflected by reported condom use might be regarded as inconsequential. The authors, in consonance with Wolday *et al.* (2004), ascribe the decline in HIV-1 incidence to the successful treatment and resultant shortened duration of clinical STI.

In 1999, Wawer *et al.* sought to evaluate the impact of a mass STI treatment strategy on HIV-1 incidence in the Rakai district of Uganda, renowned for incurring high HIV-1 and STI rates. Fifty-six communities, selected on the basis of infrastructure, HIV-1 incidence and population stability were clustered into 10 groups in such a way that STI reintroduction into the clustered regions was precluded. A further delineation into three blocks ensured that cluster communities of comparable HIV prevalence were paired. One cluster community within each pair was randomly assigned to receive home-based, directly observed therapy for STI over a 30 month time frame at 10 month intervals, while the control group received anthelminthics at corresponding time intervals. Serological HIV-1 testing was performed at each intervention point and all communities received identical education on STI prevention in community meetings. The results in this study reflected no difference in overall HIV incidence between the intervention and control group of the general population and neither was any differences detected in the subgroup of pregnant women. This pattern was sustained across allotted time intervals as well as individual cluster blocks. The only noteworthy successes in STI control between intervention and reference group were achieved after the second follow up treatment for syphilis (Prevalence Ratio (PR) 0.8, 95% CI 0.71-0.89) and TV (PR 0.59, 95% CI 0.38-0.91). In the sub sample of pregnant women, mass treatment significantly decreased the rate of cervical and vaginal infections during pregnancy, however, no reduction in HIV-1 incidence was observed either during or after pregnancy.

Masaka was the site of a three-armed randomised controlled STI intervention trial, which ran concurrently with the mass-treatment trial in neighbouring district, Rasaka. The impact of 2 distinct interventions on a sample of 18 communities spanning a 6-year period was evaluated. Communities were matched in triplets based on comparable HIV incidences. Matched communities were assigned to one of three study arms: A) information, education and communication activities (behavioural arm); B) the aforementioned activities in addition to improved management of STI (STI intervention arm); and C) general community development activities, *inter alia,*

home-based care for elderly and health promotion (control). Serological testing for HIV as well as STI assays were performed at baseline and again at 2 year intervals in an open cohort which by the final round of the study had amassed over 14 000 participants. Neither the overall incidence of HIV-1 nor the incidences at each study round varied significantly between either of the two intervention groups (A or B) and the control group (C). The incidence of all STI, bar one (CT), were significantly impacted by at least one intervention: the overall HSV-2 incidence/100 person years was lower in the behavioural (A) than control arm (Adjusted Incidence Rate Ratio (AIRR) 0.65; p=0.04); the higher titre active syphilis incidence/100pyar in the STI intervention arm (B) was well below that observed in the control arm (AIRR 0.58; p=0.04) and this pattern was sustained for NG (AIRR 0.28; p=0.02). The only noteworthy improvement in behavioural indices was observed for condom use in high risk encounters, as established by reported condom use at most recent sexual encounter with casual partner. These findings were associated with both the STI intervention arm (Adjusted prevalence ratio (APR) 95% CI 1.02-1.56) and to a lesser extent, the behavioural arm (APR 1.12; 95% CI 0.99-1.25) (Kamali *et al.*, 2003).
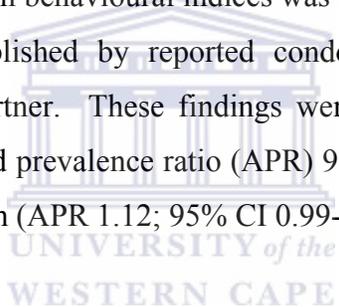
The evidently disparate findings emanating from the three community randomised controlled trials have been the subject of numerous reviews which have generated several explanatory hypotheses. Tentative explanations for the lack of appreciable reduction in HIV-1 incidence in the two Ugandan trials are categorized under population, intervention and study design differences (enumerated below) (Grosskurth *et al.*, 2000a; Hitchcock & Fransen, 1999; Boily *et al.*, 2000; Hudson, 2001; Korenromp *et al.*, 2001, 2002; O'Farrel, 2001; Dik *et al.*, 1995). Korenromp *et al.*, in 2004 employed the use of statistical modelling to test the validity of the hypotheses based on the following differences: 1) at the time of the study, the HIV epidemic in Tanzania and Uganda reflected uniquely different challenges by virtue of the diametrically opposed stages of disease; the Tanzanian epidemic was in the stage of infancy with low but steadily rising infection rates, while the Ugandan epidemic was mature and exhibiting plateauing trends; 2) sexual risk behaviours and STI

prevalence leading up to and including the study period were notably greater in the Mwanzan population; 3) the unmeasured impact of HSV-2–overlooked in all 3 trials – on the treatment of concurrent bacterial STI produced potentially spurious findings; 4) the greater degree of mobility of the Rakai population due to the open cohort design and the close geographical proximity of the study intervention and non-intervention communities constituted design differences; and 5) study interventions varied widely from syndromic treatment in Tanzania to mass STI treatment in Rakai and a combination of treatment and prevention education in Masaka. Simulation modelling of trial data led to the refutation of many of the proposed hypotheses, however three proved to render a plausible explanation for the poor impact of interventions on HIV-1 infection rates in Rakai and Masaka: low rates of curable co-factor STI, the reduction in risk behaviours prior to the trials and the advanced stage of the epidemic (Korenromp *et al.*, 2004). The concluding remarks of the authors are consonant with those of Dallabetta *et al.* (2004) which infer that in many African and Southern Asian populations where STI infection rates are high and treatment services are sub optimal, syndromic and mass treatment of STI are likely to stem the spread of HIV infection.

Therefore, the seemingly incoherent findings in the three randomised controlled trials do not discount STI control as an effective HIV prevention strategy; on the contrary, these results augment our understanding of the environmental and demographical contexts within which specific interventions are likely to succeed. The clinical and epidemiological evidence presented in this review favours the continued support of WHO advocated HIV strategies to improve STI treatment delivery. Furthermore, the clinical inferences derived from biological studies have wide applicability for both the HIV infected and uninfected populations, viz, a reduction in the host's infectiousness and transmissibility with respect to HIV (Cohen *et al.*, 1997; McCelland *et al.*, 2001; Wolday *et al.*, 2004), and amongst the seronegative population, a reduced susceptibility to HIV seroconversion (Cohen *et al.*, 1998; Dallabetta & Neilson, 2004).

In essence, syndromic treatment modalities are well suited for the South African milieu, where STI infection rates are high and more than 80% of the population relies on very basic primary healthcare services for sexual heath. STI management and control by way of syndromic treatment should therefore remain a key component in South African HIV-1 prevention programmes.

3.1.2 Syndromic approach to treating STI

3.1.2.1 *Syndromic diagnosis: algorithm validity*

In view of disparities existing between countries in terms of etiological agents implicated, syndrome prevalence and infrastructural and resource capacities, adaptations to WHO syndrome algorithms are an accepted and widespread phenomena. In resource-poor settings where even the simplest diagnostic assays are unaffordable and a deficiency of manpower to legally provide services is prevalent, the least invasive and technologically dependent procedures are preferred. But is the pursuit of a Spartan approach to STI care compromising quality and effectiveness? WHO support for revised algorithms to meet country-specific needs comes with the proviso that health ministries assume responsibility for algorithm validation against gold standard microbiological assays. The ensuing review of literature evaluates the validity – in terms of sensitivity, specificity and positive predictive values – of the most basic algorithms, which may lend themselves to infrastructurally poor environments such as community pharmacies.

Djajakusumah *et al.* (1998) evaluated the performance of the algorithm for urethral discharge syndrome (UDS) in an Indonesian city, known for its high STI prevalence. The most basic algorithm, devoid of diagnostic assays, and based solely on a clinical diagnosis underpinned by thorough risk assessment, yielded a sensitivity of 100% with a 75% chance of correctly predicting true positives (positive predictive value-PPV) in a population. This translates to no under treatment and minimal over

treatment. Comparable results were yielded in a study conducted in Benin, Russia where the sensitivity of an identical algorithm for UDS was 91.5% and the PPV was 65.2% (Alary *et al*. 1998). Authors ascribe the latter findings to a relatively low prevalence of CT and NG in this first world country, as disease prevalence is known to greatly influence the PPV. Chalamilla *et al.* (2006), in an evaluation of the relationship between syndromic management and microbiological diagnosis, corroborates the aforementioned findings and deems syndromic treatment appropriate in men with GDS. In this study concordance between GDS syndrome diagnosis and etiological findings of NG and CT was reported in 90% of cases (no validity indices supplied).

Conversely, a meta-analyses review by Sloan *et al.* (2000) of basic algorithms relying primarily on risk assessment factors, signs and symptoms in the identification of NG and CT in females reflected poor sensitivity and PPV (54.34% and 18% respectively) and reasonably satisfactory specificity (74.8%). Interestingly, the algorithm relying on a speculum examination yielded similarly poor specificity and PPV. The concluding remark emanating from the review, in concurrence with many of the authors of studies included in the meta-analysis, was that the approaches utilizing the aforementioned screening tool were found to be inefficient; these algorithms were found to have poor PPV and sensitivity (11.5-41% and 48.9-55.0% respectively), and a wide range of specificity (54.2-88.2%) for the identification of NG, CT and TV (Desai *et al.,* 2003). WHO algorithms relying on sexual risk assessment and patient symptoms only (no signs) in diagnosing BV, candidasis, TV and cervical infection yielded excellent sensitivity (100%), very poor specificity (0-56%) – due to wider spectrum of organisms investigated – and weak PPV (2-19%) (Hawkes *et al.,* 1999).

In a sample of women, Desai *et al*. (2003), detected poor GUS algorithm sensitivity for detecting syphilis (14.8%), while high specificity was noted (96.7%). The ability of the algorithm to correctly predict the true number of syphilis cases in the sample was a modest 57.1%, which authors ascribe to the low prevalence of GUS in this

Indian region. Notably, the addition of a simple and relatively cheap diagnostic test, such as RPR (rapid plasma reagin) markedly increased the sensitivity of the algorithm. A clinical diagnosis for GUS in the absence of RPR also proved unsuccessful in Dar es Salaam, Tanzania where active syphilis was incorrectly diagnosed in all the patients presenting with genital ulceration – positive serology was more often linked to GDS than GUS (Chalamilla *et al.*, 2006).

Literature demonstrates that algorithms for UDS, which rely exclusively on the objective sign of discharge, hold promise for use in infrastructurally poor settings, such as community pharmacies, provided that periodic surveillance of local etiological agents is performed and the prevalence within the said region is high. On the other hand, the basic algorithms for vaginal discharge syndromes (VDS) are not recommended for use in pharmacies due to their weak discriminative ability and poor prediction of true positive cases. Finally, the inconsistent clinical findings characteristic of syphilis warrants the reliance on phlebotomies for syphilis diagnoses in both GDS and GUS.
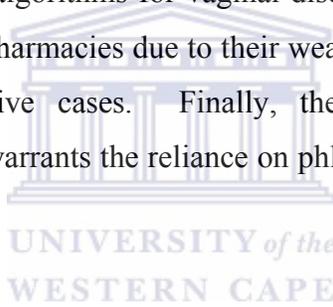
3.1.2.2   *Syndromic treatment: success rates*

While validated algorithms are essential requirements for optimal treatment outcomes, this does not guarantee efficacy. WHO regards efficacy, in terms of STI clinical cure rates, as the most important criterion for algorithm selection and sets the benchmark of success in STI treatment at 95% (World Health Organisation, 2001). Treatment successes for infectious diseases could be measured at 3 different levels viz, microbiological sterility (biological tests of cure), partial clinical cure (symptom amelioration) and complete clinical cure (absence of symptoms), although the articles reviewed below heed the latter two.

It is well known that treatment outcomes hinge on factors other than algorithm selection and consequently the studies under review controlled for potentially

confounding variables by levelling provider skill through training interventions, ensuring that effective drugs were on code at treatment intervention sites, and measuring reported client compliance to treatment regimens.

In the Tanzanian RCT described earlier (Grosskurth *et al.*, 1995) health unit register books were collected from primary health centres and dispensaries in the intervention communities at the end of the 2 year study period for an assessment of the clinical effectiveness of syndromic STI case management, as reflected by the cure rates for VDS, UDS and genital ulceration syndrome (GUS). Simple algorithms relying on risk assessment and clinical examination were utilized in case management. Entries on follow-up observations were available from 8492 (91%) of syndromes treated and the complete clinical cure rate for all syndromes at follow-up, one week after syndromic treatment, was 94%. A marginally higher percentage of males relative to females were symptom free at follow-up; 83% vs. 81% respectively for GUS and 98% vs. 96% for UDS and VDS. The overall cure rate after 1st, 2nd or 3rd follow-up was 98%. According to authors, female clinical cure rates may have been spuriously high, given the propensity towards asymptomatic cervical infection in women (Grosskurth *et al.*, 2000b).

In an attempt to refine the national STI control strategy, the National AIDS Programme in Rwanda commissioned a pilot project to assess the performance of basic STI algorithms in terms of clinical patient outcomes between September 1993 and March 1994. All algorithms relied on risk assessment and clinical assessments only, with the exception of VDS algorithms, which in addition to the aforementioned tools included a speculum examination. Twelve nurses from a primary health centre and a hospital outpatient's dispensary attended a 3-day syndromic training course that included a half-day practical session. Detailed information pertaining to management was recorded by investigators at enrolment and treatment outcomes were noted at follow up. Of the 184 patients (43%) reporting for follow-up, 84% met the definition of complete clinical cure for urethritis, which was comparable with VDS, cure rates.

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By contrast, significantly higher rates of failure were observed among men and women treated sequentially (hit and miss approach) for GUS (Steen *et al.*, 1998).

In Cambodia a study was conducted to evaluate the operational performance and effectiveness of an STI intervention programme (not described in publication) on 2 clinics, a few private pharmacies and private doctors frequented by the general population and more especially female sex workers. Patients presenting with STI complaints were treated and asked to return for follow-up one week later. Clinical outcome measures were obtained retrospectively from patient records between 1997 and 1999. Assessment of cure was completed for only 57% (5895) of syndromes. Treatment based on algorithms requiring history taking, risk assessment appraisal and clinical examination – including speculum examination for females – resulted in reported and confirmed absence of symptoms in 49 to 51% of female syndromes in the general population and slightly more impressive findings for male syndromes ranging from 52 to 74%. Cure rates were highest among men in the general population with GDS (74%) and lowest among female sex workers with GUS (39%). When combining "cured" and "cured or improved" categories, 94% of males in the general population were considered to have favourable outcomes from treatment compared with 88% of women in the general population, and 84% of female sex workers (p<0.001). Notwithstanding these more respectable figures, cure rates remain below the WHO threshold of 95% (Cararra *et al.*, 2005).

The evidence presented here warrants caution against the use of basic algorithms (inclusive or exclusive of speculum examination) for women in the absence of more conclusive diagnostic assays. On the other hand, the basic algorithms for male STI syndromes, especially UDS, consistently produce superior clinical outcomes relative to female counterparts, thereby conferring greater confidence in their use in infrastructurally poor settings such as community pharmacies. Moreover, the clear correlation between follow-up frequency (number of successive follow-up visits per

client) and cure rates (Grosskurth *et al.,* 2000b), underscores the importance of factors facilitating periodic client visits such as service convenience, accessibility and patronage – characteristic community pharmacy features.

3.1.2.3   STI recurrence and partner treatment

The treatment of sexual contacts is essential for controlling STI morbidity and transmission; treatment prevents the development of serious complications and sequelae in infected contacts, reduces reinfection of index patients (improves cure rates), reduces the transmission of infection to new contacts and potentially lowers the risk of HIV transmission. Both external and patient-specific factors may predispose to recurrent STI; lack of effective drugs, failed partner treatment or high sexual risk behaviour exhibited by partners are patient independent factors which may be implicated in patient reinfection, whereas ineffective antimicrobial therapy, patient age and poor drug compliance constitute patient dependent determinants. The purpose of this review is to assess the interplay of the aforementioned variables and to subsequently establish the relative importance of partner treatment in STI control.

Blythe *et al.* (1992) and Whittington *et al.* (2001) investigated the patient specific correlates for recurrent CT in female index patients attending adolescent clinics, while controlling for extrinsic factors, *inter alia,* effective antimicrobial therapy.

An investigation into the determinants of recurrent STI was conducted among 1308 sexually active adolescents aged from 11 to 20 years in the gynaecological unit of an adolescent clinic in Marion County, United States of America (USA). At baseline, measures for clinical presentation, laboratory findings (Chlamydial serotyping), demographics and gynaecological, STI and sexual behaviour histories were recorded and prompt and effective antimicrobial therapy ensued. Repeat baseline measurements, coupled with reported compliance to treatment and tests of cure results, were recorded at follow up visits every 3 months throughout the 5 year study

period. Only patient race was slightly predictive of the overall recurrence rate in the bivariate analysis (p=0.024), however all significance was lost after data was analysed in a multiple linear regression model. The limited impact of patient-specific factors on the high recurrence rate (38%) observed in the study strongly suggests the influence of external partner factors. The stratification of recurrence rate by serovar type elucidated the confounding role of infection relapse on the results attained: the recurrence rate for same serovar (43.8%) in index patients was not attributed to poor compliance to therapy or irregular follow-up and is therefore not likely to be a result of relapse; by contrast, relapse was deemed plausible in the instances where index patients tested positive for the same serovar while in relationship with a new partner post therapy (44.8% of those with same serovar had a new partner) (Blythe *et al.*, 1992).

A cohort of 1194 sexually active females aged 14-34 years were recruited from 5 USA adolescent medicine and reproductive health clinics, treated for CT and subsequently followed up after 1 and 4 months to monitor for recurrent CT. The measurements accrued at baseline and follow up were concordant with Blythe *et al.* (1992). In multivariate analysis, independent predictors of CT at first return visit were failure to complete treatment (RR 3.4; 95% CI 1.6-7.3), resuming sexual activity since completing treatment (RR 2, 95% CI 1.03-4.4) and return beyond the intended appointment window (RR 1.8, 95% CI 1.01-3.2). The stratification of recurrent infection according to first and second follow up elucidated the influence of relapse on the overall findings: the independent association between treatment compliance and recurrent infections at the first follow-up suggested an undermining of results due to infection relapse; recurrence at the second follow up was not however linked to compliance or any other patient factors and it was therefore conjectured that the more primary factors related to recurrence may be partner factors (Blythe *et al.,* 1992; Whittington *et al.*, 2001).

The absence of significant patient specific correlates reinforces the conjectural link between recurrent infection and STI partner factors. Although recurrent STI may be ascribed to patient and partner factors, literature suggests that the latter may be more strongly implicated (Blythe *et al.,* 1992; Whittington *et al.,* 2001). In the absence of novel, feasible and effective partner treatment strategies, STI control remains a futile objective.

3.1.2.3.1 Epidemiological treatment of STI contacts

WHO recommends the adoption of a simple and economically viable approach to treating sexual partners in developing countries viz, epidemiological/presumptive treatment. The epidemiological treatment of STI contacts is based on the assumption that sexual partners and index patients are infected with identical pathogens and are therefore subject to similar treatment regimens. Through contact card distribution to all sexual partners via the index client, the said approach targets an asymptomatic pool of STI clients who would generally have no reason to seek treatment and therefore remain untreated. Presumptive treatment forgoes laboratory investigations, which often defers treatment and increases the risk of patient abscondment. Furthermore, presumptive treatment, as observed in recent studies, attempts to bypass the need for comprehensive clinical examination in an effort to expedite partner management by way of the informal sector, *inter alia*, private pharmacies (Golden *et al.*, 2001; Schillinger *et al.*, 2003).

Alternative partner treatment strategies may be considered at the discretion of the healthcare provider, viz, immediate epidemiological treatment in addition to collecting specimens for laboratory confirmation, or deferral of treatment until laboratory results become available. In selected USA states, current legislation allows for an additional strategy, i.e. patient-delivered therapy, whereby a healthcare provider is allowed to prescribe and/or dispense antimicrobial therapy for the partner/s of clients presenting with CT via the index client, despite not having an opportunity perform a physical examination on the partner (Department of Health

California, 2001). In the ensuing review, the rationale underpinning the recommendation of epidemiological treatment, in terms of concordance of etiological agents between index client and sexual contact, is explored.

A retrospective evaluation of medical charts for microbiological findings of 8623 STI contacts against the recorded diagnosis of their index partners was undertaken by researchers in four US STI clinics over 2 years. The evaluation was limited to partners diagnosed with CT, NG, NGU, mucopurulent cervicitis or TV. CT was diagnosed in 44.1% of partners of patients with CT and prevalence ranged from 12% of 32 men having sex with men (MSM) to 53% of 1077 heterosexual men. NG was diagnosed in 38.8% of 1032 partners of patient with NG and prevalence ranged from 13% of 55 heterosexual men to 57% of 248 women (Stekler *et al.*, 2004).

A similar pattern of concordance was noted in a smaller retrospective study that reviewed clinical management and contact tracing forms in all Western Australia public sector clinics over an 8-month period; of the 169 contacts treated, 30% of infections were concordant with index patients. The sexual partners of patients with NG and CT were more likely to exhibit concordance (53% and 52% respectively) than sexual contacts of syphilis. Data reflecting gender discrepancies was not included in the article (Mak *et al.*, 2004).

The above-mentioned findings are amenable to a double-edged interpretation: on the one hand, the concordance, ranging from 12% to 57% suggests that of those presenting for treatment, ideally only 43% (minimum) would suffer misdiagnosis and inappropriate treatment under the epidemiological approach; conversely, upon the misfortune of loss to follow-up while awaiting laboratory results, an opportunity to successfully treat at least some contacts presumptively is foregone.

3.1.3 Health seeking behaviour of STI clients

Planning towards the effective delivery of health services hinges on an acute awareness and understanding of the target market's health seeking behaviour; every individual has a predilection to a particular type of service, which is based on the fulfilment of specific criteria. Surveying client preferences and the accompanying reasons for these partialities is key to matching service delivery with needs, and could consequently enhance service utilization, and in the long run, potentially improve health indicators. The inherent social stigmas and perceptions associated with STI demands a higher degree of sensitivity and privacy than the norm. Therefore, several African and Asian countries plagued by the scourge of HIV and STI have surveyed the healthcare preferences, and in some instances explored the factors influencing choice, of high risk groups such as FSW and military recruits as well as members of the general population.

To describe the health seeking behaviour of FSWs in Abidjan, Cote dĺvoire, Vuylsteke *et al*. (2001) selected and surveyed a clustered random sample of FSW (500 women in total) regarding the STI service most recently accessed by them and the underlying factors influencing this choice. For the most recent episode of STI, the majority of FSWs sought treatment in the formal sector (55.6%), some consulted the informal sector (36.9%), including private pharmacy treatments and the remainder (4.7%) refrained from consulting anywhere. The various services were deemed satisfactory by virtue of perceived efficacy of treatment (82%), absence of treatment costs (37%) and friendly health staff disposition (10%). The aforementioned factors did not however translate to actual utilization of services (kappa/level of agreement 0.16). The reason cited in a focused group discussion for lack of frequenting the public health centres was financial barriers, while foreign FSWs, in particular, cited unfriendly reception by staff workers as the greatest barrier towards utilizing public clinics.

Khamboonruang *et al.* (1996) recruited all 869 Royal Military circle conscripts – notorious for frequenting FSWs – for May 1993 in northern Thailand to survey the risk factors for HIV acquisition by way of history taking and screening for STD and HIV. Of the 282 men who had a history of STI, 184 (65.2%) had treated themselves with antibiotics without consulting a physician or other health professional. Interestingly, self-treatment for STI, particularly of bacterial origin, by way of pharmacy delivered treatment was significantly associated with a lower HIV prevalence even after controlling for other risk factors and individual STI syndromes in a multivariate analysis (OR 0.51, 95% CI 0.28-0.89). Self-treatment among men with and without history of STI was no different in terms of age, marital status, history of STI, frequency of commercial sex, or most recent, lifetime or consistent use of condoms with commercial sex workers.

Crabbé *et al.* (1996) set out to establish the incidence of urethritis and the health seeking behaviour, as recalled over the preceding 12 months, of the general male population (18-30 years), including a sample of factory workers (up to 40 years) in 2 Cameroonian cities. In addition to the formal health services available to the general population, factory workers also had the option of attending a company clinic. Utilising a cluster random sampling method, 1179 men were recruited and surveyed regarding their socio-economic characteristics, occurrence of STI signs and symptoms, health seeking behaviour and cost of treatment. Educational level served as a proxy measurement for socio-economic status, which was thought to potentially influence health-seeking behaviour. Of the 189 (16%) men in the general population who had at least one episode of urethritis, 16% had resorted to self-medication without consulting either the formal or informal sector. Overall, 32% of males from the general population first consulted the informal sector for an STI complaint; the majority consulted friends and acquaintances (15%), while the remainder visited private pharmacies (8%), traditional healers (7%) and small stores (2%). Contrastingly, 53% first consulted the formal sector of public health centres (39%) and private practitioners (13%). The corresponding results yielded in the sample of

company employees were comparable to those of the general population, although the preferred formal sector service consulted by employees was the company clinic (35%). Treatment delivery, either after consultation with the formal or informal sector or at first point of contact, was highest in pharmacies; sixty one percent of participants had obtained treatment from pharmacies, of which 39% had first consulted in the formal sector and 22% had not consulted anywhere. Level of education was significantly associated with STI service preference in the general population; consultation in the formal sector was associated with a 2.7 fold increase in odds of having attained a higher education (at least completed secondary school). Costs incurred for treatment were highest when a consultation in the formal sector was followed by treatment acquisition in a pharmacy, which contributes in part to the low utilization of the formal health sector. Participants were not asked to provide motivation for their choices.

In Lao People's Democratic Republic, a community-based cross-sectional survey was conducted among 500 household members aged 18 years or more and who had a history of antimicrobials use for the treatment of STI or RTI in the preceding 12 months. Ten villages were randomly selected from each of 2 districts (one urban, one rural) and at least 25 participants were recruited from each village. Participants were interviewed according to questionnaire eliciting information on demographics, self-reported symptoms of STI or RTI, details of antimicrobial self-medication, and the understanding and use of health information. The most commonly reported symptom was VDS; 80% of females complained of at least one episode of VDS and lower abdominal pain, although this figure is probably artificially inflated due to the inclusion of physiologically induced vaginal discharge. Eighty-five percent of males complained of UDS, almost certainly of pathogenic aetiology. Nearly as many (73%) had used at least one antibiotic for the treatment of STI symptoms in the preceding year, which was solicited from retail pharmacies, without a prescription in 91% of cases. Ampicillin, a drug renowned for its poor resistance profile in Asia, was

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prescribed most frequently, although not recommended by WHO (Sihavong *et al.*, 2006).

Bista *et al.* (2002) conducted a study in Pokhara, Nepal among a random sample of 75 chemists and druggists, some of who had been exposed to a training course in national STI case management guidelines. Pharmacists were requested to keep a register over 1 year to establish the pattern of requests for STI syndromes. Of note, seventy percent of patients made their first contact for STI management at pharmacies, while 14% presented with a prescription from private clinics and 16% from public clinics.

Evidence therefore suggests that in the general population, consultation for STI symptoms in the formal sector is high and predicted by high socio-economic status. The primary factors dominating patient preference include perception of service quality, cost of treatment and among female sex workers, a friendly/non-judgmental disposition by the healthcare staff. Pharmacies are the primary source of medicines for STI syndromes, either commissioned by the formal sector or self-prescribed, although treatment practices in response to the latter do not comply with acceptable standards and therefore raise concerns around the quality of unregulated STI services provided in pharmacies.

3.1.4 Standards of care in pharmacies

Determining the gaps in pharmacist's knowledge is essential for tailoring the content of STI courses to meet specific educational needs. In South America and parts of Africa where the formalization of STI service delivery in community pharmacies is being explored by independent research groups, the logical point of departure was to establish existing knowledge and practises of pharmacists and to subsequently develop interventions as informed by results.

3.1.4.1   *STI knowledge assessment*

Five percent of Mexico City's retail pharmacies were randomly selected to participate in a cross-sectional survey assessing attendant knowledge of STI diagnosis and drug treatment and strategies for referral, based on 3 hypothetical scenarios for UDS, HSV and TV/BV. A correct diagnosis, in accordance with syndromic approach for NG and CT was made by 9% of attendants; 12% correctly identified HSV and no attendants recognized the clinical presentation for TV. Correct treatment, defined as compliance with specified treatment guidelines and reputable references, was recommended by 16, 12 and 16% of attendants for NG, HSV and BV/TV respectively. While attendants displayed a high degree of confidence in treating VDS – 83% of them recommended pharmacological therapy – this was not reflective of their treatment proficiency since appropriate treatments were only prescribed 9 times (16% of all attendants). Ampicillin, renowned for its poor resistance profile, was the most commonly prescribed of all antibiotics, which reflects poor quality of treatment. The need for a follow-up was recommended by 67%, 65% and 26% respectively for NG, HSV and BV (Turner *et al.*, 2003). Similarly, Ward *et al.* (2003) surveyed head pharmacists from 22% of Western Cape pharmacies and the findings were not dissimilar: of those who treat STI, more than 70% of pharmacists were inclined to treat VDS although the majority failed to recognize more than one implicating agent; adherence to recommended treatment guidelines was very poor, ranging from 0% for VDS to 14.6% for UDS. Furthermore, the majority of pharmacists (>60%) had never heard of syndromic treatment of STI or Department of Health standard treatment guidelines for STI.

Poor STI treatment in pharmacies is not an isolated finding: private specialists, private doctors and occupational nurses who, by virtue of their professional training are deemed competent to diagnose and treat STI have also performed poorly against WHO benchmarks. While specialists in Pakistan were more likely than general practitioners to adhere to standard treatment guidelines as far as diagnosis and treatments were concerned, less than half of the specialists were able to correctly state

the dose and duration of antimicrobial treatment of the most common STI (Khandwalla *et al.*, 2000). In South Africa, surveys among private practitioners and occupational nurses reflect the greatest measures of success in treating UDS and GUS, and generally very poor adherence to treatment guidelines for pelvic inflammatory disease (PID) (Schneider *et al.*, 2001, 2005; Chabikuli *et al.*, 2002). Similarly, grossly inadequate treatment of PID and TV was observed among private practitioners in Peru, while sub-optimal treatment regimens were commonly adhered to in the management of VDS (Garcia & Holmes, 2003). Public sector clinics outperformed private pharmacies and clinics in every aspect of STI management in Nairobi, Kenya where treatment was deemed unsatisfactory in all, except public STI clinics (Voeten *et al*., 2001).

Pharmacists should therefore not be disqualified from delivering STI services on the basis of their lack of knowledge or poor existing practises, given the similar degree of ineptness displayed by higher skilled health professionals. Rather, their willingness to provide STI treatment, coupled with the high number of treatment requests in pharmacies (Ward *et al.*, 2003), should be acknowledged and exploited by health authorities. At this early juncture, their relative competency in treating male STI syndromes presents a potential segue towards the proposed extended pharmacy role.

3.1.4.2 *Impact of training on STI management in pharmacies*

Although knowledge and skill attained through training courses do not guarantee model behaviour in practice, they remain prerequisites for behaviour change. While pharmacy graduates are well equipped for independent clinical decision-making, the lack of application of these skills in practice due to legislative restrictions provides clear motivation for pharmacist CPD courses in STI management. Furthermore the poor quality of existing STI care provided by pharmacists practising outside of their sanctioned professional boundaries warrants additional training.

In Lima, Peru, researchers designed a pre- and post-intervention trial to evaluate the impact of a brief one-day training course on the diagnosis, treatment and counselling of STI among various cadres of pharmacy staff, of which 25% constituted qualified pharmacists. Trained simulated clients presented to 180 randomly selected pharmacies with syndromes of UDS, GUS, VDS and PID. These pharmacies were then randomise to either receive or not receive the training intervention. Although verbal commitment to participate in training was received from 93% of the intervention pharmacies, this failed to translate to actual course attendance – a meagre 23% response rate was achieved. Non-responders were accommodated through personal 1-2 hour training sessions at individual pharmacies by research staff. Approximately 2-3 months after the course simulated clients again visited all the sites to evaluate the provision of STI care. Female syndromes were least likely to be identified as an actual STI; at baseline the syndromes most often identified as STI related were genital ulcer (81%) and UDS (73%) in males, followed by VDS (43%) and PID (6%) in females. Treatments rarely (5% and less) conformed to the recommended national or international guidelines. Although slight improvements in diagnosing and treating according to the recommended guidelines were observed in the sample, none attained statistical significance. The only noteworthy findings emanating from the brief training session were improvements in counselling; "by intent to intervene analysis, intervention pharmacies provided post-counselling more often than did controls (40% vs. 27%; p=0.01)." (Garcia *et al.*, 1998). In a similar study conducted among various cadres of pharmacy staff in Ghana, of which less than one third identified themselves as pharmacists, Adu-Sarkodie *et al.* (2000) also observed significant improvements in counselling behaviour. One hundred Ghanaian pharmacies were randomly assigned to either attend a one-day STI training programme or to receive no training. The quality of care was assessed through simulated clients presenting with symptoms of urethral discharge only. Overall, the clients attending the outlet sites had received better history taking and counselling on STI than did the controls, however few of these differences were statistically significant. No simulated clients attending intervention outlets were counselled to use

condoms (0% vs.13% p<0.05), acceptable drugs and dosages were received by 39% of intervention and 18% of control (p<0.05) and partner notification in the intervention group was significantly higher than control (40% v 21%, p<0.05).

A random sample of pharmacies along a well-known transport route in a Nepali city was recruited by Tuladhar *et al.* (1998) for an STI intervention trial. The pre-and post-training evaluation, with the assistance of simulate clients presenting with urethral discharge, was performed on 160 male pharmacists in January and November 1996 respectively. Nepal Chemists and Druggists Association (NCDA) used a pre-piloted 2-day curriculum to train pharmacists in recognizing and treating STI syndromes as well as providing the necessary counselling on compliance, referrals, condom promotion and follow up visits should symptoms persist.   Precise intervals between training and post intervention surveys were controlled for in the analysis of data since evaluation could have occurred anywhere between 1 and 9 months after training; an analysis of a sub-sample of 38 pharmacists who had been trained 7-9 months before the follow-up was performed. A vast improvement in selection of correct treatment regimens at appropriate dosages was observed from 0.8% at baseline to 45% (p=0.05) and 26% (p=0.05) at follow-up in the full sample and the earlier trained sub-sample respectively. Prior to the training intervention only 47% of pharmacists made attempts to counsel patients, however this value increased to 68% and 71% (sub sample) at follow-up (p-values <0.05). Although more modest than the overall improvements, treatment and counselling remained significantly better than the baseline values 7-9 months after training. Notwithstanding the gradient of improvement attained, the absolutes (≤45%) at various time points disconcertingly reflect a degree of incompetence among pharmacists' treatment of UDS. This was also reported by Bista *et al* in 2002 where post-training treatment success rates were achieved by only 24% of pharmacists for UDS whereas risk counselling was offered by 57%, partner notification by 43% and condom promotion by 35%.

The impact of compact (1 to 2 days) STI management courses, devoid of any other interventions, produced inconsistent and short-lived results among pharmacists and other cadres of pharmacy personnel who failed to achieve notable standards of treatment – notwithstanding incremental improvements post-training. Experience borrowed from the aforementioned research paved the way for the development of more innovative and widely acceptable interventions deviating from the customary didactic modes of teaching.

Garcia *et al.* (2003) set out to modify a piloted training intervention, described earlier (Garcia *et al.*, 1998), in an attempt to gain broader participation from pharmacists and enhanced acceptability from doctors. The outcome of a focus-group discussion with relevant role-players revealed that pharmacy workers preferred small interactive group seminars near workplaces, with incentives such as lunch, material and continuing supportive contact. To increase acceptability in the medical community, physicians were trained concurrently to accept referrals from pharmacies. Within the lower SES districts in Lima, pharmacies were matched according to location, population size, population density and literacy rates into 12 pairs. Six pairs were randomly selected for the study and one of each pair was assigned to either the control or intervention/experimental group. A total of 684 pharmacies (76.2% response rate) participated in an intervention consisting of three 90-minute luncheon-training seminars over a 2-month period conducted by a pharmacist and midwife team. In addition to the seminar, resource materials were made available for pharmacists and their clients; pharmacists were issued with pocket-size STI information cards and training manuals, health promotion posters and paraphernalia and referral lists for doctors and clinics, while STI/HIV prevention packets, pamphlets and referral slips were disseminated for client use. All physicians in the said districts were enrolled into a 6-hour workshop on management of STI syndromes. The most proficient were invited to join a referral network, which included 36 physicians. The STI intervention seminars for pharmacists and physicians were followed up with monthly visits by the same trainers to discuss

HIV/AIDS prevention and to replenish STI/HIV materials for pharmacists and clients, referral lists and an STI packet. Furthermore, newsletters were distributed every alternate week to intervention pharmacies. One hundred of the pharmacies receiving the intervention were randomly selected to undergo evaluation; trained simulated clients evaluated proficiency in STI management at 1, 3 and 6 months post training. Over each evaluation time frame the intervention group consistently produced superior outcomes measures, including the recognition of STI from the presenting symptoms ($p<0.05$), adequate treatment for syndromes, except PID ($p=0.06$), condom promotion ($p=0.06$) and partner treatment recommendation ($p<0.05$). Overall the treatment of male syndromes was consistently better than female syndromes; among intervention groups, success rates for adequate treatment of STI – defined as prescribing effective drugs for UDS and VDS and at least referring for GUS and PID – was better for the treatment of UDS in males (76.7%-82.5%) than VDS (40-67.5%) and PID (50% and less) in females. Symptom recognition in the intervention group was consistently over 90% for UDS and GUS and less than 50% in the majority of other syndromes. Counselling concerning partner treatment in the intervention group was inconsistent and poor for all syndromes except for UDS, which increased from 47.5 to 84.2 over a six-month period. Recommendation of condom use to females was poorer than to male clients.

In Hanoi, Vietnam, Chuc *et al.* (2002) evaluated the effectiveness of a multi-intervention package on pharmacy practice in a clustered randomised controlled trial with a time series design. Four tracer conditions of public health importance, including case management of UDS, were used to evaluate the impact of the intervention on pharmacy practice. One in each pair of the 29-paired pharmacies was assigned to receive the multicomponent intervention and all cadres of pharmacy personnel at the selected sites were invited to participate in the study. The first intervention was a regulatory enforcement by an inspector who visited the pharmacy and drew emphasis on regulations around prescription drugs. Secondly an educational intervention consisting of two 45-minute face-to-face educational

sessions, supplemented with written information on STI management was carried out. The third intervention was to elect one participant per geographical area to conduct peer facilitated discussions with other participants highlighting implementation difficulties in practice. Four rounds of simulated client visits were conducted; one at baseline and at one month intervals following each intervention. An increased rate of referral observed in the intervention group (22-37%) was matched with a corresponding decrease in the control (20-18%) at significant p value (p=0.01). Correct syndromic treatment increased in both the intervention group (3-30%) and control group (4-19%), and while the extent of improvement was greater after the intervention (p<0.05), successful treatment rates remained low across the board. There was no difference between the intervention and control groups in terms of the number of participants who completed sexual risk assessments and promoted condom use.

The multifaceted interventions involving more interactive learning components and peer as well as physician support produced more consistent improvements in almost every aspect of STI management which did not wane over time, notwithstanding the limited (4.5 hours) training duration involved (Garcia *et al.*, 2003). Furthermore treatment success rates were more respectable when interventions targeted pharmacists only as opposed to all cadres of pharmacy personnel.

3.2   HEALTH PROFESSIONAL ROLE CONFIGURATION

Role configuration in the workplace may be defined as the establishment of innovative roles that traverse normally distinctive occupational boundaries. The purpose thereof is to optimise the utilization of skills in the workplace through vertical or lateral skill transference according to existing deficiencies and identified need. In modern healthcare systems, selected skill mix interventions are purposefully implemented in an effort to offset the skills dearth caused by shortages of essential personnel. Skill mix changes are not, however, a universal panacea and interventions of this kind should be carefully weighed in terms of cost and effectiveness before

being introduced (Royal College of General Practitioners, 2007). The object herein is to provide a theoretical framework for role redesign initiatives and to subsequently identify an existing skill mix model which has found application in the healthcare milieu and achieved success in effecting role expansion in areas of practice akin to the aspirations of pharmacists.

Hyde *et al.* (2005) asserts that transference of skills vertically within a single disciplinary hierarchy or laterally, across professional/discipline divides culminates in one or more of four role changes, viz, skill mix changes, job widening, job deepening and new role creation. Skill-mix changes through role substitution or delegation within an existing hierarchy paved the way for role extension in UK and South African pharmacy technicians to include greater dispensing and counselling responsibilities (Hyde *et al.*, 2005; Hugo, 2005). Job widening involves an extension or expansion of a role to include new functions, which had not previously been performed by any individuals. For example, a mental health pilot in the UK is currently underway to investigate the utilization of pharmacy technicians in ward chart assessment and in-patient counselling with a view to reducing prescribing errors and improving medication compliance (Hyde *et al.*, 2005). Job deepening involves enriching the knowledge and skills base within a role to an extent that it confers substantially greater responsibility, autonomy and opportunity for development within the said role. Advanced practice nursing is a prime example of maximizing the use of in-depth nursing knowledge and skill and thereby contributing towards the development and advancement of the profession (Vollman & Martin-Misener, 2005). Finally, new role creation combines new and/or existing roles and functions in innovative ways. The development of a new role "emergency care worker", allows nurses and paramedics, upon additional training, to institute immediate emergency treatment from the moment a patient is transferred into an ambulance until hospitalization (Hyde *et al.*, 2005).

With the exception of the nurse-doctor interface, there is a dearth of randomised controlled trials (RCTs) evaluating the effectiveness of other skill mix interventions

in healthcare. RCTs evaluating the myriad of advanced roles for nurses reflect wide patient acceptance, in addition to comparable costs and standards of care between nurse and doctor-led services in primary and secondary care (Kinley *et al.*, 2001, Kinnersley *et al.*, 2000, Lattimer *et al.*, 2000 and Venning *et al.*, 2000 as cited in Buchanan *et al.*, 2002).

3.2.1   Expanded scope of practice: clinical nurse practitioner model

The underlying skill mix principles applied to nursing practice and culminating in the development of extended roles at primary care level has been selected for further exploration, with a view to draw parallels between the evolution of nursing and the proposed expanded role for pharmacists. The traditional community health nurse, according to Kim (1978a, 1978b) as cited in Cho & Kashka, (2004) in pursuit of promoting community health, fulfilled nine roles, viz caregiver, advocate, advisor, facilitator, educator, manager, or researcher, community observer, and community developer. The clinical nurse practitioner, an advanced practice nurse in primary care, has acquired additional knowledge through post-basic training courses or a Master's degree (International Council of Nurses, 2001) and has traversed the boundaries of medicine by adopting roles in decision-making and leadership. An expanded scope of practice enables clinical nurse practitioners to adopt a supervisory role in primary healthcare clinics, thereby shunning previously perceived subordination to doctors (Keyzer, 1997), and to practise independent clinical judgment and action in diagnosing acute illnesses, monitoring chronic conditions, prescribing medication and making referrals to other professionals (Hicks & Hennessy, 1997).   The role of the advanced practice nurse in relation to doctors, notwithstanding clear evidence of selected role substitution, is generally recognized as a complementary one since the enhanced level of nursing expertise in selected areas of patient care remains entrenched in a nursing philosophy.

The advancements in nursing practice in most countries are based on a complementary and needs-led skill mix model (Keyzer, 1997). The complementary model enables nurses to practice at a level of expertise where functions/tasks overlap with those of doctors while the needs-led model redefines the services provided in accordance with identified community needs in lieu of traditional modes of service delivery. Lessons in the development of complementary nurse-doctor hybrid roles in primary care are borrowed from USA and UK experiences in this review for two primary reasons: i) unprecedented success has been achieved in the USA in terms of role establishment; and ii) the non-federated health system structure in the UK, as opposed to the US, shares greater commonality with South Africa.

The notion of an expanded role for nurses was birthed out of an overwhelming need for physician skills in rural and inner city urban areas in the USA during the early 1960s. Advanced practice nursing in the USA was originally based on a proxy medical and needs-led model, which ignored the unique expertise of nursing and focused on churning out doctor substitutes (Keyzer, 1997). The aforementioned allusion to nursing evolution in terms of progression up the rungs of a medicine career ladder was, however, shortsighted and patronizing to a profession that is entrenched in a unique philosophy of care. This prompted nursing representative bodies in the US to lobby for the adoption of a complementary model, which enabled nurses to retain their professional values and complement, rather than substitute doctors. Similarly, in the early 1980s, a shortfall of family doctors in primary care catalysed role redesign for nursing in the UK, based on a complementary model (Buchan *et al.,* 2002). The development and implementation of the clinical nurse practitioner in both countries was met with good success; nurse-led primary health services in the USA and UK proved to be comparable to services offered by doctors in terms of cost and standards of care (Vennin *et al.*, 2000 and Mundunger *et al.*, 2000 as cited in Buchanan *et al.*, 2002).

The major facilitator in the USA for an expanded nursing role came from within the nursing profession itself; the attitudes of nurses to role change and the ensuing lobbying role of representative organizations for nurses paved the way towards developing a nurse-doctor hybrid role firmly rooted in the primacy of care (Keyzer, 1997). Today, implementation of the role of the advanced practice nurse in the USA is unprecedented, boasting significant legislative and regulatory breakthroughs at state level and the establishment of a Council of Primary Care Nurse Practitioners. In the UK, efforts to develop a similar role was undergirded by strong governmental support, which was driven by nationally instituted policies for the reduction of working hours by junior doctors and the need for human resource support for the modernization agenda in the National Health Service. The absence of regulatory bodies to oversee the advanced level of nursing practice in the UK, as opposed to the USA, has resulted in the development of poorly defined roles and job titles (Buchanan *et al.*, 2002). These contrasting facilitators for change initiation in the UK (top-down in the hierarchy) and the USA (bottom-up in hierarchy) may well be central to the disparate progress in role establishment across the two countries.

3.2.2 Potential application of model to pharmacists

The proposed expanded role for pharmacists, in concurrence with the clinical nurse practitioner role, calls for job deepening towards enhanced decision-making responsibility and higher levels of autonomy. This, coupled with the dire need for optimising existing workforce skills in South Africa in the face of disconcertingly high losses of healthcare professionals to the overseas market (Paradath *et al.*, 2003), warrants the adoption of a complementary and needs-led skill mix model, based on a doctor-pharmacist hybrid role.

The eight roles of a pharmacist, according to WHO and the International Pharmaceutical Federation, are as follows: caregiver, communicator, decision-maker, teacher, lifelong learner, leader, manager and researcher (Wiedenmayer *et al.*, 2006). In a broad sense, the aforementioned roles are convergent with the 5 roles fulfilled by

doctors, viz, caregiver, decision-maker, communicator, community leader and manager (Jha *et al.*, 2005) and hence role substitution is an inept description of the proposed advanced role pharmacist in primary care. Rather, the envisaged role remains entrenched in the 8 defining characteristics of pharmacists, while the level of autonomy sanctioned in the area of clinical and therapeutic decision-making is challenged. This translates to enhanced functions at primary care level, including advanced clinical assessments and diagnostic decision-making on selected acute and chronic illnesses for which established guidelines exist and enhanced prescribing autonomy, allowing broader application of skills inherent to the pharmacy profession, *inter alia*, rational pharmacotherapy and overall disease management. In order for pharmacists to retain their professional identity and independence from doctors, notwithstanding blurring task/function boundaries, their new roles must be grounded in the philosophy of pharmaceutical care.

Unique facilitating factors proved instrumental in the development and implementation of the clinical nurse practitioner role in UK and USA primary healthcare facilities. Governmental support was vital to the development of the advanced nursing role in the UK and a similar level of political backing for South African initiatives in pharmacy may pave the way to comparable successes. Nursing advances in the USA, however, teach that political support should serve to augment strong pharmacy advocacy in order to drive the agenda of pharmacists and not vice-versa.

In South Africa, selected national policies potentially offer the same conduit for governmental support toward role redesign initiatives for pharmacists. Role redesign interventions are in consonance with the National Drug Policy (NDP) of 1996 and the National Health Act (Act 61 of 2003): the NDP supports the conferral of prescribing powers to any health professional on the basis of competency attainment (Department of Health, 1996); while the Health Act mandates the Minister of Health to accommodate new categories of healthcare personnel in human resource regulations,

in an effort to offset the deficit in respect of scarce skills, expertise and competencies (Republic of South Africa, 2003). Further opportunities for skill mix interventions exist in the implementation of new quality assurance programmes at higher education institutions in SA (Republic of South Africa, 1997c). The ensuing outcomes based competency standards instituted by various health professional councils, *inter alia*, the South African Pharmacy Council (Summers *et al.*, 2001) may encourage multiple entry and exit points for various non-pharmaceutical healthcare professionals in the future. The nursing profession, by way of section 38A of the Nursing Act, has already made significant strides in this regard; registered nurses, upon completion of supplementary courses may receive permission from the Director General to prescribe and dispense drugs in areas devoid of the skills of doctors and pharmacists (Republic of South Africa, 1978). The resultant job deepening for selected nurses is purportedly patterned on a complementary and needs-led skill mix model, which demonstrates current legislative support towards role redesign initiatives. Amendments to the Pharmacy and Nursing Acts further corroborate the aforementioned interventions; skill mix changes for post-basic pharmacist assistants and nursing assistants by way of uni-disciplinary role substitution and delegation have recently been effected in South Africa (Republic of South Africa 1978, 1997b).

Notwithstanding inherent differences between the national and state level of healthcare and legislative control in the UK and USA respectively, the successful driver for nursing change initiation in the latter underscores the importance of mobilizing pharmacists toward professional change in South Africa.

3.3   LESSONS LEARNT FROM LITERATURE

The prioritisation of STI management and control through syndromic treatment modalities with respect to the treatment of male clients is supported by literature and the inclusion thereof in HIV/AIDS strategic plans of developing countries remains justifiable.   The increasing demand for STI services in community pharmacies coupled with the availability of selected simple, yet valid and effective diagnostic tools underline the importance of targeting private community pharmacies for specific interventions and education programmes focused on syndromic STI management. Furthermore, the global evidence of increasing political support for role redesign in the healthcare workforce, the evidence of existing overlaps between the proposed role for pharmacists and existing skill mix models, and the varied experiences gained from pharmacist training interventions in STI management, provide motivation for further exploration into an expanded pharmacist role in syndromic treatment.

CHAPTER 4

STUDY RATIONALE

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A myriad of interconnected problems have emerged from the literature scan and these have been set against a unique geographical backdrop. An enumeration of the dominating issues discussed in preceding chapters will provide the required underpinnings to the primary research question for this study. Furthermore, an outline of the specific research objectives set out to answer the research question will bring lucidity to all ensuing study undertakings.

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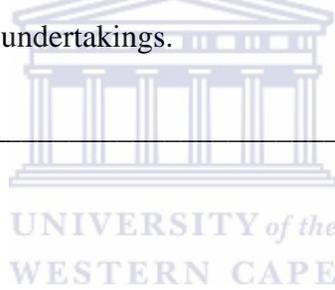
4.1 DEVELOPMENT OF RESEARCH QUESTION

Several issues pertinent to conceiving the generalised and more specific research question were discussed in preceding chapters (background and literature review); these are collated and summarized in bullet-point form below and the sequential refinement of the research question is provided in shaded and bordered text.

- The private health sector, servicing a minority of the South African population, is inordinately well resourced (in human resources and other) in comparison to a scantily resourced public health sector (Dayi & Gray, 2006).

- Under-allocation of healthcare budgets have translated to measly financial compensation of public sector employed health professionals and therewith, poor incentive for long-term state employment (Paradath *et al.,* 2003).

- Notwithstanding the implementation of key interventions to offset migration of human resources into the private sector and to engender a sense of public servitude within the healthcare workforce, the South African public health sector remains beset with enormous human resource challenges (Paradath *et al.,* 2003).

- Government's role in selected private health regulation is likened to a double-edged sword; benefits to the public at large have been indisputable, however the perceived encroachment by government on free enterprise has engendered much animosity between the private and public sector and has undermined the requisite sectoral synergism (Republic of South Africa, 2002).

- Public-private interactions are strongly advocated by the Department of Health, notwithstanding the anomalies encountered during implementation, which are

thought to stem from an absence of clear policy around the issue (Leon & Mabope, 2005).

> Future attempts to develop cohesive strategies involving both the public and private sector are certainly at a premium in the face of immense public health challenges, not least of all a burdensome HIV epidemic. Private sector human resources (doctors, nurses and pharmacists) are potentially under-utilised in public health initiatives and should be targeted more effectively, possibly through the establishment of public-private interactions.
>
> Could private sector community retail pharmacists plausibly fill some of the current public health gaps created by human resource deficiencies within the public sector?

- Notwithstanding the mature stage of the epidemic in South Africa, the incidence of HIV remains high and reaffirms the need for continued prevention interventions, *inter alia*, STI management and control (Department of Health, 2007b).

- Clinical and epidemiological evidence presented in the review favours the continued support of WHO advocated HIV strategies to improve STI treatment delivery (Ghys *et al.,* 1997; Grosskurth *et al.,* 1995; McCelland *et al.,* 2001; Wolday *et al.,* 2004).

- Despite the objections from certain quarters as to the effectiveness of syndromic management approaches, the literature has reaffirmed the value of employing simple syndrome algorithms, particularly in the management of male clients presenting with STI in infrastructurally poor settings (Alary *et al.,* 1998;

Chalamilla *et al.,* 2006; Desai *et al.,* 2003; Djajakusumah *et al.,* 1998; Hawkes *et al.,* 1999; Sloan *et al.,* 2000)

- In a bid to effect standardised management approaches in South Africa, national STI management and control strategies have extended into the private sector. Poor quality of STI treatment by private doctors and nurses, however, remains substandard (Sonko *et al.,* 2003).

- Community retail pharmacies are a regular port of call for clients presenting with STI (Gilbert, 1998), however, a deficiency of skills in conducting invasive clinical examinations, coupled with legislative barriers against prescribing antimicrobials (Republic of South Africa, 1997a) have limited their role to one of referring for clinical management.

The prioritisation of STI management and control through STI syndromic treatment modalities with respect to the treatment of male clients is supported by literature and the inclusion thereof in HIV/AIDS strategic plans of developing countries, including South Africa remains justifiable. In a healthcare system fraught with human resource deficiencies, the utilization of private community retail pharmacists could facilitate the implementation of national HIV plans. The increasing demand for STI services in community pharmacies coupled with the availability of selected simple, yet valid and effective diagnostic and treatment tools underline the importance of targeting private community pharmacies for specific interventions and education programmes focused on syndromic STI management of index clients.

Would South African community retail pharmacists be willing to receive training for and subsequently offer clinical syndromic STI management services to male clients in their pharmacies?

- A WC survey of community retail pharmacists revealed that although pharmacists were inadequately trained to provide syndromic management of STI, their level of willingness to receive training and provide most aspects of management was high. There was, however, a general reluctance to encroach on an exclusive practice of nurses and doctors, i.e. conducting a thorough physical examination of the genitalia (Ward *et al.,* 2003).

- Since the presumptive treatment of STI partners, based on the diagnosis of the index client, often forgoes invasive clinical examinations and laboratory investigations, some countries, *inter alia*, the USA rely on patient-delivered therapies for partners who are unlikely to present to the formal health sector for treatment (Department of Health California, 2001).

- "Presumptive" partner treatment is no misnomer; concordance in etiological agents between the index client and their partner/s ranges from as low as 12% up to 57%. However, this concessional approach is used when all other methods are deemed ineffective in targeting partners for treatment (Mak *et al.,* 2004; Stekler *et al.,* 2004)

- Community retail pharmacies are the primary source of medicines for STI syndromes, either commissioned by the formal sector or self-prescribed, although treatment practices with respect to the latter are of notoriously poor quality (Bista *et al.,* 2002; Crabbé *et al.,* 1996; Khamboonruang *et al.,* 1996; Sihavong *et al.,* 2006; Vuylsteke *et al.,* 2001).

- The inception of pharmaceutical care, coupled with changing pricing regulations, has engendered a patient-centred approach to pharmacy that is service- and not product-driven (Gilbert, 1998; Republic of South Africa, 1997a).

- Research in selected developing countries have shown that multifaceted training interventions in community retail pharmacies that included, inter alia, STI packets for utilisation during clinical management produce consistent long-term improvements in almost every aspect of STI management (Garcia *et al.,* 2003; Chuc *et al.,* 2002)

No studies have evaluated the impact of training interventions on the syndromic management of STI in South African community retail pharmacies. Maximising the existing skills of pharmacists in rational pharmacotherapy and chronic disease management for the presumptive treatment of STI partners will certainly strengthen human resource deficient STI partner management programmes in South Africa and therewith potentially stem the continued spread of disease.

By providing direct patient care, as is done in the epidemiological treatment of STI contacts, pharmacists may charge for their services, thereby offsetting the loss of income from the change in pricing of medications. Providing specific STI syndromic training and provision of treatment packets combined with the changing role of community pharmacist has the potential to increase appropriate treatment of STIs in the private sector thereby decreasing the overall burden of these conditions.

What lessons can be learnt from other health professions as regarding expanded scopes of practice?

- In the face of disconcertingly high losses of healthcare professionals to the overseas market, a dire need for optimising existing workforce skills

through role redesign initiatives in South Africa exists (Paradath *et al.*, 2003).

- Job deepening involves enriching the knowledge and skills base within a role to an extent that it confers substantially greater responsibility, autonomy and opportunity for development within the said role (Hyde *et al.*, 2005).

- Advanced practice nursing is a prime example of maximising the use of in-depth nursing knowledge and skill through job deepening (Vollman & Martin-Misener, 2005).

- Randomised controlled trials evaluating the myriad of advanced roles for nurses reflect wide patient acceptance, in addition to comparable costs and standards of care between nurse and doctor-led services in primary and secondary care (Kinley *et al.,* 2001; Kinnersley *et al.,* 2000; Lattimer *et al.,* 2000; Venning *et al.,* 2000 as cited in Buchanan *et al.,* 2002.)

- The major facilitator in the USA for an expanded nursing role came from within the profession itself: the attitudes of nurses to role change and the ensuing lobbying role of representative organisations for nurses paved the way toward developing a nurse-doctor hybrid role firmly rooted in the primacy of care (Keyzer, 1997).

- Governmental support proved instrumental in the development and implementation of the clinical nurse practitioner in the UK (Buchanan *et al.,* 2002).

The proposed expanded role for pharmacists, in concurrence with the clinical nurse practitioner role, calls for job deepening towards enhanced decision-making responsibility and higher levels of autonomy. Global evidence of increasing political support for role redesign in the healthcare workforce and the evidence of existing overlaps between the proposed role for pharmacists and existing skill mix models, provide motivation for further exploration into an expanded pharmacist role in primary healthcare initiatives.

The overarching purpose of this study was therefore to contribute to the small but growing body of evidence underpinning a proposed expansion in the scope of practice of pharmacists with a view towards enhancing their utilization in public health strategies, inter alia, syndromic STI management.
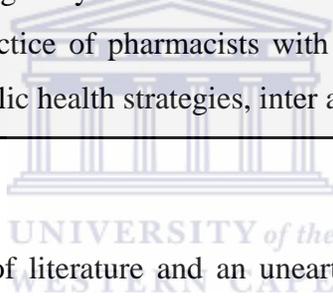
Thus an extensive survey of literature and an unearthing of gaps within the current South African health system culminated in the following general research question:

"Are community retail pharmacists capable of providing an acceptable quality of STI management to the male partners of index clients?"

Further refined into sequential measurable research questions, it reads:

"Will a training intervention close the expected knowledge gaps around STI among community retail pharmacists?" and "Could trained community retail pharmacists, with the aid of STI information packets, provide appropriate syndromic counselling and treatment to male STI partners?"

4.2   AIMS AND OBJECTIVES

In an attempt to answer the aforementioned questions, the following aims and objectives were set out:

a) To quantitatively evaluate the effect of an STI training intervention on the knowledge of pharmacists around STI, and

b) To quantitatively determine whether the allocation of STI information packets augments the skills of community retail pharmacists with respect to the counselling and treatment of the male sexual partners of recently diagnosed and treated females.

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CHAPTER 5

METHODOLOGY

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In selecting the most appropriate methods and design procedures for this study, consideration was given to budgetary constraints, socio-political and geographic factors unique to the study location, desired representivity of study sample and the accuracy and reproducibility of measurements.

Several extraneous factors, unique to the current South African milieu, were taken into consideration in the design, sampling and recruitment phases of the methods. Firstly, the differences in accessibility to primary health care facilities within the South African health regions necessitated stratification within the sampling frame so as to ensure representation from urbanised and rural areas. Secondly, the prevailing acrimony and negativity between community retail pharmacists and the Department of Health as a result of recent legislative impositions affecting pharmacy profit margins necessitated unique recruitment strategies that highlighted the potential benefits of this research in terms of professional growth and economic viability. Thirdly, the preponderance of recent DOH research surveys concerning the single exit price and associated dispensing fees has generated generalized aversion towards research participation by pharmacists which warranted an approach which was least demanding upon business practice in terms of time, money and interference with normal routine.

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5.1 DESCRIPTION OF THE TARGET POPULATION

The target for this study was the 437 community retail pharmacies situated in the Western Cape province of South Africa. Approximately ten percent of South Africa's population resides in this province, of which nearly 80% find domicile in the urbanized Cape Metropole. Similarly, approximately 75% of community retail pharmacies are established in the Cape Metropole (population density: $1267/km^2$), while the remaining practices are distributed across the Cape Winelands (population density: $29/km^2$), West-Coast (population density: $9/km^2$), Overberg ($18/km^2$), Central Karoo (population density: $2/km^2$) and Garden Route ($19/km^2$) (Baron et al., 2006).

5.2 DESIGN AND SAMPLING

Eighty community pharmacists from the Western Cape province of South Africa who had participated in a previous survey regarding STI knowledge practices and attitudes towards providing treatment, and had further indicated an interest in receiving training in the future (Ward *et al,* 2003) were recruited telephonically in June 2006 to enrol in an 8-week STI distance-learning course between July and August of 2006. The effect of the training course on pharmacists' knowledge of STI, including syndromic management, was determined in identical pre and post-training evaluations. In order to attain the desired sample size (refer to "statistical issues") an additional twenty pharmacies were randomly selected from two South African Pharmacy Council lists, viz the Cape Metopole pharmacies and pharmacies situated in the regions outside of the Metropole (hereafter referred to as urban and rural regions respectively). The final study sample reflected the proportion of pharmacies located in each region; 75 pharmacies were selected from the urban WC and 25 from rural WC. These additional pharmacists were recruited telephonically and detailed about the study. At the end of the training all participants who completed the pre and post-training tests were then randomly assigned to either receive an STI management intervention (information packets) or no intervention and within a period of 6 months (October 2006 through February 2006) all pharmacists were visited by three trained males presenting as partners of patients with diagnosed GUS and three trained males presenting as

partners of patients with diagnosed UDS. Simulated patients then reported back to the study investigators regarding the actions (counselling and treatment) taken by the pharmacists.

5.2.1 Design and sampling rationale

5.2.1.1   Training intervention

Traditionally, the pre and post intervention testing is used when the researcher wishes to remove the between-subject part of the variability of the outcome variable (Hulley *et al.*, 2001). In this study, a pre-post design was employed due to the advantage of being able to track the same participant. Ideally, the inclusion of a control group would account for further explanatory factors for the outcomes obtained in the study (Hulley *et al.*, 2001), however the difficulty in recruiting pharmacists who would not stand to benefit from a free training intervention weighed against the decision of employing a pre-post control group design.

The gold standard of sampling techniques, randomised sampling, was employed since it offers a scientific basis for making inferences about the results to the general population (Hulley *et al.*, 2001).

As previously alluded to, a decision was taken to stratify the target sample by region, thereby ensuring representivity from urban and rural pharmacies. Attitudes toward advanced roles for pharmacists may vary between urban and rural pharmacists depending on the healthcare needs within the communities they serve and the extent to which other primary health care facilities are able to meet those needs.

5.2.1.2   STI management intervention

In a previous WC baseline survey, Ward *et al*., (2003) found that pharmacists failed to manage STI adequately and that a great need and willingness to receive training existed. Since STI management (and partner management) currently falls outside the pharmacist's scope of practice, there was speculation that untrained

pharmacists would possess neither the knowledge of epidemiological partner treatment approaches nor experience with accepting partner notification slips (a means of conveying medical diagnoses of the index patient between health care workers in the public sector). Therefore, untrained pharmacists were not assessed against their trained counterparts in the evaluation of the distance-learning course on actual management of STI partners; instead, an experimental-control design was employed to evaluate the differences in STI management between trained pharmacists who had either received additional assistance through information patient packets or those who had not.

5.3   SUBJECTS AND RECRUITMENT STRATEGIES

5.3.1 Study population

The study population consisted of owners or full-time managers with a minimum qualification of a Bachelor of Pharmacy degree or Pharmacy Diploma. Less senior pharmacists who lacked the authority to implement changes in the pharmacy were excluded.

Eligible participants were recruited telephonically and study aims and procedures were described to them. Assenting individuals received a consent form via facsimile and were requested to return the signed documentation to the researcher within 2 days of receipt.

5.3.1.1   *Recruitment   strategies   implemented   to   maximise   participation*

Experience in recruiting community pharmacists for research has taught that the role of the recruiter is pivotal in determining the eventual response rate. As such the responsible researcher was sensitised to the professional struggles and frustrations facing community pharmacists and trained to diffuse emotional verbosity tactfully and empathetically. Additionally, in view of professional services, as opposed to medicines being the primary profitable commodity in pharmacies, the researcher emphasized the economic benefits of offering services

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for STI management from retail pharmacies in the future. Finally the distance-learning course was provided at no charge as this was envisaged to incentivise participation.

5.3.1.2 *Strategies implemented to minimise loss to follow-up*

The characteristically high staff turnover in private retail pharmacies was recognised as a potential threat to securing follow-up visits with enrolled pharmacists. This factor supported the decision to involve only head pharmacists (owners and managers) who were presumed to be more likely to retain their positions until the end of the study period. Although this approach compromised the generalisability of study findings, the trade off was deemed vital in this relatively mobile study population.

5.4 STI TRAINING AND MANAGEMENT TOOLS

Preliminary studies on pharmacists revealed a generalized reluctance toward engaging in a training programme imposing high time demands. Participants had, however, reflected partiality toward distance learning courses, as is customary with the instructional methods employed in many continuous professional development (CPD) courses.

A pre-existing WHO training package (World Health Organisation, 1997), adopted by the South African Department of Health for the training of physicians and nurses in STI syndromic management, lent itself to a distance learning approach and was therefore employed in this study (Appendix III). The training materials included six modules that used a workbook format and included assignments that were mailed to the study investigators at the completion of each module. The topics covered in the training included the following: STI glossary, public health significance of STI, using flow-charts for syndromic management, history-taking and examination, diagnosis and treatment, educating the patient and partner referral and care. The training materials included an electronic atlas of STI visuals as well as a pocket-sized copy of WC treatment guidelines (Appendix XI) which included 13 key elements of STI counselling (methods of STI transmission, STI signs and symptoms, need for prompt treatment, potential sequelae, risk of

HIV transmission associated with STIs, recommendation for HIV testing, methods of and promotion of risk reduction, condom promotion, provision/sale and demonstration, abstinence during treatment, treatment compliance and promotion of partner treatment).

Throughout the duration of the course a clinical nurse practitioner was available by phone or electronic mail to offer learner support. Submissions of set modular assignments, while not formally assessed, were mandatory for all participants so as to assure that the participant had read the course materials. Participants completed the training at their own pace over an 8 week period.

At the completion of their course, the principal investigator visited each participant over a one month period to reinforce the procedures for the impending evaluation of STI management and to deliver the STI management toolkit, consisting of blank prescriptions designed for the purposes of the study which could not be legally filled at any dispensary and samples of partner notification slips (Appendix VI) for all participants. In addition to the aforementioned package, pharmacists in the experimental group received STI information packets containing information leaflets for patient education and counselling, a condom, an HIV testing referral note and contact details of neighbouring Voluntary Counselling and Testing sites which were designed to facilitate STI management[7].

5.5   EVALUATIONS

5.5.1 Pre and post tests/examination

The first evaluation consisted of pre- and post-training examinations that were administered by telephone at prearranged times. The questions covered each of the key topic areas of the training modules and the same examination was used before and after the training. No control measures were instituted to prevent pharmacists from consulting information from books or colleagues since this was

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[7] The original plan to include antimicrobials in the packets was thwarted after the request for a research waiver allowing pharmacists to prescribe and dispense antimicrobials for the purposes of the study was denied by the Medicine's Control Council.

highly unlikely to occur during a telephonic testing with imposed time limits. Treatments were considered appropriate when they matched any of the recommended regimens in WC syndromic guidelines for the management of STI (Appendix XI).

5.5.2 Simulated client method

The simulated client method, an internationally applicable tool for measuring outcomes in pharmacy practice research, particularly the effects of behaviour change or training strategies (Watson *et al*., 2006), was used in the evaluation of the impact of STI information packets on STI management up to 6 months after the completion of the training course. Research has proven that the majority of individuals seeking STI management in pharmacies are in fact males, and for this reason, only male simulated partners were included in this study. In this evaluation three trained male research staff presented to the study pharmacies with notification slips indicating that they had sexual contact with someone who was diagnosed with genital ulcer syndrome (GUS) and a similar scenario was depicted by three males presenting as partners of individuals diagnosed with vaginal discharge syndrome (VDS) treatment. All simulated partners were to deny any symptoms of STI. The simulated partners then reported back to the study investigators regarding the actions taken by the pharmacists (Appendix VII). The main outcome required was to provide correct STI counselling and prescribing appropriate antimicrobials.

5.5.2.1 *Strategies employed to enhance accuracy and reproducibility*

Six simulated client visits paid to each pharmacy ensured adequate replication of the outcome measurement and would therefore provide a good summary measure for each clinic. Simulated clients were blinded to the assignment of experimental and control pharmacies and were therefore unbiased during their exchange with participants. Although pharmacists were aware of the evaluation by means of simulated clients, the actual timing of the visit was not disclosed to them. Anonymous calls were placed to pharmacies prior to each visit to ensure that the

enrolled pharmacist was on duty at the time of the visit. Pharmacists were instructed to manage sexual contacts only, i.e. clients presenting with a partner notification slip (sample provided in their STI management toolkit) describing the diagnosis of the index patient. Since partner notification slips are generally filled in public clinics and not in community retail pharmacies, the management of actual partners was not a concern; as such, there was no ethical concern of potentially mismanaging actual clients from the general population.

Pharmacists were instructed to manage STI partners in the following sequential way:

1) diagnose the simulated client based on partner's diagnoses;

2) write out a prescription for recommended treatment, and

3) educate, counsel and provide STI information packet to patient (if in experimental group)

5.5.2.2   *Simulated client training*

Six final year pharmacy students from the University of Western Cape, School of Pharmacy, were recruited as simulated patients, since their prior knowledge of STI syndromic management was expected to be adequate due to the courses completed in undergraduate training.

Simulated clients were trained to present with a script and were provided with clear guidelines for improvisation if required.

"Good afternoon...I'm not really sure whether I have a problem or not. My girlfriend has recently been diagnosed with an infection [hand over partner notification slip for either genital ulceration or vaginal discharge] and the health care workers suggested that I present for treatment at a pharmacy as soon as possible. I feel absolutely fine and have not noticed anything suspicious-looking in the genital area. I just came to find out whether I should still be concerned or not."

The mock patients were trained to respond to additional questions when probed by the pharmacist.

"My partner was diagnosed one week ago and has subsequently completed her course of medication. We did not engage in sex during this time. This is a relatively new relationship, which to my knowledge is mutually monogamous. I have no history of STI. In our sexual relationship, condom use is irregular and depends entirely on the insistence of my partner. I have no fear of contracting HIV/AIDS since my girlfriend comes from a good home. I have no allergies to medication and have no other conditions or medication history."

5.6   HYPOTHESES AND STATISTICAL ISSUES

5.6.1 Hypotheses

5.6.1.1   Null hypotheses

   I. Test scores achieved before and after participation in an STI correspondence course, coupled with learner support, will be equal.
   II. An STI information packet will not influence the treatment recommendations made by pharmacists trained in STI management.
   III. An STI information packet will not influence the appropriateness of counselling delivered by pharmacists trained in STI management.

5.6.1.2   Alternative Hypotheses I (two-tailed)

   I. Test scores achieved before and after participation in an STI correspondence course, coupled with learner support will be different.
   II. An STI information packet will influence the treatment recommendations made by trained pharmacists.
   III. An STI information packet will influence the appropriateness of counselling delivered by trained pharmacists.

5.6.2 Measurements

5.6.2.1 *Predictor and outcome variables in STI training intervention study*

Pharmacist gender (male or female), regional pharmacy location (urban or rural), age (>40 years or ≤40 years) and year of graduation (<1990 and ≥1990) were selected as binary predictors of change in STI knowledge. The outcome, mean difference in score (%) obtained by pharmacists, was a continuous measurement. The knowledge of STI was graded in terms of scores (%) achieved in pre- and post-tests.

5.6.2.1.1 *Anticipated effect of predictors*

In a baseline survey, Ward *et al*. (2003) discovered an independent association between pharmacist gender and willingness to treat STI in retail pharmacies; male pharmacists were more amenable to treating STI than their female counterparts after potential confounding variables were controlled. These findings prompted the inclusion of a gender variable as a possible explanatory factor for differences in STI test scores. Younger pharmacists (<40 years) may be construed as having greater mental agility than older pharmacists and are thus expected to complete the comprehensive distance-learning programme with greater ease and fluidity. Pharmacists who graduated before 1990, the year marking the global shift in the profession towards pharmaceutical care and a patient-centred philosophy (Pearson, 2007), were expected to have a more marked improvement in knowledge than those who had graduated from a more clinically oriented curriculum post 1990.

5.6.2.2 *Predictor and outcome variables in STI management intervention study*

The assignment of STI information packets was expected to be the main predictor of competent STI management; the dichotomous outcome was simply "yes" or "no". Additional predictors of counselling and treatment were anticipated and measured dichotomously, i.e. pharmacist gender, age, year of graduation, regional

location of pharmacy, dispensed information packets and differences in STI pre and post test scores. Variables overlapping with the training intervention were not remeasured, although the age variable was recoded into binary measurements (<40 and ≥40 years) for analysis. Furthermore, the difference in test scores in the training phase was rank ordered according to the range of knowledge differentials; a score of less than 20% was categorized as "1" and greater than or equal to 20% was categorized as "2".

The main outcomes of interest were the counselling and treatment of partners presenting with GUS and UDS. Each of the 13 counselling elements was measured dichotomously ("yes" if mentioned and "no" if omitted), and summation of affirmative responses constituted the aggregate counselling score. Binary measurements for treatment recommendations were either "correct combination of antimicrobials" or "incorrect combination of antimicrobials". Secondary outcomes measured in this study were referral patterns, i.e. referrals to a doctor without counselling or treatment or no referrals.
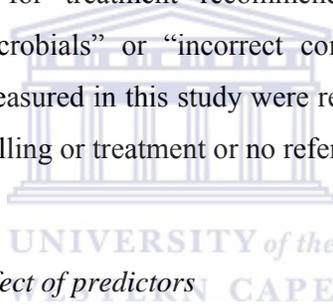
5.6.2.2.1 Anticipated effect of predictors

Gender was included as a variable on the same basis as before. The rationale for the age categorization (<40 and ≥40) was that older pharmacists were expected to offer more resistance to changes in scope of practice than younger pharmacists, thereby possibly exhibiting poorer confidence in managing STI and making more referrals elsewhere for clinical management. Additionally, the anticipated conservatism among older pharmacists was identified as a possible barrier to treating STI. The year of graduation, as alluded to before, was expected to influence the degree of ease or difficulty in transitioning towards STI management based on the undergraduate training orientation of pharmacists. Since the allocation of STI information packets to the intervention group does not necessarily translate into utilization by pharmacists during partner management, a binary measurement was included to ascertain whether or not the information packet was dispensed to the simulated partner.

5.6.3 Statistical issues

5.6.3.1 *Sample size and power*

The sample size estimation was based on the Hypothesis C, i.e. whether or not STI information packets are able to improve the counselling of STI by community pharmacists. Due to the anticipated non-normal distribution of data for appropriate counselling and treatment, an adjustment to the sample size estimate derived from the t-test was made (Motulsky, 1996). According to Lehman *et al.* (2006), when using a non-parametric test to determine score differences between two independent groups, it is acceptable to still compute the sample size required for a t-test, provided that the final figure is adjusted by adding 15%.

Therefore, the t-test was used to estimate the sample size for the intervention and control group according to the following procedure (Hulley *et al*, 2001):
   a) The null hypothesis was stated and it was decided that the alternative hypothesis was two-sided.
   b) The effect size (E) was estimated as the difference in the mean value of the outcome variable between the study groups.
   c) The variability of the outcome (S), as its standard deviation (SD), was estimated.
   d) The standardised effect size was calculated, i.e. the effect size divided by the standard deviation of the outcome variable.
   e) Alpha (α) was set at 0.05, and beta (β[8]) at 0.2
   f) Used mathematically computed sample size table for the comparisons of means of continuous variables when using the t-test (Hulley *et al.*, 2001, p.85) to determine estimated sample size based on the values of E, S, α and β

The estimated effect size was derived from two studies found in literature as well as factors unique to the proposed study. The value of STI information packets has not previously been assessed in any studies, except when this intervention was coupled to STI training; Harrison *et al*. (2000) showed that after nurses and

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8 $\beta = 1$-Power

doctors received this intervention in rural Hlabisa clinics, their counselling (at least 3 of 5 messages) of STI clients improved by 18%. After an STI intervention consisting of training only, a greater proportion of pharmacists (21% more) in a sample of private community retail pharmacies provided any type (at least one) of counselling (Tuladhar, 1998). It is therefore assumed that the impact of the STI information packets is very small, potentially less than 5%. In this study, however, given the anticipation of greater variation in responses between the possible zero and 13 counselling elements assessed, it is hypothesised that the information packet will achieve a difference of 10% in the counselling of STI clients with an estimated standard deviation of 15%. A calculation of the standardised effect size, i.e. the effect size divided by the standard deviation, equals 0.7.

Therefore, with alpha set at 0.05 and beta at 0.2 it is estimated that a sample size of 34 per group (Hulley *et al.,* 2001, p.85) will afford 80% power to detect an association between the intervention and control group. Since the intention is to apply non-parametric statistical tests to the data, the final figure was scaled up by 15% to 79 (Lehman & Erich, 2006). A further scale up to 100 was considered sufficient to account for poor response rates and a high number of dropouts.

5.6.3.2. *Analysis of data*

All data was entered onto an Excel spreadsheet and analysed using SPSS (SPSS Inc). To ensure ease of reading, the description of statistical analyses will be distinct for the two phases of the study.

5.6.3.2.1 *STI training intervention*

5.6.3.2.1.1 *Univariate analyses*

Continuous variables will be described in terms of means and standard deviations (SDs) while categorical variables will be expressed as frequencies.

5.6.3.2.1.2 *Bivariate analyses*

The effect of the training on the general STI knowledge was assessed statistically through the Wilcoxon signed-rank test (Wilcoxon, 1945). This non-parametric analogue of the paired t-test was selected since all the assumptions for paired t-tests were unlikely to be met, given the expected variances between the pre- and post-test scores. The Wilcoxon signed-rank test statistically determines whether or not the median difference between pairs of observations (in this case pre-and post-test scores) is zero. Stratification of these pairs of observations by region, age, year of graduation, and gender accounted for the influence of these variables on the final outcome. A p-value of less than 0.05 would suggest a statistically significant difference between the underlying distribution of the pre- and post-test scores and on this basis the null hypothesis would be rejected in favour of the alternative hypothesis.

The differences in observed and expected frequencies of correctly answered test questions before and after the intervention (stratified by region) were evaluated statistically using the Chi-squared test, a statistical test that accommodates categorical data and assumes that the expected values for each cell in a contingency table is 5 or higher. When this assumption was not met, an alternative to the Chi-squared test i.e. the Fisher's exact test was used (Hicks, 1999). A significant difference ($p<0.05$) suggested that the frequency distribution of the pre- and post-test scores were not equal and this was interpreted as a significant effect of the training programme.

5.6.3.2.2   *STI management intervention*

5.6.3.2.2.1   *Univariate analyses*
Mean and SD descriptive statistics will be employed in order to summarise the findings obtained through continuous measurements, while all categorical data will be summarised in terms of frequencies.

5.6.3.2.2.2   *Bivariate analyses*

To measure the effect of the STI management intervention on training, each pharmacist received a sum score for correct treatment of patients presenting with GUS and a sum score for correct treatment of patients presenting with UDS (i.e. a pharmacist may receive a score of 66% for correctly treating 2 of the 3 urethral discharge patient and a score of 0% for not correctly treating any of the three genital ulcer patients). In the instances when pharmacists were lost to follow-up, the scores assigned were averages of the number of clients actually managed (i.e. if pharmacists correctly managed 1 of 2 partners they received a score of 50%). The differences in scores between the experimental and control group in urban and rural arms were compared using the Wilcoxon (unpaired) rank-sum test (Wilcoxon, 1945). This measurement was done separately for management of GUS and UDS. The same procedures were followed to ascertain the differences in counselling and referral between the experimental and control group in urban and rural pharmacies for both GUS and UDS; sum scores for counselling of patients presenting with GUS disease and a sum score (maximum of 13) for counselling of patients with UDS (i.e. if three simulated partners received counselling on 3, 4 and 6 counselling points respectively, then pharmacists were given an average score of 3). A significant difference ($p<0.05$) suggested that the median scores for the experimental and control group were unlikely to be equal and this was interpreted as a significant effect of the intervention package.

5.6.3.2.2.3   *Multivariate analyses*

Multivariate analysis was employed to control for potential confounders of outcome variables. A multiple ordinal regression model was fitted to establish independent associations between the predictors and the ordinal outcome variables and the direction in which the predictor is related to the ordinal outcome (O'Connell, 2006). Normal binary logistic regression accepts categorical data, provided that only 2 possible categories of responses exist for a particular outcome variable. However, collapsing scores into binary outcomes limits the interpretability of the findings. A decision was taken to ordinalise the data into rank-ordered categories, and to fit an ordinal logistic regression model instead.

The basic assumption of ordinal logistic regression (an extension of binary logistic regression) is that the response variable behaves in an ordinal fashion with respect to each predictor. The proportional odds model is the most commonly used and assumes that the odds ratio of the event is independent of the category of outcome (Bender & Grouven, 1998). The odds ratio is assumed to be constant for all categories, i.e., if the ordinal outcome has 4 levels, then the odds ratio is assumed to be equal for group 1 vs. 2,3,4; 1,2 vs. 3,4 and 1,2,3 vs. 4.

The proportional odds ratios, calculated manually from the logits (log odds) generated in the data output in SPSS (SPSS Inc.), relates the predictor to the outcome in an ordinal way, i.e. if the proportional odds for one category of a predictor variable equals 10, then the odds of being in the higher (4) outcome category versus lower outcome categories (1,2,3) will be 10 times greater for that category of the predictor variable compared to the reference category. If the odds ratio is less than one, then the odds of achieving lower versus higher outcome categories are greater, and if the odds ration equals one, then this implies that a particular category of predictor variable is independent of the outcome variable.

For the purposes of the multivariate analysis all continuous outcomes were rank ordered: counselling was ordinalised into 4 categories: (1) poor scores of 23% (3 out of 13) and less; (2) average scores ranging from above 23% through 46% (6 out of 13); (3) good scores ranging from above 46% through 69% (9 out of 13), and (4) excellent scores of above 69%; and treatment of GUS and UDS was ordinalised into 4 categories: (1) poor scores of less than 33%(1 out of 3); good scores ranging from 33% through 50% (1 out of 2); (3) very good scores ranging from above 50 through 67% (2 out of 3), and (4) excellent scores above 67%. Gender, year of graduation, age, allocation of STI information packets to pharmacists, usage of STI information packets and differences in pre- and post-test score variables were initially incorporated into the 4 separate ordinal regression models to test associations with counselling and treatment of the 2 conditions. The models accounting for the most variation in outcome, i.e. the combination of predictors yielding the highest R-squared values, were selected as

the best models and only these were included in the final results. P-values of less than 0.05 were considered to reflect independence in the associations between predictor and outcome variables.

Preliminary ordinal regression models and the measurements for all outcomes and risk factors are summarized in Table 1.

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Table 1: Ordinal regression models for counselling and treatment recommendation of GUS and UDS

MODEL	MEASUREMENTS
Outcome variables	
Counselling for GUS	Ordinal
Counselling for UDS	Ordinal
Treatment recommendations for GUS	Ordinal
Treatment recommendations for UDS	Ordinal
Predictor variables for each of the above outcomes	
Age	Binary
Gender	Binary
Region	Binary
Pharmacist year of graduation	Binary
Allocation of STI information packets to pharmacists	Binary
Dispensed information packets	Binary
Difference in pre and post-training test score	Binary
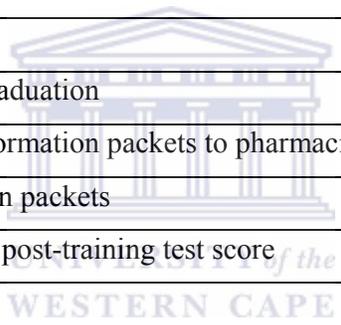
5.7   ETHICAL CONSIDERATION

Ethical clearance was obtained from the institutional review boards of the University of Western Cape and the Committee on Human Research (CHR) in San Francisco. The primary ethical issue taken into consideration was that of confidentiality.

5.7.1 Potential risks

Participants were assigned a unique study number that was used on the pre- and post-tests and the form documenting the management of the simulated clients. Personally identifying information was retained separately from other study data. The personally identifying data included the contact information, the link between study number and name, and the signed consent forms. All information was retained in locked file cabinets in a locked room of one of the investigators. Data was entered into a research database and was identified only using the study number. Dissemination of findings will not contain any personally identifying information
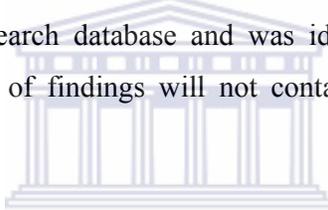
To minimize this risk, only those pharmacists who scored at least 70% on case management questions were included in the portion of the study that involves patient care. For those pharmacists who did not demonstrate this level of proficiency a recommendation not to provide syndromic treatment for STI was provided at the completion of the training.

Currently health regulations do not permit pharmacists to dispense antimicrobial agents without a prescription from a doctor. Since no medication was dispensed to the patients, the risks of erroneously prescribed medication were negated.

While private pharmacies are often called upon for treatment of symptomatic STI clients, they are seldom, if ever, presented with written partner notification slips from sexual contacts, which are invariably presented to public primary healthcare facilities. This notwithstanding, safeguards were instituted to prevent actual sexual contacts from missed pharmacological treatment opportunities; study participants

(pharmacists) were primed to accept "valid" partner notification slips and to refer all other cases immediately. A valid slip bore a reference to the study.

5.7.2 Potential benefits

The subjects were the pharmacists who, if interested in moving towards patient service, as is anticipated given restrictions on pricing medications, will most likely acquire the skills for syndromic management of STI.

The purpose of this study was to address a serious public health problem. Untreated or inadequately treated STI contribute to ongoing transmissions of infections, to maternal and child morbidity and mortality, and have been shown to increase both the acquisition and transmission of HIV infection which is responsible for substantial number of deaths and years of potential life lost in South Africa. If this study is successful, expanded opportunities for treating STI and possibly reducing HIV transmission will results. The risk to subjects is limited while the potential benefit to society is great.

5.7.3 Informed consent process

Pharmacists were contacted telephonically and a consent form, signed by the investigator was faxed to these participants explaining the study objectives and procedures. Willing pharmacists returned the consent form to the study investigators and interested pharmacists were scheduled for training.

All participating pharmacists were provided with verbal explanation of the study at the start of the training.

At each point of contact with the pharmacists, information about the study and its procedures, risks, and benefits were explained. Potential participants were also informed of the voluntary nature of the study. Much of the contact was by phone or in person, which facilitated clarifying any confusing aspects of the study.

CHAPTER 6

RESULTS

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The study findings are summarized in text, tables and figures according to the sequence in which the data was collected; the results of the STI training and management interventions are described in the order of descriptive, bivariate and multivariate analyses. A summary of the most salient results concludes this chapter.

All univariate and bivariate results are tabulated according to stratification by region. In the multivariate analysis, the ordinal regression models reflect only those predictor variables, which collectively accounted for maximal variation for the outcome variable, as determined by the highest R-squared value (not reported in results). Furthermore, for the purpose of multivariate analysis, confounding variables were omitted from the regression model.

P-values below 0.05 demonstrated statistical significance.

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6.1 STI TRAINING INTERVENTION

6.1.1 Univariate descriptive statistics

Forty-one out of a possible 100 (41%) pharmacists initially consented to participate in both phases of the study; however, participation had diminished to 39% at the post-training evaluation. This translated to 31 urban and 8 rural pharmacies, representing 10% of urban and 7% of rural WC community retail pharmacies respectively. The relatively poor response rate achieved in this study relative to similar interventions in other countries (Chuc *et al.,* 2002; Garcia et al., 1998; Garcia *et al.,* 2003; Harrison *et al.,* 2000) is investigated further in Chapter 8. Only 8 pharmacists represented rural WC although the stratification of pharmacies by urban and rural WC reflected favourably against the regional proportion of pharmacies; 80% of consenting pharmacists were from urban WC and 20% were from rural WC (Figure 1). Of those participants who provided a reason for declining to participate, the majority cited time constraints and disinterest. Figures 2 to 4 show that participants were predominantly middle-aged to old (83% were between the ages of 40 and 69 years), of male gender (80%) and had graduated before the implementation of a more clinically oriented pharmacy curriculum (88%).

Figure1: Regional distribution of pharmacists in the original study sample (N=41)
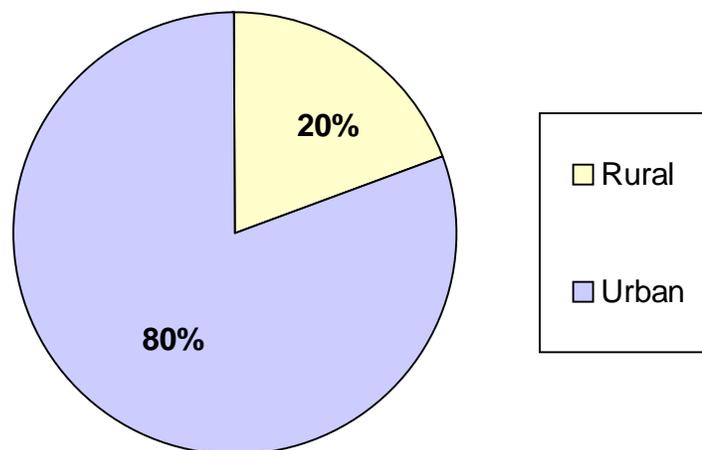
Figure 2: Age distribution (in years) of pharmacists in the original study sample (N=41)
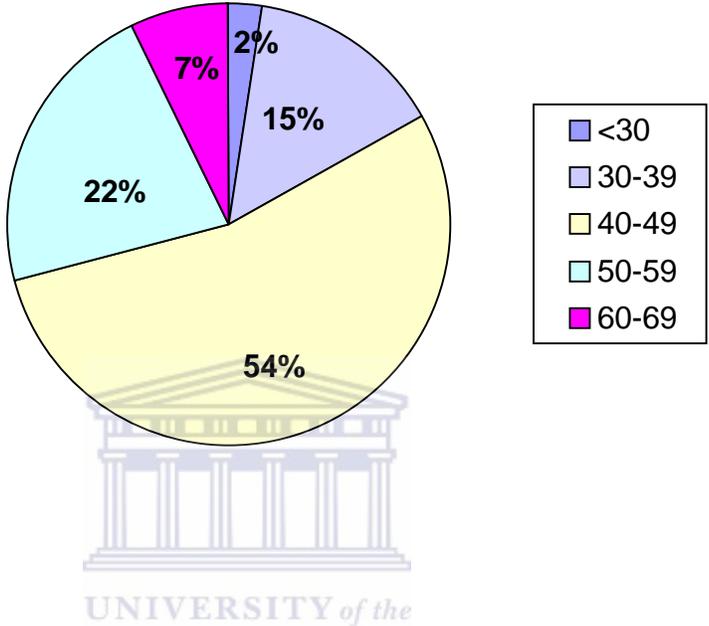
Figure3: Gender distribution of pharmacists in the original study sample (N=41)
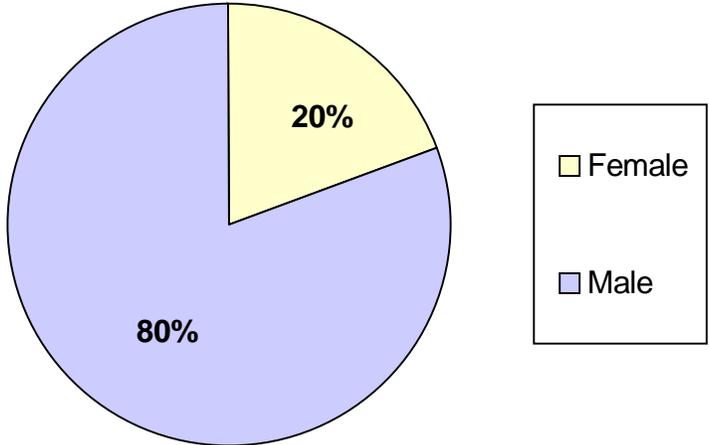
Figure 4: Year of graduation of pharmacists in the original study sample (N=41)
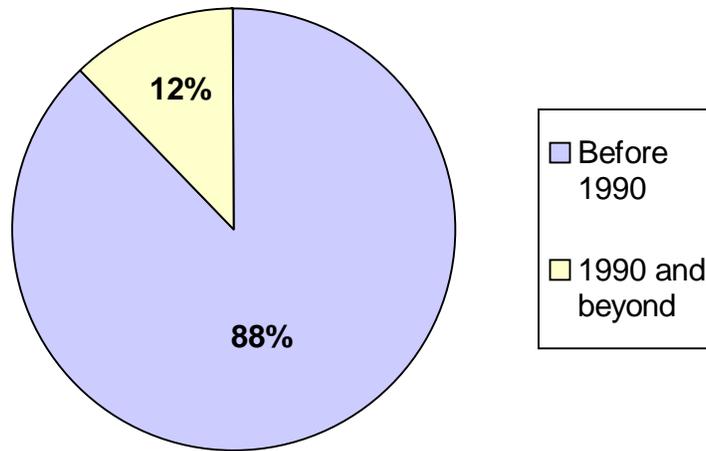
The level of general STI knowledge prior to the training was fairly good. Figure 5 shows that the average score attained by pharmacists at baseline was 73.8% (with SD of 10.1) and that the scores were of normal distribution. The bar graph in figure 6, however, shows a preponderance of scores to the right of the curve, hence the higher average of 87.1% and smaller SD of 7.3%.

Figure 5: Frequency distribution of pre-training scores of pharmacists in urban and rural Western Cape
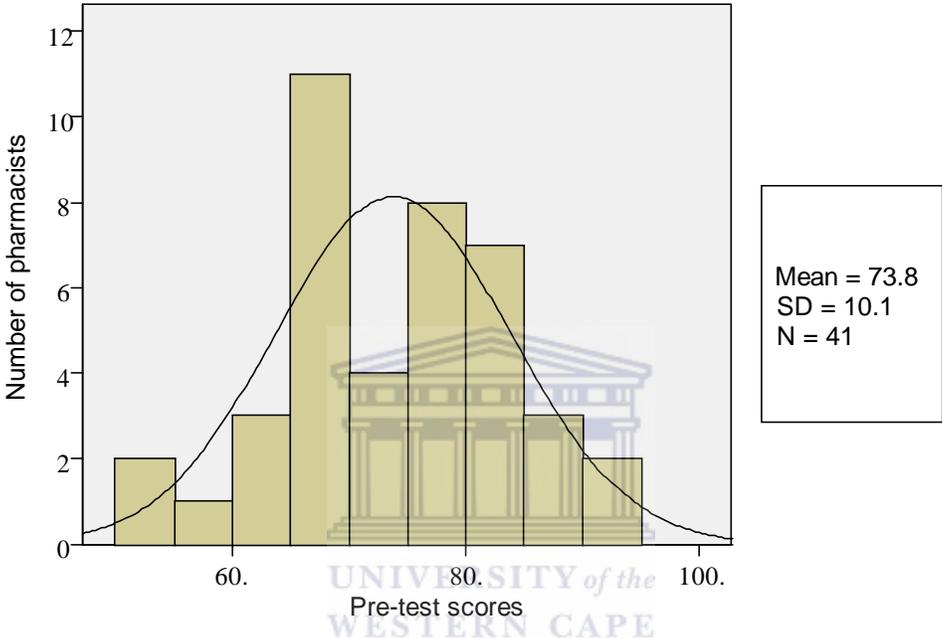
Figure 6: Frequency distribution of post-training scores of pharmacists in urban and rural Western Cape

Mean =87.1
SD =7.3
N =39
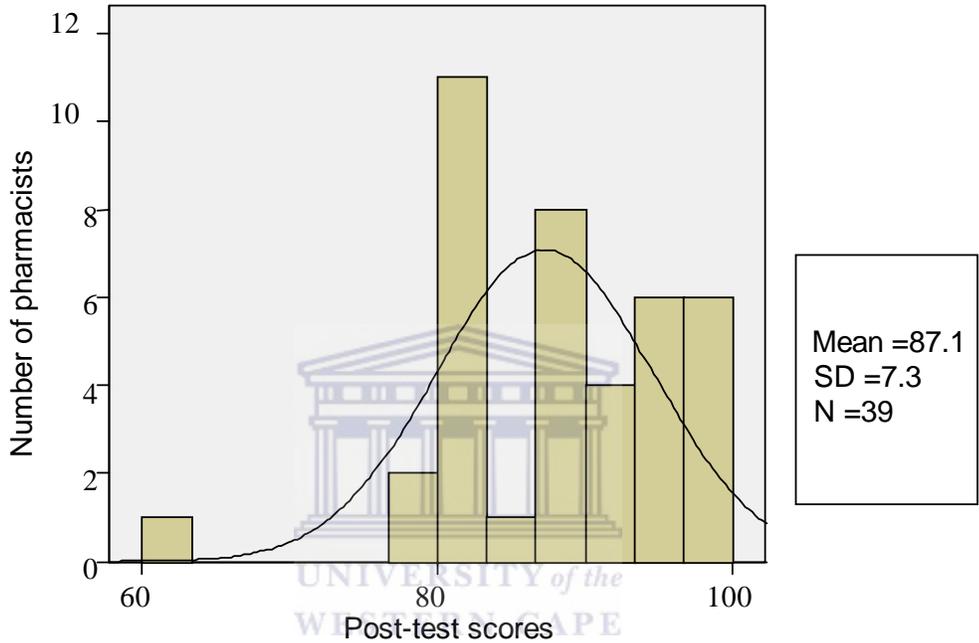
Table 2 summarizes the frequencies of correctly answered questions. Rural pharmacists were decidedly more knowledgeable about STI in the lead up to the training; all 8 pharmacists knew that, syphilis, gonorrhoea, chlamydia, trichomoniasis and candidiasis can be cured and that HIV is incurable, that GUS treatment is based on a syndromic rationale and that condoms offer 95% protection against HIV. By contrast, only gonorrhoea and candidiasis were correctly identified as curable STI by all urban pharmacists. Pharmacists displayed poor knowledge of treatment for GUS (0%) and UDS (<30%) before training was instituted. Subsequent to the training 100% of rural pharmacists additionally (compared to baseline observations) identified high-risk STI behaviours. Interestingly, this group of pharmacists experienced a lapse in knowledge regarding the curability of syphilis. By the end of the training all urban pharmacists additionally (compared to baseline observations) knew that chlamydia and trichomoniasis are curable and that HIV is incurable. Twice as many pharmacists could recall the appropriate treatment regimen for UDS, whereas none were able to list the correct GUS antimicrobials after training.   .
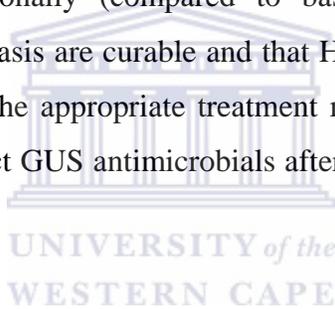
Table 2: STI knowledge levels before and after an STI training intervention expressed in terms of frequencies (number of correct responses) and overall mean scores achieved by pharmacists in urban and rural WC pharmacies.

Test topics	Urban			Rural		
	Pre-training (N=31)	Post-training (N=31)	P-value [†]	Pre-training (N=8)	Post-training (N=8)	P -value[†]
	n(%)	n(%)		n(%)	n(%)	
Knows if the STI can be cured						
HIV	30(96.8)	31(100)	-	8(100)	8(100)	-
Syphilis	27(87.1)	29(93.5)	0.01	8(100)	7(87.5)	-
Chlamydia	30(96.8)	31(100)	-	8(100)	8(100)	-
Gonorrhoea	31(100)	31(100)	-	8(100)	8(100)	-
Herpes	16(51.6)	24(77.4)	0.04	4(50)	5(62.5)	1
Trichomoniasis	30(96.8)	31(100)	-	8(100)	8(100)	-
Candidiasis	31(100)	31(100)	-	8(100)	8(100)	-
Chancroid	25(80.6)	29(93.5)	0.03	3(37.5)	6(75)	0.46
Knows the link between STI and HIV	14(45.2)	26(83.9)	0.08	5(62.5)	7(87.5)	0.71
Identifies STI risk behaviours	29(93.5)	30(96.8)	1	6(75)	8(100)	-
Understands rational for partner treatment	19(63.1)	27(80.6)	<<0.05	3(37.5)	7(87.5)	0.05
Understands rational for syndromic treatment of UDS	17(54.8)	25(80.6)	0.003	6(75)	6(75)	-
Understands rational for syndromic treatment of GUS	19(61.3)	26(83.9)	0.005	8(100)	8(100)	-
Knows condom effectiveness	26(83.9)	31(100)	-	8(100)	8(100)	-
Knows UDS treatment	9(29)	18(58.1)	0.61	2(25)	5(62.5)	0.63
Knows GUS treatment	0	0	-	0(0)	0(0)	-
Overall score (mean %)	**73.4**	**87.5**	**<<0.001***	**75.4**	**86.3**	**0.02***

[†]Fisher's Exact Test   *Wilcoxon Signed-Rank Test

6.1.2 Bivariate statistics

6.1.2.1   Testing of hypothesis

Null hypothesis: Test scores achieved before and after participation in an STI correspondence course, coupled with learner support, will be equal, i.e. the median differences in test scores will equal zero.

Alternative hypothesis: Test scores achieved before and after participation in an STI correspondence course, coupled with learner support will be different, i.e. the median differences in test scores will not be equal to zero.

Table 3: Wilcoxon Signed-Ranks Test for pre- and post-test score difference (urban arm)

	Difference in pre- and post-test score
Z	-4.5
Two-tailed significance	<<0.001

The results suggest that the median differences in pre- and post-test scores among urban pharmacists are not equal to zero (z = -4.5, p=<<0.005), and the null hypothesis is therefore rejected in favour of the alternative hypothesis.

Table 4: Wilcoxon Signed-Ranks Test for pre- and post-test score difference (rural arm)

	Difference in pre- and post-test score
Z	-2.4
Two-tailed significance	0.02

The results suggest that the median differences in pre- and post-test scores among rural pharmacists are not equal to zero (z = -2.4, p=0.02), and the null hypothesis is therefore rejected in favour of the alternative hypothesis.

Therefore, the observed differences in mean test scores in urban (from 73.4% to 87.5%) and rural WC pharmacies (from 75.4% to 86.3%) were unlikely to have occurred due to chance alone and is probably reflective of the true impact of the training on STI knowledge (table 2). The transition in general STI knowledge was highest in urban WC, while rural pharmacists reflected smaller, yet equally significant improvements (Figure 7).

Figure 7: Mean differences in test scores
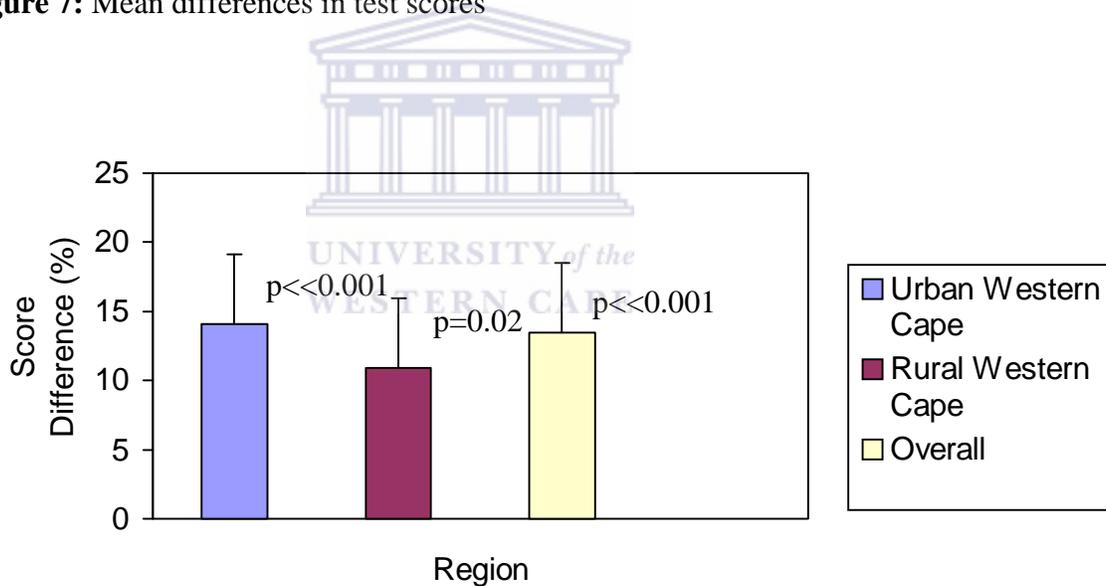
6.1.2.2 *Additional bivariate statistics*

Questions assessing knowledge about the curability of STI were answered correctly by more pharmacists after training, although the only significant improvements were noted for questions around the curability of GUS, viz, chancroid (p=0.03), syphilis (p=0.01) and herpes (p=0.04) in urban WC pharmacies (table 2). The knowledge of STI transmission, risk behaviours and what constitutes safe sexual practices improved

in urban and rural pharmacies, although the significance was inconsequential. Furthermore, the rationale for using a syndromic treatment approach and treating partners presumptively was poorly understood in urban WC before treatment and increased significantly after the training intervention in both regions. Knowledge of treatment for UDS was marginally better after the training in urban and rural WC, although of no significance statistically (p=0.61 and p=0.63 respectively).

Table 5 shows that older and younger pharmacists improved their knowledge on STI after the training intervention, although the significance associated with the latter group was narrowly insignificant (p=0.05). Similarly, the improvements in knowledge were evident among long-standing and recent graduates (table 6), although the significance associated with the latter groups was narrowly insignificant (p=0.05). Male and female pharmacists received comparable (significant) gains in knowledge as shown in table 7.
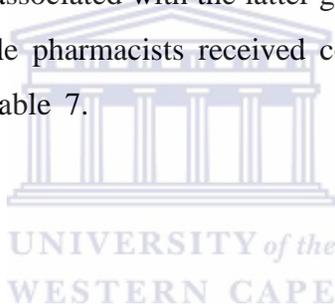
Table 5: STI knowledge levels before and after an STI training intervention, expressed in terms of overall mean scores achieved by younger (<40 years) and older (≥40 years) pharmacists.

	<40 years			≥40 years		
	Pre-training (N=7)	Post-training (N=6)	P-value [†]	Pre-training (N=34)	Post-training (N=33)	P-value[†]
	n (%)	n (%)		n (%)	n (%)	
Overall score (mean)	75	90.1	0.05	73.5	86.8	<<0.001

[†]Wilcoxon Signed-Rank Test

Table 6: STI knowledge levels before and after an STI training intervention, expressed in terms of overall mean scores achieved by pharmacists of recent (≥ 1990) and long-standing (<1990) graduation.

	<1990			≥ 1990		
	Pre-training (N=34)	Post-training (N=33)	P-value [†]	Pre-training (N=7)	Post-training (N=6)	P-value[†]
	n (%)	n (%)		n (%)	n (%)	
Overall score (mean)	73.5	86.8	<<0.001	75	90.1	0.05

[†]Wilcoxon Signed-Rank Test

Table 7: STI knowledge levels before and after an STI training intervention, expressed in terms of overall mean scores achieved by male and female pharmacists.

	Male			Female		
	Pre-training (N=33)	Post-training (N=32)	P-value [†]	Pre-training (N=8)	Post-training (N=7)	P-value[†]
	n (%)	n (%)		n (%)	n (%)	
Overall score (mean)	73.6	87.5	<<0.001	74.8	86.2	0.03

[†]Wilcoxon Signed-Rank Test

6.2   STI MANAGEMENT INTERVENTION

6.2.1   Univariate statistics

The second phase of the study, aimed at evaluating the differences in quality of STI management as determined by the influence of STI information packets on correct counselling and treatment of STI male partners yielded response rates of 31%.

The data in table 8 suggests that the general characteristics of pharmacists in the experimental and control arm were a close match in terms of gender, age, year of graduation and region.

Table 8: Community pharmacist demographics stratified by intervention and control group

Characteristics	Experimental group n (%) N=15	Control group n (%) N=16
Age		
<30	1(6.7)	0(0)
30-39	2(13.3)	1(6.3)
40-49	8(53.3)	9(56.2)
50-59	2(13.3)	5(31.2)
60-69	2(13.3)	1(6.3)
Gender		
Female	3(20)	3(18.7)
Male	12(80)	13(81.3)
Year of graduation		
<1990	12 (80)	15 (93.7)
≥1990	3 (20)	1 (6.3)
Region		
Urban	12(80)	12(75)
Rural	3(20)	4(25)

A treatment score of 33% and higher in table 9 is indicative of "good" treatment; by implication at least one third of simulated partners received the correct medication. GUS treatment was therefore deemed to be adequate, with an exception of the experimental arm in urban WC where a mean score of only 24% was attained. A score above 46% demonstrates adequate partner counselling; the implication is that an average of 7 out of a possible 13 messages were covered. The counselling of partners receiving treatment for GUS was therefore considered to be mostly inadequate, with an exception of the rural, experimental arm, where average scores of 7 out of 13 were achieved. A similar pattern of results emerged for the treatment and counselling of partners with suspected UDS (table 10); all pharmacists with an exception of those in the rural, experimental arm (average scores of 70%), counselled inadequately and all pharmacists with an exception of those in the rural, control arm (average scores of 25%) treated UDS adequately. A referral score of 33% and higher is indicative of having referred at least one of the simulated partners without attempting to prescribe antimicrobial drugs. High referral rates are possibly a reflection of the pharmacist's poor confidence in treating partners. In this study, scores were generally higher than 33%, with 2 notable exceptions, viz, partners presenting with suspected GUS and UDS in rural, control and urban, control pharmacies respectively.

Table 9: Quality of GUS management in experimental and control WC community retail pharmacies expressed as mean scores for aggregate counselling (fractions), elements of counselling (%), referral without treatment (%) and recommended treatment (%).

	Urban			Rural		
	Experimental Mean score as fraction or % N=12	**Control** Mean score as fraction or % N=12	**P-value***	**Experimental** Mean score as fraction or % N=3	**Control** Mean score as fraction or % N=4	**P-value***
Aggregate counselling	5/13	4/13	0.56	7/13	4/13	0.16
STI transmission	42	5	0.57	89	5	0.43
STI signs &symptoms	58	5	0.59	44	25	0.43
Prompt treatment	51	33	0.24	89	25	0.13
Possible complications	17	31	0.2	89	33	0.06
Risk HIV transmission	28	33	0.9	33	25	0.82
Promote VCT	38	44	0.57	89	38	0.14
Risk reduction	56	53	0.83	78	50	0.43
Promote condom use	49	61	0.4	78	75	1
Condom provision	25	6	0.08	33	28	0.44
Condom demonstration	8	11	0.71	33	0	0.25
Promote abstinence	5	31	0.2	67	25	0.31
Complete treatment	47	39	0.55	56	25	0.43
Promote partner treatment	53	44	0.57	44	42	0.85
Refer	43	36	0.61	33	0	0.25
Correct treatment combination (GUS)	24	36	0.4	33	100	0.07

*Wilcoxon rank-sum test

Table 10: Quality of UDS management in WC retail pharmacies expressed as mean scores for aggregate counselling (fractions), elements of counselling (%), referral without treatment (%) and recommended treatment (%).

	Urban			Rural		
	Experimental Mean score as fraction or % N=12	**Control** Mean score as fraction or % N=12	**P-value***	**Experimental** Mean score as fraction or % N=3	**Control** Mean score as fraction or % N=4	**P-value***
Aggregate counselling	4/13	5/13	0.58	8/13	3/13	0.06
STI transmission	46	56	0.51	100	33	0.03
STI signs &symptoms	28	29	0.98	78	33	0.19
Prompt treatment	42	42	0.91	83	42	0.27
Possible complications	17	31	0.2	89	33	0.06
Risk HIV transmission	15	28	0.63	5	17	0.2
Promote HIV testing	38	25	0.58	67	83	0.04
Risk reduction	49	64	0.34	89	33	0.14
Promote condom use	63	58	0.85	100	50	0.18
Condom provision	49	3	0.003	22	0	0.25
Condom demonstration	0	8	0.32	22	0	0.25
Promote abstinence	26	56	0.07	33	25	0.71
Complete treatment	25	53	0.03	61	25	0.21
Promote partner treatment	47	58	0.57	78	42	0.27
Refer	39	28	0.57	33	42	0.84
Correct treatment combination (UDS)	54	56	0.92	67	25	0.27

*Wilcoxon rank-sum test

6.2.2 Bivariate statistics

6.2.2.1   Testing of hypotheses

6.2.2.1.1   Hypothesis Ia

Null hypothesis: An STI information packet will not influence the treatment recommendations made by pharmacists trained in GUS management, i.e. the median scores for treatment in the experimental and control group will be equal.

Alternative hypothesis: An STI information packet will influence the treatment recommendations made by pharmacists trained in GUS management, i.e. the median scores for treatment in the experimental and control group will not be equal.

Table 11: Wilcoxon Rank-Sum Test for differences in correct GUS treatment recommendations between the intervention and control groups (urban arm)

	Correct treatment recommendations for GUS
Z	-0.8
Two-tailed significance	0.4

The results suggest that there is no statistically significant difference between the underlying score distributions (and therefore medians) of the intervention and control groups (z =-0.8, p=0.4). The null hypothesis is therefore accepted.

Table 12: Wilcoxon Rank-Sum Test for differences in correct GUS treatment recommendations between the intervention and control groups (rural arm)

	Correct treatment recommendations for GUS
Z	-1.8
Two-tailed significance	0.07

The results suggest that there is no statistically significant difference between the underlying score distributions (and therefore medians) of the intervention and control groups (z =-1.8, p=0.07). The null hypothesis is therefore accepted.

6.2.2.1.2   Hypothesis Ib

Null hypothesis: An STI information packet will not influence the treatment recommendations made by pharmacists trained in UDS management, i.e. the median scores for treatment in the experimental and control group will be equal.

Alternative hypothesis: An STI information packet will influence the treatment recommendations made by pharmacists trained in UDS management, i.e. the median scores for treatment in the experimental and control group will not be equal.

Table 13: Wilcoxon Rank-Sum Test for differences in correct UDS treatment recommendations between the intervention and control groups (urban arm)

	Correct treatment recommendations for UDS
Z	0.1
Two-tailed significance	0.93

The results suggest that there is no statistically significant difference between the underlying score distributions (and therefore medians) of the intervention and control groups (z =0.1, p=0.93). The null hypothesis is therefore accepted.

Table 14: Wilcoxon Rank-Sum Test for differences in correct UDS treatment

recommendations between the intervention and control groups (rural arm)

	Correct treatment recommendations for UDS
Z	-1.1
Two-tailed significance	0.27

The results suggest that there is no statistically significant difference between the underlying score distributions (and therefore medians) of the intervention and control groups (z =-1.1, p=0.27). The null hypothesis is therefore accepted.

6.2.2.1.3   Hypothesis IIa

Null hypothesis: An STI information packet will not influence the appropriateness of counselling delivered by pharmacists trained in GUS management, i.e. the median scores for counselling in the experimental and control group will be equal.

Alternative hypothesis: An STI information packet will influence the appropriateness of counselling delivered by pharmacists trained in GUS management, i.e. the median scores for counselling in the experimental and control group will not be equal.

Table 15: Wilcoxon Rank-Sum Test for differences in GUS counselling scores
between the intervention and control groups (urban arm)

	Level of counselling for GUS partners
Z	-0.6
Two-tailed significance	0.56

The results suggest that there is no statistically significant difference between the underlying score distributions (and therefore medians) of the intervention and control groups (z =-0.6, p=0.56). The null hypothesis is therefore accepted.

Table 16: Wilcoxon Rank-Sum Test for differences in GUS counselling scores between the intervention and control groups (rural arm)

	Level of counselling for GUS partners
Z	-1.4
Two-tailed significance	0.16

The results suggest that there is no statistically significant difference between the underlying score distributions (and therefore medians) of the intervention and control groups (z =-1.4, p=0.16). The null hypothesis is therefore accepted.
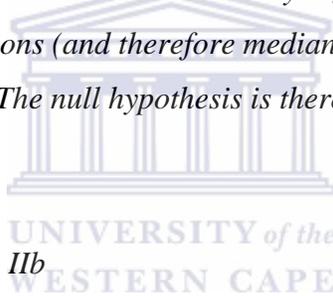
6.2.2.1.4   Hypothesis IIb

Null hypothesis: An STI information packet will not influence the appropriateness of counselling delivered by pharmacists trained in UDS management, i.e. the median scores for counselling in the experimental and control group will be equal.

Alternative hypothesis: An STI information packet will influence the appropriateness of counselling delivered by pharmacists trained in UDS management, i.e. the median scores for counselling in the experimental and control group will not be equal.

Table 17: Wilcoxon Rank-Sum Test for differences in UDS counselling scores

between the intervention and control groups (urban arm)

	Level of counselling for UDS partners
Z	0.6
Two-tailed significance	0.54

The results suggest that there is no statistically significant difference between the underlying score distributions (and therefore medians) of the experimental and control groups (z =0.6, p =0.54). The null hypothesis is therefore accepted.

Table 18: Wilcoxon Rank-Sum Test for differences in UDS counselling scores

between the intervention and control groups (rural arm)

	Level of counselling for UDS partners
Z	-1.8
Two-tailed significance	0.07

The results suggest that there is no statistically significant difference between the underlying score distributions (and therefore medians) of the experimental and control groups (z =-1.8, p =0.07). The null hypothesis is therefore accepted.

6.2.2.2   Additional bivariate statistics

In a bivariate analysis (table 9) to determine the extent to which STI information packets improved the breadth of counselling for partners with suspected GUS, it is noted that, in the absence of information packets (control groups), pharmacists conveyed minimal information to partners (4/13 messages in both urban and rural pharmacies) in comparison with the slightly more extensive counselling provided when information packets were readily available as was the case in the intervention groups (5/13 and 7/13 in urban and rural pharmacies respectively).   These differences, however, failed to achieve any statistical significance ($p=0.56$ and $p=0.16$ in urban and rural strata respectively). As regarding the correctness of suggested antimicrobial therapy, these were more often recommended by pharmacists in the control group (no information packets), although the differences in treatment scores between intervention and control arms again revealed no statistical significance ($p=0.4$ and $p=0.07$ in urban and rural strata respectively).

With respect to UDS, bivariate analyses (table 10) revealed no significant differences in aggregate counselling between the experimental (4/13 and 8/13 in urban and rural pharmacies respectively) and control (5/13 and 3/13 in urban and rural pharmacies respectively) groups ($p=0.58$ and $p=0.06$ in urban and rural strata respectively), although selected elements of counselling varied significantly; the provision of condoms ($p=0.003$) during counselling and promoting compliance to a full course of antimicrobial therapy ($p=0.03$) was mentioned in more counselling sessions delivered by urban pharmacists to whom information packets were assigned, while education on STI transmission ($p=0.03$) and promotion of HIV testing (0.04) were raised more frequently in rural intervention pharmacies. Suggested antimicrobial drugs for the treatment of UDS were correct in a similar percentage of urban, control pharmacies (56%) and experimental pharmacies (54%), although without statistical significance ($p=0.92$). Although correct UDS treatments were recommended more often by rural

pharmacists in the intervention (67%) than the control arm (25%), the proposed treatment differentials did not approach statistical significance (p=0.27).

6.2.3 Multivariate statistics

Ordinal regression (tables 19-22) identified very few factors independently associated with counselling and treatment. Pharmacists who never utilized or dispensed the information packets during the counselling of partners presenting with UDS had 0.01 times the odds of delivering good to excellent counselling than poor to average counselling (p=0.01) than pharmacists who always utilised the information packets (referent); essentially, these pharmacists counselled poorly in comparison to those who gave the information packets to clients (table 20). Additionally, compared to rural pharmacies (referent), urban pharmacies were more likely to attain poor scores than good to excellent scores (adjusted odds ratio 0.1; p=0.03) for the treatment of GUS (table 21).
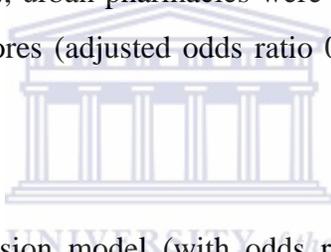
Table 19: Ordinal regression model (with odds ratios and their 95% confidence intervals) for predictors of effective counselling for genital ulcer syndrome

	GUS Counselling		
RISK FACTORS	**Odds ratios**	**95% CI**	**p-value**
Region			
Urban pharmacists	5.24	0.23-117.6	0.69
Rural pharmacists	Referent		
Received information packets			
Assigned to pharmacists	0.91	0.15-5.55	0.92
Not assigned to pharmacists	Referent		
Used information packets			
Never (0/3)	0.32	0.01-20	0.59
Rarely (1/3)	0.6	0-73.7	0.83
Often (2/3)	2.57	0.01-605.7	0.74
Always (3/3)	Referent		
Difference in STI training			

scores			
<20%	0.39	0.06-2.6	0.33
20 through 40%	Referent		

Table 20: Ordinal regression model (with odds ratios and their 95% confidence intervals) for predictors of effective counselling for urethral discharge syndrome

	UDS Counselling		
RISK FACTORS	**Odds ratios**	**95% CI**	**p-value**
Gender			
Female	0.25	0.02-4.12	0.33
Male	Referent		
Region			
Urban pharmacists	0.19	0.02-1.74	0.14
Rural pharmacists	Referent		
Received information packets			
Assigned to pharmacists	0.09	0.01-1.12	0.06
Not assigned to pharmacists	Referent		
Used information packets			
Never (0/3)	0.01	0-0.35	0.01
Rarely (1/3)	0.17	0-6.28	0.34
Often (2/3)	-	-	-
Always (3/3)	Referent		
Difference in STI training scores			
<20%	0.74	0.12-4.7	0.75
20 through 40%	Referent		

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Table 21: Ordinal regression model (with odds ratios and their 95% confidence intervals) for predictors of effective treatment for genital ulcer syndrome

	GUS treatment		
RISK FACTORS	**Odds ratios**	**95% CI**	**p-value**
Gender			
Female	0.75	0.09-6.58	0.8
Male	Referent		
Region			
Urban pharmacists	0.1	0.01-0.81	0.03
Rural pharmacists	Referent		
Difference in STI training scores			
<20%	3.65	0.55-24.38	0.18
20 through 40%	Referent		

Table 22: Ordinal regression model (with odds ratios and their 95% confidence intervals) for predictors of effective treatment for urethral discharge syndrome

	UDS Treatment		
RISK FACTORS	**Odds ratios**	**95% CI**	**p-value**
Gender			
Female	0.53	0.07-3.85	0.53
Male	Referent		
Region			
Urban pharmacists	1.49	0.24-9.01	0.67
Rural pharmacists	Referent		
Difference in STI training scores			
<20%	1.71	0.36-8.01	0.5
20 through 40%	Referent		

No independent predictors of UDS treatment and GUS counselling were identified in similar ordinal regression analyses.

6.3   SUMMARY OF MAIN FINDINGS

The findings of note in this study are summarised in bullet-point form below.

- A relatively poor response rate was achieved despite numerous verbal commitments (Ward *et al.,* 2003) from pharmacists to participate in the training and management phases of the study.

- Prior to the intervention, pharmacists were reasonably knowledgeable about STI issues (mean score of 73.8%) and this was further (significantly) enhanced after training (score difference of 13.3%, $p \ll 0.001$).   The performance of urban pharmacists in the lead up to the training (pre-test) was slightly inferior to that of their rural counterparts and the improvements in scores post-training were subsequently higher among urban pharmacists (score differences of 14.1 and 10.9 were achieved in urban and rural pharmacists respectively, $p < 0.05$).

- Younger and more recent graduates derived no benefit from the training as evidenced by statistically insignificant ($p = 0.05$) differences between pre- and post-test scores.

- Pharmacists had no knowledge of the recommended treatments for GUS before (0%) and after training (0%).

- At baseline, the rationale for treating partners presumptively for UDS and GUS was poorly understood by urban pharmacists (54.8% and 61.3% for UDS and GUS respectively), however, their understanding of this concept improved significantly after the intervention ($p = 0.003$ and $p = 0.005$ for UDS and GUS respectively).

- With an exception of the rural intervention group which couns, the level of counselling provided by pharmacists subsequent to the training ranged from poor to average (in most cases, less than half of the counselling messages were mentioned).

- Acceptable treatment recommendations were offered to at least one out of three simulated partners in the experimental and control groups.

- Pharmacists were generally confident in prescribing antimicrobial therapies as evidenced by their preference to treat rather than refer without treating (a maximum of one out of every three simulated client visits ended with a referral sans treatment).

- Simulated partners treated in rural pharmacies generally received more extensive counselling, more appropriate therapies and fewer referrals without prescriptions than those who visited urban pharmacists.

- The allocation of STI information packets was not a significant predictor of overall higher counselling aggregates.

- When STI information packets were assigned to urban pharmacists, their counselling on condom provision and treatment compliance was superior to relative to the (urban) control pharmacists.

- When STI information packets were assigned to rural pharmacists, they provided better education on STI transmission and recommended HIV testing more frequently than the (rural) control pharmacists.
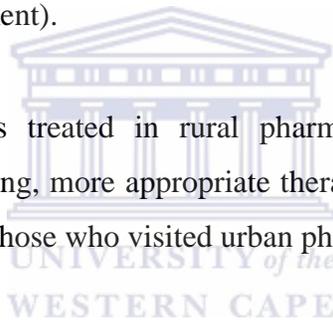
- Compared to their urban counterparts, rural pharmacists were more likely to offer correct antimicrobial therapies (good to excellent, as opposed to poor treatment scores) for GUS.

- When 100% of assigned STI information packets were utilised by pharmacists, they delivered superior counselling to those who used the packets infrequently.

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CHAPTER 7

DISCUSSION

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The proceeding discussion explores plausible underpinnings for the results obtained within this thesis. The main findings, dictated by the primary hypotheses, will be central to the discussion, while subsidiary findings of statistical note will supplement this discussion by way of brief elucidation. The impact of the STI training intervention on academic performance will be explored along the lines of the actual content and method of course delivery, while the overall lack of profound impact of information packets on STI management in general will be traced back to the strength of a comprehensive STI correspondence course. Literature has shown that the quality of STI management in the private sector is often undesirable and one of the goals of this discussion will be to draw comparisons between the quality of STI management provided by pharmacists in this study and more clinically adept practitioners. The chapter ends with an identification of the strengths and limitations of the study as well as the ramifications thereof with respect to the results obtained.

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7.1 STI MANAGEMENT: THE CONCEPT OF DISTANCE LEARNING

Several developing countries have evaluated the impact of various STI management interventions on knowledge and practice, although an intervention consisting of comprehensive distance learning course has not previously been tested (Chuc *et al.,* 2002; Garcia *et al.,* 1998; Garcia *et al.,* 2003; Garcia & Holmes 2003; Green *et al.,* 1998; Schneider *et al.,* 2005; Tuladhar, 1998). In this study, the favourable effect of an STI correspondence course on the knowledge of slightly older pharmacists with relatively long-standing qualification in pharmacy points to its immense value in the training of "experienced" pharmacists. It could therefore be postulated that distance-learning courses successfully breach the gap of STI knowledge amongst these pharmacists and therefore have a definite place in the expansion of STI partner management to community retail pharmacies. The enhancement of clinical skills through distance-learning programmes is not a foreign concept: in the United States of America, distance learning courses in clinically-oriented programmes such as clinical laboratory science and Doctor of Pharmacy programmes have consistently reflected an equivalent learning experience when compared to traditional classroom-based methods; in fact distance learners (of slightly higher mean age) consistently outwitted their on-campus counterparts in course examinations (Russel *et al.,* 2007; Lenz *et al.,* 2006).

In addition to the unique method of instruction, further attributes that set this study apart from others are the comprehensiveness of course content and the variable pace at which learning was allowed to transpire; while clinical management predominated in past STI training interventions targeting pharmacists and various other health practitioners, this 8-week self-study course covered a broader spectrum of topics that was entrenched in public health principles. The contributing factors toward the observed increments in general STI knowledge are therefore assumed to be multiple.

Learner support offered by a clinical nurse practitioner was an important facet of the training intervention. As such, the bivariate analysis (Fisher's exact test), revealing

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significantly higher aptitudes in answering case-study-type questions (employed to test the pharmacists understanding of the rationale for using the syndromic approach and for treating partners presumptively) after the correspondence training, was not entirely surprising. These findings are in line with the views of Jonassen (as cited in Huang 2002) who asserts that when interactive learning is encouraged through instructor's guidance in distance learning courses, students are in fact able to develop critical thinking skills. The telephonic and on-line learner support provided for the duration of the STI correspondence course plausibly produced the evident leveraging effect on critical thinking skills. Therefore, the assistance afforded to pharmacists during training also numbered among the multiplicity of contributory factors influencing the knowledge gain.

7.2   IMPROVING PRIVATE SECTOR QUALITY OF CARE

Despite improved scores on the post-training test and in particular, the relatively high proportion of pharmacists who indicated an understanding of the need for STI partners to receive management, the general counselling provided to the simulated male STI partners was poor. Only the rural pharmacists who had been equipped with STI information packets provided an acceptable level of counselling, i.e. at least 7 out of a possible 13 messages. Community retail pharmacists often work under severe time constraints and this often leads to very brief interaction with clients. Perhaps rural pharmacists, in view of the greater inaccessibility of clients to healthcare facilities, are more willing to spend appreciable time counselling clients. The suggestion that the more conscientious approach to counselling was linked to the higher proportion of female pharmacists in the rural intervention arm was rejected after multivariate ordinal regression models proved that gender accounted for negligible variation in the ordinal counselling outcome. However, the small sample size of 6 female pharmacists provides poor confidence in the derived statistical conclusions. The general counselling competencies of private doctors and nurses at

the end of a similar intervention study[9] (Harrison *et al,* 2000) was greater than what was reported in this study, although the comparison may be unfair due to differences in the standards of what constitutes appropriate counselling; while Harrison considered "three out of five counselling messages" to be appropriate, this study raised the total number of messages to remember to 7 out of a possible 13. In this study the frequencies of condom promotion, provision, and often demonstration were higher in pharmacies utilising information packets, pointing to the value of including condoms in information packets. The high percentage ($\geq 33\%$) of condom promotion indicates that pharmacists counselled at least one of the three clients on risk reduction. These findings are atypical to previous studies that failed to improve counselling on condom promotion, regardless of the STI management intervention (Adu-Sarkodie *et al.,* 2000; Chuc, 2002; Garcia *et al.,* 1998).

Garcia *et al.* (2003) measured the impact of a multifaceted STI management intervention, comprised of STI seminars, STI manuals, STI/HIV prevention packets and other project resource materials. The independent impact of the information packets on counselling and treatment could not be disaggregated from the intervention mesh, however the failure of the entire intervention to boost the counselling proficiency of pharmacists was telling. Similarly, the counselling competencies of nurses and doctors in rural Hlabisa (South Africa) who received training and STI packets were not significantly greater than a control, although treatments were more often correctly aligned with local guidelines (Harrison *et al.,* 2000). In this study, information packets contained STI information, referral notes for HIV testing and a list of neighbouring HIV testing sites, condoms and a diagrammatic aid for demonstrating condom use. In contrast to the aforementioned studies, our findings suggest that the utilization of information packets, aimed at facilitating STI counselling, promoted more comprehensive information exchange to clients in rural pharmacies only, whereas comparable treatment patterns were observed in the experimental and control groups of urban and rural arms (given the

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[9] STI training and STI packets containing drugs, information pamphlets, condoms and partner cards

absence of drugs in packets). Indisparate counselling levels in the intervention and control arms of urban pharmacies could possibly be attributed to the time pressures that urban pharmacists face on a daily basis; time constraints may have lead to poor utilization of information packets, which in turn minimised the effect of the intervention. The independent predicting influence of packet utilization in the multivariate analysis of the counselling outcome for UDS further corroborates this rationalization. It is plausible to suggest that community pharmacists practicing in rural areas feel more compelled to adopt an advanced primary healthcare role due to the relative inaccessibility to primary care clinics in these areas. Rural pharmacists may have been more proactive in implementing new tools (information packets) that could potentially bolster healthcare services in the community. The edge that rural pharmacists had over their urban counterparts in the treatment of GUS is perhaps also ascribed to the hypothesized needs-driven role of pharmacists in the towns of WC and subsequent independent upgrading of skills. Furthermore, rural pharmacies have a greater tendency to employ nurses on their premises (Ward *et al.,* 2003) with the effect that an environment more conducive to the exchange of clinical knowledge and skill becomes prolific. Notwithstanding the reasons furnished for the differences noted between urban and rural pharmacists, these should be considered in light of the very small sample size.

Although few of the comparative counselling scores in this study reached statistical significance, these findings could possibly be spurious due to the weak statistical power generated from a very poor response rate. On the other hand, unmeasured predictors may also have come into play: as alluded to earlier, the training materials utilized in the first phase of this study included pocketsize STI guidelines for the WC, containing the 13 elements of counselling, all STI algorithms and recommendations for partner treatment. These booklets were promoted as a tool to be used during practice and could have been more predictive of the counselling outcomes in the experimental and control group than the information packet itself. Since this variable was however not measured during the simulated client interview, this link remains

conjectural. A further reason for the lack of significant differences in counselling depth could be attributed to variances in the inherent counselling skills of pharmacists. Although pharmacists in South Africa and worldwide are extensively trained during their undergraduate years in general interpersonal communication and counselling (Hargie *et al.,* 1987), the actual counselling skill levels attained by individual pharmacists are subject to differences. Since an experimental-control design, as opposed to a pre-post design, is unable to remove the between-subject part of the variability of the outcome variable, the influence of this factor too remains unknown.

With regards to the therapies prescribed, a noteworthy finding was the apparent incongruence between behaviour and knowledge with respect to GUS treatment. Despite their inability to list even a solitary correct treatment regimen for GUS in the pre- and post-testing stage, pharmacists displayed a reasonable level of competence in treating simulated partners with suspected GUS. A plausible explanation for these seemingly contradictory findings is that pharmacists, for the purpose of the pre-post tests, studied from copious notes and were not provided with any leads as to the post-test content, while summarised clinical management guidelines were accessed during the treatment of simulated partners. The inclusion of these treatment algorithms in all training packages probably accounts for the reasonable level of success attained in the treatment of STI partners in control pharmacies as well. Therefore, the combination of an in-depth distance learning course coupled with pocket-sized STI management guidelines is recommended for enhancing actual practice.

Notwithstanding DOH efforts to improve access to STI management services in the South African public sector, the positive attributes of private sector care such as shorter waiting times, perceived guarantee of privacy and confidentiality, and after-hour access seem more appealing to clients (Aljunid, 1995; Swan & Zwi, 1997). In fact, it is speculated that the majority of clients (particularly males) seek STI care in the private sector (Schneider *et al.,* 2001; Wilkonson *et al.,* 1998). Regrettably, the

lack of regulated quality assurance in the private sector presents a major deterrent to achieving standardization of STI management (according to the syndromic approach) and this undermines public sector efforts to reduce the annual incidence of new infections. This problem is not unique to the South African milieu: surveys of private general practitioners and nurses in Karachi (Pakistan) found that only 33% of general practitioners were able to correctly treat UDS (Khandwalla *et al.,* 2000); 32% of Jamaican private practitioners issued appropriate therapies for mucopurulent cervicitis after a training intervention (Green *et al.,* 1998); in Gauteng, South Africa, only 20% of general practitioners could treat GUS while the appropriateness of UDS therapies depended on the medical insurance status of patients –46% of uninsured and 54% of insured patients received an effective drug combination – (Chabikuli *et al.,* 2002) and effective UDS baseline treatments (prior to an intervention) were provided by less than 30% of general practitioners in the same province (Schneider et al., 2005). In this study absolute treatment scores of 33% and above implied that pharmacists generally treated at least one of the three simulated clients with the correct combination of antimicrobials. As such, the overall results obtained in the intervention and control group reflect predominantly "good" therapeutic interventions, proving that pharmacists are able to (at the very least) provide equivalent standards of STI treatment to health care practitioners in private practice. One could argue that these results fall short of reflecting actual practice, given the directive from researchers to prescribe antimicrobials and ignore the incentives of selling the most profitable medicine. It is well known, for example that choices of medication prescribed and dispensed by private doctors are influenced by factors such as the medical aid/insurance status of the client, and marketing ploys of pharmaceutical companies (Chabikuli *et al.,* 2002). Therefore, the absence in this study of conflicting business and health care provider interests may have confounded the outcome of good adherence to recommended treatment guidelines, and may be a misrepresentation of actual practice in the future. In South Africa, however, this conflict has being mitigated by three legislative changes: firstly, the recent introduction of a new medicine pricing structure in South Africa does not allow for

hugely discriminating profit mark-ups between low and high costing medicines; secondly, the promotion of more affordable generic equivalents has become a mandatory element in the sale of medicine, and thirdly, the provision of perverse incentives during the marketing of medicines by pharmaceutical companies is now legally prohibited (Republic of South Africa, 1997a). Since profits now emanate from the provision of professional services – for which fees are levied – as opposed to gratuitous mark-ups on medicines, any future involvement in the management of STI bodes well for pharmacists economically and for DOH efforts to promote adherence to treatment guidelines in private practice.

7.3   STI PARTNER MANAGEMENT IN COMMUNITY RETAIL PHARMACIES

Evidence suggests that recurrent chlamydial infections in females – a risk factor for developing sequelae, including infertility – are predominantly a result of untreated or inadequately treated male sex partners (Blythe, *et al.,* 1992). Notwithstanding the relatively poor treatment and counselling levels achieved in this study, support for utilization of pharmacists in the management of male partners of previously diagnosed and treated STI index patients remains warranted. If patient-delivered therapy to partners places the responsibility for safe and efficacious use of antimicrobials with lay people, as is fast becoming acceptable practice in industrialized countries (Department of Health California, 2001), then surely pharmacists (medicine custodians) are prime candidates for delivering partner therapy from one of the most frequented settings for STI management, viz, community retail pharmacies.

7.4   STRENGTHS AND LIMITATIONS OF THIS STUDY

A strength in the design was the application of stratification and randomisation techniques to ensure representation from urban and rural WC in the correct

proportions; subsequently, this study was able to detect an independent correlation between regional and counselling variables. Additionally, the accuracy of study findings was enhanced through the repeated measurements of the same outcome variables by way of 6 – as opposed to a single – visits from simulated clients. Because simulated clients were instructed to request therapy from the head pharmacist only, this study provides accurate impressions and observations of how qualified pharmacists treat STI. Standardisation of assessments was further augmented by blinding simulated clients to the intervention and control assignment of pharmacies.

There are several limitations to this study. Perhaps the greatest weakness concerns the low participation rate. Although 80 pharmacists who participated in the first study (Ward *et al.,* 2003) had expressed interest in participating in a STI training course, few of them actually volunteered once the opportunity presented itself. This was particularly problematic for pharmacists from the rural Western Cape where only eight pharmacists began the study and seven completed it. In some of the analyses conducted it may be that this small number did not provide sufficient power to detect statistically significant differences that were being measured. The discord between expressed willingness to engage in STI training and actual participation was investigated in a subsidiary study reported in Chapter 8. In addition, to measure the pharmacist's ability to provide correct treatment to the partners, the study pharmacists were told that they could prescribe medication to clients who show up with the Department of Health partner notification slips. Since this is not a current practice in South Africa, the pharmacists were likely to assume that the men who presented to the pharmacy with this notification slips were, in fact, research assistants. Given the fact that these simulated STI partners were actually not in need of treatment may have left the study pharmacists less interested in spending their limited work time with those who were not truly in need of services.

Another possible limitation stems from the eligibility criteria in which only head pharmacists were permitted to participate, which inadvertently excluded younger pharmacists. This was done to ensure that participants were in decision-making roles and thus could freely adopt expanded clinical services. However, a consequence of this selection criterion is that the younger, newer graduates from pharmacy schools were not included. The concept of expanding clinical responsibilities of pharmacists is relatively new. It is quite possible that the younger, more recently trained pharmacists would have been more likely to participate in the study and to correctly apply the acquired skills and knowledge to the simulated partners than the older pharmacists whose training and work experience are directed towards dispensing prescribed therapies with a minimum of independent patient care.

Finally, the unique contextual factors within the South African milieu (described in the opening chapters of this thesis), which are difficult to control with rigorously designed and implemented research alone, may have influenced the outcomes of this study to some degree. As such, the evidence produced in thesis may have limited extrapolative power for other global contexts.

CHAPTER 8

RESISTANCE TO CHANGE: PREDICTOR OF POOR PARTICIPATION IN STI TRAINING COURSE BY COMMUNITY PHARMACISTS?

In a previous baseline survey, a group of randomly selected pharmacists in the Western Cape (WC) was surveyed to ascertain their knowledge, perceptions, attitudes and practices about the treatment of STIs (Ward *et al.*, 2003). Study findings suggested a great need for pharmacist training in STI management: when provided with a hypothetical clinical situation, it was found that for various STI, a maximum of only 17% of pharmacists (urban and rural) identified the correct medication. With a view to designing a future training intervention study, the interest of pharmacists in participating in this project was surveyed at the end of the evaluation. A large portion of both urban and rural pharmacists indicated a willingness to participate in the syndromic management of STIs and to receive the necessary training.
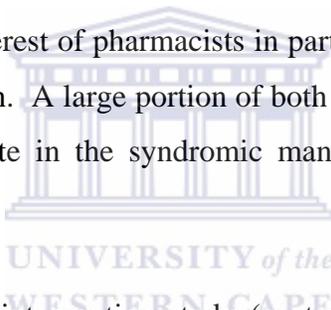
In the follow-up training intervention study (central to this thesis), several pharmacists who had previously indicated willingness to be trained subsequently declined on the basis of time constraints and/or disinterest; only 41% of a possible 100 were agreeable to the STI training. Given the established need and acknowledgment by pharmacists to being under-utilised in HIV prevention efforts, the question that arose was why the indication of willingness to participate in the training was not correlated with actual participation. In the face of a fundamental shift in the practicing scope of pharmacists, could resistance to professional growth be linked to the lack of participation in the STI training intervention study? In a bid to answer this question, an explorative study into resistance to professional growth ensued.

8.1   BACKGROUND

While the resistance to change is usually construed as a negative disposition, Marris (1984) explains how this "conservative impulse" and characteristic ambivalence to change is a vital precursor to adapting to a new situation. This applies provided that a "thread of continuity" with past ideas, representations and principles remains in the order that the link with the past system is preserved. As Robinson (1991, p.823) explained, "Where resistance occurs it should not necessarily be perceived as a negative force within the process of change. It should, rather, be examined for its function in terms of coping with and finding meaning in a rapidly changing (nursing) world".

8.1.1   Organisational resistance to change

Patrick (2001) described meaningful improvement in any organisation as involving three major questions: 1) what to change, ii) what to change to, and iii) how to make the changes happen. The first two issues are usually appropriately identified, but it is the third question that involves the dreaded "resistance to change". He detailed two of what he calls "layers of resistance" which correspond to this third question: i) the lack of a perceived clear path around the obstacles to the proposed change, and ii) a lack of follow-through even if agreement was reached to proceed with the solution. TOC (thinking and communication) processes involve sufficiency logic and necessity logic. The former involves ideas about "*if...then...because*" and the latter "*in order to...we must*". The human mind appears to have an innate ability to know whether these two constructs are congruent and logically consistent. This ability facilitates ease of communication and renders our world understandable and predictable.

Mauer (1996) identified three levels of intensity of resistance, namely: i) the questioning or opposition of an idea; ii) underlying forces contributing to resistance; and iii) deeply embedded generalised resistance. The first two levels imply that certain extrinsic factors determine the level of resistance and that if these factors are addressed and resolved, change can still occur. The third level, however, involves a resistance that is acontextual.

It is rooted in the psychologies of both the individual and the organisation. Because it reflects a general characteristic, and not opposition to specific change, it is therefore more difficult to address.

In her study, Trader-Leigh (2002) found the second level of resistance to be the most relevant. Based on the nature of this level, the underlying factor(s) can be addressed and change can thus be facilitated. In the follow up to a baseline survey by Ward *et al*. (2003), a lack of participation was exhibited by a large number of pharmacists who had expressed minimal concern about perceived obstacles to future management of STI, provided that legislation allowed for it. In Patrick's conceptualisation alluded to earlier, (Patrick, 2001), a clear path around any identified obstacles was perceived, yet a lack of follow through of an agreed-upon solution was perceived – that of training. Therefore, the poor response rate by community retail pharmacists in the main intervention outlined in this thesis could indicate a deeper level of resistance, which expresses itself as reticence to following through on the agreed-upon plan of action.

Studies on change and resistance to professional growth in the health care context are minimal compared to those done in non-health care organisational settings. Project 2000 was a UK project, which aimed to fundamentally change the manner in which nurses were educated and the manner in which they practiced. This was to meet the needs of a changing society and to provide a more holistic treatment programme which optimised the use of resources and which embraced a community–health-normalcy orientation as opposed to a hospital-ill-health one. Resistance was operationalised as increased stress, anxiety and ambivalence towards the project and was assessed by qualitative and exploratory methods by the use of interviews. The piloting phase of the evaluation of the project found that nurses in training were resistant to the increased focus on academic skills because they felt it was at the expense of "real" nursing skills (Robinson, 1991). This resistance could thus be due to the fact that the traditional concept of "the nurse" was being challenged. STI management is a proposed extended scope of practice for pharmacists, which could also challenge the traditional concept of a pharmacist.

Rosemann and Szecsenyi (2004) conducted a study amongst general practitioners (GPs) in Germany. These practitioners were asked whether they were willing to participate in a study aiming at improving the quality of care of patients with osteoarthritis, a condition considered to be relevant to the German context (as is STI management in the South African context). The time requirement was indicated as being approximately 30 minutes. Of the 76 general practitioners who were approached, only 27 agreed to participate in the proposed research. For the 49 GPs who did not want to participate (64%), the two most common reasons given for non-participation were lack of time and state-imposed administrative workload. The time factor was also cited as problematic by some community retail pharmacists who declined to participate in the main intervention study, however, addressing and removing these obstacles could positively favour the future provision of presumptive partner management, as an aspect of professional growth.

No studies regarding resistance to professional growth in the field of pharmacy have been conducted, certainly indicating a context that needs to be explored.

8.1.2 Formularising resistance to change

If individual resistance to change was to be measured, it would be necessary to find some form of quantitative measure. In the 1960's, David Gleicher of Arthur D. Little devised a formula for successful change. The formula, although derived from experience and untested in any systematic way, was popularised by Beckhard (of Beckhard & Harris) in the 1980's and by Dannemiller (of Dannemiller Tyson Associates) in the late 1990's (Adams, 2003). The formula, now come to be known as the Dannemiller-Tyson change formula, elegantly attempts to quantify the natural human tendency to resist change. The formula expresses change in terms of certain variables in a descriptive, non-mathematical way although the multiplication operator indicates that a synergy, as opposed to a mere summation, between the variables exists:

$$C = V \times D \times F > R,$$

where:

C refers to change that is a function of

V, a positive vision for the future,

D, dissatisfaction with the status quo, and

F, the first steps that have been identified and/or already done to accomplish change

Collectively, these variables must be greater than the natural human resistance to change (R). Dissatisfaction with the status quo in a business setting or scope of practice is not necessarily realised by the individual. Communicating the impact of not changing by management may sometimes be required before an individual becomes dissatisfied with the current situation. Only after the realisation that change is vital is it possible to envision a new and viable system to replace the current one. For this new vision to be a positive one, it must be attractive, attainable and credible. The first steps include the work that has already been done to make the change a reality, the identification of work processes and systems which will be impacted, how the change will impact both the internal structure (employees) and the external relationships (customers, suppliers, etc), and the resources required for the change to become a reality (Silverman, 2001). In Ward *et al*. (2003, p.610), "pharmacists regarded their role in the management of STI as under-utilised, and the majority strongly agreed or slightly agreed that there is a need for STI treatment services in community pharmacies". This sentiment could be regarded as both a positive vision for the future and dissatisfaction with the status quo. More than 90% of pharmacists indicated willingness to conduct a history-taking, counsel on prevention of STI and HIV, conduct partner-notification and provide follow-up. The majority of pharmacists were willing to conduct visual genital inspections, and a few indicated that they would perform a physical examination. Although "willingness" does not necessarily always translate into reality, this could tentatively be regarded as "first steps" because they indicate an altered mind set vis-à-vis traditional pharmacy practice.

As in Trader-Leigh's (2002) study, the concept of "natural human resistance to change" was not defined in the formula, but could be seen as a composite of Maurer's (1996) three levels of resistance above. In Marris' (1984) conceptualisation of change, it could be viewed as the "conservative impulse" which optimises human adaptation to a complex society.

In the context of community pharmacy practice in South Africa, these variables are applicable. The dramatic reaction to the pricing regulations implemented in 2004 indicated a great deal of dissatisfaction with the "new" status quo. As a result, morale is low. The fact that pharmacists are part of the general South African "brain drain" could be viewed as an expression of the lack of positive vision for the future.

Although the Dannemiller-Tyson model was formulated for an organisational context and refers to groups of people, it can also be individualised. Two pharmacists can have more or less the same dissatisfaction with the existing system and the same degree of vision of a new system, yet change occurs in the one case and not in the other because of innate differences in the degree to which the individual opposes change or develops personal vision and first steps for their pharmacy business.

8.1.3 Quantifying individual resistance to change

At this point, it is relevant to highlight two important issues. Firstly, although any kind of organisation, institution or society exhibits a synergy whereby its character is greater than the sum of the individuals comprising that group, individual factors definitely also play a role. As Oreg (2003, p.680) wondered, "some individuals seem to resist even changes that are consonant with their interests". Although addressing individual factors in any resistance to transformation is not sufficient in itself, it certainly will contribute to problem resolution.

Secondly, it appears as if the phrase "resistance to change" has become a concept in its own right. This state of affairs, however, has received some criticism. Dent and Goldberg (1999a) pointed out that Lewin first used the term as a systems concept to describe a force affecting both managers and employees, but the term has been perpetuated in an acontextual manner and increasingly interpreted in terms of individual psychological factors. In another article (Dent & Goldberg, 1999b, p.46), they pointed out that "*Change is too broad a term for people (individuals) to resist*". This is revealed by the fact that some people actively seek out and embrace change. They pointed out that perhaps the term "resistance to loss" may be more appropriate: fearing the loss of the known, the loss of status and the loss of comfortable routines. While this idea adds another dimension to the understanding of the conservatism and lack of transformation found in a multitude of aspects of our society, the concept of resistance to change cannot be completely discarded. In addition, because any organisation is by definition composed of people, both individual factors and dynamic context-based factors will play a role in any resistance to change.

The Dannemiller-Tyson formula represents simple quantification of the idea of change, but does not involve assessment of the actual resistance factor. This lead to the search for some kind of assessment and quantification of the resistance to change dimension of the formula. Because of the lack of congruence between willingness to participate in STI training and actual participation over a diverse group of pharmacists and contexts, it was postulated that individual and psychological factors could explain this apparent resistance to professional growth.

In their work on a work-orientated concept of coping with change, Judge *et al.* (1999) found that factor analysis combined various personality traits and characteristics into two factors that were linked to change behaviour. The Positive Self-Concept factor is composed of locus of control, generalised self-efficacy, self-esteem and positive affectivity. The Risk Tolerance factor consists of openness to experience, tolerance for ambiguity and risk aversion. These findings were based on assessment of managers at different levels in large corporations, which had recently undergone major changes such as

reorganisation, downsizing, alteration in top management, mergers and acquisitions. Wanberg and Banas (2000) obtained measures of self-esteem, optimism and perceived control from employees. By interpreting these measures as indicative of psychological resilience, they found that the greater subjects rated in their resilience scores, the greater their willingness to accept changes at work. This data was obtained from United States state organisations during, and not after, changes had occurred. Both these studies were beneficial in showing that resistance and change behaviours can be explained in part by individual psychological factors.

In both of these studies, the authors focused on measuring resistance to change as arising out of individual personality traits or tendencies. No attention was paid to whether the subjects exhibited a resistance based on Mauer's first two levels, namely whether they questioned the value of the new ideas, or whether there were certain factors within the organisation which contributed towards reticence to embrace the changes. Some subjects, for example, may have had legitimate reasons for not viewing the changes as beneficial. Organisational factors such as poor motivation by management structures, unfair practices, etc could have given the proposed changes less credibility. It is thus certainly a shortcoming of these two studies that such variables were not controlled for. The primary reason could be attributed to the particular professional discipline of the authors - psychology - where the emphasis is placed on the individual and where other broader factors are considered beyond their scope of investigation.

8.1.4   Resistance to change scale

In response to such and other studies, which used assessment instruments that had originally been designed for other purposes, Oreg (2003) developed the *Resistance to Change Scale* in an attempt to assess this disposition directly. This scale was "designed to tap an individual's tendency to resist or avoid making changes, to devaluate changes generally and to find change aversive across contexts and types of change" (Oreg, 2003, p.680). The development of the scale involved the assumption that resistance to change is

a multidimensional disposition with behavioural, cognitive and affective components. Based on a literature search, Oreg identified 6 sources of resistance that appeared to derive from an individual's personality, namely:

1) reluctance to lose control

2) cognitive rigidity

3) lack of psychological resistance

4) intolerance to the adjustment period involved in change

5) preference for low levels of stimulation and novelty

6) reluctance to give up old habits

For each of these sources, 4 – 10 questionnaire items were generated. In addition, four items were written to tap a general attitude towards change. Examination of the items for ambiguity and redundancy lead to elimination, addition or rephrasing of items. The final pool of items was administered in the form of a 6-point Likert scale to over 200 volunteers. Only 57% of these volunteers identified themselves as students, a common subject source of many studies. This adds validity to the scale because in part it controls for the fact that students may generally be more radical and open to change than non-students. Volunteers were approximately equal in terms of gender division, and ages ranged from 18 – 67 years. This controls for resistance being a function of personality traits as opposed to the demographic factors of gender and age. No significant differences were found between the different groups in terms of age, gender or student status. Factorial analysis of the items yielded four sub-scales:

1) Routine-Seeking

2) Emotional Reaction

3) Short-term Thinking

4) Cognitive Rigidity

Routine seeking measures a person's desire for novelty and unexpected events. Emotional reaction is an indication of how a person reacts to changes that do occur. Short-term thinking involves assessment of ideas of temporary inconvenience caused by change. Cognitive rigidity is a measure of the degree to which a person changes his/her mind and how consistent his/her views and opinions are.

To establish construct validity, the scale was administered to a sample of students. Independent scales to measure risk aversion, locus of control, dogmatism, tolerance for ambiguity, generalised self-efficacy, self-esteem, sensation-seeking and the "Big Five" (openness to experience, neuroticism, agreeableness, extraversion and conscientiousness) were also completed. The highest correlates of resistance to change scores were sensation seeking, risk aversion and tolerance for ambiguity. Self-esteem, extraversion and generalised self-efficacy exhibited a small but negative correlation with some of the subscales.

To establish concurrent and predictive validity, the scale was used to assess whether scores were able to predict voluntary change and resistance to innovation. It was found that student subjects with a high resistance to change as scored on the scale were significantly less likely to change their academic schedules than those with lower scores. In particular, the cognitive rigidity and the short-term focus scales were more important predictors. In another sub-study, "resistance to innovation" was operationalised as the degree of use by faculty members of a template for creating course websites. These websites were designed to facilitate administration and to offer interactive communication features. It was found that the higher the resistance to change scores of professors, the less likely they were to use these templates. It was also found that for those who did use the template, a high score predicted a longer time between introduction of the template and initial use thereof. These results helped establish the concurrent and predictive validity to the scale. The predictive validity of the scale is important in the current study because it can be used to predict resistance to professional growth prior to any change being implemented, i.e. the change involving a movement towards STI management.

8.1.5 Distillation of findings

If resistance is a human characteristic that enables adaptation, it can be expected that this trait would show individual variability. The second of Patrick's (2001) two layers of

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resistance involves lack of follow-through even if agreement was reached to proceed with the solution. Willingness to participate in training was not followed by action on behalf of the pharmacists. Willingness to participate indicated that the TOC concepts of necessity and sufficiency logic were congruent for pharmacists: *if* we are to treat STI's syndromically, *then* we need to be trained. Other factors thus appear to be linked to lack of participation. The lack of participation could not be accounted for by Mauer's (1996) first and second levels of intensity because training was agreed as necessary and was not opposed, and underlying factors underlying resistance such as lack of time were addressed by the fact that the training format was distance learning. The third, more deeply embedded form of resistance could thus be operating. The *Resistance to Change Scale* thus seems a useful measure to determine whether the natural human resistance to change was a factor in predicting participation in the STI syndromic management training.

The role of two other factors was also be explored. Since Ward *et al*. (2003) found that the male gender predicted willingness to provide syndromic STI treatment; it is possible that gender will also predict participation in the training. For two reasons, the year of graduation is also a possible predictor of participation in training. Firstly, pharmacists who had been practising in *apartheid* years might have been exposed to more changes due to the advent of democracy than those who only began practising post 1994. Exposure to a greater number of changes perceived as negative could result in a greater resistance to change. Secondly, there has been a trend in pharmacist training over the last 15 years to place increasing focus on clinical skills as opposed to academic knowledge and theory in isolation. Pharmacists who thus graduated before this change in focus may be more inclined to view STI management and treatment as beyond their scope of practice and hence may exhibit greater resistance to such training.

8.2   METHODS

Ethical approval was obtained from the institutional review boards of the University of Western Cape. The primary ethical issue taken into consideration was that of confidentiality.

8.2.1 Sampling and design

The design of this study was experimental, in that two independent groups, selected on the basis of either having participated in an STI training programme or not, were assessed for differences in underlying resistance to change.

The Cape Metropole stratum for the main study was selected as the sampling frame for this subsidiary study. Community retail pharmacies were divided into two groups, namely those who agreed to participate and those who declined. A random selection of twenty pharmacies from each group based on a t-test[10] estimate for sample size was selected for this study. During the data collection process, the sample frame for the control group had to be increased to thirty-two due to lack of response.

The experimental group consisted of those pharmacists who were participating in the syndromic management training provided by Ward. The control group consisted of those who had indicated that they wanted to participate, but then failed to do so when training began.

8.2.1.1 *Preliminary considerations*

A pilot study, conducted on five pharmacies from the initial sampling frame, informed the decision favouring telephonic as opposed to face-to-face recruitment and interviewing. Pharmacists cited variable time and space constraints as deterrents to spontaneous face-to-face interviews. The ensuing inconvenience of making multiple return visits to pharmacies instead of repeated telephone calls became the deciding factor.

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[10] The sample size was computed using the t-test and an additional 15% was added to the final number (Lehmann & Erich, 2006). With alpha set at 0.05 and beta at 0.2, a sample size of 13 per group (t-test +15%) was estimated to afford 80% power to detect an association between the two unpaired groups. A larger sample of 20 per group accounted for possible poor response rates.

8.2.2 Recruitment

Eligible pharmacists were contacted by a member(s) of the research group, informed of study aims and procedures, and given the assurance of confidentiality. Informed consent was obtained verbally, after which the interviewee was requested to complete a consent form, which would be faxed to him/her before the formal evaluation and returned to the interviewer before administration of the questionnaire. Participants were assured that their responses would be confidential and that questionnaires would not be linked with their names or other personally identifying information.

8.2.3 Instrument

A structured questionnaire was immediately administered telephonically to the participants by an interviewer. The overall resistance to change (RTC) score, the dependent variable, was a composite of 4 subcategories. Each of the following subcategories, in turn, was a composite of 4 or more statements, measured according to a likert scale ranging from 1 "strongly disagree" to 6 "strongly agree":

    (1) routine seeking (R/S), for example "I'd rather be bored than surprised." ;

    (2) emotional reaction (E/R), for example "When things don't go according to plans, it stresses me out" ;

    (3) short-term thinking (STT), for example "Changing plans seems like a real hassle to me" and

    (4) cognitive rigidity (C/R), for example "I often change my mind".

8.2.4 Statistical issues

8.2.4.1 _Measurements_

Age, year of graduation and gender were the independent variables of interest, which were hypothesized to influence resistance to change. The two latter variables were collected as

continuous data and later categorized for statistical analysis, while the gender variable was nominal. Ages were categorised into 10-year intervals: 30-39; 40-49, 50-59; 60-69.

Age data was collected because it was hypothesised that older pharmacists may be more rigid and less likely to adopt STI management in the scope of their practice. Additionally, increased age may be associated with a more conservative approach to matters of a sexual nature, as well as a lack of familiarity with STI's and HIV/AIDS due to not growing up in the culture of HIV awareness.

The year of graduation was categorised into three groups: pre-1990 (primarily drug-oriented care era), 1990-1995 (transition phase) and post-1995 (pharmacist-initiated, patient-centred care era). The rationale for this categorisation was to discriminate between those pharmacists who had obtained their degrees before, during or after pharmacy curricula changes (Pearson, 2007). One example of recent curricular changes was the implementation of pharmacist-initiated therapy at the University of Western Cape, which gave further emphasis on the pharmacist's role in patient care and counselling. The transition phase was included because paradigm changes occur gradually. The new school of thought may thus have met with some resistance and it may have taken time for the patient-driven concept to become entrenched. The third category of graduates was probably more inclined to accept this, since the focus of their degree had been centred around this concept.

It was thought that gender may be predictive of willingness to participate in the training because in Ward *et al*. (2003), the male gender was predictive of willingness to provide STI treatment.

8.2.4.2   *Statistical analyses*

The Wilcoxon rank-sum test (Wilcoxon, 1945) was used to establish whether a significant difference in RTC and sub-category mean scores existed between participants and non-participants. Statistical significance was set at a p value of less than 0.05.

An ordinal regression model consisting of the sub-categories (R/S, E/R, STT and C/R), group (participation or non-participation) age, gender and year of graduation was also applied to the data to ascertain whether these variables were significantly correlated with RTC scores. To enable this multivariate analysis, the average Likert scale scores were categorised: scores between 1 and less than 2 were termed "group 1", between 2 and less than 3 "group 2", between 3 and less than 4 "group 3", between 4 and less than 5 "group 4", between 5 and less than 6 "group 5" and scores of 6 "group 6".

8.3   RESULTS

Fifty-two pharmacists were approached to participate in the study: twenty comprised the experimental and thirty-two the control group. The final experimental group was composed of fifteen pharmacists. One pharmacy had closed down and three pharmacists indirectly refused to participate. A pharmacist was classified as indirectly refusing to participate if s/he persistently did not return telephone calls, asked the interviewer to telephone again at a later stage or put the interviewer on hold. In the control group, a total of thirteen pharmacists participated. Four pharmacies had closed down. Five pharmacists refused to participate, five indirectly refused to participate, three were no longer employed at the particular pharmacy and two were on leave. The final sample size was, however large enough to confer high statistical power.

The response rate for participation in the experimental group was 75%, while that in the control group was 40.6%. Of the combined group, ten pharmacists fell into the ages of 30-39, twelve pharmacists into the ages 40-49, four pharmacists into the ages 50-59 and two pharmacists into the ages 60-69 (table 12). Seventeen pharmacists graduated before 1990,

nine pharmacists between 1990-1995 and only two pharmacists after 1995. Twenty-five pharmacists were males and only three were female pharmacists.

The mean resistance to change score (RTC) of the experimental group was 3.1 and that of the control group 3.4. Although the experimental group thus exhibited a lower RTC score, group differences proved to be insignificant by use of the Wilcoxon rank-sum test for ordinal data ($p=0.08$).

In the experimental group the means for the subscales of Routine Seeking (R/S), Emotional Reaction (E/R), Short-term Thinking (STT) and Cognitive Rigidity (C/R), were 2.7, 3.4, 2.8 and 3.7 respectively. The corresponding mean scores in the control group were 2.8; 3.6; 3.1 and 3.9 respectively. For both groups, the C/R subscale yielded the highest mean, and the R/S subscale the lowest.

To determine whether, group (experimental/control), age, year of graduation, gender, R/S, E/R, STT and C/R were predictive of the total RTC score, ordinal logistical regression was used. None of these factors were found to have a significant association with the total RTC, and were not included in the results.

Table 23: Subject demographics, overall Resistance to Change scores and subscale scores expressed as frequencies and mean scores respectively (N=28)

	Participants N=15	Non-participants N=13
	n (%)	n (%)
Age		
30 – 39 years	7(43.8)	3(23)
40 - 49	5(31.3)	7(53.8)
50 - 59	3(18.8)	1(7.7)
60 - 69	0(0)	2(15.4)
Year of graduation		
Pre-1990	7(43.8)	10(76.9)
1990 – 1995	6(46.2)	3(23)
Post 1995	2(12.5)	0(0)
Gender		
Female	1(6.3)	2(15.4)
Male	14(87.5)	11(84.6)
	Means	Means
Subscales		
Routine seeking	2.7	2.8
Emotional Reaction	3.4	3.6
Short-term Thinking	2.8	3.1
Cognitive Rigidity	3.7	3.9
Resistance to change score (mean aggregate)[†]	3.1	3.4

[†]p-value=0.08 (Wilcoxon rank-sum test)

8.4   DISCUSSION

It was found that there was a greater success rate amongst the participants (experimental group) for the telephonic interviewing in comparison to the non-participants, which could be attributed to the fact that these pharmacists were already participating in the STI training, thus exhibiting a greater willingness to participate.

The insignificant differences with respect to resistance to change between the participants and non-participants indicate that lack of participation is not attributable to any natural human resistance to change. The apparent resistance to proposed training can therefore be interpreted as not being an intrinsic human characteristic, but due to external factors. The more superficial levels of resistance as outlined by Maurer (1996) could thus have been pertinent. Although the pharmacists were not related organisationally in terms of place of employment, they could be viewed as being organisationally related because of the practice of the same profession. The fundamental working conditions, economic stresses relating to both single exit pricing and a generally competitive market, and time constraints are common to the majority of practicing retail pharmacists. If the various extraneous factors can be altered in such a manner as to create a more favourable professional environment, there would be less resistance to professional growth - operationalised as resistance to change in this study. Participation in syndromic STI management could thus potentially be increased.

The high C/R score demonstrated by both groups suggests an inherent rigidity in mindset among pharmacists in general. Similarly, the low R/S score achieved by both groups possibly indicates that pharmacists in general would cope with alterations in daily routine; this may create the opportunity to gradually incorporate STI syndromic management. The similar scores obtained across both groups could also provide further support for the validity of the Oreg RTC scale.

Another reason for lack of participation could possibly be the content matter of the training. Rosemann and Szecsenyi (2004) approached 76 general practitioners, requesting whether they were willing to participate in a study requiring thirty minutes of their time. The study was aimed at improving the quality of care of osteoarthritis patients, a condition deemed to be relevant in the German context, as are STIs in the South African one. Only 36% were prepared to participate in the research, the others giving reasons of lack of time and administrative workload. For pharmacists, for whom treatment of clinical conditions is currently beyond their scope of practice, the nature of the treatment required could also be relevant. It may be more threatening to interact with patients regarding sexually transmitted infections than with arthritis. If a lack of participation was exhibited by general practitioners whose scope of practice by definition incorporates examination and treatment, how much more so in the case of a health care profession traditionally primarily involved in the dispensing of drugs?

Over the last twenty years, many changes have occurred in the practice of retail pharmacy such as, lay ownership, chain store pharmacies (MediRite, Click's, Dischem pharmacies to name a few) and the introduction of clinics or consultation rooms into pharmacies.

The latter could be viewed in a positive light and an implementation thereof may suggest a pharmacist's desire to have a more hands-on approach in the medical arena.

On the other hand, and perhaps the most controversial change has been the introduction of the recent pricing regulations and associated dispensing fees. When this was first proposed and introduced, it was met with outrage by the majority of retail pharmacists, primarily non-chain storeowners. The state-set prices permitted to be charged for prescription items drastically reduced profits. Smaller pharmacies are particularly affected because size, location or operating costs are not taken into account. Of the pharmacists interviewed,

the majority indicated that they felt disheartened by the situation and felt that the pricing structure was not conducive to the survival of a independently-owned community retail pharmacies, resulting in some pharmacies closing their doors. Some consequently did not see a future for their business and thus did not see the value in participating in research related to professional growth, particularly when experiencing stress related to ensuring the day-to-day survival of the operation.

Non-participation in training could thus rather reflect a negativity created in pharmacists by the pricing system rather than a lack of interest in professional growth. Refusal to participate in this study could also have reflected this generalized negativity rather than resistance towards STI training itself.

In the time period since the proposed introduction of an alternative pricing system however, many pharmacists have managed to be creative by generating alternative means of income or altering business hours. They have all thus adopted mechanisms to cope with the impending changes. This supports the above suggestion that professional growth in the form of STI management is achievable if favourable environmental and profession-related factors are created.

If retail pharmacies could charge for STI treatment and management, monthly turnover would be increased. In a situation of decreased profit margins, this may make pharmacists more inclined to participate in such treatment. The patient would also benefit because although s/he would need to pay for the service, the cost would be less than with a private medical practitioner, and less work time would be missed compared to receiving treatment at a public primary health care setting. Although the motive for providing treatment should ideally not be economically driven, it must also be understood that some pharmacists are operating under a great deal of economic stress and that any additional service provided would need to be economically viable and provide what the pharmacist would view as worthwhile remuneration.

It was thought that gender may be predictive of willingness to participate in the training because in Ward *et al*. (2003), the male gender was predictive of willingness to provide STI treatment. In this study, gender was not predictive of resistance to change, and hence of possible willingness to be trained. The sample, however, consisted of only three women. This small number may have therefore not provided sufficient power to detect gender differences. Had more women been included in this study, it may have been found that the male gender did predict participation. In the context of unequal power relations between the sexes, women may be more reluctant to manage STIs by means of physical examination of male patients. This may then be generalised to any patient, both male and female. Anecdotal evidence from the data collection process provides some support for this assertion. One of the male pharmacists said that all of the pharmacists who worked for him were women. These employees had expressed their unwillingness to become involved in this type of treatment as their pharmacy served a predominantly male, working-class clientele.

It was expected that participants who had graduated before 1990 would be more likely to resist this form of expanded scope of practice. The discipline of pharmacy practice was introduced into curricula in the earlier 1990s (Pearson, 2007). The objective was to develop in undergraduates a greater patient-centred as opposed to drug-focused orientation. Graduates having been exposed to this philosophy may have been considerably more amenable to the clinical interaction and history taking required by the syndromic management approach. Year of graduation, however did not significantly predict the RTC. This could indicate that pharmacists with primarily drug-oriented training can adapt to changes in their scope of practice.

It was also hypothesised that pharmacists practising in apartheid years might have been exposed to more changes in many realms of their daily living - due to the advent of democracy - than those who only began practising post-1994. The age of pharmacists could thus possibly be associated with change

behaviour. Two opposing outcomes could be possible. In the first instance, such pharmacists may have become more familiar with change and would therefore be less resistant to further changes. Alternatively, however, if all of these changes were perceived as negative, then an additional change would not be embraced. Naturally the latter outcome could be influenced by race group to a large degree. Year of graduation, however, was not significantly associated with RTC scores. This suggested that even the experience of many societal and economic changes experienced over the years did not create negativity towards an increased scope of, and hence change in, pharmacy practice.

8.5 SUMMARY OF MAIN FINDINGS

The most salient findings are summarised in bullet-point form below:

- No statistically significant difference was found between levels of RTC between participants and non-participants
- Year of graduation, gender, age and the various subcategories of resistance to change did not significantly predict the RTC scores

CHAPTER 9

CONCLUSION AND RECOMMENDATIONS

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The object of this final chapter is to reconcile the findings of this thesis with the primary research questions. In addition, a list of recommendations for follow-up studies and a proposed plan of action for the implementation of STI partner management in community retail pharmacies in South Africa are presented.

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9.1   DISTILLATION OF FINDINGS

The evidence presented in this thesis demonstrates that community retail pharmacists are able to improve their overall knowledge of STI, although their difficulty in memorizing correct treatment regimens points to the drawbacks of a potentially overloaded correspondence course. The poor translation of knowledge to general partner management among the majority of pharmacists, potentially demonstrates the importance of including a practical component in future training interventions. Furthermore, the limited demonstrable impact of STI information packets on partner management in fast-paced community retail pharmacies underscores the need to explore less cumbersome interventions.   Finally, despite the inconsistencies demonstrated by community retail pharmacists in the management of STI simulated partners, the continuing demand for these services in the informal sector warrants their future involvement in presumptive STI partner management.

The literature has demonstrated that professional change is most successful when it is instigated and driven by the profession itself, therefore, the unfounded concern that underlying resistance to change may have predicted poor participation in this study bodes well for future initiatives geared towards professional role expansion.

9.2   RECOMMENDATIONS FOR FUTURE TRAINING INITIATIVES

With a view to improve the impact of training interventions on future STI management in community retail pharmacies, the following recommendations are proposed:

a) Course material should be more succinct; presumptive management of partners should be the main emphasis, while all other STI topics should be provided as background information only.

b) Given the reality of pharmacist time constraints and the clear benefit of learner support, future training interventions targeting qualified pharmacists

should utilize communication technology that fosters greater intra- and interdisciplinary interaction, possibly through chat room forums.

c) With a view to close the gaps in knowledge and management of STI partners between urban and rural pharmacists, a further investigation into the explanatory factors behind the relative successes achieved in rural areas is warranted.

9.3   PROPOSED FOLLOW-UP PLAN

The proposed plan (and it's rationale) for effecting policy change and implementing the presumptive management of STIs in community pharmacies in South Africa is outlined below.

Presented in this thesis is a substantial body of evidence that supports the role of community retail pharmacists in the presumptive management of STI partners. The immediate way forward will be to disseminate the arguments and evidences presented in this thesis at a national and international level through: a) publication in a reputable journal known to have a wide audience ranging from practising private and public healthcare workers (particularly general practitioners and pharmacists) to health policy-influencers and makers, and b) presentations at selected public health, pharmaceutical and STI/HIV national conferences and at least one highly reputable and traditionally well-publicized international conference such as an HIV/AIDS conference. Further attempts will be made to engage directly with the STI/HIV directorate of the Western Cape, with a view to presenting elements of the study and a plan for implementing presumptive management services for STI partners in WC community retail pharmacies. Furthermore, a business case for the feasibility of offering STI partner management services will be developed for community retail pharmacies. This evaluation will take into account, inter alia, time taken to counsel, cost of treatment, willingness to pay by medical schemes and government, and cost of training.

The proposed plan for implementing partner management services will include strategies for: a) pharmacist training, b) PPI establishment, c) promoting interdisciplinary consultation, d) ensuring the regulatory oversight of services in community retail pharmacies.

 a) Training at undergraduate level

In theory, pharmacists already possess generic skills in prescribing, dispensing and counselling. However, the poor application of these skills in the area of syndromic partner management may stem from the limited attention conferred to the subject at an undergraduate training level – undergraduate courses offered in syndromic STI management are traditionally brief and purely theoretical. Thus, interventions should ideally be targeted at an undergraduate level of training. Future incorporation of partner management course material into a problem-based learning format coupled by opportunities for role-play and objective structured clinical examinations (customarily used to good effect in the training and assessment of pharmacy students in the management of selected acute and chronic health conditions) could potentially maximize the use of skills inherent to the profession.

b) Establishing PPIs

A mutually beneficial relationship between community retail pharmacies and the public health sector could be established: community retail pharmacists, in providing a vital public health service to the partners of index STI clients could potentially contribute to reducing the transmission of STI and therewith become a key role-player in lowering the incidence of HIV in the WC, while government funded treatments and professional remuneration for professional services rendered by community retail pharmacists could potentially increase the revenue-making capacity of community pharmacies.

c) Establishing local health professional networks

A professional network could be established between community retail pharmacists and the more traditional providers of STI management in public primary healthcare facilities, thereby fostering opportunities for consultation during the early implementation stages. Furthermore, this network could facilitate the implementation of a central record-keeping system whereby private sector partner management records (including partner notification slips received from partners) are fed into a centrally located PHC facility.

d) Regulation and supervision of services

The authenticity of partner management records (as determined through reconciling partner notification slips issued to index clients from public PHC facilities with slips "filled" by community retail pharmacists) could be verified and later archived by administrators employed in designated, centrally located public PHC facilities and subsequent quarterly stock checks in community retail pharmacies against the archived partner management records could be conducted by administrators of the local Department of Health. Furthermore, regular evaluation of the quality of STI partner management in community retail pharmacies could be evaluated through regular review of partner management records.

9.4   CONCLUDING REMARKS

The future of pharmacy hinges on the human constituents embodying the profession and while this thesis has proposed one potential avenue of change, it will remain a mere suggestion unless the profession is mobilised behind this ideology. To this end, external barriers toward change such as legislative restrictions, opposition by the medical fraternity and poor remunerative incentives should be minimised, while the evidence qualifying proposed advances within the profession should be maximised.

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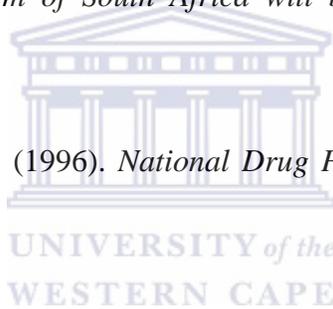
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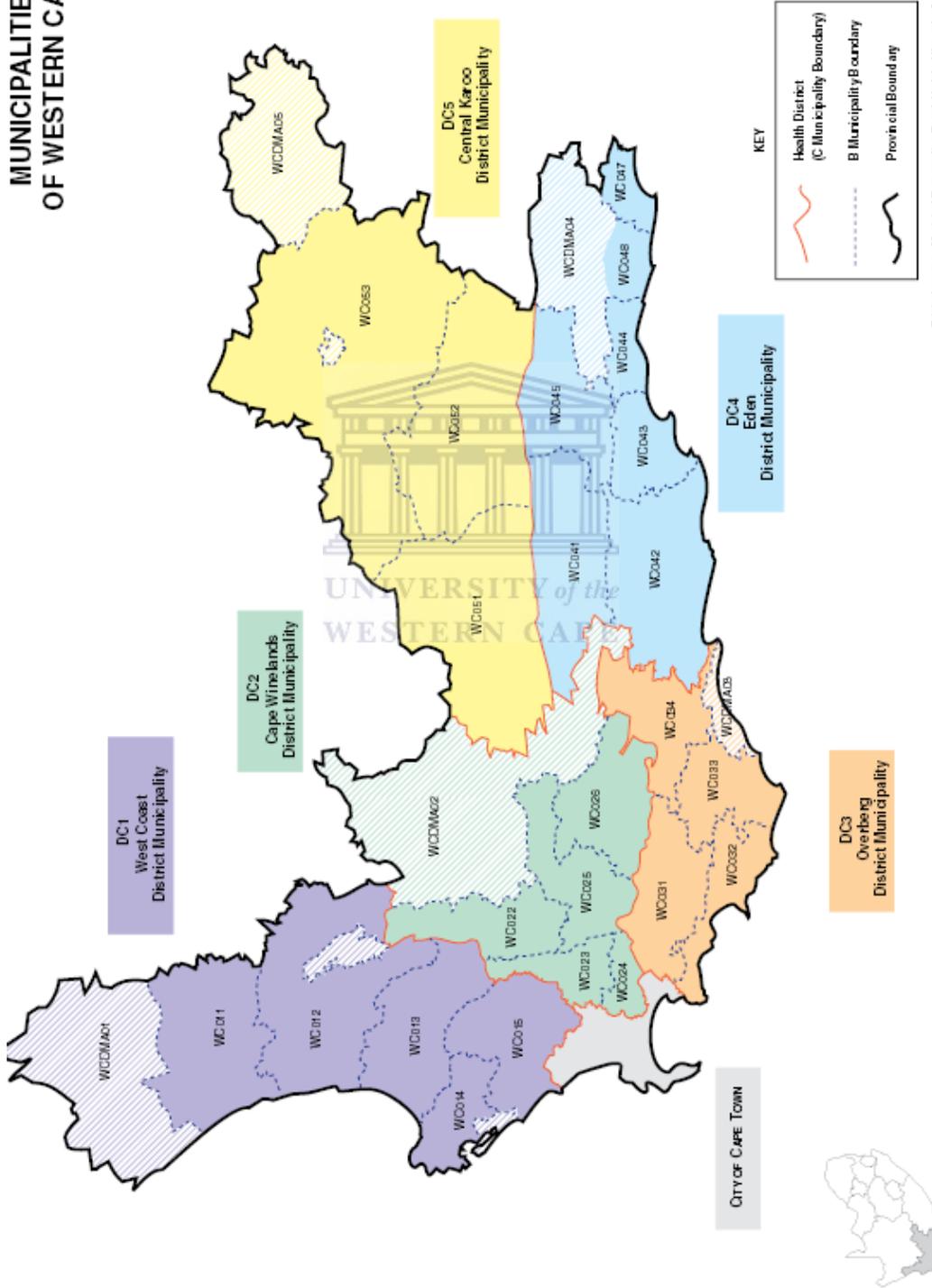
Source: South African Health Review (Dayi & Gray, 2006)

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FACULTY *of* NATURAL SCIENCES

SCHOOL OF PHARMACY

CONSENT TO PARTICIPATE IN RESEARCH

Expanding Presumptive Partner Management Of Sexually Transmitted Infections (STIs) To Western Cape, South African Community Retail Pharmacies: An Intervention Study.

Purpose and Background

Kim Ward (M. Pharm.), Professor Nadine Butler, and Prof. Peirre Mugabo from the University of Western Cape, School of Pharmacy are conducting a research study to measure the impact of providing training on the syndromic management of sexually transmitted infections to community pharmacists will have on their treatment practices.

A previous study of community pharmacists in the Western Cape confirmed anecdotal reports that patients often seek care for symptomatic sexually transmitted infections from community pharmacists. This study also identified knowledge gaps in syndromic management of sexually transmitted infections and demonstrated willingness on the part of community pharmacists to be trained in order to provide syndromic treatment for sexually transmitted infections.

You are being asked to participate in this study because you are a registered community pharmacist in the Western Cape.

Procedures

If you agree to participate in this study the following will occur:

1. You will participate in an STI distance-learning course on the theoretical aspects of syndromic management of sexually transmitted infections.

2. You will complete a written test that will assess knowledge of the theoretical aspects of syndromic management of sexually transmitted infections before the course begins.

3. You will complete a written test that will assess knowledge of the theoretical aspects of syndromic management of sexually transmitted infections after completing the course.

4. After the post-test you will be selected to either receive patient treatment packets to be distributed to simulated (mock) male partners who seek care for asymptomatic genital ulcer disease or urethral discharge or not to receive these packets.

5. You will receive a copy of manuals that describe treatment protocols for syndromic management of sexually transmitted infections.

6. You will receive visits by six male research staff who will pose as sexual contacts of patients with urethral discharge or genital ulcer disease.

7. You will treat these simulated partners as per study directive (referring elsewhere or counselling and providing a prescription for filling at public health dispensary).

8. These research staff will identify themselves as simulated patients after you have completed the management of their complaints.

9. The research staff will complete a form that indicates how you managed their cases.

10. You will be provided with written feedback from the investigators regarding how well you managed the simulated patients.

Risks/discomforts

1. The pre- and post-tests and materials presented in the training course may be unfamiliar. You may feel some discomfort learning about sexually transmitted diseases or your performance in the course.

2. You are free to discontinue the course and end your participation in the study at any time.

3. You may discuss your discomfort with the training staff.

4. Participation in research may involve a loss of privacy; however, your records will be handled as confidentially as possible. Your names will not be used on the pre- or post- tests or other printed materials associated with the study. You name will be linked to your study number and only research staff will have access to this linking file. Any publications or presentations of the findings from this study will not include personally identifying information.

Benefits

You may increase your knowledge of the theoretical aspects of syndromic management of sexually transmitted infections. This may assist you in the service you provide to patients who request information and or treatment from you at your pharmacy. There may be a societal benefit if presumptive partner management by community pharmacists reduces the incidence and prevalence of sexually transmitted infections and thereby, possibly reduce transmission and acquisition of HIV infection.

Costs

You will be required to fax this consent form back to the research assistant.

Questions

You have talked to Mrs. L. Maritz about this study and have had your current questions answered. If you have additional questions you may call her or Ms Ward at the University of Western Cape, School of Pharmacy (telephone:021-9593440).

If you have any comments or concerns about participation in this study, you should first talk with the researchers. If for some reason you do not wish to do this, you may contact the Committee on Human Research, which is concerned with the protection of volunteers in research projects. You may reach the University of California committee office between 8:00 and 16:00 Monday through Friday by calling 091 415 476 1814 or by writing: Committee on Human Research, Box 0962, University of California, San Francisco, CA, USA 94143

Consent

You will be given a copy of this consent form to keep.

Participation in research is voluntary. You are free to decline to be in this study, or to withdraw from it at any point without penalty of loss of benefits to which you are otherwise entitled. If you agree to participate, you should sign below.

_____   _____

Date   Signature of study participant

_____   _____

Date   Signature of person obtaining consent

PLEASE RETURN BY FAX TO MRS MARITZ AT 021-9593407

STD CASE MANAGEMENT

THE SYNDROMIC APPROACH

FOR PRIMARY HEALTH CARE SETTINGS

THE TRAINING MODULES

MODULE 1:
THE PUBLIC HEALTH SIGNIFICANCE OF STDs

- The epidemiology of STDs.
- Why STDs are a major burden for individuals, families, health services and national economies.
- The impact of STDs in the Western Pacific Region.
- The reasons for using the syndromic approach.

LEARNING OBJECTIVES

- Identify how STDs are transmitted and the factors that influence transmission.
- Appreciate the complications that can result from untreated STDs.
- Explore the extent of STDs, the true level of infection in a population, and why these are sometimes difficult to see from statistics.
- Understand how STDs are linked with the spread of HIV.

- Explain why the control of STD is so difficult, and what must be done to achieve control.
- Talk about STD rates in your country or area and explain why these rates may or may not reflect the true STD burden

- Explain some of the serious consequences and complications that can arise if STDs are left undiagnosed and untreated.

- Describe the two-way link between STDs and the spread of HIV and explain why STD control is important for HIV prevention.

MODULE 2:
USING FLOW-CHARTS
FOR SYNDROMIC MANAGEMENT

- Traditional approaches to STD case management and their limitations.
- The syndromic approach.
- The benefits of the syndromic approach for treating and preventing STDs.
- Flow-charts.
- How flow-charts are used to diagnose and treat STDs.

LEARNING OBJECTIVES

- Describe the problems with syndromic approach to treating patients with ST
- Describe the advantages that syndromic case management offers.
- Identify the main features and benefits of syndromic case management.
- Explain that there are different steps specified by flow-charts to diagnose an STD syndrome and treat patients.
- Identify your further learning needs, which will depend on your responsibilities as a member of a health care team.
- Be able to defend the using traditional approaches to those who criticize it.

MODULE 3:
HISTORY-TAKING AND EXAMINATION

- Verbal and non-verbal communication skills.

- How to interview and examine patients comfortably to get the greatest benefit from the flow charts when diagnosing an STD syndrome.

LEARNING OBJECTIVES

- Identify the four areas of information to cover during the interview.
- Recall the steps in conducting a clinical examination for men and women.
- List both non-verbal and verbal communication skills.
- Explain the value of using communication skills to gather information effectively, conduct a clinical examination and ensure patient compliance.
- Describe the challenges of interviewing a patient with a suspected STD and the need to offer privacy and confidentiality.
- Explain the importance of demonstrating your respect for each patient.
- Use the techniques, including several non-verbal skills, to establish rapport with a patient and begin a productive encounter.
- Ask questions effectively, keeping them free of moral judgement, preserving confidentiality, and using clear words that patient's understand.
- Use verbal skills to respond to a patient's emotions appropriately.
- Use open and closed questions appropriately and employ techniques to improve two-way communication with patients.
- Conduct an efficient examination of both male and female patients.
- Anticipate patients' anxiety and embarrassment, and acknowledge your own feelings.

MODULE 4:
## DIAGNOSIS AND TREATMENT

- The flow-charts for four syndromes, including specific signs and symptoms and a list of recommended drugs for each condition.
- The options for treating a patient with an STD syndrome.

LEARNING OBJECTIVES

- Remember and name the decisions and actions that consitute the four flow-charts to diagnose STD accurately.
- List the drug therapies and dosages for each diagnosis.
- Identify which drugs are recommended compared with those you have available in your health centre.
- Explain that patient education on a number of important issues and partner referral are a part of all the flow-charts.
- Use the four flow-charts to make a clinical diagnosis for a variety of case studies.
- Give the correct drug therapies and dosages for each diagnosis.

MODULE 5:
EDUCATING THE PATIENT

- Practical ways to inform and motivate patients about what they can do to help cure their infection(s) and prevent another one in the future.
- Skills to make education more effective.
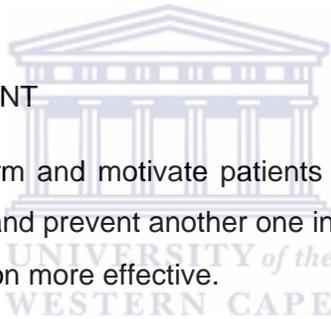
LEARNING OBJECTIVES

- Explain the differences between information-giving and education to encourage behaviour change.
- Explain why educating and motivating patients is vital in STD case management.
- Identify the main topics on which to educate STD patients.
- Identify six skills that will help you to educate and motivate patients.
- List the benefits of using condoms.
- Recall the basic steps for putting on condoms.
- Recognize and use a range of communications skills and a range of education skills for encouraging behaviour change in patients.
- Explain the benefits of using condoms to the patients.

- Demonstrate correct use of condom.

MODULE 6:
PARTNER MANAGEMENT

- Why partner management is important.
- Two methods of partner management.
- A practical approach to treating the partners of patients whom you have diagnosed with a STD syndrome.

LEARNING OBJECTIVES

- Discuss the importance of partner management.
- Explain its possible impact on individuals.
- List the differences between patient referral and provider referral.
- List the four issues to discuss with the patient.
- Name the skills to use when educating STD patients on the need to treat partners.
- Describe the value of referral cards at the health centre.
- Describe how to manage a referred partner based on the patient's diagnosis.
- Demonstrate the ability to manage a patient's partners, while maintaining each person's confidentiality.
- Demonstrate the ability to identify proper treatment action for a referred partner based on the patient's diagnosis.

PRE- AND POST-TRAINING TEST

Study number: _____

Region: Rural ☐   Urban ☐

Pharmacist's gender   Male   ☐   Female ☐

Pharmacist's age in years: < 30   ☐   30-39 ☐
                                    40-49 ☐   50-59 ☐
                                    60-69 ☐

Pharmacist's year of graduation: <1990 ☐   ≥1990 ☐

Total test score (out of 15marks):   ____

Total test score percentage: ____%

Question 1   (7 marks)

Indicate which STIs are curable or incurable by ticking the appropriate box (✔).

	Curable	Incurable
a) HIV/AIDS	☐	☐
b) Syphilis	☐	☐
c) Chlamydia	☐	☐
d) Gonorrhoea	☐	☐
e) Herpes	☐	☐
f) Trichomoniasis	☐	☐
g) Candidiasis	☐	☐
h) Chancroid	☐	☐

Question 2   (1 mark)

The STI most likely to facilitate HIV transmission is:

    a) Genital ulcer syndrome

    b) Any STI that causes genital inflammation

    c) An STI that causes urethral discharge or cervicitis

    d) An STI that causes vaginitis

Question 3   (1 mark)

Which of the following is the most high risk behaviour for STI?

    a) A man having unprotected oral sex with another man

    b) A man and a sex worker/prostitute having vaginal sex without a condom

c) Receiving manual stimulation (hand job) from a prostitute

Question 4   (1 mark)

A 21-year old man is complaining of frequent urination. After taking a history and examining him, you now know that he has some discharge from his penis. You also learn that he is recently married to a very young woman and has had unprotected intercourse with three different prostitutes since his wedding day. The BEST RESPONSE of the health worker is:

a) We will treat you today but it is important to treat your wife as soon as possible. Let's talk about how to do that.

b) We will treat you today and if your wife has similar symptoms to yours, she must go to her doctor right away.

c) It is critical for your wife to be treated immediately. If she is pregnant, this could cause big problems for her or the baby.

Question 5   (1 mark)

A 30-year old male has a three-day history of a thick, greenish discharge from his penis. He has received a stat dose of medication at a health facility. He returns in one week still complaining of a discharge. Which of the following is <u>likely</u> to be an explanation of the persistent discharge?

a) He had gonorrhoea, but has been reinfected.

b) The cause of his discharge was chlamydia infection

c) He had gonorrhoea which was resistant to the treatment given.

d) He was infected initially with both gonorrhoea and chlamydia

Question 6   (1 mark)

The practice of treating for two different types of genital ulcer disease (chancroid and syphilis) at the same time is:

a) Bad because an individual is rarely infected with two different pathogens

b) Wasteful because a good clinical examination will almost always lead to a specific diagnosis

c) Necessary because it is difficult to predict clinically the cause of many genital ulcers

d) Dangerous because of drug interactions

Question 7   (1 mark)

The protection against HIV provided by using condoms properly for each act of sexual intercourse is best expressed as:

   a) 25%
   b) 65%
   c) 95%

Question 8   (1 mark)

Which drugs are used in the syndromic management of STI to treat urethral discharge?

Question 9   (1 mark)

Which drugs are used in the syndromic management of STI to treat genital ulcers?

FACULTY *of* NATURAL SCIENCES
SCHOOL OF PHARMACY

Date:

Dear pharmacist,

We would like to thank you for your participation in the training phase of the project entitled: "The impact of an STI intervention on the syndromic management of STI in community pharmacies". Your participation has assisted us in evaluating the impact of a short STI correspondence course on the knowledge of STI management. Dissemination of the results at this point would be premature, given the incomplete statistical computation; however a reference to the final published work will be made available in the future.

We are now embarking on the second phase of this study: the provision of STI services in community pharmacies. We have enlisted the co-operation of local health authorities for the implementation of this phase; the sexual partners of individuals diagnosed and treated for an STI at neighbouring public STI clinics, will, for the purposes of the study be diverted to selected pharmacies for management by way of a partner notification slip bearing the encoded diagnosis of the index patient and the private community retail pharmacy as an alternative option to a public health clinic for seeking management. Interspersed with these real patients, we will send mock

patients to your pharmacy over the next 6 months to gather data pertaining to your proficiency in STI management. Mock patients will not be disparate from actual patients and you are therefore encouraged to manage every case equally. Partner treatment is based on the diagnosis of the index patient in the event of the partner being asymptomatic; conversely, if the partner presents with specific symptoms, the treatment is based on his/her clinical presentation (see manual for clarification).

STI management offered in pharmacies will not encompass any legally prohibitive actions such as conducting a physical examination or prescribing and dispensing of antimicrobials. It may however, at your discretion entail some or all of the following:

- Diagnosing the syndrome (using flowcharts) to be treated based on the diagnosis of the partner and/or the presentation of symptoms

- Reaching a treatment decision based on rational pharmacotherapy and in line with the flowcharts

- Writing out a prescription for the antimicrobials – valid for the purposes of this study for filling at a nearby public health dispensary free of charge.

- Counselling and educating patient about disease.

We implore you, as the pharmacist enrolled in this study, to attend to patients for this study. The data collected from any other pharmacist will render results invalid.

We have enclosed STI information packets intended to facilitate your provision of STI management. You may incorporate them into your counselling session with clients and dispense them to study patients at no cost.

Also included in the package received, is a sample partner notification slip which patients will produce to you. These slips will be encoded with the diagnosis of the index patient which can be decoded by making quick reference to the manual provided as part of the course material (pg. 9 of "Guidelines for the syndromic management of STI in the Western Cape"). Any patient presenting with an STI, yet failing to produce a contact slip, are not enrolled in the study, and you may handle these cases as you ordinarily would.

A researcher should contact you shortly to confirm your receipt of this package and to answer any questions you may have.

Kind regards

Kim Ward (M.Pharm)

PARTNER NOTIFICATION SLIP   DEPARTMENT OF HEALTH

CLINIC NAME:

Dear Madam/Sir,

Please go to a clinic as soon as possible. Although you might feel well, you need to be treated.
Take this slip with you to the clinic.

Besoek asseblief u naaste kliniek. Al voel u gesond, het u steeds behandeling nodig.
Neem hierdie briefie saam na die kliniek.

Nceda uye ekliniki msinyane. Noxa usiva ngathi uphilile kufuneka ufumene unyango.
Yiza neliphetshana e kliniki

THANKYOU   DANKIE   ENKOSI

This person's partner was treated for:

☐	MUS	☐	GUS	☐	GW	☐	RPR+
☐	VDS	☐	SSW	☐	PL		
☐	LAP	☐	BAL	☐	MC		

Please provide the appropriate syndromic management.
 For any questions, please call telephone number below.

Name: _____   Signature: _____

Date: _____   Clinic Stamp:

Tel:_____Fax:_____

CLINICAL MANAGEMENT ASSESSMENT FORM

A. In the management of the simulated client, did the pharmacist broach the following 13 elements of counselling?

	Yes	No
1. Inform about STIs transmission		
2. Inform about STI signs and symptoms		
3. Explain importance of prompt treatment		
4. Mention possible complications		
5. Risk of HIV transmission		
6. Promote VCT		
7. Counsel about risk reduction		
8. Promote condom use		
9. Provide/sell/attempt to sell a condom		
10. Explain how to use a condom		
11. Promote abstinence for the duration of treatment		
12. Explain the importance of completing treatment		
13. Promote treatment of other partners		

B. Did the pharmacist prescribe the correct treatment regimen (according to WC treatment guidelines)?

Yes ☐   No ☐

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CONSENT TO PARTICIPATE IN RESEARCH

Resistance To Change: Predictor Of Poor Participation In STI Training Course By Community Retail Pharmacists?

Purpose and Background

Kim Ward (M. Pharm.) from the University of Western Cape, School of Pharmacy is conducting an exit interview with a sample of participants and non-participants from the study entitled, "Extending presumptive partner management of sexually transmitted infections to Western Cape, South African community retail pharmacies: An intervention study." The poor enrollment into the aforementioned study will be investigated to determine underlying contributory factors.

You are being asked to participate in this study because you were approached to participate in the above-mentioned study.

Procedures

If you agree to participate in this study, you will participate in a telephonic interview that will last 7-8 minutes.

Risks/discomforts

Participation in research may involve a loss of privacy; however your records will be handled as confidentially as possible. Your name and location of your pharmacy will not appear on the questionnaire and will only be linkable by code.

Costs

You will be required to fax this consent form back to the research assistant.

Questions

You have talked to James Stocken about this study and have had your current questions answered. If you have additional questions you may call him or Ms Ward at the University of Western Cape, School of Pharmacy (telephone:021-9593440).
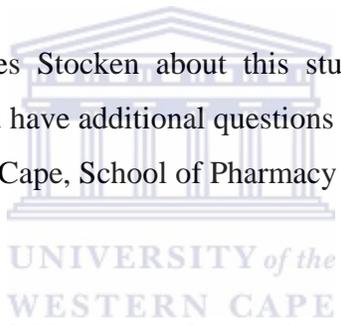
Consent

You will be given a copy of this consent form to keep.

Participation in research is voluntary. You are free to decline to be in this study, or to withdraw from it at any point without penalty of loss of benefits to which you are otherwise entitled. If you agree to participate, you should sign below.

_____   _____

Date   Signature of study participant

_____   _____

Date   Signature of person obtaining consent

PLEASE RETURN BY FAX TO JAMES STOCKEN AT 021-9593407

RESISTANCE TO CHANGE QUESTIONNAIRE

Study number: _____

Region: Rural ☐   Urban ☐

Pharmacist's gender   Male ☐   Female ☐

Pharmacist's age in years: < 30 ☐   30-39   ☐

                                        40-49 ☐   50-59 ☐

                                        60-69 ☐

Pharmacist's year of graduation: <1990 ☐   ≥1990 ☐
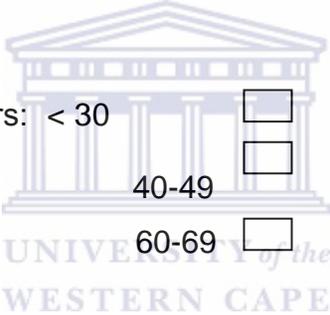
Please provide the most appropriate answer, where 1 indicates strongly disagree and 6 indicates strongly agree

1. I generally consider changes to be a positive thing.

1	2	3	4	5	6

Strongly disagree   Strongly agree

2. Once I've come to a conclusion, I'm not likely to change my mind.

1	2	3	4	5	6

Strongly disagree   Strongly agree

3. I like to do the same old things rather than try new and different ones.

1	2	3	4	5	6

Strongly disagree   Strongly agree

4. Often, I feel a bit uncomfortable even a about changes that may potentially improve my life.

1	2	3	4	5	6

Strongly disagree   Strongly agree

5. I'd rather be bored than surprised.

1	2	3	4	5	6

Strongly disagree   Strongly agree

6. If I were to be informed that there's going to be a significant change regarding the way things are done at work, I would probably feel stressed.

1	2	3	4	5	6

Strongly disagree   Strongly agree
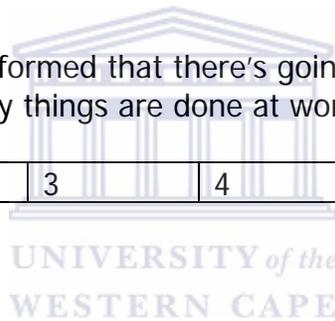
7. Once I've made plans, I am not likely to change them

1	2	3	4	5	6

Strongly disagree   Strongly agree

8. When things don't go according to plans, it stresses me out.

1	2	3	4	5	6

Strongly disagree   Strongly agree

9. I often change my mind

1	2	3	4	5	6

Strongly disagree   Strongly agree

10. My views are very consistent over time.

1	2	3	4	5	6

Strongly disagree   Strongly agree

11. Whenever my life forms a stable routine, I look for ways to change it.

1	2	3	4	5	6

Strongly disagree   Strongly agree

12. When someone pressures me to change something, I tend to resist even if I think the change might benefit me.

1	2	3	4	5	6

Strongly disagree   Strongly agree

13. When I am informed of a change of plans, I tense up a bit.

1	2	3	4	5	6

Strongly disagree   Strongly agree

14. I sometimes find myself avoiding changes that I know will be good for me.

1	2	3	4	5	6

Strongly disagree   Strongly agree

15. If my boss changed the criteria for evaluating employees, it would make me feel uncomfortable even though I would do just as well without having to do any extra work.

1	2	3	4	5	6

Strongly disagree   Strongly agree

16. I'll take a routine day over a day full of unexpected events any time

1	2	3	4	5	6

Strongly disagree   Strongly agree

17. I change my mind easily.

1	2	3	4	5	6

Strongly disagree   Strongly agree

18. Changing plans seems like a real hassle to me.

1	2	3	4	5	6

Strongly disagree   Strongly agree

Thank you for your time and cooperation.