
Improving STI/HIV Passive Partner Notification using Quality Improvement Methods in Malawi



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DECLARATION

I, Mitch Matoga, declare that this research report is my own original work. It is being submitted for the degree of Master of Science Epidemiology in the branch of Implementation Science to the faculty of Health Sciences at the University of Witwatersrand - School of Public Health, Johannesburg. This work has not been submitted before for any degree or examination at this or any other university.



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ABSTRACT

Introduction

Human Immunodeficiency Virus (HIV) and other curable Sexually Transmitted Infections (STIs) constitute a large public health burden world-wide. The control of HIV and STIs is incomplete if sexual partners of individuals with HIV and STIs are not identified and treated. The proportion of sexual partners that present to health facilities for screening and treatment is low in the sub-Saharan African (SSA) region. A recent study in Malawi reported a sexual partner referral proportion of 24% through passive partner notification. Several other approaches to partner notification (PN) have been shown to be feasible, acceptable and cost-effective for SSA. However, passive PN is widely used as the standard of care (SOC) and is the most preferred approach for resource-limited settings including Malawi. The low proportion of sexual partner referral points to the need to improve the efficiency and effectiveness of the SOC method of PN in order to realize a better yield of sexual partners in Malawi and SSA.

Methods

A pre- and post-intervention quasi-experimental study was conducted at Bwaila STI Unit (BSU) in Lilongwe Malawi from January to June 2017. At baseline, we estimated the proportion of sexual partner referral and identified health system-related factors that influenced PN at BSU through interviews with health workers and clinic observations. Based on the baseline findings, a three-prong intervention was designed through expert consultation and implemented with a quality improvement (QI) team using the model for improvement (MFI). The intervention included: early start time of the clinic; shortening of the group health talk and expedited clinic flow for sexual partners. Each intervention was tested twice through 1-week long test cycles and then combined into one package and tested twice. Process data were collected and monitored using run charts. We used run charts to assess for non-random signals of change in the PN process and assessed for a 10%

increase in the sexual partner referral proportion between the pre- and post-intervention periods at 95% power and at $\alpha=0.05$.

Results

At baseline, the proportion of sexual partner referral was 15.6%. Experts included BSU staff, research staff and Ministry of Health officials who were involved in the selection of interventions based on findings from the interviews and clinic observations. The QI team consisted of the investigator, a nurse-in-charge, a counselor, a clinic receptionist and a clinic aide who championed implementation of the intervention. In the post intervention period, we assessed 267 patient records. The median age was 29 years and 56% were female. Out of the three interventions, the team managed to shorten the duration of the group health talks from 56 minutes to less than 40 minutes and expedited the clinic flow for partners by reducing the duration of clinic stay by 45 minutes. However, the target clinic start time of 08:00 hours was not achieved. The post-intervention proportion of sexual partner referral was 21.4% representing a statistically significant increase of 37% ($P=0.04$). There was an upward trend in data points on the run chart which was indicative of a non-random signal of improvement in the proportion of sexual partners.

Discussion

Our results demonstrate that passive PN can be successfully improved through use of the model for improvement in Malawi and suggest that our intervention was highly effective at increasing the proportion of sexual partner referral. However, despite this increase, the proportion of sexual partner referral remains suboptimal. More effort is required to increase the proportion of sexual partner referral in Malawi.

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ACRONYMS

AIDS	-	Acquired Immunodeficiency Syndrome
ART	-	Antiretroviral therapy
BSU	-	Bwaila STI Unit
ERIC	-	Expert Recommendation for Implementing Change
HIV	-	Human Immunodeficiency Virus
HPTN	-	HIV Prevention Trials Network
HREC	-	Human Research Ethics Committee University of the Witwatersrand
HTS	-	HIV Testing Services
IQR	-	Interquartile range
MFI	-	Model for Improvement
MoH	-	Ministry of Health
NHSRC	-	National Health Sciences Research Ethics Committee
PDSA	-	Plan-Do-Study-Act
PITC	-	Provider Initiated Testing and Counseling
PN	-	Partner Notification
QI	-	Quality Improvement
RLS	-	Resource-Limited Settings
SOC	-	Standard of care
SPC	-	Statistical Process Control
SSA	-	Sub-Saharan Africa

STI - Sexually Transmitted Infections

TasP - Treatment as Prevention

UNAIDS - United Nations Program on HIV&AIDS

UNC - University of North Carolina

WHO - World Health Organization

Table of Contents

Declaration	i
Abstract.....	ii
Acknowledgements	iv
Acronyms.....	v
Table of Contents	vii
List of Tables.....	x
List of Figures	xi
 CHAPTER ONE.....	 1
 1.0 INTRODUCTION.....	 1
1.1 BACKGROUND	1
1.2 PROBLEM STATEMENT	3
1.3 JUSTIFICATION	4
1.4 LITERATURE REVIEW.....	4
1.4.1 HIV in Malawi.....	4
1.4.2 Sexually Transmitted Infections in Malawi.....	5
1.4.3 Sexually Transmitted Infections and HIV infection	5
1.4.4 Partner Notification.....	6
1.4.5 Partner Notification in Malawi.....	8
1.4.6 Barriers and Facilitators for Partner Notification.....	8
1.4.7 Quality Improvement in Health Research.....	9
1.4.8 Quality Improvement Research on Partner Notification in Malawi.....	10
1.5 AIMS AND OBJECTIVES	10
1.5.1 Overall Aim	10
1.5.2 Specific Objectives	10
 CHAPTER TWO.....	 11
 2.0 METHODOLOGY.....	 11
2.1 STUDY DESIGN	11
2.2 STUDY SETTING	12

2.3	STUDY POPULATION	13
2.4	SAMPLING PROCEDURES	13
2.5	SAMPLE SIZE.....	14
2.6	THE PROCESS AND MEASURES (OUTCOME, PROCESS AND BALANCING MEASURES)	14
2.6.1	The Process.....	15
2.6.2	Outcome Measures	16
2.6.3	Process Measures.....	17
2.6.4	Balancing Measures.....	17
2.7	STUDY PROCEDURES AND DATA COLLECTION	18
2.7.1	Pre-intervention Phase: Baseline Assessment	18
2.7.2	Intervention Phase: Implementation	21
2.7.3	Formation of a Quality Improvement Team (QI team).....	23
2.7.4	Implementation of the QI interventions	23
2.7.5	Post-intervention Phase: Post-intervention assessment	29
2.8	DATA ANALYSIS	30
2.9	ETHICAL CONSIDERATIONS	33
CHAPTER THREE.....		34
3.0	RESULTS.....	34
3.1	BASILINE ASSESSMENT	35
3.1.1	Demographic Characteristics.	35
3.1.2	Key-informant Interviews	36
3.1.3	Clinic Observations.	40
3.2	THE IMPROVEMENT PROCESS (THE INTERVENTION)	41
3.2.1	Intervention One: Clinic Start Time	41
3.2.2	Intervention Two: Shortened Duration of the Group Health Talk...43	
3.2.3	Intervention Three: Expedition of sexual partner clinic flow	44
3.2.4	Combined Intervention.....	46
3.3	POST-INTERVENTION ASSESSMENT.....	48
CHAPTER FOUR.....		50
4.0	DISCUSSION.....	50
4.1	PARTNER NOTIFICATION.....	51
4.2	BENEFITS OF PARTNER NOTIFICATION.....	51

4.3	BASELINE PROPORTION OF SEXUAL PARTNER REFERRAL.....	52
4.4	HEALTH SYSTEM-RELATED FACTORS INFLUENCING PN	52
4.5	THE USE OF THE EXPERT OPINION (CONSULTATIVE MEETING) AND QI TEAM.....	54
4.6	OUR INTERVENTION: CHOICE, IMPLEMENTATION (PDSA) AND RESULTS.....	55
4.7	STRENGTHS AND LIMITATIONS	58
4.8	CONCLUSION AND RECOMMENDATIONS	59
BIBLIOGRAPHY.....		61
APPENDIXES.....		68
	Appendix I: Plagiarism Declaration	69
	Appendix II: Sexual Partner Notification Slips for Bwaila STI Unit.....	70
	Appendix III: Bwaila STI Unit Group Health Talk Job Aide.....	71
	Appendix IV: Improving STI/HIV passive Partner Notification Using Quality Improvement Methods In Malawi Research Study	74
	Appendix V: Improving STI/HIV Passive Partner Notification using Quality Improvement Methods	80
	Appendix VI: Improving STI/HIV Passive Partner Notification using Quality Improvement Methods	81
	Appendix VII: Model for Improvement	82
	Appendix VIII: Formative Phase HREC Approval.....	83
	Appendix IX: Intervention Phase HREC Approval.....	84
	Appendix X: NHSRC Ethics Approval.....	85
	Appendix XI: Letter of support from Lilongwe District Health Office. . .	86

List of Tables

Table 1: The three-prong intervention and process and balance measures .	26
Table 2: Demographic characteristics of patients attending Bwaila STI Unit from June 2016 to December 2016	36
Table 3: Results for the baseline clinic observations	40
Table 4: Demographic characteristics of patients at Bwaila STI Unit in the post-intervention period (May 2017)	48

List of Figures

Figure 1: Schema of the clinic flow and partner notification process at BSU	16
Figure 2: Schema showing distribution of patients at BSU in the pre-intervention period	35
Figure 3: PDSA cycle 1 for Clinic Start Time	41
Figure 4: PDSA cycle 2 for Clinic Start Time	42
Figure 5: PDSA cycle 1 for Duration of Health Talk	43
Figure 6: PDSA cycle 2 for Duration of Health Talk	44
Figure 7: PDSA cycle 1 for Expedited Partner Visit	45
Figure 8: PDSA cycle 2 for Expedited Partner Visit	46
Figure 9: PDSA cycle 1 for Combined Intervention	47
Figure 10: PDSA cycle 2 for Combined Intervention	47
Figure 11: Trend in proportion of sexual partners during the study period	49

Chapter 1

1.0 INTRODUCTION

The purpose of this research was to identify health system factors that influenced passive partner notification and to design a quality improvement project to improve the proportion of sexual partners identified at Bwaila STI Unit in Lilongwe, Malawi. This chapter details the broad issues in literature around the research topic and narrows down to the gap in knowledge from which the research question was derived, why the research question is important, the specific aims and objectives of the research.

1.1 BACKGROUND

Curable sexually transmitted infections (STIs) date back to ancient times. Since then, curable STIs have remained a major public health problem worldwide. From around 1980, the burden of curable STIs has been compounded by Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome (HIV and AIDS) [1] which has resulted in HIV and AIDS being one of the greatest public health challenges of this generation. Curable STIs are an important co-factor in HIV transmission as they increase the risk of HIV acquisition by three-fold or more [1]. In 2015, there were 2.1 million new infections with 36.7 million people living with HIV worldwide. Eastern and southern Africa is the world's most affected region with about 19 million people living with HIV by 2015 [2]. On the other hand, more than 1 million people acquire curable STIs every day worldwide [1]. Gonorrhea, chlamydia, trichomoniasis and syphilis, the four most common STIs, account for an estimated 499 million new cases each year with the largest burden experienced in resource-limited settings (RLS) [3]. Sub-Saharan Africa (SSA) is estimated to experience about 69 million cases per year [3]. HIV and curable STIs together constitute a huge public health burden.

Malawi is one of the countries within the SSA region that is significantly affected by the HIV and AIDS pandemic. In 2015, Malawi had about 1 million people living with HIV and an estimated HIV prevalence of 9.1% [4]. Malawi is also heavily burdened by curable STIs. Data on national STI prevalence in Malawi are rare however it was estimated that in 2015, from a population of about 16 million, 15% of women and 10% of men reported to have had an STI nationwide [5].

People with HIV and/or other curable STIs share similar sexual characteristics and are considered to have high risk sexual behavior [6]. Additionally, people with curable STIs, especially with those genital ulcer disease and penile discharge, have a higher likelihood of acquiring HIV, and transmitting HIV if already HIV-positive [7]. In recognition of this dual burden, The Joint United Nations Program on HIV and AIDS (UNAIDS) and the World Health Organization (WHO) recommend that priority should be placed on programs aimed for prevention and care of STIs which in turn help to prevent transmission of HIV [8].

Despite the UNAIDS and WHO recommendation, over the years, effort and resources have been directed towards fighting HIV neglecting curable STIs. The fight against HIV and AIDS has yielded promising results both globally and within the region. For instance, the number of people on treatment in eastern and southern Africa has doubled and AIDS-related deaths have decreased by 36% since 2010 [2]. However, despite the observed gains in treatment and mortality reduction, the number of new HIV infections has been estimated to have remained static at about 1.9 million globally [8]. One of the reasons for the stagnated progress in fighting HIV could possibly be as a result of neglecting STIs which increase the risk of HIV acquisition [1]. This underscores the need for focusing effort and resource towards STI care and prevention.

Identifying people with STIs, who are predominantly people with high risk sexual behavior, is a pivotal step in the care and prevention of STIs and HIV. Equally important is the identification of sexual partners of people with STIs as they are at risk for acquisition of

STIs and HIV [9]. Index-partner trailing presents an opportunity for screening, early detection, treatment and prevention of transmission of STIs and HIV [10]. STI clinics are an important entry point for reaching out to partners of individuals infected with STIs or HIV [7]. The method used in STI clinics and other service points to reach out to sexual partners is called partner notification (PN) [10]. PN is defined as a process of informing sexual contacts of a patient with an HIV/STI that they may be at risk [9].

There are three main approaches to PN; provider-oriented (active), patient-oriented (passive) and contract partner notification. Provider-oriented PN is conducted by a trained healthcare provider, patient-oriented PN is conducted by the patient and contract PN can be conducted by either the patient, the healthcare provider or both [9]. Contract PN is an approach where index patients provide contact information of their sexual partners and are given a period of time to notify and refer/bring their partners to the hospital [10]. However, passive PN is the recommended first step in partner notification for RLS by WHO and it is the most widely used and preferred method for patients and their partners in many settings [11, 12].

1.2 PROBLEM STATEMENT

Despite being the preferred and widely used method, passive PN has had minimal success in identifying of sexual partners for both STIs and HIV [9]. In Malawi for instance, a recent study showed that only 24% of partners returned to a clinic for HIV testing and counseling through passive PN [9]. Reasons for the poor yield of sexual partners are largely setting-specific [10,11]. Efforts to improve the yield of sexual partners through PN have shown promising results in research settings but have not been satisfactory in routine practice because most PN interventions have not been widely adopted and utilized by the ministries of health [9,13]. Furthermore, most research efforts have focused on designing and testing new interventions for partner notification and not improving already existing PN approaches [9,13]. The low proportions of partner referral through passive PN are unsatisfactory and pose a big challenge for prevention of HIV and STI transmission.

1.3 JUSTIFICATION

Research has shown that other approaches to PN are feasible and cost-effective for Malawi [9,14] and the SSA region [15,16]. However, despite the low yield of partners, passive PN has remained the standard of care (SOC) method for partner notification in Malawi and many other countries within the region. This points towards the need to improve the effectiveness of passive partner notification in Malawi and within the region.

In this study, we intend to increase the proportion of sexual partners who present to health facilities through PN by using a quality improvement method called the Model for Improvement (MFI). By using this method, we hope to improve the efficiency and effectiveness of the passive partner notification process without necessarily designing a new intervention. Our approach will concentrate on identifying health systems-related factors that affect the passive partner notification process and tailor design setting-specific interventions to improve the efficiency of the processes involved in passive PN and ultimately, the proportion of sexual partner identified. So far, no quality improvement research on partner notification has been conducted in sub-Saharan region, including Malawi. We hope that this study will demonstrate a quality improvement approach that the ministries of health can adopt and scale-up with ease. We believe that the information gained through this research will contribute towards the body of literature in implementation science epidemiology.

1.4 LITERATURE REVIEW

1.4.1 HIV in Malawi

In Malawi, HIV and AIDS was first discovered in 1985. Since then the prevalence significantly increased and peaked at 16.4% among persons aged 15-49 years in 1999. Subsequently, the prevalence has been decreasing steadily to reach the current low at 9.1% in 2015 [4]. This decline has been attributed to strong multi-faceted interventions [14].

Even though this trend is reassuring, Malawi remains one of the countries highly burdened by the HIV epidemic. In 2015, there were 1 million people living with HIV and AIDS and about 27,000 HIV-related deaths. The HIV prevalence is twice as high in urban areas compared to rural areas (14.6% versus 7.4%) [5]. Despite the high HIV prevalence rates, HIV testing rates are reported to be low. In 2015, 95% of women and 96% of men knew where to access HIV testing but only 44% of women and 42% of men had been tested for HIV [5]. However, when HIV testing is offered, the response rate is 90% meaning that there is need for better avenues to provide HIV testing to the population [5].

1.4.2 Sexually Transmitted Infections in Malawi

Malawi, just like many other countries in resource limited settings, uses syndromic approach for management of STIs as recommended by WHO [17]. Syndromic approach refers to treatment of STI symptoms and signs based on the most common organisms responsible for each syndrome [14]. Due to this approach, recent country estimates for prevalence rates of individual STIs are scarce. However, the burden of STIs is reported to be higher in developing countries like Malawi [18]. In addition, many STIs are asymptomatic especially in women and men who have sex with men making definitive diagnosis and incidence estimates of STI difficult in these populations [1]. In one quarter of 2016, an estimated 94,437 cases of STIs were treated nationwide with the majority (59%) being female, 11% were asymptomatic and 9% were sexual partners – a proportion much lower than that reported by Brown et al of 24% in 2011 [9]. Also, abnormal vaginal discharge was the most common syndrome followed by urethral discharge, genital ulcer disease and lower abdominal pain in that quarter. Noteworthy is that most cases (71%) were recurrences of STIs from more than 3 months ago signifying a high prevalence of high risk sexual behavior among this population or reinfection potentially due to failure to treat partners [19].

1.4.3 Sexually Transmitted Infections and HIV Infection

The predominant mode of transmission for both HIV and STIs is through unprotected sexual intercourse. As mentioned above, the sexual characteristics between people with HIV and/or other curable STIs are similar and are considered to have high risk sexual

behavior [6]. Also, STIs facilitate the transmission of HIV and individuals with HIV have a higher likelihood of acquiring STIs [7]. In sub-Saharan Africa, STI clinics have very high HIV prevalence rates of 46-50%. In Malawi, in the third quarter of 2016, 22% of STI patients were co-infected with HIV – a prevalence rate more than twice the national prevalence and a majority (74%) were already known HIV positive patients highlighting the need for sexual behavior risk reduction interventions among HIV positive patients and their partners [19]. The high HIV prevalence rates make STI clinics the ideal place for identifying HIV cases and notifying their partners while providing STI treatment and counseling services [10].

1.4.4 Partner Notification

Partner notification was invented around the 19th century [12]. PN was originally designed for use in syphilis control and since 1985 it has been used to control HIV transmission [20]. It has been shown to be cost-effective in identifying and averting STIs and HIV [20, 21] and it is being used for STI and HIV screening, treatment, prevention and control across the globe [12, 22]. However, till date, some RLS do not commonly provide partner notification services in their health systems [15].

Provider-oriented PN is most commonly used in high-income countries [22]. The main approaches used in provider-oriented PN are use of electronic methods such as telephone, mobile phone messaging, fax and email by provider to contact partners.

Contract PN is a recent approach to partner notification. In this approach, index patients provide contact information of their sexual partners and are given a period of time to notify and refer/bring their partners to the hospital. If partners are not notified and referred to the hospital within the agreed time period, the health providers contact sexual partners through use of electronic methods or by physical tracing [22].

Under passive PN, the patients contact and notify their sexual partners on their own and refer or bring the partner(s) with them to the hospital [22].

Despite their predominant use in high income countries, provider-oriented and contract PN have been shown to be potentially feasible and cost-effective for low-income countries in some studies [9, 14]. However, passive PN is the standard of care for partner notification for many low income countries and remains the most preferred method in many settings including some high income countries [11, 12, 23]. Noteworthy is that in some low income countries patients preferred provider-oriented PN suggesting the need for support from health care providers in PN [24]. There are three approaches to passive PN. These include: (1) simple passive PN where index patients inform their sexual partners on their own that they may be at risk of HIV or STI and accompany/refer their partners to the hospital; (2) enhanced passive PN where additional counseling, education and/or written support from the provider in form of a partner notification slip is given to index patients to help facilitate the notification process; (3) expedited partner therapy where the index patients deliver test kits, medications or prescriptions to their partners. In some cases this is combined with assistance from providers by a follow-up telephone, email or face-to-face consultation with the prescriber [22, 25].

The choice of a PN strategy depends on setting – whether the strategy is acceptable and feasible to both patients and providers, the cost-effectiveness and compliance to legislative guidelines [26]. Further, the choice also depends on the purpose of PN; STI and HIV case detection, proportion of partners notified, and proportion of partners evaluated/referred [9, 14, 22, 27]. Due to these factors, there is wide variation in the practice and policy of PN across the globe with no single approach being effective for all settings [12] and with some settings lacking standardized protocol for PN [10]. For instance, enhanced patient referral was found to be more effective in India [27], New Zealand [11] and in other western countries in a systematic review [22]. Accelerated partner therapy was more effective in England [28], the United States of America (USA) [27] and other resource-rich countries [22]. Provider-oriented PN was effective in USA and Europe [9] and Cameroon [15]. Despite these variations, passive PN referral remains the most preferred and widely used method [11].

1.4.5 Partner Notification in Malawi

Treatment of STIs in Malawi is provided at health centres (primary care facilities), private clinics and specialized STI clinics. HIV testing is mandatory at all facilities that offer STI treatment and so is PN for all STI/HIV clients [13]. Enhanced passive partner notification is the standard of care in Malawi. The Malawi STI management guidelines for health care providers state that the health care provider should advise and assist HIV positive or STI infected individuals to notify their partners [13]. At Bwaila STI unit (BSU), all patients receive education and counseling on partner notification through a group health talk and later individually when they receive clinical care. STI patients and newly diagnosed HIV positive patients are given notification slips (referral cards) to hand out to their sexual partners (Appendix II). These slips are used to identify partners at the clinic and for administration of appropriate treatment based on the index patient's STI syndrome especially when the partner is asymptomatic. In a recent national quarterly review, PN slips were issued to about 30% of index cases, missing the majority of cases [19].

Provider-oriented and contract partner notification were feasible in a Malawian urban setting as the partner referral proportion doubled with both methods compared passive PN [10]. Contract partner notification was also shown to be effective in identifying male partners for HIV testing at antenatal clinics in Malawi [29]. Provider-oriented partner referral was potentially cost-effective in the same setting [14]. However, despite these reassuring results, the policy and practice for PN in Malawi has remained passive PN.

1.4.6 Barriers and Facilitators for Partner Notification

The uptake of PN is influenced by social, cultural, ethical and structural factors. PN approaches have to be acceptable, feasible, cost-effective and comply with ethical guidelines within settings in order to succeed [26]. The above factors may function either as barriers or facilitators to the PN process.

Barriers to partner notification can be grouped into two main categories; health system-related barriers and patient-related barriers. For patient related barriers, the

barriers that have been reported are; fear of social discrimination/stigma, fear of breaking relationships, uncertainty of how to notify partners, young age, cultural background, nature of relationship with sexual partner, lack of contact information for partners, concerns of intrusion of privacy, financial dependence on partner especially among females, distrust or fear of positive test results, lack of understanding of STIs and HIV, and fear of inconvenience to partners for seeking medical attention [30, 31]. The health system related barriers that have been reported include; limited resources, poor diagnostic and management infrastructure, work overload for providers, lack of trained staff and unclear ethical guidelines for PN [12, 31, 32]. These barriers are generally common between settings with some setting-specific differences.

Facilitators of PN reported are: concerns about transmitting disease to fetus for pregnant women, fear that spouses may become infertile, fear of spreading infection to a spouse or being re-infected [12], being in a steady relationship, having a regular sexual partner and recent sexual contact [33], clear clinical and ethical guidelines, legal frameworks around PN, financial incentives, raising awareness on HIV and STIs in the community and training and support for health workers conducting PN [34].

1.4.7 Quality Improvement in Health Research

In the past two decades, the use of QI research has been growing steadily in the health sector [35] and it has shown great potential to enhance health systems to produce high-quality care while optimizing use of the few available resources [36]. So far, QI research has been used widely in many areas of the health sector in both resource-rich and resource-limited settings. In SSA, a number of QI studies have been conducted in different areas of health care in South Africa, Ghana, Niger and a few other countries [4,37,38]. However, to our knowledge, our study is the first to attempt the use of QI methods on PN in the region.

1.4.8 Quality Improvement Research on Partner Notification in Malawi

Quality improvement methods and tools have been used in other areas of the health sector globally and within the region [38,35–37,39]. Within the field of partner notification, few authors have reported results from quality improvement research [40, 41]. In the USA, Huppert et al increased the proportion of STI positive women successfully contacted within 7 days using the Plan-Do-Study-Act test (PDSA) cycles [40]. To our knowledge, no research using quality improvement frameworks and tools has been conducted within the field of partner notification in the sub-Saharan region and Malawi. This study will pioneer this effort. However, implementation research has been conducted to improve the uptake and identify barriers and new approaches to partner notification in Malawi [6, 9, 14, 24, 36, 37].

1.5 AIMS AND OBJECTIVES

1.5.1 Overall Aim

The aim of this research was to identify health system-related factors that influenced passive partner notification and to increase the proportion of sexual partner referral using a quality improvement method by 10% at Bwaila STI Unit (BSU) from January to June 2017 in Malawi.

1.5.2 Specific Objectives

1. To estimate the baseline proportion of partner referrals at BSU in Lilongwe, Malawi.
2. To identify health system-related factors that influenced passive partner notification at BSU and identify areas for change.
3. To assess the change in the partner referral proportions before and after implementation of a three-prong intervention.

Chapter 2

2.0 METHODOLOGY

This chapter details the methods used to conduct this study. It describes the study design, setting and population; the sampling procedures; the process that was improved; the QI intervention implemented and the methods used for selection; how the QI intervention was implemented; sample size, data collection and data analysis; and ethical considerations for the study.

2.1 STUDY DESIGN

A pre- and post-intervention quasi-experimental study design was used to conduct this QI study. Within this study design, a mixed methods approach was used. We collected both quantitative and qualitative data pre-intervention followed by quantitative data during implementation of the intervention and post-intervention. The pre-and post-intervention study design was used because it allowed us to measure change in the outcome before and after the intervention. This design allowed us to use the pre-intervention period to identify factors that affected the PN process and to design the QI intervention. Furthermore, we did not have a control group for comparison. We implemented the intervention and then measured the outcome in the post-intervention period. In summary, this study was conducted in three main phases which were; pre-intervention, intervention and post-intervention. The pre-intervention phases lasted four weeks, the intervention phase lasted eight weeks and the post-intervention phase was completed in one week based on the required sample size (Box 2.1).

Box 2.1: Study Outline and Timeline
1. Pre-intervention phase • Baseline Assessment * Week 1: Record review, interviews and clinic observations * Week 2: Record review, interviews and clinic observations * Week 3: Record review, interviews and clinic observations * Week 4: Consultative meeting – identifying interventions 2. Intervention phase • Implementation * Week 5: PDSA cycle 1 for intervention one * Week 6: PDSA cycle 2 for intervention one * Week 7: PDSA cycle 1 for intervention two * Week 8: PDSA cycle 2 for intervention two * Week 9: PDSA cycle 1 for intervention three * Week 10: PDSA cycle 2 for intervention three * Week 11: PDSA cycle 1 for combined intervention * Week 12 PDSA cycle 2 for combined intervention 3. Post-intervention phase • Post-intervention assessment * Week 13: Record review

2.2 STUDY SETTING

The study was conducted at BSU of the Bwaila District Hospital, a facility under the Ministry of Health (MoH) in Lilongwe, the capital city for Malawi. The health system in Malawi is divided into primary, secondary and tertiary care levels. Bwaila district hospital was the only secondary level facility in Lilongwe and the only facility offering specialized STI services through BSU. Many other public primary care and private facilities also offered STI services which were non-specialized and referred complicated STI cases to BSU. BSU is situated in a busy central town area of the Lilongwe district. The unit offers STI care services to the public residing within or passing through Lilongwe and attends to about 60 to 80 patients per day. BSU operated on week days from 7:30 am to 4:30 pm.

BSU collaborated with the University of North Carolina project (UNC project) and the Lighthouse Trust to provide general care to STI patients and was used for research activities. The clinic was mainly run by two to three MoH nurses, three HIV Testing Services (HTS) counselors from the Lighthouse Trust, one receptionist and one clinic aide who were responsible for providing general STI care services. In addition, there were four nurses,

one medical doctor and two data assistants from UNC project and five HTS counsellors from lighthouse clinic who were mainly involved in research activities but also helped with general care occasionally.

2.3 STUDY POPULATION

To measure the baseline proportion of sexual partners who presented to BSU (objective one), the study population comprised individuals, 13 years of age and above, and their sexual partners who sought STI care at BSU during the pre-intervention period.

In order to identify health system-related factors that influenced passive PN at BSU and identify areas for change (objective two), we included all health care providers working at BSU who consented to the key-informant interviews.

Finally, we included individuals and their sexual partners who sought STI care at BSU in the post-intervention period to measure the proportion of sexual partners who attended the clinic (objective 3).

Patients below 13 years and neonates who had a diagnosis of neonatal conjunctivitis were excluded because these age groups are believed to not engage in consensual sexual intercourse and neonatal conjunctivitis is not transmitted sexually to neonates.

2.4 SAMPLING PROCEDURES

We collected records of all patients who attended BSU prior to implementing our project to estimate the baseline proportion of sexual partners. In order to identify factors that influenced PN, all health care workers who were willing to provide informed consent were interviewed and we randomly conducted clinic observations. Clinic observations were conducted randomly in order to collect data that were representative of the partner notification process at BSU. Lastly, records of all patients who attended the clinic were collected based on the sample size to estimate the post-intervention proportion of sexual partners.

2.5 SAMPLE SIZE

For the post-intervention phase, the initial calculated sample size was 182 patient records with a 10% adjustment. We assumed that clinic attended to about 40 patients a day and that one index case would refer one partner based on previous data. We used a baseline partner referral proportion of 24% based on literature. The sample size of 182 was calculated to have 80% power to detect, at $\alpha=0.05$ (two-sided test), a difference of 10% in the proportion of partner referrals between the pre- and post-intervention phases. However, during implementation of our study, BSU attended to roughly 70 patients per day. Data from records were collected on a weekly basis. We collected records for 267 patients for a period of one week post-intervention. Due to this, we recalculated the power of the study to detect a 10% difference at $\alpha=0.05$ (two-sided test) and found 95% power.

2.6 THE PROCESS AND MEASURES (OUTCOME, PROCESS AND BALANCING MEASURES)

In public health, QI is used to maximize the effectiveness of a service [42]. The service to be improved is called the “Process”. QI involves ongoing effort to attain measurable improvements in effectiveness, efficiency, accountability, performance, outcomes and quality of services in order to improve the health of a community [42]. In order to attain these measurable improvements, outcome measures, process measures and balancing measures are collected.

Outcome measures: are the ultimate goal that the improvement project is aimed to achieve [42].

Process measures: are steps within the process that contribute towards achieving the outcome. Process measures describe the outcome in detail, the exposure to the intervention and the experience of those exposed to the intervention [43].

Balancing measures: are measures that track any unintended consequences of the improvement project. Improving one or several aspects of a service or system may result in impacting other aspects of the same system or interrelated systems [42].

2.6.1 The Process

The process we aimed to improve is enhanced passive PN. As standard of care, BSU used enhanced passive PN. The PN process started with a group health talk which was conducted by a trained receptionist or HTS counselor with the help of a nurse using a job aide (Appendix III). The clinic conducted up to three group health talks in a day. The health talks included topics on; services provided at the clinic, general knowledge on STIs and HIV, partner notification and research activities being conducted at the clinic. After each health talk, the receptionist checked through the patients' health passport books to look for evidence of HIV testing. Patients with evidence of a positive HIV test or a recent (within 3 months) negative HIV test were directed to receive treatment while those without evidence of an HIV test or with an old (>3 months) negative result were directed to the HTS rooms for HIV testing. HIV testing was administered by trained HTS counselors through Provider-Initiated HIV Testing and Counseling (PITC), a "opt-out" policy, as stipulated by the Malawi Ministry of Health STI management guidelines [13]. From the HTS rooms patients were attended to by specialized STI nurses who provided medical care. In the treatment rooms, patients were asked about their sexual partners and discussed any issues concerning informing their partners with the provider and were given PN slips to present to their sexual partners. Upon return to the clinic, sexual partners presented a PN slip to the receptionist who logged them into the clinic registers as partners.

THE BSU CLINIC FLOW AND PARTNER NOTIFICATION

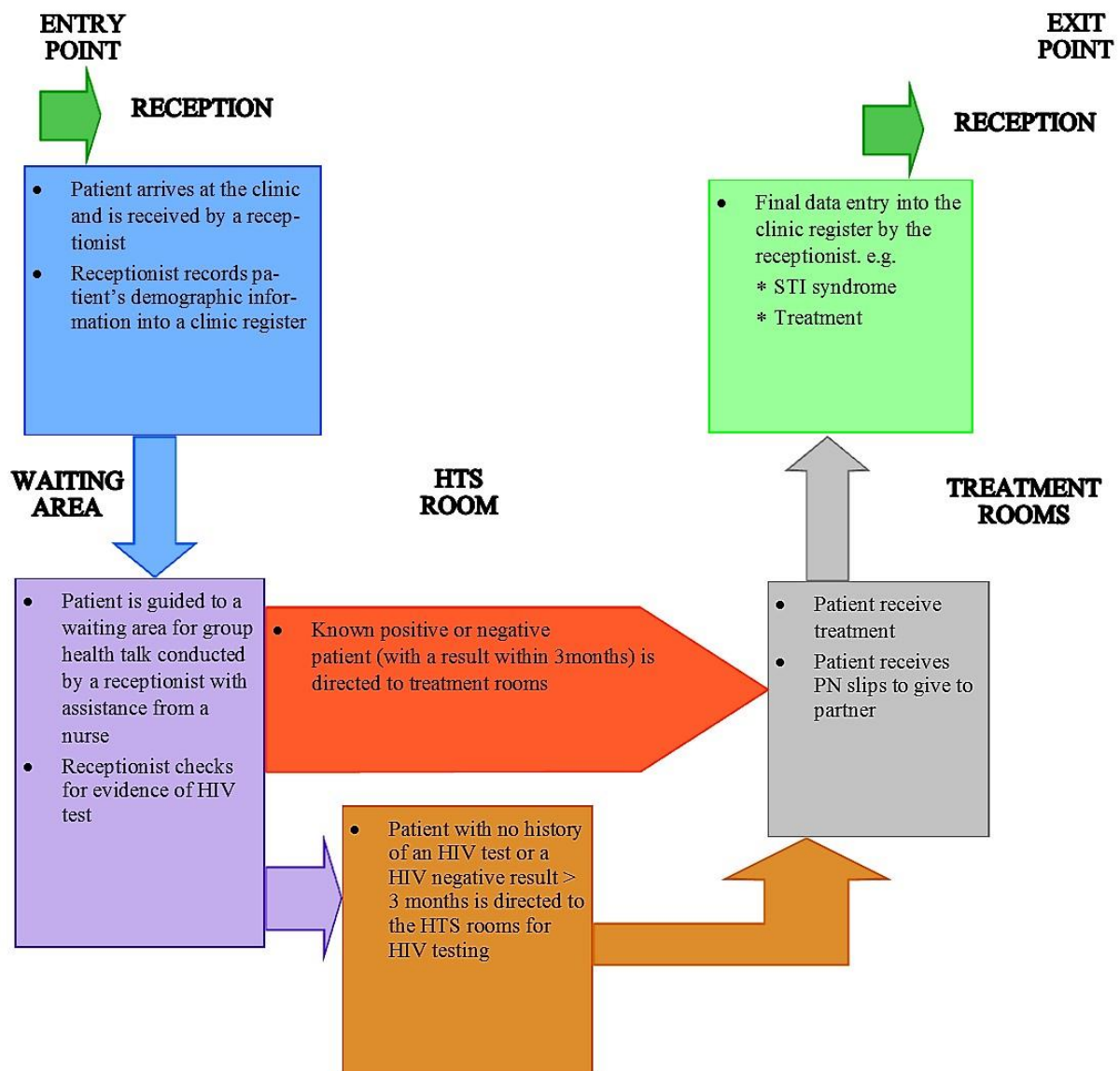


Figure 1: Schema of the clinic flow and partner notification process at BSU

2.6.2 Outcome Measures

The outcome measure for this study was the proportion of sexual partners who presented to the clinic.

Proportion of sexual partners was defined as: the number of individuals who presented to the clinic with a PN slip and were logged into the clinic register as partners out of the

total number of individuals who attended the clinic within the study period. This outcome measure was chosen a priori because it was what this research study aimed to improve (Box 2.2).

2.6.3 Process Measures

All process measures were chosen through an expert consultative meeting based on results of key-informant interviews, clinic observations and the identified QI interventions. Process measures chosen were:

1. *Average start time of the clinic*: This was defined as the time that the group health talk, the first activity at the clinic, started. The indicator was the average start time for the clinic.
2. *Average duration of the group health talk*: This was defined as the total duration of the group health talk – from start to finish. The indicator was the average duration of the group health talk
3. *Average duration of clinic visit for sexual partners*: This was defined as the total time spent by a partner at the clinic from the time the partner was logged into the clinic register at arrival and logged out at departure. The indicator was the average total duration of a visit.

These process measures were chosen because they represented important steps in the process of partner notification at BSU based on expert opinion (Box 2.2).

2.6.4 Balancing Measures

We collected other measures to ensure that our intervention was not disrupting other processes within the partner notification process or other interrelated systems. The balancing measures collected were:

1. Average duration of clinic visit for index cases.
2. Average wait-time for all patients waiting to receive treatment.

Box 2.2: The Process, Outcome Measure, Process Measures and Balancing

The Process

- Enhanced passive partner notification.

Outcome Measure

- Proportion of sexual partners that presented to the clinic

Process Measures

- Average start time of the clinic
- Average duration of the group health talk
- Proportion of patients who received PN slips
- Average duration of a clinic visit for partners

Balancing Measures

- Average time spent at the clinic by index cases
- Average wait-time for patients waiting to receive treatment

2.7 STUDY PROCEDURES AND DATA COLLECTION

2.7.1 Pre-Intervention Phase: Baseline Assessment

Record review

In order to estimate the baseline proportion of sexual partners, we conducted a record review to identify individuals who presented to the clinic as sexual partners from June to December 2016 (6 months). We collected data from the BSU registers on age, sex, HIV status, STI syndromes, and whether a patient was an index case or a partner. Records from 28 September to 06 November 2016 were missing due to a missing clinic register. The patient records were collected by a data assistant and transferred into a Microsoft Excel spreadsheet.

Key-informant Interviews

In order to identify health system-related factors that influenced the passive PN process, key-informant interviews were conducted. Key-informants were health care workers at BSU. Before conducting each interview, the aim, objectives and importance of the study were explained to each participant through the informed consent process.

Written consent for audio recording of interviews and willingness to participate in the study was obtained from each participant (Appendix IV).

An open-ended topic interview guide (Appendix V) was developed and used as the tool for data collection. The interview guide was developed in English by the investigator and translated into a local language (*Chichewa*) by a translator (nurse) at UNC project. The guide was then back-translated into English by the nursing supervisor at UNC project. All interviews were conducted by the investigator in *Chichewa*.

The interview guide touched on the following areas related to the PN process and the conduct of the clinic: The clinic flow of index patients and their partners; the common characteristics among the index patients/partners; the health system-related factors that either positively or negatively influenced PN at BSU; and the changes that could be made within the facility that would result in an increase in proportion of partners who present to the clinic. Demographic information such as age, sex, cadre and marital status of respondents were also collected for each respondent. Data were collected as notes and audio recordings by the investigator. Audio recordings were obtained to allow the investigator enough time to listen and transcribe interviewees' responses accurately. About two to three interviews were conducted per day lasting about 15-30 minutes with typed transcripts averaging 6 pages.

The interview process started with one interview which was used to test and validate our interview guide ensuring that it prompted and elicited the information it was intended to. All necessary modifications to the interview guide were made by the investigator. Fifteen (15/20) health care workers participated in the interviews. Five health care workers were not readily available at the clinic to participate in the interviews. The health care workers interviewed included eight counselors, five nurses, one receptionist and one clinic aide. After the first interview, the investigator proceeded to transcribe information. Subsequent interviews were conducted and transcribed in real time.

Clinic Observations

In order to better understand health system-related factors that influenced PN at BSU, key-informant interviews were complemented by clinic observations. Clinic observations were guided by findings from the interview. Observations were conducted to better understand the general conduct of the clinic (clinic systems) and the PN process. Clinic observations were conducted by the investigator, data assistant and receptionist depending on the process being observed. Observations were conducted randomly on different days of the week and different times of the day in order to obtain results that were representative. Observations were conducted without the knowledge of the staff or patients to avoid a Hawthorne effect.

Processes observed were:

- Start time of the clinic/group health talk
- Duration of the group health talk
- Proportion of patient who received at least one PN slip to give to their partner(s)
- Duration of waiting time for treatment (after HIV testing)
- Total duration of visit and the clinic flow for index cases at the clinic
- Total duration of visit and clinic flow for partners at the clinic

All these processes were observed within three consecutive weeks. Ten random observations for the start time of the clinic were conducted by a data assistant and the investigator. The data assistant also observed 10 health talk for duration. The receptionist observed 10 patients for duration of waiting time to receive treatment after HIV test, 20 patients for the proportion of patients who received PN slips before departing the clinic and 40 patients (20 index cases and 20 partners) for the duration of patient visits.

Data on clinic observations were collected using study-specific data collection forms (Appendix VI) and entered onto Microsoft Excel spreadsheets.

Expert consultative meeting: Selecting change ideas (interventions)

After the interviews and clinic observations, an expert consultative meeting was conducted to debrief the clinic staff and other stakeholders on the findings from the interviews and clinic observations. The meeting was aimed to prioritize and select areas of PN that needed to be addressed and the best interventions for these areas. Key stakeholders included the clinic management staff from Lilongwe District Hospital, research and management staff from UNC project and Lighthouse Trust, and representative from the STI department at the MoH. Interventions to improve the passive PN process were suggested and selected by voting. Voting for interventions was based on; clinic needs assessment, availability of resources, good fit, available capacity, buy-in and ease of change at clinic level. The team set targets for each of the interventions and selected process measures. Findings from the expert consultative meeting were collected by the investigator as notes. These notes were shared with the team and endorsed as a true reflection of what was discussed and agreed in the meeting.

2.7.2 Intervention Phase: Implementation

The QI Intervention

Our QI intervention consisted of three change ideas (three-pronged) based on expert opinion. These were;

1. Early clinic start time

This was the time at which the group health talk, the first activity of the day at the clinic, started. The team agreed to start its clinic activities at 08:00 hours every day. The rationale for choosing this change idea was that by starting the early, the clinic was going to be better organized and able to execute its functions efficiently as lack of efficiency may have negatively influenced referral of partners. Also, starting early meant that the clinic will be able to see more patients including partners (Box 2.3).

2. Shorten duration of the group health talk

This was the time from start to finish of the health talk. The duration of the group health talk was agreed to be not more than 40 minutes. The rationale for choosing this intervention was that by shortening the duration of the group health talk, the clinic was going to create more time to cater for more patients and also create more time for value-added activities like health worker discussions on PN with patients individually (Box 2.3).

3. Expedition of sexual partners or couple clinic flow

This was improving the clinic flow for sexual partners or couples to expedite their visit at the clinic. This was done by identifying and isolating partners or couples after the group health talk. Partners or couples were identified by presenting a PN slip to the receptionist. The receptionist then checked in their health passport books for evidence of HIV testing. Those who were eligible for HIV testing were directed to a designated HTS counselor. The designated HTS counselor was solely responsible for testing partners/couples. This step prevented partners and couples from queuing with the rest of the patients for HIV testing thereby expediting their visit. After HIV testing and counselling partners were escorted by the counsellor to the treatment rooms to receive care/treatment for their STI. Partner who had valid HIV test result were escorted by the receptionist directly to receive treatment. The target duration for partners at the clinic was one hour. The rationale for choosing this intervention was that expediting partners/couples through the clinic would positively reinforce the importance of bringing a sexual partner to the clinic (Box 2.3).

2.7.3 Formation of a Quality Improvement Team (QI team)

A quality improvement (QI) team consisting of the investigator, one government nurse-in-charge, one HTS counsellor and the receptionist was formed. A quality improvement team is group of key facility personnel who can act as champions, drivers, and agents of change [38]. The success of a QI project depends on how well the QI team members work together, and with the rest of the health system [38]. The roles and responsibilities of this team were to lead the efforts in improving the process of passive PN at all clinic organizational levels. The investigator was the team leader, the nurse-in-charge

Box 2.3: The Quality Improvement Intervention

1. Early clinic start time.
 - The start time for the group health talk which was the first clinic activity
 - Target start time: 08:00 hours
2. Shorten the duration of the group health talk
 - Reducing the duration of the health talk
 - Target duration: 40 minutes
3. Expedition of partner clinic flow.
 - Expediting the partner clinic flow to reduce the time spent at the clinic
 - Target duration: 1 hour

was the team facilitator and the HTS counsellor and receptionist were team members (champions of change). The QI team met weekly to discuss the progress of the QI research and decide on change actions based on findings from each small test of change cycle.

2.7.4 Implementation of the QI Interventions

We used the Expert Recommendations for Implementing Change (ERIC) tool to select the implementation strategy [44]. The ERIC tool is an expert compilation of implementation strategies based on expertise of implementation scientist and clinical

practitioners. The tool has 73 implementation strategies. The implementation strategy that was chosen was to conduct cyclical small-scale tests of change using the “Model for Improvement” (MFI) (Appendix VII). The MFI is one of the approaches derived from old traditions of practice in management [38], the “Plan-Do-Study-Act” (PDSA) cycles. PDSA cycles originated from industry and were first defined by Walter Shewhart and Edward Deming in the early 1900 [45]. The MFI precedes the use of PDSA cycles and emphasizes on identification of gaps by use of data and testing of solutions to improve quality of care and operational processes that support the effective delivery of care. It strengthens the system capacity by creating processes and practices that are relevant to local context [38]. The MFI was chosen because it allows for improvement of processes over time through cyclical small tests of change.

The MFI has 3 questions and the PDSA cycles [35]. The three questions are; (1) Aim: What are you trying to accomplish? (2) Measures: How will you know a change is an improvement? (3) Changes: What changes can you make that will result in an improvement? These questions guided the planning process before implementing each of our interventions. We defined the aim for each intervention to be certain of what we were trying to accomplish. We set targets and selected process measures and in some cases balance measures to ascertain improvement. The QI team met weekly at the end of each PDSA cycle and discussed the results. Learning points (change actions) were identified and implemented in the subsequent test of change.

The QI team proceeded to plan how each of the intervention was implemented in the “plan” phase. The QI interventions were then implemented in the “do” phase. Each of the test cycles was lasted one week. We conducted two test cycles for each of the interventions and then combined them to conduct two more test cycles making a total of eight PDSA cycles.

In the “study” and “act” phases, results from each test cycle were studied and decisions were made on the change actions for the subsequent cycles. Questions were asked regarding what went wrong, what went right, and what needed to be changed in the next test cycle. Data from each one of the PDSA test cycles for the interventions were collected using data collection forms. The investigator collected the data. Data collected were entered into a Microsoft Excel spreadsheet for each test cycle.

Intervention one: Early start of the clinic

Aim: Improve the clinic start time to 08:00 hours

Measure: Average start time of the group health talk

Change: Early start time of the group health talk

Plan: The QI team reminded and encouraged the rest of the clinic team to come early and ensure that the clinic starts by 08:00 hours. The receptionist, who was part of the QI team, was the champion of this intervention. The team planned that the nurse assisting with the group health talk would replace the receptionist in cases where the receptionist is not available. Data on start time was to be collected by the data assistant.

Do: The intervention was implemented starting on a Monday morning. The receptionist conducted the health talks with the help of a nurse. The data assistant collected data on the start time on a daily basis using the data collection form.

Study: In this phase, the investigator compiled the data in Microsoft Excel, summarized it and data points were plotted using run charts. The QI team met at the end of each test cycle and discussed results.

Act: Learning points were identified and change actions for the second cycle were decided and agreed upon based on the findings from each test cycle. Findings from the test cycles and change actions have been detailed in the results section. The rest of the clinic staff were briefed on the change actions during the clinics weekly meetings.

Table 1: The three-prong intervention and process and balance measures

Intervention	Process Measure	Balance Measure
Early clinic start time Target: 08:00 hours	Average start time of the clinic	None
Shorten the duration of the group health talk Target: 40 minutes	Average duration of health talks	Waiting time to receive treatment
Expedition of partner clinic flow Target: 1 hour	Average duration spent by partners at the clinic	Duration spent at the clinic by index patients

Intervention two: Shorten the duration of the group health talk.

Aim: Shorten the duration of the health talks to not more than 40 minutes.

Measure: Average duration of the group health talks.

Change: Concise and precise group health talks.

Plan: The QI team conducted dry runs of the health talk with the receptionist as the point person and ensured that all vital points of the talk were delivered within 30 minutes. The remaining 10 minutes was reserved for questions from the audience. Data on duration was collected by the data assistant.

Do: The health talks were conducted as agreed and monitored for progress by obtaining data on the duration and observations were made to denote any circumstances that affected the duration. The data assistant collected data daily using the data collection forms.

Study: The investigator compiled the data in Microsoft Excel, summarized it and data points were plotted using run charts. The QI team met at the end of each test cycle and discussed results.

Act: Learning points were identified and change actions for the second cycle were decided and agreed upon based on the findings from each test cycle. Findings from the test cycles and change actions have been detailed in the results section. The rest of the clinic staff were briefed on the change actions during the clinics weekly meetings.

Intervention three: Expedition of partner clinic flow

Aim: Reduce the duration of time spent at the clinic by sexual partner to not more than one hour.

Measure: Average duration of time spent by partners at the clinic.

Change: Fast-track partners by allocating a designated HTS counselor.

Plan: The QI team identified a HTS counselor whose sole responsibility was to test partners. The counselor was also assigned the responsibility to escort patients to the treatment rooms to receive treatment. A HTS counselor who was located next to the treatment rooms was deliberately selected for ease of escorting patients. It was agreed that partners were to be identified through the usual procedure - by presenting a partner notification slip to the receptionist who checked for evidence of an HIV test. Partners with a valid test were to be escorted directly to the treatment rooms by the receptionist. Data on the duration of visit was agreed to be collected by the receptionist.

Do: The receptionist identified and directed partners as described above. A counselor conducted the HIV testing and directed tested patients to the treatment rooms as agreed. Data on the entry and exit times for 10 patients (5 partners and 5 index cases) per day were collected randomly by the receptionist using data collection forms on a daily basis.

Study: The investigator compiled the data in Microsoft Excel, summarized it and data on average daily duration were plotted using run charts. The QI team met at the end of each test cycle and discussed results.

Act: Learning points were identified and change actions for the second cycle were decided and agreed upon based on the findings from each test cycle. Findings from the test cycles and change actions have been detailed in the results section. The rest of the clinic staff were briefed on the change actions during the clinics weekly meetings.

Combined intervention

All three interventions were implemented concurrently as a combined intervention and tested through another two small test cycles. All learning points from the last individual test cycles were incorporated in the combined test cycles. The investigator collected data on proportion of sexual partners daily using clinic registers. Data were compiled, summarized and plotted on run charts using Microsoft Excel by the investigator. The QI team met at the end of each test cycle to discuss findings and to identify learning point and change actions. Findings from the test cycles have been detailed in the results section.

2.7.6 Post-Intervention Phase: Post-Intervention Assessment

Finally, we conducted another record review to identify individuals who had presented to the clinic as partners after implementation of the QI interventions in order to assess the outcome of the study. Patient records from the clinic registers were used to identify individuals who presented to the clinic as partners. We collected data on age, sex, HIV status, STI syndromes, and whether a patient was an index case or a partner. The patient records were collected by a data assistant and transferred into a Microsoft Excel spreadsheet. Data were collected for a period of one week based on the calculated sample size to detect a 10% difference in proportion of sexual partner

referral between the pre- and post-intervention periods.

2.8 DATA ANALYSIS

We used descriptive statistics such as mean, median and proportion to describe the demographic characteristics of patients that presented to the clinic prior to the study. We estimated the baseline proportion of partner referral at BSU by calculating the proportion of partners that presented to the clinic using Stata Version 14.0 as follows;

$$\text{Proportion of partners} = \frac{\text{Number of partners who presented to the clinic 6 months prior to the study}}{\text{Total number of patients who visited the clinic within the same period}} \times 100$$

In order to identify health system-related factors that influenced PN, preliminary data analysis of the interviews was done concurrently with data collection to identify salient themes and areas that required further exploration in the subsequent interviews. Responses from the interview were translated to English and transcribed by the investigator. Transcripts were proofread several times by the investigator and all unclear sections were checked and corrected against the audio recordings and notes. Outliers were carefully examined and possible explanations were thought out. Transcripts were transferred onto ‘NVivo’ version 11 which were used to organize the data and facilitate the analysis. We used a thematic analysis approach to conduct the data analysis. The interview guide was used to develop a codebook with parent and child nodes. Emergent codes were linked to raw data from the transcripts. The interview topics were prioritized when developing the codebook but other emergent codes were appropriately incorporated into the codebook. The codebook was arranged into the following nodes:

A. *Clinic Activities*: under clinic activities we had “index patient clinic flow” and “sexual partner clinic flow” as the child nodes. These nodes were developed to better

understand the processes involved or the flow for these two categories of patients while accessing care within the clinic. The aim was to identify inefficient areas of the clinic flow that could be improved.

- B. *Patient characteristics*: under this parent node, we had “index patient characteristics” and “sexual partner characteristics” as child nodes. This was aimed to better understand the perception of health workers on the nature of patients they catered for at the clinic.
- C. *Health system related factors*: this parent node had “factors” and “suggested improvements” as child nodes. Under the “factors” node we had positive and negative drivers as the sub-categories. These were aimed to identify factors that the health workers thought either positively or negatively influenced the PN process.

Under the “suggested improvements” we had four sub-categories. These were: Systems – these were factors that had to do with the entire Malawi health system; Clinic – these included factors specific to the BSU systems and structure. These were factors that could be changed/improved at a clinic level; Personnel – these were factors to do with the conduct of the health workers at the clinic like attitude; and Pivotal Change – under this sub-category, we asked health workers to mention one attainable change that could have the greatest impact on the proportion of partners seen. Queries and reports were run in NVivo and we compared for code frequency, configuration of code co-occurrences and salience to complete the analysis.

We used clinic observations to complement findings from the interviews. We used descriptive statistics such as count, mean, range, and proportion to analyze the data using Microsoft Excel.

During implementation of our interventions, process data were analyzed in real time using statistical process control (SPC) which is a branch of statistics that uses times series analysis methods with graphical presentation of data to make interpretation of data easy and understandable [35]. The SPC was conducted using run charts in Microsoft excel by the investigator. For early start time of the clinic, we plotted data of the actual start time for each day and calculated an average start time for each cycle. For shortened duration health talk, we plotted the actual duration of the health talk for each day and calculated the average for each test cycle. Five sexual partners were randomly observed per day for their duration of visit and the average duration for each day was calculated and plotted on run charts. The overall average duration for each test cycle was also calculated. Finally, for the outcome measure, proportion of sexual partners, data were entered from clinic registers onto a Microsoft excel spreadsheet and transferred to Stata SE, Version 14.0. The proportion of partners was calculated as follows:

$$\text{Percentage change} = \frac{\text{Postintervention partner proportion} - \text{Baseline partner proportion}}{\text{Baseline partner proportion}} \times 100$$

The percentage change between the pre- and post-intervention proportion of sexual partners was then calculated as follows:

$$\text{Percentage change} = \frac{\text{Postintervention partner proportion} - \text{Baseline partner proportion}}{\text{Baseline partner proportion}} \times 100$$

The proportion of partners who attended the clinic during the post-intervention period was compared to the baseline partner referral proportion for statistical significance using a test of comparison of two independent proportions in Stata.

2.9 ETHICAL CONSIDERATIONS

This protocol and all study related documents were reviewed and approved by the University of Witwatersrand Human Research Ethics Committee (HREC) for both the pre-assessment and intervention periods (Appendix VIII and IX) and the National Health Sciences Research Ethics committee of Malawi (NHRSC) (Appendix X). Approval was also sought from the Lilongwe District Health Officer for use of patient records and to conduct clinic observation (Appendix XI). Data were not collected directly from patients so informed consent was not sought directly from patients. Informed consent was obtained from clinic staff who participated in the interviews. All data collection forms, informed consent forms, interview notes and voice recorders were stored in lockable cabinets at the UNC Project during the study period. Data was stored in a password-protected database. There was no identifiable information on all study material.

Chapter 3

3.0 RESULTS

This chapter presents the study findings. The findings have been outlined in three sections; the baseline assessment, the improvement process (the intervention) and the post-intervention assessment. The proportion of sexual partner referral and demographic characteristics of patients who attended BSU prior to this study have been presented under baseline assessment. Results from the key-informant interview and clinic observations have also been included within this segment. Some quotes have been included in the results and to maintain confidentiality, only the identification number and age of the responded have been used against each quote. Under the improvement process, findings from the small tests of change and the change actions for subsequent tests of change for each of the interventions implemented have been detailed. Finally, the proportion of sexual partners and demographic characteristics of patients who attended BSU after the intervention have been presented under the post-intervention phase. Results of the impact of our intervention to the proportion of sexual partners who presented to the clinic have been included in this section.

3.1 BASELINE ASSESSMENT

3.1.1 Demographic Characteristics.

We collected a total of 1948 records. Twenty-six (26) records were excluded for individuals who were below 13 years of age and 25 records were excluded for individuals with a diagnosis of neonatal conjunctivitis leaving 1897 records available for analysis (Figure 2).

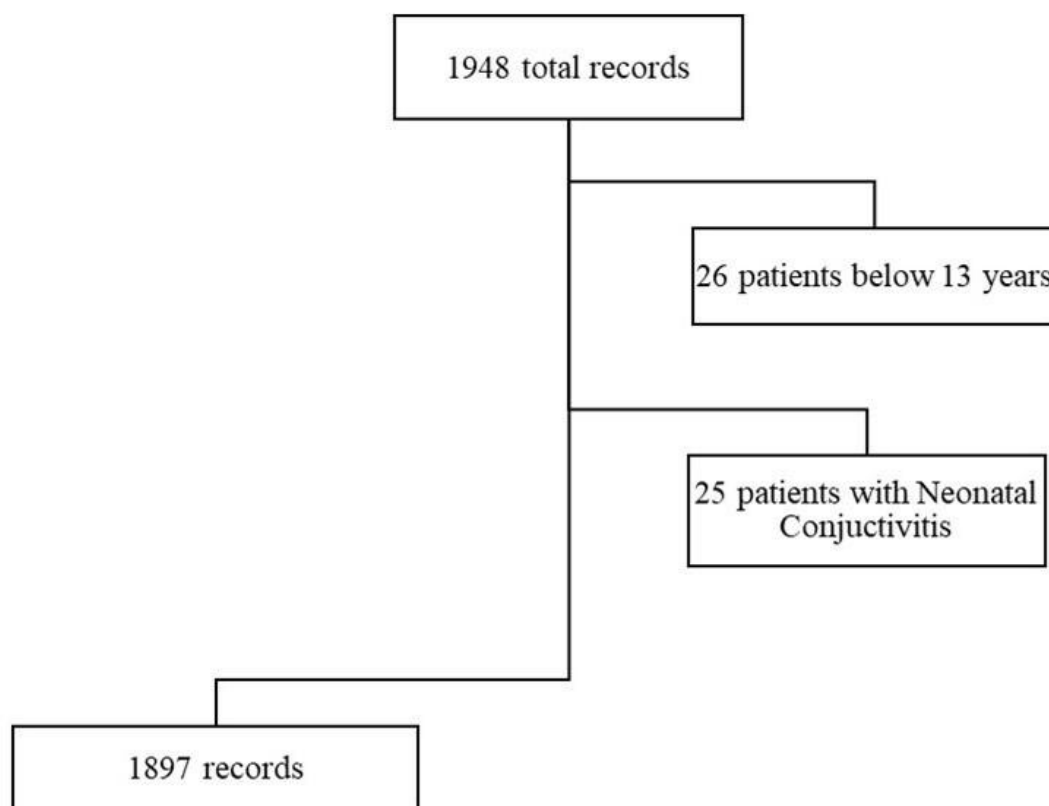


Figure 2: Schema showing distribution of patients at BSU in the pre-intervention period

The median age was 28 years (IQR: 25, 35). Sexual partners were slightly older than index patients (30 years versus 27 years, $P < 0.001$). There were more females (1132, 59.7%) than males (763, 40.3%) (Table 1). The baseline sexual partner referral rate was 15.6% and the overall HIV prevalence rate was 10.2% with the majority of HIV positives being index patients. There were 30 (1.6%) patients with unknown HIV status. Overall, the most common STI syndrome was urethral discharge (26.9%) followed by high risk

vaginal discharge (25.6%). Among index females, high risk abnormal vaginal discharge (45.5%) and lower abdominal pain (34.7%) were the most common syndromes while urethral discharge (65.5%) and genitoulcer disease (18.9%) were the most common syndromes among index males. There were 147 (7.7%) with more than one STI syndrome.

Table 2: Demographic characteristics of patients attending Bwaila STI Unit from June 2016 to December 2016

Characteristic	Total (n=1897)	Index 1602 (84.4%)	Partner 295 (15.6%)	P-Value
Age (years) Median (IQR)	28 (23, 35)	27 (23, 35)	30 (24,37)	*P<0.001
Sex n (%)	Male 763 (40.3) Female 1132 (59.7)	607 (79.5) 994 (87.8)	156 (20.5) 138 (12.2)	**P<0.001
HIV status n (%)	Positive 194 (10.2) Negative 1673 (88.2)	169 (87.1) 1409 (84.2)	25 (12.9) 264 (15.8)	**P=0.345
Diagnosis	Index Male n (%)	Index Female n (%)		
	Genito-ulcer disease	108 (18.9)	Genito-ulcer disease	34 (4.2)
	Urethral discharge	375 (65.5)	Low risk abnormal vaginal discharge	72 (8.9)
	Scrotal Swelling	17 (3.0)	High risk abnormal vaginal discharge	370 (45.5)
	Balanitis	21 (3.7)	Lower abdominal pain	282 (34.7)
	Bubo	16 (2.8)	Bubo	2 (0.2)
	Genital warts	8 (1.4)	Genital Warts	21 (2.6)

*Wilcoxon rank sum test **Chi-squared test

Note: There were 147 patients with more than one STI syndrome

3.1.2 Key-informant Interviews

Demographic characteristics of Key-informants.

Out of 20 health care workers, 15 were interviewed. Five were not readily available to be interviewed. The median age of respondents was 32 years (IQR: 28, 38). The age of respondents ranged from 30 years to 54 years. Majority (11/15) of the respondents were female and married (14/15). Among those interviewed, there were eight HTS counsellors, five nurses, one receptionist and one clinic aide.

Clinic Activities: Index patient and sexual partner clinic flow

All the health care workers (15/15) reported that there was no difference in the clinic flow between index cases and sexual partners. They reported that index cases and sexual partners followed the same clinic flow and spent the same duration of time at the clinic without any preferential treatment as illustrated below:

“Actually, index patients and sexual partners are treated the same way here. They all go through the same steps within the clinic and they spend the almost same amount of time at the clinic.” (ID 12, 32 years).

Patient Characteristics: Index cases and sexual partners

Majority (12/15) of the health care workers reported that most of their patients were business people from the busy town area around the clinic. They reported that this was true for both index cases and sexual partners. They also reported that some of the patients were not residents of Lilongwe which made them difficult to be traced.

“Majority of our clients are business people. It is mostly people from the market, bus depot and shops around town – they are vendors, shop keepers, minibus drivers including sex workers. These people do not want to stay on long queues and spend hours here. Also a good number of our clients actually don’t stay in Lilongwe. They come from surrounding districts to the city to conduct business for a short while and return to their homes making them untraceable” (ID 13, 36 years).

Health system-related factors: Positive and negative influences and pivotal change idea

Few (5/15) of the health care workers reported health facility-related factors that had positive influence on PN. Among the few who responded, the availability of a television, chairs and a water dispenser in the reception area were the most common factors mentioned.

“I think that the television, the comfortable chairs and water dispenser in the reception area help to entertain patients and make them feel comfortable as they wait to be assisted. This could be a factor that encourages patients and their partners to come or refer partners to the clinic” (ID 07, 35 years).

The following were the most common health facility-related factors that health care workers thought had a negative impact on PN:

Late start time of clinic activities: Majority (10/15) of the health care workers reported that the clinic usually started its activities late. Due to this, there was poor organization as some patients were sent back home and asked to return the following day due to large volume of patients. They felt that the lack of organization and sending back of patients discouraged patients from coming to seek care at the clinic therefore negatively influenced PN.

“We see too many patients here, especially after the closure of 7C at KCH (Kamuzu Central Hospital STI clinic). We start the clinic late and usually have few nurses working everyday plus we also have very few clinic rooms for attending to patients. Due to this and the large volumes of patients, we send some patients back home and ask them to come the following morning” (ID 02, 28 years).

Lack of incentives for partners and couples: Most (12/15) of the key-informants felt that the fact the sexual partners and couples were not incentivised negatively impacted on PN at the clinic as illustrated below:

“Our clinic does not reward partners or patients who come with their partners to the clinic. Unlike other clinics like the antenatal clinic, women who come with their partners are given preferential treatment and in some cases they are given perks like a maternity start-up pack with a variety of items. I think we need to reward sexual partners and couples in a certain way here.” (ID 03, 32 years).

Lack of space and staff at the clinic: Almost all the key-informants (14/15) alluded to lack of space and staff for efficient conduct of the clinic. They expressed concern that the clinic attended to a lot of patients and that the space and staffing levels available were not adequate to cater for the large patient volumes. They felt that these factors demoralised patients and sexual partners from seeking care at the clinic.

“To be honest, I feel our clinic is too small compared to the number of patients we see. To add to that, we also have few staff working here at Bwaila. And, even if we were to get more staff, we wouldn’t have enough space to accommodate them. Even extending the clinic wouldn’t work because there is no space at all” (ID 12, 32 years).

Poor staff attitude: Some key-informants reported that some of the health care workers had poor attitude towards patients. They reported that in some cases patients are shouted at and judged for having an STI. They felt that such poor attitude discouraged patients or partners from coming to the clinic as expressed below:

“There are some staff, I will not mention their positions, who shout at patients like children – especially those who come with recurrent STIs. I do not know if it is due to the large patient volumes or their religious beliefs or whether it’s because they naturally have bad attitudes, but the way they speak to patients sometimes is very inappropriate. There have been cases where some patients, especially females, have come out of some rooms crying. Do you think that such a patient would come with their partner or refer their partner?” (ID 06, 48 years).

Pivotal change: When asked about what single change idea that health care workers thought would have the greatest impact in increasing the number of sexual partners accessing care at the clinic, majority (11/15) felt that incentivising partners and couples by expediting them through the clinic would be the best approach. Others reported increasing the staffing levels and space at the clinic.

3.1.3 Clinic Observations.

We observed a total of six clinic flow and partner notification processes. Out of the 10 observations we conducted on clinic start time, the average start time was 09:02 hours. We observed 10 health talks for the duration of health talks and found an average of 56 minutes. All patients (20/20) who were observed for PN slips had at least one PN slip given to them before exiting the clinic. The average duration of waiting time for treatment after testing was 22 minutes. Total duration of clinic stay for index cases was 1 hr 41 minutes and 1 hour 36 minutes for partners (Table 3)

Table 3: Results for the baseline clinic observations

Process Observed	Number of Observations	Findings
Start time of the clinic	10	Average start time: 09:02 hours Range: 08:40 – 09:45 hours
Duration of health talk	10	Average duration: 56 minutes Range: 20 minutes – 1 hour 17 minutes
Duration of wait-time for treatment	10	Average duration: 22 minutes Range: 8 minutes – 46 minutes
Proportion of PN slips	20	Proportion: 20/20 (100%)
Duration of clinic visit Index cases	20	Average duration: 1 hour 41 minutes Range: 34 minutes – 2 hours 30 minutes
Duration of clinic visit Partners	20	Average duration: 1 hour 36 minutes Range: 32 minutes – 2 hours 09 minutes

3.2 THE IMPROVEMENT PROCESS (THE INTERVENTION)

A total of eight small tests of change (PDSA cycles) were conducted. We conducted two test cycles for each of the three interventions and then combined all the interventions into one package and conducted another two test cycles. Below are the results for each of the test cycles.

3.2.1 Intervention One: Clinic Start Time

PDSA cycle one

The average clinic start time at the end of PDSA cycle one was 08:46 hours. Notably, the clinic start time was closer to the 08:00 hours target at the beginning of the week (Monday and Tuesday) and was far from the target time towards the end of the week (Figure 3).

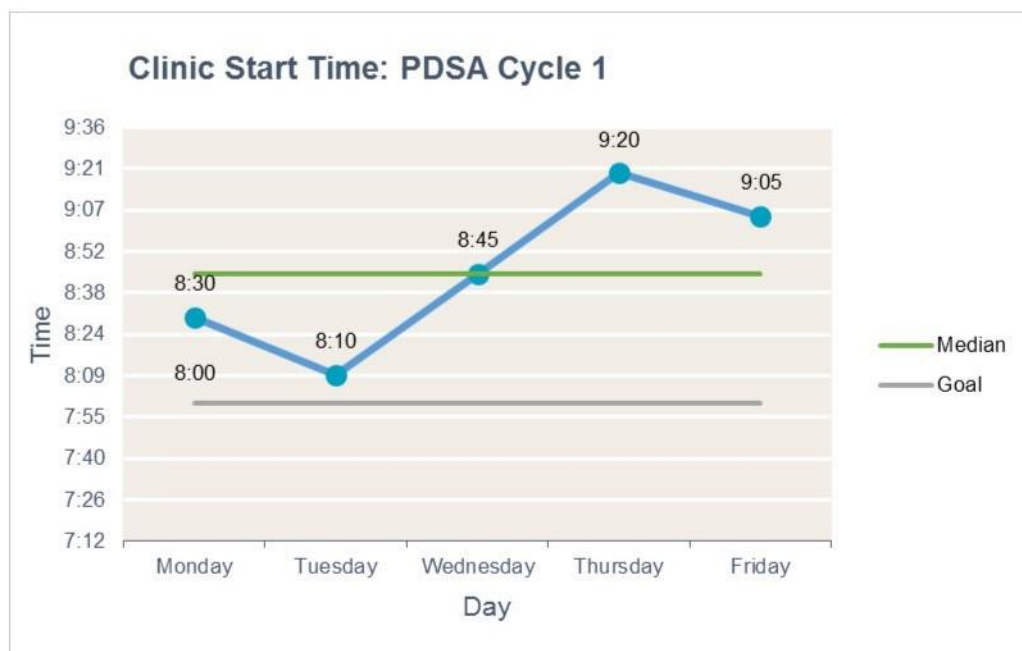


Figure 3: PDSA cycle 1 for clinic start time

After the QI team met, the lessons learnt were that the receptionist was ready to start the health talk on time but patients were coming late. Also, there were more patient numbers at the beginning of the week and less towards the end of the week which made it more difficult for the health talk to start on time towards the end of the week (Thursday and Friday).

Change Action: The QI team agreed that going into the second test cycle, the receptionist was going to announce during each health talk that the start time of the clinic had changed to 08:00 hours to encourage patients to come early.

PDSA Cycle Two

After incorporating the change action from PDSA cycle one, the clinic start time changed to 08:17 hours but still fell short of the target time. A similar pattern in start time by day of the week was seen in the second test cycle (Figure 4).

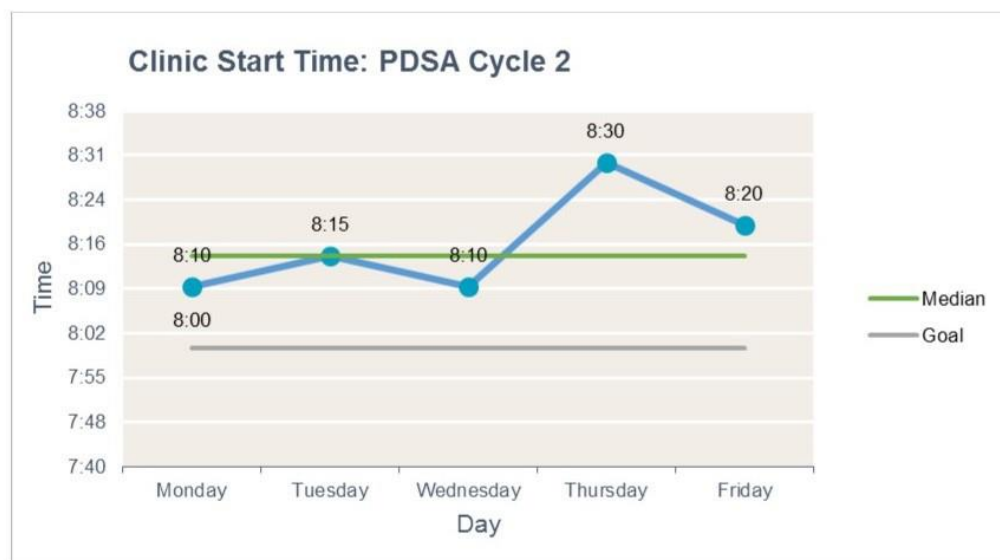


Figure 4: PDSA cycle 2 for clinic start time

The lessons learnt from the second test cycle were that patients had started to come early but this still needed reinforcement. The QI team agreed to continue encouraging patients

to come early.

3.2.2 Intervention Two: Shortened Duration of the Group Health Talk

PDSA cycle one

With the first PDSA cycle, the average duration of the health talk was 49 minutes. This was slightly above the target of 40 minutes (Figure 5).

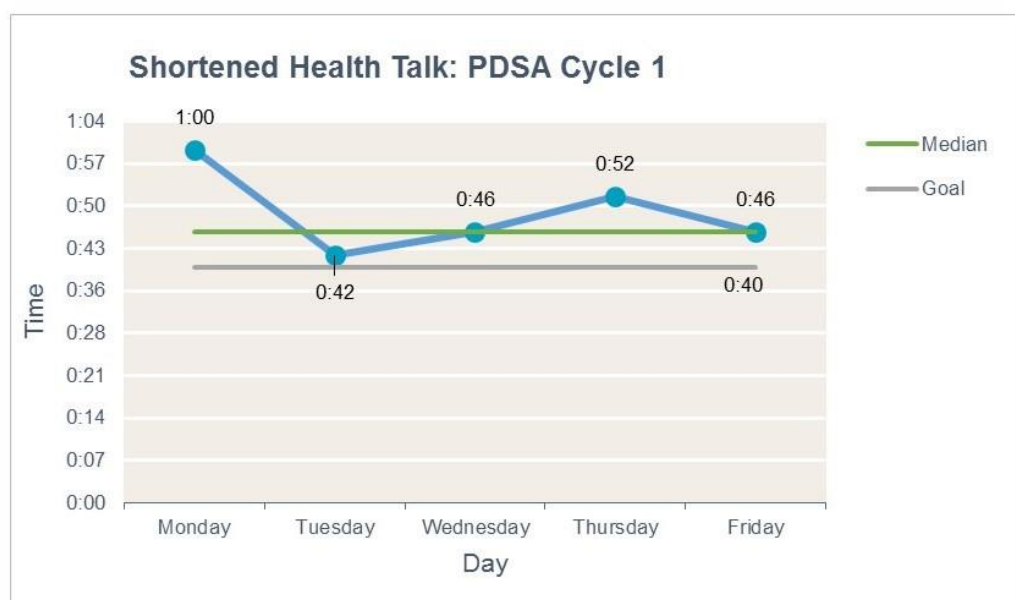


Figure 5: PDSA cycle 1 for duration of health talk

During implementation, it was observed that the first day (Monday) and fourth day (Thursday) the duration of the health talk was much longer because there were many questions from the audience. The QI team agreed that the change action for the second cycle was that the receptionist, with the help of the nurse, were going to control the audience to ensure that the talk was completed within the targeted duration. It was also agreed that the audience would be told that if they had any further questions, they could ask the nurses in the treatment rooms where they could spend more time to discuss with patients individually.

PDSA cycle two

In the second PDSA cycle, the target time was met. The average duration of the health talk was 38 minutes, shortening the duration by 18 minutes (Figure 6). The health talks were delivered without missing any important points. As a balancing measure, we monitored the waiting time for patients to receive treatment and found that the average waiting time increased from 22 minutes to 27 minutes. We learned that clinical care nurses were coming late. As a result, patients were waiting longer to receive treatment since the clinic was starting early. Another change action for the next PDSA cycle (combined) was that the nurse-in-charge who was in the QI team was going to motivate the rest of the nurses to come early.

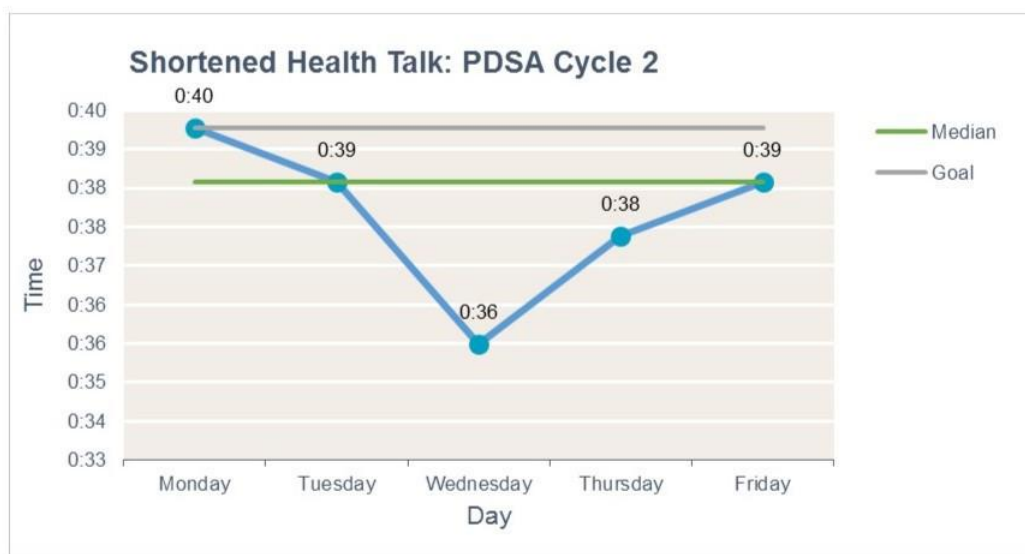


Figure 6: PDSA cycle 2 for duration of health talk

3.2.3 Intervention Three: Expedition of Sexual Partner Clinic Flow (Visits)

PDSA cycle one

We randomly observed five partners per day for each cycle making a total of 25 partners

per week for their duration of visit. For both test cycles, we were able to meet our target of less than one hour for the duration of partner visit. The weekly average after the first test cycle was 54 minutes. The lesson learned from the first test cycle was that it was relatively easier to expedite patients on days when there were fewer patient numbers like day three (Wednesday) (Figure 7). The change action was that the research nurses were going to help with providing clinical care on busy days whenever they would be free.

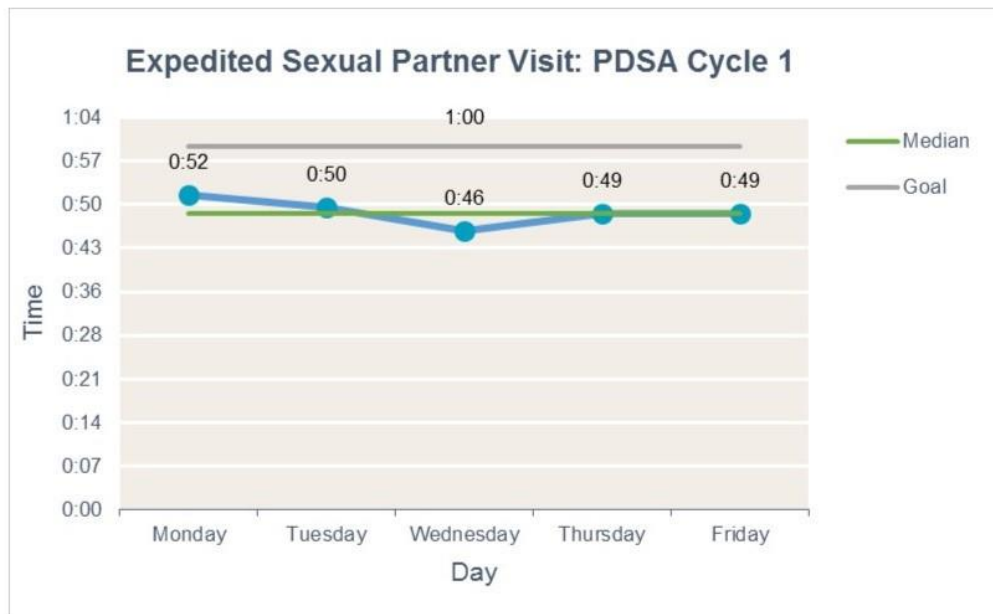


Figure 7: PDSA cycle 1 for expedited partner visit

PDSA Cycle Two

In the second cycle, the average duration of partner visit was 51 minutes (Figure 8). As a balancing measure, we randomly observed 25 index cases for their visit duration for each cycle. We found that expediting the partner flow improved the index patient visit duration from 1 hour 41 minutes to 1 hour 13 minutes. There were no key lessons learned from this cycle. The QI team agreed to continue reinforcing expedited partner visits going into the combined tests cycles and commended the entire clinic team for their effort.

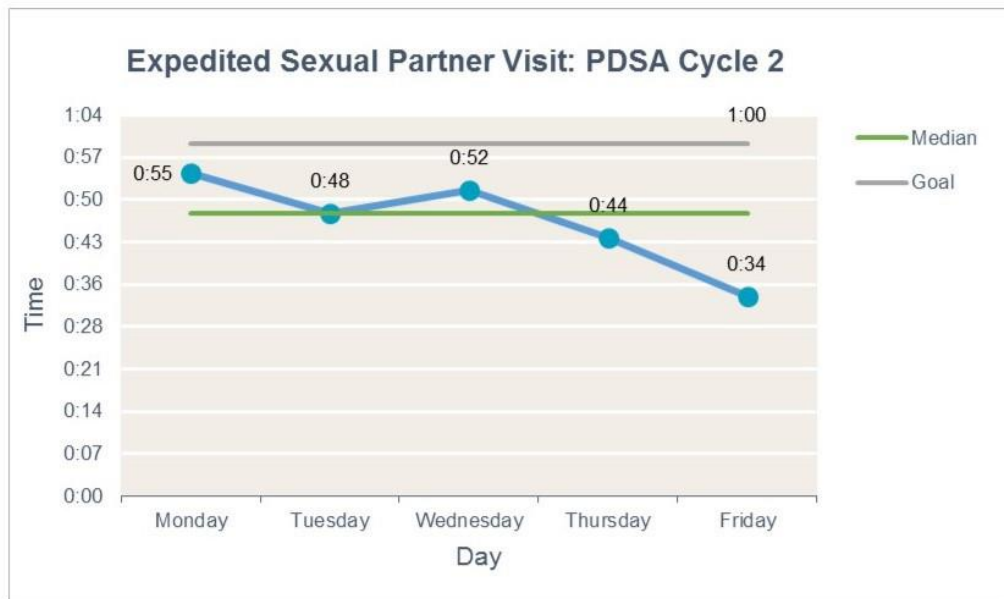


Figure 8: PDSA cycle 2 for expedited partner visit

3.2.4 Combined Intervention

PDSA Cycle one

For the combined intervention, all the three interventions were implemented together and we monitored the daily proportion of sexual partners who presented to BSU. We randomly 5 observed partners per day to estimate an average daily proportion of sexual partners that presented to the clinic. The average proportion of sexual partners was 19.9% for cycle one and 20.2% for cycle two (Figures 9 and 10). There were no patterns or trends observed. The proportion of sexual partners who presented to the clinic generally ranged from around 19% to 22%. At the end of the first cycle, there were no new learning points so the QI team continued reinforcing all the action points from the individual PDSA cycles.

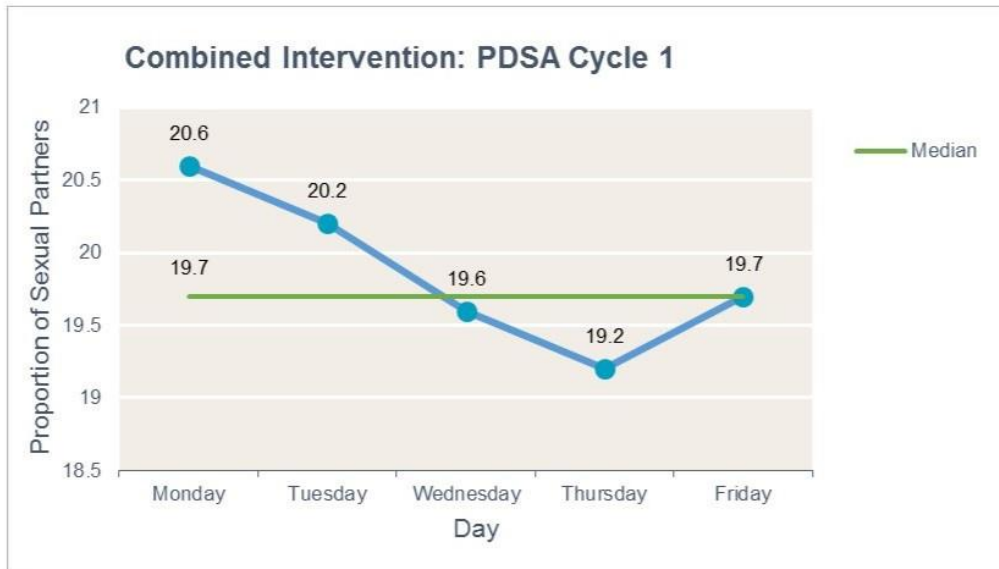


Figure 9: PDSA cycle 1 for combined intervention

PDSA Cycle Two

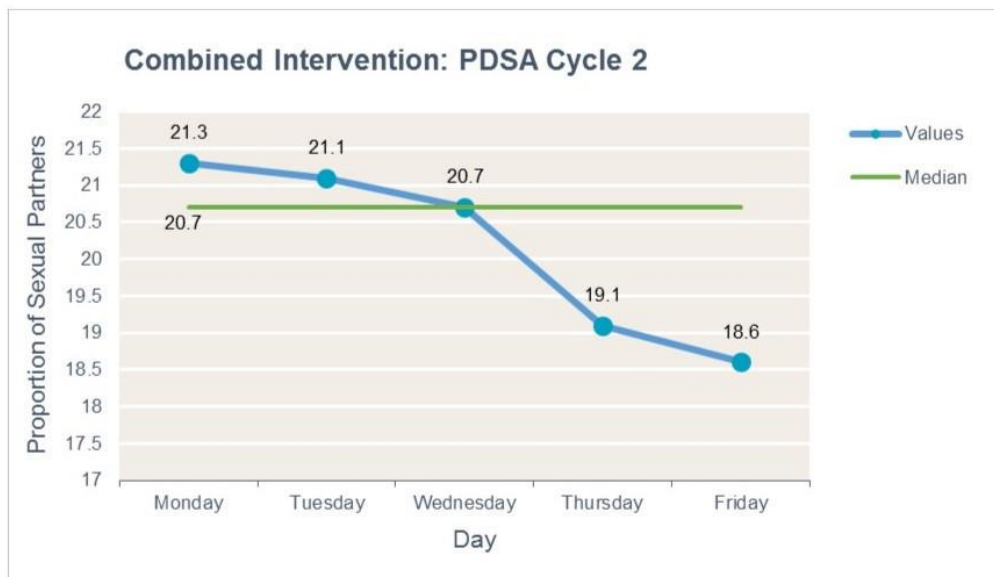


Figure 10: PDSA cycle 2 for combined intervention

3.3 POST-INTERVENTION ASSESSMENT

Table 4: Demographic characteristics of patients at Bwaila STI Unit in the post-intervention period (May 2017).

Characteristic	Total (n=267)	Index 210 (78.7%)	Partner 57 (21.4%)	P-Value
Age (years)	29	29	30	*P=0.738
Median (IQR)	(24, 35)	(24, 35)	(24,35)	
Sex	Male			
n (%)	117 (43.8)	93 (79.5)	24 (20.5)	**P=0.444
	Female			
	150 (56.2)	117 (78.0)	33 (22.0)	
HIV status	Positive			
n (%)	9 (3.4%)	5 (2.4)	4 (12.9)	**P=0.345
	Negative			
	258 (96.6)	1409 (84.2)	264 (15.8)	
Diagnosis n (%)	Index Male	n=93	Index Female	n=117
	Genito-ulcer disease	32 (34.4)	Genito-ulcer disease	8 (6.8)
	Urethral discharge	53 (57.0)	Low risk abnormal vaginal discharge	16 (13.7)
	Scrotal Swelling	2 (2.2)	High risk abnormal vaginal discharge	49 (41.8)
	Balanitis	5 (5.4)	Lower abdominal pain	41 (35.0)
	Bubo	2 (2.2)	Bubo	0 (0.0)
	Genital warts	0 (0.0)	Genital Warts	4 (3.4)

*Wilcoxon rank sum test **Chi-squared test

Note: 28 patients had a missing diagnosis

We collected data from 278 patients in the post-intervention period and excluded data for 11 individuals who had a diagnosis of neonatal conjunctivitis and were also below 13 years leaving 267 patient records available for analysis. The median age was 29 years (IQR; 24, 35) and 56% were female and HIV prevalence was 3.4%. There were no differences in age, sex, and HIV status by index/partner status. Overall, similar to the pre-intervention

period, the most common diagnosis was urethral discharge (24.3%) followed by high risk abnormal vaginal discharge (24.0%) (Table 4). Also, the distribution of STI syndromes by sex were similar between the two periods. The most common diagnoses among index males were urethral discharge (57.0%) and genitoulcer disease (34.4%). The most common diagnoses among index females were high risk abnormal vaginal discharge (41.8%) and lower abdominal pain (35.0%). The pre- and post-intervention populations had similar demographic characteristics except for the HIV prevalence which was lower in the post-intervention population.

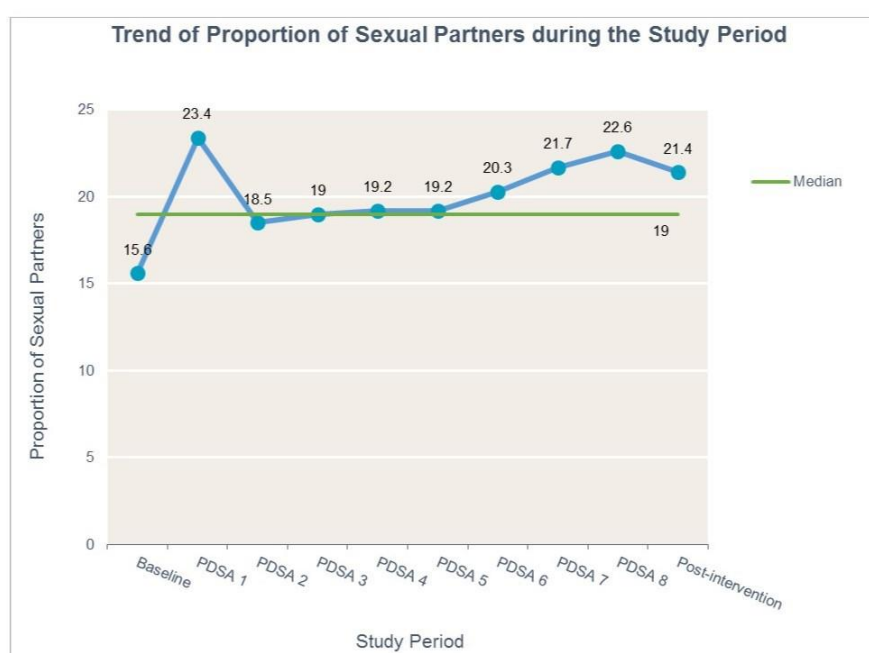


Figure 11: Trend in proportion of sexual partners during the study period

After implementing our intervention, the proportion of sexual partners who presented to BSU increased from 15.6% to 21.4% representing a 37% increase. This difference was statistically significant when compared to the baseline proportion ($P=0.040$). Figure 11 shows the trend in proportion of sexual partners who presented to BSU through the study period. The figure shows an upward trend with more than five consecutive data points showing an increasing trend which is indicative of a non-random signal of improvement in the proportion of sexual partners.

Chapter 4

4.0 DISCUSSION

The aim of this research project was to identify health system-related factors that influenced passive partner notification at BSU, use these factors to tailor-design and test improvement interventions in order to increase the proportion of sexual partner referral by 10 % from baseline using the MFI. Our intervention significantly increased the proportion of sexual partner referral by 37%. In this chapter, we discuss our findings in relation to available literature and highlight the strengths and limitations of the study. Finally, we conclude our findings and suggest recommendations from the study.

In this study, we demonstrated that it is possible to improve the proportion of sexual partner referral for the passive partner notification method through use of a quality improvement method, the MFI, at a dynamic clinic setting in a RLS. We used local data in form of key-informant interviews and clinic observations to identify drivers of poor sexual partner referral for passive PN and used local experts' opinion to design interventions. Despite not meeting the target for one intervention (clinic start time) out of the three in our package (expediting partners and duration of health talk), we managed to improve the passive PN process at BSU through use of small cyclical and incremental tests of change.

4.1 PARTNER NOTIFICATION

PN for STIs and HIV is acceptable, feasible and cost-effective in RLS [9,12,14,46]. Despite the high burden of STIs and HIV in these settings and the growing evidence of the effectiveness of PN in STI and HIV management, its use has developed slowly as some countries do not have policies on PN [24]. In a systematic review on PN in developing countries, many studies reported the success of PN in the notification, referral and treatment of sexual partners for both HIV and STIs. In the same review, most patients diagnosed with STIs preferred to inform their partners on their own making passive PN the most preferred method in these settings [12].

However, there is evidence that provider-initiated PN has a role in RLS. A large-scale implementation study in Cameroon showed that patients preferred provider-initiated PN over passive PN suggesting the need for some clinical-level support in the PN process [15,24]. In Malawi, Brown et al reported that provider-initiated PN was particularly useful in identifying male partners, casual partners, short-term relationship partners, partners with non-ulcerative STIs and more educated partners [9]. Despite such evidence, passive PN remains the widely used and recommended method for RLS highlighting the need for strengthening its effectiveness through use of implementation science methods.

4.2 BENEFITS OF PARTNER NOTIFICATION

Benefits of PN for both STI and HIV care have been detailed under literature review in chapter one of this report. Additionally, recent evidence suggests a potential role of PN to facilitate the recent WHO's 'test and treat' and treatment as prevention (TasP) HIV policies [24]. Both of these policies originate from the undisputed evidence that ART substantially reduces the risk of transmission as was demonstrated by the HIV prevention trials networks (HPTN) 052 study [47]. The 'test and treat' policy states that all people diagnosed with HIV infection should start ART as soon as possible [48]. The TasP policy

recommends use of ART to treat persons infected with HIV in order to reduce their viral load which in turn reduces their risk of transmission [48]. Since the inception of these policies in 2015, they have been adopted by many countries and have shown benefits in reducing HIV incidence and mortality [48].

PN identifies more people with HIV infection who can benefit from the ‘test and treat’ policy upon starting treatment and then help prevent further transmission of HIV to their uninfected partners if adherent to treatment (TasP). This crucial role corresponds with the UNAIDS 90-90-90 targets [18]. The aim for these targets are to have; 90% of people living with HIV know their status, 90% of people who know their HIV-positive status on treatment and 90% of people on treatment have viral suppression by 2020 [18]. Improving the yield of sexual partners from passive PN holds a great promise in contributing towards achieving the ‘first 90’ target.

4.3 BASELINE PROPORTION OF SEXUAL PARTNER REFERRAL

In this study, the baseline proportion of partner referral achieved through passive PN was very low. Compared to a previous study in at Kamuzu central hospital where partner notification achieved 24% partner referral in 2011 [9], our baseline proportion of partner referral was lower at 15.6%. Since around 1997, the proportion of sexual partners presenting for STI and HIV care has been less than one-third in Malawi [46]. In comparison with other developing countries, the low proportions in Malawi are comparable to proportions reported in a recent systematic review of about 20% to 34% [12]. The low proportion of partner referral at BSU is an indication that our QI intervention was vital and timely. Broadly, the low proportions within the region highlight the need for more QI interventions to increase the yield of sexual partners.

4.4 HEALTH SYSTEM-RELATED FACTORS INFLUENCING PN

Generally, sexual partners for index STI and HIV patients can be difficult to find because they may be asymptomatic hence they are not the ones seeking medical care for a primary health condition [46]. This background coupled with the many health system factors such as general lack of resources, poor diagnostics, poor management infrastructure, work overload, lack of trained staff and lack of policies and ethical guidelines that affect the efficiency of service make PN a more challenging task [12,34,35].

Similar to other developing countries [12], health system-related factors that influenced passive PN in our study were inadequate space and staff, poor staff attitude, late start time of the clinic and lack of incentives for partners or couples who presented to the clinic. Inadequate staffing and space was the most common health system factor reported by health workers at BSU. Health workers felt that the inadequate space and staff, coupled with late start of clinic activities, compromised the clinic from running efficiently due to congestion of patients and overload of work. These results were substantiated by findings from the clinic observations where the average clinic start time was 9:02 am and the average length of visit for both index patients and partners was above 1 hour. These factors were suggestive of a lack of key resources at BSU.

Lack of resources is a common factor affecting PN in developing countries as reported in a systematic review [12]. Lack of resources has been a longstanding problem that cannot be easily addressed in many health system settings. However, our intervention demonstrated that redirecting and reordering the few available resources is an effective way of improving the efficiency of health systems and health outcomes. A similar approach was used by researchers in Canada where they redirected the flow of non-urgent patients in the emergency room and appointed specific nurses from the existing team to attend to these patients [49].

Poor staff attitude among health workers at BSU was also reported to be demotivating for PN to index patients and their partners in our study. Osterlund et al reported that in order to achieve efficient PN, high motivation, training on open attitudes and

motivational interviewing techniques are needed [41]. This suggests the need for periodic training of staff on PN to keep them motivated, improve their counseling skills and help them improve their attitude towards STI/HIV patients.

Lack of incentives for partners or couples who presented to BSU was another important finding in our study. Majority of the key-informants and other experts suggested use of incentives as the best way to improve PN outcomes quickly at BSU. Use of incentives in health care has been shown to improve outcomes. Use of unconditional and conditional monetary or non-monetary incentives have been shown to increase HIV testing [50], increase retention in HIV care [51], increase condom use and safe sex behavior, and reduce unwanted pregnancies and HIV acquisition [52] among many other indicators. In Malawi, prioritizing care for pregnant women who came with their spouses coupled with other incentives helped to improve identification of new HIV infections and recruitment of male partners [53].

By using this approach, we managed to reduce the duration of clinic stay for sexual partners by 45 minutes and also indirectly reduced the duration of clinic stay for index patients by 28 minutes as a balancing measure. Use of incentives in STI and HIV PN should be considered by ministries of health in order to improve the yield of sexual partners through passive PN. Finally, as effort is put towards addressing health system factors, attention should not be lost on patient-related factors like stigma and discrimination that may escalate as a result of improving the effectiveness of passive PN.

4.5 THE USE OF THE EXPERT OPINION (CONSULTATIVE MEETING) AND QI TEAM

The use of local data and expertise in developing QI interventions are instrumental for successful implementation. These are useful for tailor-designing interventions that are acceptable and feasible for a particular setting as demonstrated by several studies

[38,49,54]. For instance, Twum-Danso et al worked with nurses and physicians as QI team members, district and regional management team members as change agents, local project facilitators and the health service officials as leaders in Ghana to generate and test local change ideas which contributed towards the success of the “Fives Alive” project [54]. Similarly, in our study, we used data collected locally through clinic observations and interviews with key-informants, the clinic staff. We then proceeded to hold a consultative meeting with clinic staff, research staff and the Malawi MoH officials as experts to develop interventions. We believe this was a key step towards the success of our intervention as it led to the development of a locally-fit intervention and brought a sense of ownership of the intervention to the frontline workers at BSU.

In addition, as aforementioned in the methods, the success of a QI project depends also on how well the QI team members work together, and with the rest of the health system [38]. The QI team champions the QI project. A QI team brings together knowledge, experiences, skills and perspectives of a range of people at different levels within a system which is vital for identifying areas for improvement and developing improvement interventions that are acceptable and feasible [38]. Benefits of using QI teams have been demonstrated in several studies. In Sweden, a specially trained QI team consisting of five nurses that conducted PN improved Chlamydia case detection by 12% [41]. Chartier et al used a QI team of frontline workers at an emergency department in a Canadian hospital to reduce the length of stay and wait time for physician assessment for non-urgent patients [49]. Similarly, we believe our QI team was instrumental to the success of our intervention as it owned and championed the intervention. Also, our QI team had a representation of individuals from different levels within the BSU health system ranging from leadership (nurse-in-charge) to frontline workers (nurses and counselors) to stewards (clinic aide) which was vital for the implementation of our intervention.

4.6 OUR INTERVENTION: CHOICE, IMPLEMENTATION (PDSA) AND RESULTS

The choice of the three interventions tested in our study was arrived at based on expert opinion through a unanimous vote. The criteria for voting was based on clinic needs assessment, availability of resources, good fit, available capacity, buy-in and ease of change at clinic level. This approach is similar to other approaches like the Delphi technique which is an eliminative voting process that allows experts choose and agree on the best interventions unanimously [55].

The first intervention we tested was early start time of clinic activities with a target of 08:00 hours. After the first test cycle we learnt that it was challenging to start the clinic early because patients were coming late. All patients at BSU went through the outpatient department in the morning which opened at 07:30 hours where they were attended to first and directed to the appropriate clinic/ward based on their presenting symptoms. Bwaila hospital being the only government secondary care hospital which offers free service and in a busy town area, it receives high volumes of patients therefore it takes long for patients to arrive at the respective clinics. This was the reason why the team chose 08:00 hours as the target start time. The QI team also learnt that sometimes patients got lost because the clinic did not have a sign post however, there were reservations from some members of the team to put up a sign post identifying the clinic as a STI clinic to avoid stigma and discrimination which would also deter patients and partners from visiting the clinic. A suggestion to put up a sign post with an alternative name of the clinic as it is famously referred to as “Room 8” was made however we were not able to implement this because it was outside the scope and budget of the study.

The second intervention we tested was shortening of the group health talk to less than 40 minutes. After observing the health talks pre-intervention, we found that the health talks were inconsistent and were either taking too long or there were too short and too brief. The health talks were used as the starting point for the PN process as patients were told about the rationale and advantages of PN and were allowed a chance to ask questions as a group. The start time and duration of health talks were mainly affected by the time that patients came to the clinic, the availability of a receptionist or their replacement, the time

the receptionist came to the clinic and started the talk and the time that the rest of the staff, especially clinical care nurses, came to the clinic. The experts suggested that these talks needed to be more consistent and concise so a retraining of the receptionist and nurses through practice of the sessions as dry-runs were done.

On the other hand, the QI team learnt that by shortening the duration of the health talks, the duration of wait time for treatment increased by 5 minutes because the government nurses who provided clinical care were coming late to the clinic. We believe this was a result of the fact that patients were coming late to the clinic so the nurses were not motivated to come early or vice versa. In response, we encouraged both the nurses and the patients to come early to the clinic to improve its efficiency. By shortening the duration of the health talk and starting the clinic early the experts hypothesized that this would eliminate unnecessary wastage of time and create more time for value-added activities like a concise health talk, clinical care and individual counseling on PN in the treatment rooms.

Eliminating unnecessary wastage of time in QI research is called the “Lean Methodology”. This was first described by a Japanese motor vehicle engineer in the early 1950s and its use has grown in QI research over time [35]. This methodology is used to identify and remove process inefficiencies by identifying non-value-added activities or “waste” to maximize use of resources on value-added activities [35]. At BSU, we eliminated wastage of time by improving the consistency of health talks and the start time of the clinic, though the target was not met, in order to create more time for one-to-one counseling on PN in the treatment rooms. Adequate counseling for PN is an important value-added activity for successful PN. In a trial in Zimbabwe, index patients in the counseling arm were more likely to notify their partners compared to patients who did not receive counseling [12]. Similarly in Zambia, more patients in the counseling arm were treated compared to those in the control arm [12].

The last intervention we tested was expedition of the sexual partner clinic flow. This originated from the finding that there was no incentive for partners or couples who

presented to the clinic. Also, the duration of clinic visits was similar for both index patients and partners. Considering that BSU patients were largely business people, our experts felt expediting partner visit was the most appropriate non-monetary incentive that would be feasible, acceptable, sustainable and adoptable by the ministry of health. Expedition of the clinic flow was achieved by allocating a designated HIV testing counselor which reduced the duration of visit for partners by 45 minutes. A similar approach was used by Chartier et al to expedite the clinic flow by assigning a special group of nurses to attend to non-urgent cases which led to a reduction in the wait time for patients to be seen by a physician and the total length of stay at an emergency department [49].

Regardless of the fact that we were not able to meet our target for one the process measures, we managed to increase the proportion of sexual partner referral by 37% from baseline. This demonstrates the potential of using QI methods to improve efficiency and effectiveness of passive PN. In addition, there was an upward trend in data points on the run chart which was indicative of a non-random signal of improvement in the proportion of sexual partners attributable to the intervention.

4.7 STRENGTHS AND LIMITATIONS

To our knowledge, this is the first research to attempt improving the PN process and its yield of sexual partners through use of a quality improvement method. The results will help inform researchers and policy makers on the role of quality improvement research in PN. Further, we believe our results are generalizable to other hospital settings apart from STI clinics since the QI approach used in our study can be adopted or adapted in any other clinical setting. Another strength of our study is in the sample size and power. We had a large sample size which achieved 95% power to detect a difference in the pre-post evaluation. Despite not directly measuring the acceptability of intervention, another strength in our study was in the use of local data and expert opinion as this led to development of an intervention that the health workers, as key implementers, played a major role in designing. This brought a sense of ownership of the intervention and was important for sustainability as our intervention was adopted as SOC at BSU. Also, the use

of a diverse QI team was another strength of our study as it involved all cadres of staff at BSU which made all levels of staff be involved in the intervention and feel responsible for the success of the intervention.

Even though the proportion of sexual partner referral increased from 15.6% to 21.4%, the post-intervention proportion is still not satisfactory. The post-intervention proportion may have been affected by several factors as limitations. Firstly, despite the clinic not having a sign post, the fact that our study was conducted at a STI clinic may have negatively influenced partners from presenting to the clinic due to the stigma and discrimination associated with STI clinic. BSU largely catered for busy small-scale business people like vendors and bus drivers some of whom did not stay in Lilongwe. These people may have been involved in short-term casual relationships and may have been too mobile to be traced or present to the clinic. Also, BSU being a very busy clinic to the extent that some patients are sent back home and told to return the following day, some partners may have reported to other clinics to avoid the busy clinic. However, despite all these limitations, we managed to increase the proportion of sexual partners by 37%. Additionally, the short duration of the study may have also affected the final outcome of our intervention. A review of QI projects from 12 countries showed that significant outcomes in practices and processes are often achieved within 6 to 12 months [56]. The duration of the study was 13 weeks with only one week in the post-intervention period. Due to this short duration we only powered our study targeting a 10% difference in the proportion tested from baseline and it also resulted in fewer weekly data points in the post-intervention period. However, based on the volume of patients at BSU, we could have been able to test for a larger effect difference if given more time to accrue a larger sample size and allow the interventions more time to mature.

4.8 CONCLUSION AND RECOMMENDATIONS

Our results demonstrate that passive PN can be successfully improved through use of the MFI in a RLS. Our intervention increased the proportion of sexual partners referred to the BSU using locally developed, sustainable and easily adoptable solutions. However, the proportion of sexual partner referral remains very low. Further improvement is still

required so future research must evaluate the long-term impact of our intervention, the potential for scalability, and other strategies for further improvement. Also, research to understand the impact of our intervention in a different setting unlike a specialized STI clinic is needed. More research exploring health system factors that affect PN in different settings and development of similar multi-pronged QI projects that would address issues cross-cutting the entire health system is also required. We did not observe how the one-on-one counseling was conducted by nurses in the treatment rooms. Counseling may have varied between individuals so further research looking at improving counselling techniques on PN is required.

We did not collect data on the number of partners referred per index case, cost-effectiveness of implementing the intervention and the number needed to invite to identify a positive STI or HIV case. Research estimating these parameters is required as it is important for policy makers in understanding the merits of an intervention. Also, further research involving patients, as consumers of the services of the health system, to get their perspective on the health system factors that influenced PN, their satisfaction/experience with the intervention and social harms is required.

Bibliography

1. WHO. WHO | Sexually transmitted infections (STIs). WHO. World Health Organization; 2016.
2. UNAIDS. Global Aids Up. Global AIDS Update. 2016.
3. WHO - World Health Organization. Global prevalence and incidence of selected curable sexually transmitted infections overview and estimates. overview and estimates. WHO Geneva. 2001;29.
4. AVERT. Global information and education on HIV and AIDS [Internet]. [cited 2017 Apr 18]. Available from: www.avert.org/professionals/hiv-around-world/sub-saharan-africa/malawi
5. The Malawi Ministry of Health. Demographic Health Survey. Malawi. 2015.
6. Brown LB, Miller WC, Kamanga G, Kaufman JS, Pettifor A, Dominik RC, et al. Predicting partner hiv testing and counseling following a partner notification intervention. *AIDS Behav*. 2012;16(5):1148–55.
7. UNAIDS, WHO. Sexually transmitted diseases: policies and principles for prevention and care. 1999. 48 p.
8. UNAIDS. UNAIDS PREVENTION GAP REPORT. 2016.
9. Brown LB, Miller WC, Kamanga G, Nyirenda N, Mmodzi P, Pettifor A, et al. HIV partner notification is effective and feasible in sub-Saharan Africa: opportunities for HIV treatment and prevention. *J Acquir Immune Defic Syndr*. 2011 Apr 15;56(5):437–42.
10. Brown LB. HIV partner notification in Malawi: Comparing methods and predicting

partner testing. Vol. 71, Dissertation Abstracts International: Section B: The Sciences and Engineering. 2010.

11. Azariah S. Partner notification for sexually transmitted infections. Why can't we talk about it? *N Z Med J.* 2012 May 25;125(1355):62–70.
12. Alam N, Chamot E, Vermund SH, Streatfield K, Kristensen S, Potterat J, et al. Partner notification for sexually transmitted infections in developing countries: a systematic review. *BMC Public Health.* 2010;10(1):19.
13. The Malawi Ministry of Health. Management of Sexually Transmitted Infections using Management Guidelines for Service Providers Third Edition Ministry of Health - Malawi. Third. 1-82 p.
14. Rutstein SE, Brown LB, Biddle AK, Wheeler SB, Kamanga G, Mmodzi P, et al. Cost-effectiveness of provider-based HIV partner notification in urban Malawi. *Health Policy Plan.* 2014 Jan;29(1):115–26.
15. Henley C, Forgwei G, Welty T, Golden M, Adimora A, Shields R, et al. Scale-Up and Case-Finding Effectiveness of an HIV Partner Services Program in Cameroon: An Innovative HIV Prevention Intervention for Developing Countries. *Sex Transm Dis.* 2013;40(12):909–14.
16. Tafuma TA, Ntwayagae BC, Moalafhi CK, Bolebantswe JM. Patient-initiated sexual partner notification in Botswana and time taken for sexual contacts to report for treatment. *S Afr Med J.* 2013 Oct 11;104(1):42–4.
17. WHO. Guidelines for the Management of Sexually Transmitted Infections. 2003. 1-98 p.
18. UNAIDS. 90-90-90 An ambitious treatment target to help end the AIDS epidemic. [Http://Www.Unaids.Org/Sites/Default/Files/Media_Asset/90-90-90_En_0.Pdf](http://www.unaids.org/sites/default/files/media_asset/90-90-90_en_0.pdf). 2014. 40 p.
19. Malawi Ministry of Health. Government of Malawi Ministry of Health Integrated HIV Program Report April - June 2016. 2016. 1-37 p.

20. Kissinger P, Niccolai L, Magnus M, Farley T, Maher J, Richardson-Alston G, et al. Partner Notification for HIV and Syphilis. *Sex Transm Dis*. 2003 Jan;30(1):75–82.
21. Nichols BE, Götz HM, van Gorp ECM, Verbon A, Rokx C, Boucher CAB, et al. Partner Notification for Reduction of HIV-1 Transmission and Related Costs among Men Who Have Sex with Men: A Mathematical Modeling Study. Khudyakov YE, editor. *PLoS One*. 2015 Nov 10;10(11):e0142576.
22. Ferreira A, Young T, Mathews C, Zunza M, Low N. Strategies for partner notification for sexually transmitted infections, including HIV. Low N, editor. *Cochrane Database Syst Rev*. 2013 Oct 3;10(10):Cd002843.
23. Buchsbaum A, Gallo MF, Whiteman MK, Cwiak C, Goedken P, Kraft JM, et al. Sexually Transmitted Disease Partner Notification among African-American, Adolescent Women. *Infect Dis Obstet Gynecol*. 2014;2014:1–9.
24. Hosseinipour MC, Rosenberg NE. HIV Partner Notification. *Sex Transm Dis*. 2013 Dec;40(12):915–6.
25. Ward H, Bell G. Partner notification. *Medicine (Baltimore)*. 2010;38(5):239–41.
26. Estcourt CS, Sutcliffe LJ, Shackleton T. Achieving successful partner notification: putting together the pieces of the puzzle. *Int J STD AIDS*. 2009 Sep 1;20(9):601–2.
27. Hogben M. Partner notification for sexually transmitted diseases. *Clin Infect Dis*. 2007 Apr 1;44 Suppl 3(Supplement 3):S160-74.
28. Estcourt CS, Sutcliffe LJ, Copas A, Mercer CH, Roberts TE, Jackson LJ, et al. Developing and testing accelerated partner therapy for partner notification for people with genital *Chlamydia trachomatis* diagnosed in primary care: a pilot randomised controlled trial. *Sex Transm Infect*. 2015 Dec;91(8):548–54.
29. Rosenberg NE, Mtande TK, Saidi F, Stanley C, Jere E, Paile L, et al. Recruiting male partners for couple HIV testing and counseling in Malawi's option B+ programme: An unblinded randomised controlled trial. *Lancet HIV*. 2015 Nov;2(11).
30. Potterat JJ. Puzzling Observations in a Trial of HIV Partner Notification in Sub-

- Saharan Africa. *JAIDS J Acquir Immune Defic Syndr*. 2011 Apr;56(5):381–3.
31. Wang AL, Peng R-R, Tucker JD, Cohen MS, Chen X-S. Partner notification uptake for sexually transmitted infections in China: a systematic literature review. *Sex Transm Infect*. 2012;88(5):386–93.
 32. Morris JL, Lippman S a., Philip S, Bernstein K, Neillands TB, Lightfoot M. Sexually transmitted infection related stigma and shame among African American male youth: Implications for testing practices, partner notification, and treatment. *AIDS Patient Care STDS*. 2014;28(9):499–506.
 33. Thurman AR, Shain RN, Holden AEC, Champion JD, Perdue ST, Piper JM. Partner notification of sexually transmitted infections: a large cohort of Mexican American and African American women. *Sex Transm Dis*. 2008;35(2):136–40.
 34. Reed JL, Huppert JS, Gillespie GL, Taylor RG, Holland CK, Alessandrini EA, et al. Adolescent Patient Preferences Surrounding Partner Notification and Treatment for Sexually Transmitted Infections. Bonsu B, editor. *Acad Emerg Med*. 2015 Jan;22(1):61–6.
 35. Varkey P, Reller M, Resar R. Basics of quality improvement in health care. *Mayo Clin Proc*. 2007;82(6):735–9.
 36. Marshall M, Pronovost P, Dixon-Woods M. Promotion of improvement as a science. *Lancet*. 2013;381(9864):419–21.
 37. Clarke DL. Trauma quality improvement: The Pietermaritzburg Metropolitan Trauma Service experience with the development of a comprehensive structure to facilitate quality improvement in rural trauma and acute care in KwaZulu-Natal, South Africa. *S Afr Med J*. 2015 Jan 3;105(2):92–5.
 38. Ramaswamy R, Bios GD, Iracane S, Srofenyoh E, Bryce F, Floyd L, et al. Transforming Maternal and Neonatal Outcomes in Tertiary Hospitals in Ghana : An Integrated Approach for Systems Change. *J Obstet Gynaecol Canada*. 2015;37(10):905–14.

39. Apoola A, Radcliffe KW, Das S, Robshaw V, Gilleran G, Kumari BS, et al. Preferences for partner notification method: Variation in responses between respondents as index patients and contacts. *Int J STD AIDS*. 2007;18(7):493–4.
40. Apoola A. Radcliffe K. Das S. Robshaw V. Gilleran G. Kumari B. Boothby M. Rajakumar R, Apoola A. Radcliffe KW. Das S. Robshaw V. Gilleran G. Kumari BS. Boothby M. Rajakumar R, Apoola A, Radcliffe KW, Das S, et al. Patient preferences for partner notification. *Sex Transm Infect*. 2006;82(4):327–9.
41. Österlund A. Improved partner notification for genital chlamydia can be achieved by centralisation of the duty to a specially trained team. *Int J STD AIDS*. 2014 Dec;25(14):1009–12.
42. McLees AW, Nawaz S, Thomas C, Young A. Defining and assessing quality improvement outcomes: A framework for public health. *Am J Public Health*. 2015;105:S167–73.
43. Hulscher ME, Laurant MG, Grol RP. Process evaluation on quality improvement interventions. *Qual Saf Health Care*. 2003;12(1):40–6.
44. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implement Sci*. 2015;10(1):21.
45. Taylor MJ, McNicholas C, Nicolay C, Darzi A, Bell D, Reed JE. Systematic review of the application of the plan – do – study – act method to improve quality in healthcare. 2014;290–8.
46. Kamanga G, Brown L, Jawati P, Chiwanda D, Nyirenda N. Maximizing HIV partner notification opportunities for index patients and their sexual partners in Malawi. *Malawi Med J*. 2015 Dec;27(4):140–4.
47. Cohen MS, Mccauley M, Gamble TR. HIV treatment as prevention and HPTN 052.
48. WHO. Progress Report 2016, prevent HIV, test and treat all. *Prog Rep 2016, Prev*

HIV, test treat all. 2016;64.

49. Chartier L, Josephson T, Bates K, Kuipers M. Improving emergency department flow through Rapid Medical Evaluation unit. *BMJ Qual Improv reports*. 2015;4(1 PG-10.1136/bmjquality.u206156.w2663. eCollection 2015):10.1136/bmjquality.u206156.w2663. eCollection 2015.
50. Bassett I V., Wilson D, Taaffe J, Freedberg KA. Financial incentives to improve progression through the HIV treatment cascade. *Curr Opin HIV AIDS*. 2015 Nov;10(6):451–63.
51. Solomon SS, Srikrishnan AK, Vasudevan CK, Anand S, Kumar MS, Balakrishnan P, et al. Voucher incentives improve linkage to and retention in care among HIV-infected drug users in Chennai, India. *Clin Infect Dis*. 2014 Aug 15;59(4):589–95.
52. Rosenberg M, Pettifor A, Nguyen N, Westreich D, Bor J, Bärnighausen T, et al. Relationship between receipt of a social protection grant for a child and second pregnancy rates among South African women: A cohort study. Hahn S, editor. *PLoS One*. 2015 Sep 23;10(9):e0137352.
53. Mphonda SM, Rosenberg NE, Kamanga E, Mofolo I, Mwale G, Boa E, et al. Assessment of Peer-Based and Structural Strategies for Increasing Male Participation in an Antenatal Setting in Lilongwe, Malawi. *Afr J Reprod Health*. 2014;18(2):97–104.
54. Twum-Danso N a Y, Akanlu GB, Osafo E, Sodzi-Tettey S, Boadu RO, Atinbire S, et al. A nationwide quality improvement project to accelerate Ghana's progress toward Millennium Development Goal Four: design and implementation progress. (Special Issue: Quality of care in low and middle income countries.). *Int J Qual Heal Care*. 2012;24(6):601–11.
55. Yousuf MI. Using experts' opinions through Delphi technique. *Pract Assessment, Res Eval*. 2007;12(4):Available online: <http://pareonline.net/getvn.asp?>
56. Franco LM; Marquez L; Ethier K; Balsara Z; Isenhower W. Results of collaborative

improvement: Effects on health outcomes and compliance with evidence-based standards in 27 applications in 12 countries. Univ Res Co. 2009;

APPENDIXES

Appendix I: Plagiarism Declaration

Appendix II: Partner Notification/Referral Slips

Appendix III: Bwaila STI Unit Health Talk Job Aide

Appendix IV: Information Sheet and Informed Consent Form

Appendix V: Interview Guide

Appendix VI: Data Collection Form

Appendix VII: Model for Improvement

Appendix VIII: Formative Phase HREC Approval

Appendix IX: Intervention Phase HREC Approval

Appendix X: NHSRC Ethics Approval

Appendix XI: Letter of Support from Lilongwe District Hospital.

Appendix I: Plagiarism Declaration



PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I **MITCH MATOGA** (Student number: **1314741**) am a student registered for the degree of Master of Science in Epidemiology – Implementation Science in the academic year **2016 - 2017**.

I hereby declare the following:

- ❖ I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- ❖ I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- ❖ I have followed the required conventions in referencing the thoughts and ideas of others.
- ❖ I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.

A handwritten signature in black ink, appearing to read 'Mitch Matoga', with a long horizontal line extending to the right.

Signature: _____ Date: November 13, 2017

Appendix II: Sexual Partner Notification Slips for Bwaila STI Unit

CHIDZIWITSO Chonde bwerani ndi kalata iyi mwansanga ku chipatala cha Bwaila ku Room 8, kuti mudzathandizidwe mwachangu Notice: Please come with this card to Bwaila Hospital room 8, as soon as possible so that you can be assisted quickly Date:.....	CHIDZIWITSO Chonde bwerani ndi kalata iyi mwansanga ku chipatala cha Bwaila ku Room 8, kuti mudzathandizidwe mwachangu Notice: Please come with this card to Bwaila Hospital room 8, as soon as possible so that you can be assisted quickly Date:.....
CHIDZIWITSO Chonde bwerani ndi kalata iyi mwansanga ku chipatala cha Bwaila ku Room 8, kuti mudzathandizidwe mwachangu Notice: Please come with this card to Bwaila Hospital room 8, as soon as possible so that you can be assisted quickly Date:.....	CHIDZIWITSO Chonde bwerani ndi kalata iyi mwansanga ku chipatala cha Bwaila ku Room 8, kuti mudzathandizidwe mwachangu Notice: Please come with this card to Bwaila Hospital room 8, as soon as possible so that you can be assisted quickly Date:.....
CHIDZIWITSO Chonde bwerani ndi kalata iyi mwansanga ku chipatala cha Bwaila ku Room 8, kuti mudzathandizidwe mwachangu Notice: Please come with this card to Bwaila Hospital room 8, as soon as possible so that you can be assisted quickly Date:.....	CHIDZIWITSO Chonde bwerani ndi kalata iyi mwansanga ku chipatala cha Bwaila ku Room 8, kuti mudzathandizidwe mwachangu Notice: Please come with this card to Bwaila Hospital room 8, as soon as possible so that you can be assisted quickly Date:.....

Appendix III: Bwaila STI Unit Group Health Talk Job Aide

Bwaila STI Unit Health Talk Job Aide

- Welcoming Clients
- What is done at STI Clinic
 - HIV Testing
 - STI Treatment
- About partners and partner notification slips
 - Counsellor finds out who came with partner notification slips
 - Notify the listeners that partners and couples will be expedited through the clinic
- **STIs**
 - A. **Types of STIs**
 - Syphilis
 - Gonorrhea
 - Urethral Discharge
 - Lower Abdominal pains
 - Rash - Zoyabwa
 - Scrotal swelling
 - Bubo
 - Genital warts
 - B. **Complications of STIs**
 - Abortions

- Premature births
- Neonatal Conjunctivitis
- Mental problems
- Infertility

C. How STIs are contracted

D. Prevention

- Abstinence
- Condom use
- Faithfulness to partner
- One partner

• **HIV**

A. Relationship between HIV and STI

B. Why get HIV test

- Everyone should know his/her current status
- Everyone should receive proper counselling accordingly
- Everyone should be referred for care in proper places

C. How HIV is spread

- Not knowing your status/your partner's status
- Multiple partners
- No condom use, etc

D. How to prevent HIV and STIs

• **How to prevent HIV and STIs**

- Abstinence
- Condom use
- Faithfulness to partner
- Have one partner

- **Current Studies**

- a. Introduction of the study
- b. Why participate in the study
- c. Advantages of participating in the study

*** Identify people who have partner notification slips and those who have come as a couple

If they have an HIV result, escort them to the clinic nurse for treatment If they do not have an HIV test result, escort them to a designated counselor for testing partners and couples only.

** Identify index patients who already have an HIV test and escort them to the clinic nurse for treatment.

Appendix IV: Improving STI/HIV passive Partner Notification Using Quality Improvement Methods in Malawi Research Study

A. INFORMATION SHEET (Clinic staff)

Hello, my name is Dr. Mitch Matoga, I am a Master in Epidemiology – Implementation science student in the School of Public Health at the University of Witwatersrand.

As a partial fulfilment of the requirements of my training I will be conducting a research study to investigate the health facility related factors that influence passive partner notification at Bwaila STI unit. Furthermore, I will implement changes that will address the factors with an aim of improving the partner referral process and rates.

What is the purpose of this study?

You are being asked to take part in this research study because:

- You are part of staff at Bwaila District Hospital STI unit.

Before you decide if you want to join this study, we want you to know about the study. We will explain the study to you. You are free to ask questions at any time. If you decide to join, we will ask you to sign this consent form. You will be offered a copy to keep.

The primary goal of the study is to identify factors within the health facility and health system that affect whether or not sexual partners of index patients present to the clinic for medical attention. This study will also attempt to address some of the identified factors in order to increase the partner referral rates. Before you decide to participate, we would like you to understand why the research is being done, and what it would involve for you.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.

You may refuse to join, or you may withdraw your consent to be in the study, for any reason and at any time.

Deciding not to be in the study or withdrawing consent will not affect your relationship with the researcher, your superiors, or your employer

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above any questions you have about this study at any time.

What is involved in the study?

If you agree to take part in this study, we will conduct an interview to ask you question on the following main topics:

- Your knowledge concerning how the clinic functions.
- Your knowledge of any factors that you think may affect the referral process positively or negatively.
- Your knowledge on some changes that you think may help improve the referral process.

Please note that the interview will be recorded using an MP3 recorder to aid transcription of the information you provide. All information provided will be confidential and shall be handled with utmost care. Information from the recordings shall not be shared directly to any other authority.

Procedure

Interview

This interview will be conducted once at the beginning of the study. It is expected to last about 10 to 20 minutes. As stated above, it will include question about the health facility structures and systems that may influence whether or not a sexual partner to an index case presents to the clinic. It will also include questions on what could be improved within the facility that would improve the partner referral process and help increase the rate of partners that present to the clinic.

You will also be asked to participate in a workshop that will be conducted after the interview results are put together to get feedback on the interview findings and also to contribute towards the prioritizing changes within the referral process to be tested at the clinic in order to improve the partner referral rates.

If you are uncomfortable about answering any of the questions you need not answer them. If you refuse to answer a question, you will not be penalized or lose any benefits to which you may be entitled.

What are the possible benefits of this study?

Research is designed to benefit the health facility and the society by gaining new knowledge. This study may or may not be of direct benefit to you. The results of the study will be shared with you through a workshop that will be arranged later.

What are the possible risks or discomforts involved with study screening?

There are very minimal, if not none, risks that you may incur from participating in this study. Information on the recordings will be handled with confidentiality and identification number will be used when collecting notes during the interview. However, in extreme cases where the recorded information leaks, it may result into resentment from colleagues

or employers.

Will it cost you anything to be in this study?

The interview will be done at no cost.

Records of your participation in this research: What about confidentiality?

You have the right to privacy. The principal investigator will keep the voice recorders with the recorded information in lockable cabinets. Notes from the interviews will also be kept in a lockable cabinet. We will use identification numbers on both the voice recording and the notes. This means that no personal information will be used on any of the study material that would enable anyone to link any of the information to you personally.

- Ethical approval: This study protocol has been submitted to the University of the Witwatersrand's, Human Research Ethics Committee (HREC) in South Africa, the National Sciences Research Ethics committee in Malawi and written approval has been granted by both committees. Ethics Clearance numbers: M161198 and 1657.
- Publication of the results of the research: The results of this research may appear in scientific publications without identifying you in any way.

Your questions:

The investigator listed on the first page of this form is available to answer your questions about this research. You may contact the investigator at any time on the following number (265) 999511726. If you require any further information or have any questions/complaints about the study please contact the National Health Sciences Research Ethics Committee chairperson, Dr. Damson Kathyola on (265) 888-344-443 or contact the Human Research Ethics Committee of the University of the Witwatersrand on (011) 717-1234 or anisa.keshav@wits.ac.za

YOU WILL HAVE A COPY OF THIS INFORMATION SHEET TO KEEP

If you are happy to take part in the study, please read and sign the attached consent form and contact us to confirm your participation.

Your signature on the consent form certifies the following:

- You have read the information provided in this consent form
- You have received answers to all of your questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.

B. CONSENT FORM

I agree to myself being a participant in the study. The goals and methods of the study are clear to me.

I understand that the study will involve an interview that will be recorded. All the details and purposes of this study have been explained to me. I understand that I have the right to refuse to participate in the study at any time.

I agree to participation in the study on the condition that:

1. I can withdraw voluntarily from the study at any time and that no adverse consequences will follow on withdrawal from the study.
2. I have the right not to answer any or all questions posed in the interview.
3. The University of the Witwatersrand's Human Research Ethics Committee and the National Health Sciences Research Ethics Committee have approved the study protocol and procedures.
4. Recorded information will be treated with the strictest confidentiality.
5. Only collective interview results, and not my individual results, will be published in scientific journals and/or in the media.
6. The investigator is committed to treating participants with respect and privacy through the interview conducted in private.

Appendix V: Improving STI/HIV Passive Partner Notification using Quality Improvement Methods

Interview guide for health care providers

Id No_____ Age_____ Sex_____ Marital Status _____

Cadre_____ Date of interview _____

Start time _____ Stop time _____

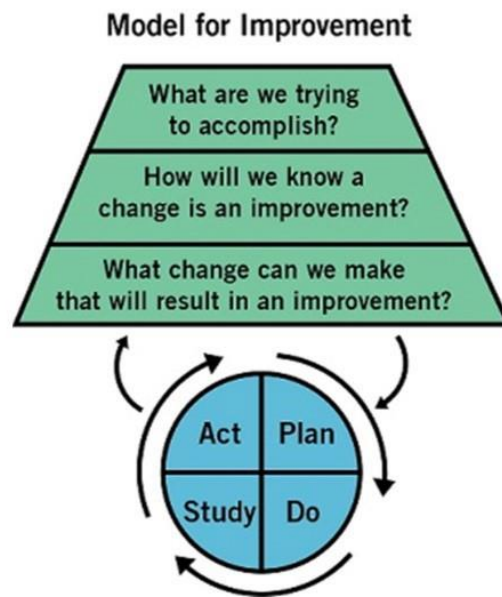
1. Can you please describe the steps/flow/ process for a clinic visit for all patients?
2. How do the steps/flow/process for a clinic visit differ if the patient is identified as a partner, if at all?
3. Are there any common characteristics that you have observed about the nature of patients that come to the clinic as either as index cases or partners of an index case that you think may have an influence on the partner referral process?
4. What are some of the health facility related factors that you think may impact on whether or not a patient will refer their sexual partners to the clinic?
5. What are some of the health facility related factors that you think may discourage a sexual partner from coming for medical attention?
6. What are some of the health facility related factors that may discourage a patient from identifying themselves as a partner upon presenting to the clinic?
7. What are some of the ways you think we can change to improve the way the health facility operates that you think may help increase the number of partners that present to the clinic for care?
8. If you were to choose one very important change that you think would have the greatest impact on the partner referral process, what would that be?

Appendix VI: Improving STI/HIV Passive Partner Notification using Quality Improvement Methods

Data Collection Form

Date	Start time: Stop time:
Activity being observed	
Activity Setting (Where is it being conducted)	
Purpose of the activity	
Duration of the activity	Start: Stop: Total:
Who is conducting the activity (Cadre)	
Notes on the attitude of the person conducting the activity	
Notes on the patient's attitude	
Number of providers conducting the activity	
Notes on any contextual impediments noted	
Notes on any contextual facilitators noted	
Any other notes	

Appendix VII: Model for Improvement



Source: www.ihi.org

1. **Aim:** What are we trying to accomplish?
2. **Measures:** How will we know a change is an improvement?
3. **Changes:** What change can we make that will result in improvement?

AND PDSA Cycles.

Appendix VIII: Formative Phase HREC Approval

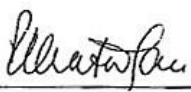


R14/49 Dr Mitch Matoga

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M161198

NAME: Dr Mitch Matoga
(Principal Investigator)
DEPARTMENT: Epidemiology and Biostatistics
Bwaila District Hospital's Sexually Transmitted Infections
(STI) Clinic, Lilongwe, Malawi
PROJECT TITLE: Improving Sexually Transmitted Infections/Human
Immunodeficiency Virus (STI/HIV): Passive Partner
Notification using Quality Improvement Methods in Malawi
DATE CONSIDERED: 25/11/2016
DECISION: Approved unconditionally
CONDITIONS: Phase One
SUPERVISOR: Prof Charles Chasela

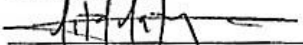
APPROVED BY: 
Professor P Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 23/01/2017

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and ONE COPY returned to the Research Office Secretary in Room 301, Third Floor, Faculty of Health Sciences, Phillip Tobias Building, 29 Princess of Wales Terrace, Parktown, 2193, University of the Witwatersrand. I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. I agree to submit a yearly progress report. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in November and will therefore be due in the month of November each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).


Principal Investigator Signature

Date

28 January 2017

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix IX: Intervention Phase HREC Approval



R14/49 Dr Mitch Matoga

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M161198

NAME: Dr Mitch Matoga
(Principal Investigator)
DEPARTMENT: Epidemiology and Biostatistics
Bwaila District Hospital, Lilongwe, Malawi

PROJECT TITLE: Improving Sexually Transmitted Infections/Human Immunodeficiency Virus (STI/HIV): Passive Partner Notification using Quality Improvement Methods in Malawi

DATE CONSIDERED: 25/11/2016

DECISION: Approved unconditionally

CONDITIONS: (Phase 2)

SUPERVISOR: Prof Charles Chasela

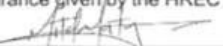
APPROVED BY: 
Professor P. Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 07/04/2017

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

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


Principal Investigator Signature

Date

April 08, 2017

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix X: NHSRC Ethics Approval

Telephone: + 265 789 400
Facsimile: + 265 789 431

All Communications should be
addressed to:

The Secretary for Health and Population



In reply please quote No.

MINISTRY OF HEALTH AND POPULATION

P.O. BOX 30377
LILONGWE 3
MALAWI

29th November, 2016

Mitch Matoga
UNC Project
Lilongwe

Dear Madam,

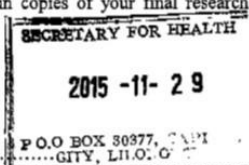
RE: PROTOCOL # 1657: 'IMPROVING STI/HIV PARTNER NOTIFICATION USING QUALITY IMPROVEMENT IN MALAWI'

Thank you for the above titled proposal that you submitted to the National Health Sciences Research Committee (NHSRC) for review. Please be advised that the NHSRC has **reviewed** and **approved** your application to conduct the above titled study.

- **APPROVAL NUMBER** : 1657
- The above details should be used on all correspondences, consent forms and documents as appropriate.
- **APPROVAL DATE** : 29/11/2016
- **EXPIRATION DATE**
This approval expires on 28/11/2017. After this date, this project may only continue upon renewal. For purposes of renewal, a progress report on a standard form obtainable from the NHSRC Secretariat should be submitted one month before the expiration date for continuing review.
- **SERIOUS ADVERSE EVENT REPORTING**: All serious problems having to do with subject safety must be reported to the NHSRC within 10 working days using standard forms obtainable from the NHSRC Secretariat.
- **MODIFICATIONS**: Prior NHSRC approval using forms obtainable from the NHSRC Secretariat is required before implementing any changes in the protocol (including changes in the consent documents). You may not use any other consent documents besides those approved by the NHSRC.
- **TERMINATION OF STUDY**: On termination of a study, a report has to be submitted to the NHSRC using standard forms obtainable from the NHSRC Secretariat.
- **QUESTIONS**: Please contact the NHSRC on phone number +265 888 344 443 or by email on mohdocentre@gmail.com.
- **OTHER**: Please be reminded to send in copies of your final research results for our records (Health Research Database).

Kind regards from the NHSRC Secretariat.

For: **CHAIRPERSON, NATIONAL HEALTH SCIENCES RESEARCH COMMITTEE**
Promoting Ethical Conduct of Research



Executive Committee: Dr B. Chilima (Chairperson), Dr B. Ngwira (Vice-Chairperson)
Registered with the USA Office for Human Research Protections (OHRP) as an International IRBIRB
Number IRB00003905 FWA00005976

Appendix XI: Letter of support from Lilongwe District Health Office

Ref. No.:
Telephone No.: 265 726 466/464
Telefax No.: 265 727817
Telex No.:
E-Mail: lilongwedho@malawi.



In reply please quote NO DZH/MALAWI,
Lilongwe District Health Office
P.O. Box 1274
Lilongwe
Malawi

COMMUNICATIONS TO BE ADDRESSED TO:

3rd November, 2016

The Research Ethics Committee
The University of Witwatersrand
Johannesburg
SOUTH AFRICA

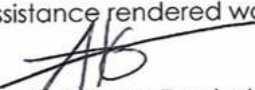
Dear Sir/Madam

PERMISSION TO CONDUCT A STUDY IN LILONGWE DISTRICT

Approval has been granted to the bearer of this letter:- **Dr. Mitch Matoga**,
from University of Witwatersrand, to Conduct a study at Bwaila STI clinic,
Lilongwe, Malawi.

**"Improving STI/HIV Passing Partner Notification using quality Improvement
Methods in Malawi"**

Any assistance rendered would be appreciated.


Dr. Alinafe Mbewe Tambala
DISTRICT HEALTH OFFICER - LILONGWE

