

Cluster randomized intervention trial to evaluate the impact of the ‘Opt-out’ versus ‘Opt-in’ strategy on the uptake of HIV counseling and testing of tuberculosis patients in the Province of the Eastern Cape, South Africa: A Report for the Health Departments

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## INTRODUCTION

As the World Health Organization (WHO), the Global Fund for AIDS, TB and Malaria, the President's Emergency Plan for AIDS Relief and other initiatives work toward the goal of providing antiretroviral therapy to millions of eligible HIV infected individuals, it is imperative that populations have adequate access to appropriate HIV counseling and testing. Building on the WHO model of the ProTEST initiative, this study introduced a strategy beyond Voluntary Counseling and Testing (VCT), the "opt-out" strategy, increasing the probability that more HIV-positive patients will learn their infection status and have access to life-saving therapies.

Health care workers trained in the current model of HIV counseling and testing typically ask a patient if he or she wants HIV counseling and testing. The burden of decision-making is placed on the individual patient; to receive HIV counseling the patient must say 'yes' – to opt-in. The opt-out strategy shifts the burden of HIV counseling from the patient to the health care provider. HIV counseling is carried out routinely; patients receive counseling unless they refuse it – opt-out. HIV testing is done only when patients have given their informed consent.

We carried out a study using a pragmatic design to enable us to evaluate the impact of implementing the opt-out strategy in a clinic environment where HIV counseling and testing typically takes place. We reasoned that if the strategy could have an impact in a setting with high TB case rates, lack of funds and a lack of staff, then the opt-out strategy could be successfully implemented anywhere.

Our clinic-based study was cluster-randomized, using constrained randomization to allocate clinics to intervention or control arms. Random allocation removes bias from the process of assignment to an intervention. The unpredictability of allocations can be problematic in studies with relatively small sample sizes, typical in cluster-based studies. Constrained randomization is a method that has been developed specifically for studies with clusters as the level of inference and makes it more likely that there will be balance between study arms, while maintaining the benefits of random assignment (1, 2).

The uptake of HIV counseling and testing varies widely by setting and circumstance (3-7). Counseling and testing is complicated by more than access and availability of resources; many individuals do not seek testing for a variety of reasons, including fear of being stigmatized, lack of privacy at clinics, lack of transportation to clinics and perceived or real lack of treatment and support after diagnosis (8, 9). Signing a consent can be a barrier for some patients (10). It has been demonstrated that selective counseling and testing based on perceived risk, by either the patient or the health care provider, is not effective in identifying all individuals with HIV infection (6, 10). The end result is that people who need to know their HIV status to obtain life-sustaining treatment are not receiving it.

In June, 2004 UNAIDS/WHO made a joint policy statement that illustrated a fundamental shift from the purely voluntary model of HIV counseling and testing (VCT)

that had been recommended up until then, and had been the model for the ProTEST initiative. The policy statement made specific recommendations related to populations for whom diagnostic HIV testing should be administered.

“Diagnostic HIV testing is indicated whenever a person shows signs or symptoms that are consistent with HIV-related disease or AIDS to aid clinical diagnosis and management. This includes HIV testing for all tuberculosis patients as part of their routine management...patients retain the right to refuse testing, i.e. To ‘opt out’ of a systematic offer of testing p.2.(11).”

## **CHAPTER 1**

### **STUDY DESIGN AND METHODS**

The goal of this community-based, cluster (clinic) randomized study was to measure the impact of the implementation of the opt-out strategy on the uptake of HIV counseling and testing by TB patients newly registered at public health clinics in the Eastern Cape. Carried out in a public health system already forced to function well beyond capacity, a pragmatic design was implemented with the explicit intention of enhancing TB nurses’ knowledge and capacity to perform routine HIV counseling and testing without additional burdens of documentation. Pragmatic trials measure effectiveness; they measure the degree of beneficial effect in real clinical practice.

We selected TB clinics and randomly assigned them to receive training in the opt-out strategy or to serve as controls. The primary study outcomes were the proportion of newly registered TB patients that received HIV counseling and testing in those clinics where the opt-out strategy was implemented, in comparison to those clinics that served as controls and continued with the status quo. Secondary outcomes were the proportion of HIV-tested patients with positive results and, of those, the proportion that were prescribed cotrimoxazole and/or were referred for HIV care.

At the conclusion of data collection for the quantitative component of the study, a qualitative sub-study was carried out with the intention of gaining more information to interpret the study’s quantitative findings. Focus groups comprised of the designated TB nurses at each of the study clinics and interviews of selected key informants were held in January 2006.

#### **Protection of study subjects**

Permission to go forward with the study was obtained from the Department of Health of the Eastern Cape Province on October 25, 2004, with the qualifications that the study protocol and study results be shared with the Department. The Johns Hopkins Bloomberg School of Public Health Committee on Human Research delivered a certificate of exemption for the study protocol on March 9, 2005. The Faculty of Health Sciences Human Research Ethics and Bio-safety Committee of the University of

Transkei, located in the Eastern Cape Province, gave approval on April 4, 2005, following an expedited review. An amendment to the original proposal, requesting permission to proceed with qualitative interviews and focus groups was approved by the Johns Hopkins CHR on November 3, 2005 and by the newly renamed Walter Sisulu University on December 13, 2005.

### **Selection of study clinics**

Clinic inclusion was based on the monthly TB patient load and the reported presence of an HIV counselor, presence of HIV rapid test kits, and access to cotrimoxazole and antiretroviral therapy. Study criteria were submitted to the municipal health department. The selection of clinics was limited by a concurrent intervention being carried out in the fifteen largest clinics by a USAID-funded project named TASC II TB. Twenty medium-sized clinics in the Nelson Mandela Metropolitan Municipality (NMMM), in the Eastern Cape Province of South Africa were assigned, based on clinic size, to our study by the health department. Of the twenty clinics assigned, six were situated in one sub-district and the remaining clinics were equally divided between two more sub-districts in the municipality.

### **Study population**

In order to ensure that the participants reflected the population for which the intervention is ultimately intended, exclusion criteria were kept to a minimum (12). The target population was newly diagnosed adult TB patients in the Eastern Cape Province primary care clinics. Therefore, the sampling frame was composed of adult patients newly registered at the study clinics during the study period.

***Inclusion criteria:*** Adults ( $\geq 18$  years) newly registered as TB patients at primary care clinics in Eastern Cape defined study inclusion criteria. Data were collected on all adult TB patients for ease of data collection. We did not want to miss eligible patients that may have been misclassified.

***Exclusion criteria:*** Age less than 18 years, and individuals not newly registered as TB patients were excluded from the study. TB patients originally diagnosed, registered and treated elsewhere and referred to the study clinic were not eligible because the intervention was targeted to newly registered TB patients. Although TB patients could be HIV counseled and tested at any time during their course of treatment, the focus of this study was on testing them as early in their treatment as possible.

***Study Outcomes:*** The main study outcomes were the proportion of TB patients HIV counseled and tested in each study clinic. Secondary outcomes included the proportion of patients with a positive HIV test, and the proportion of the HIV positive patients that were prescribed cotrimoxazole and/or referred for HIV care.

### **Study activities**

#### ***Overview***

The study began in May 2004 with clinic assessments which were completed in June. HIV counseling and testing training for TB nurses in six of the study clinics was carried

out by the health department. In July, an HIV Counseling and Testing Register was designed and documentation training was completed in all study clinics. Randomization was carried out on August 1, 2005. Training in the opt-out strategy was carried out over two days in August and the data collection period commenced the following day. Following the completion of data collection on November 10, the qualitative study was launched and focus groups and key informant interviews were planned and were carried out in January, 2006.

### ***Clinic situation analysis***

Clinic evaluations were carried out by study staff with the intention of ascertaining monthly clinic statistics that could be used as the basis for the randomization of study clinics. In addition, we were interested in learning the state of HIV counseling and testing for TB patients at each study clinic. At least one nurse was interviewed at each clinic -- the TB nurse was interviewed when available. The nurse was asked to explain the process for HIV counseling and testing, whether (s)he was trained, what documentation was used to document counseling and testing and whether cotrimoxazole was regularly stocked. HIV counselors were also questioned about who did the HIV counseling and testing, whether or not they were trained, and whether the clinic was regularly stocked with HIV rapid tests. See appendix A for the specific questions in the analysis.

### ***HIV counseling and testing training***

Most TB nurses had been trained in VCT. Six TB nurses were identified during the situation analysis that had not been certified in HIV counseling and testing. These nurses received standard health department training prior to the study's initiation. The training was attended by the study manager to learn exactly what was taught, and to learn how to design our intervention training to complement the HIV counseling and testing training.

### ***New HIV Counseling and Testing Register***

To collect standardized information about the HIV counseling and testing of TB patients at the study clinics it was necessary to design and print HIV counseling and testing registers. The register was intentionally designed in a familiar format, often referred to as a *tick* register, acknowledging the many columns that required only a 'tick', or check. Modeled on the HIV counseling and testing registers developed in Cape Town, Western Cape Province, we added categories requested by the municipal health department and had copies made for each study clinic.

### **Randomization**

The twenty study clinics were randomized in a 1:1 ratio using data obtained during the clinic situation analyses. We selected variables for our constrained randomization that could have influenced the study outcomes. For each study clinic, the total number of clinic patients seen during one month, the number of TB cases registered in one month, the number of TB patients that received HIV counseling and testing in one month, and a summary score of TB/HIV collaboration were used to define the strata for constraint.

Randomization was completed by the study statistician on August 1, 2005 and the results were promptly communicated by email to the study manager in South Africa. Only the study manager had the key to determine which clinic was represented by what name (C01 – C20). The biostatistician and student investigator knew the clinics only by the coded names.

### **Training in the opt-out strategy August 10 – 11, 2005**

Following the random assignment to intervention or control, TB nurses from each of the ten designated intervention clinics were invited to attend a two-day training designed by the study team and approved by the municipal health department. The style of the training was modeled on the HIV counseling and testing course with the intention of creating a learning environment with which the nurses were already familiar. A local nurse trainer from the Regional Training Center was hired to carry out the training and was assisted by two members of the study staff.

### **Qualitative study methods:**

A qualitative study was carried out at the conclusion of our preliminary data analysis with the intention of improving the researchers' understanding of factors that could explain the study results. Combining quantitative and qualitative methods is a strategy to strengthen the interpretation of the study outcomes by reaching the same conclusions through different types of information through techniques of triangulation (13, 14)

Semi-structured interviews (15) were held with key informants from the district and provincial health departments and other related organizations because these individuals would be able to give detailed information about the context in which the study was carried out. Interviews were chosen as the most appropriate method for key informants because of limited time of the subjects of the interviews and because the roles, knowledge, and perspective of each key informant had the potential of being quite different from one another. Individual interviews provided a venue to structure questions specifically for an individual's level of expertise.

Focus groups have been shown to be useful in evaluating programs or interventions (16). Focus groups are particularly useful when exploring people's knowledge and experiences (17). This method offered anonymity to the nurses and an environment that we believed they would be comfortable, as the nurses all knew one another. It also prevented us from directly correlating the knowledge or beliefs of a particular nurse with the outcomes in a particular clinic. The focus groups did afford the opportunity to explore common experiences of the TB nurses; focus groups are useful for studying dominant cultural values, including work place cultures (17). Therefore, this may be a particularly valid method to explore system-wide issues that may have influenced the study's success.

### ***Sampling***

We sought a homogenous grouping for the focus groups, a form of purposeful sampling (18). Nurses from the clinics allocated to the control arm of the study were seen in one focus group session. Nurses from the clinics in the intervention were divided into two groups, one made up of nurses from the clinics that performed the best, and the second

group composed of the nurses from the intervention clinics that did not perform any better than the control clinics. The nurses from the control clinics were grouped together because that group represented the experience and knowledge of the clinics without the intervention, and the opt-out strategy was not included in the discussion.

***Participant characteristics***

Seven key informant interviews were carried out. Five interviews were conducted face-to-face as an individual interview, three in that individual’s office, one in a hotel lobby during a break in a conference the informant was attending, and one at a public place selected by the study manager. Two key informants were interviewed by telephone because their schedules did not permit face-to-face interviews. All interviews used the same semi-structured interview guide which can be found in appendix C.

Three focus groups were conducted. Details of the group composition are shown in table 1. Ideal group size is generally agreed to be between four and eight people (17), and we came very close to that ideal. Each of the group discussions were facilitated with the aid of a semi-structured guide (appendix D), and free expression and discussion was encouraged throughout. In the analysis, when differentiating between focus groups, they will be referred to as focus group 1, 2, and 3.

**TABLE 1. Focus group characteristics**

	<b>Number of participants</b>	<b>Male:Female</b>	<b>Opt-Out Study Results</b>
Group 1	5	1:4	Intervention arm – little change
Group 2	4	0:4	Intervention arm – greatest change
Group 3	9	0:9	Control group

Verbal informed consent was obtained from all participants, and permission asked for both note taking and tape-recording. All interviews and focus groups except those conducted via telephone, were tape recorded. In addition to the recordings, detailed notes were taken during interviews and discussions.

To illustrate the time a nurse perceived (s)he had to devote to the TB program, pieces of paper with a ‘pie’ marked into four quarters were handed out to the nurses in the focus groups. Each paper had written on it *“If the circle below represents a work day at your clinic, please shade the portion of your time that is devoted to the TB programme.”* Papers were collected prior to the focus group meetings, at individual clinics, and were identified only by and ‘I’ or ‘C’ to designate the intervention arm of the study.

The qualitative researcher completed all the transcriptions verbatim from recordings she made during the interviews and focus groups. These were supplemented by handwritten notes that described how the group responded to questions or how others felt about what one participant was saying. Key informants and participants in the focus groups composed of nurses from the intervention clinics were assigned numbers. There were too many participants in the control group focus group to distinguish all the voices, so participants in that focus group did not receive numbers.

Using the transcribed text, prepared by the qualitative researcher, the process chosen by the qualitative researcher (and used by all three that carried out the initial analysis) was similar to that described in Grandeheim and Lundman (19). The process was as follows:

- Transcriptions and notes were read and re-read to gain familiarity with the data
- Transcriptions were divided into meaning units – phrases expressing an idea
- Meaning units were compressed and transformed into codes
- Categories were created on the basis of codes, and
- Codes and meaning units were inserted under each category

Once the categories were created, similarities and differences among groups and participants were explored. Constant comparison was used to ensure that the categories remained true to the original text. Categories were modified and some codes placed under new categories as the analysis proceeded. Where appropriate, relevant quotations were included in the categories and, where possible, the participant, as well as a detailed reference of where the quotation could be found on the transcripts, was included. Relationships between categories were explored, and the texts were examined for both manifest (obvious) and latent (hidden) content.

When each of the independent analyses was complete to the point of classification of categories, discussion was carried out via email messages until there was consensus. Themes were initially suggested by the qualitative researcher, and modified considerably by the student researcher, discussed, modified again and ultimately agreed upon by all three.

### ***Participant context***

The focus group participants all worked in Nelson Mandela Metropolitan Municipality primary care clinics; some were provincial and most were local. All participants had very similar clinic responsibilities. The facilities themselves were generally old, and inherited from the Apartheid era, thus not ideal in space, layout, and not designed for the number of patients attending the clinics. The Eastern Cape is poor and relatively rural when compared to the Western Cape and Gauteng. These characteristics may influence who continues to work in the primary care clinics.

## **CHAPTER 2**

### **QUANTITATIVE STUDY RESULTS**

#### ***Assessment of clinic situation analysis results***

Data collected during the clinic situation analyses can be found in table 2. The addition of study arm allocation in the table is intended to increase the ease of interpretation. Allocation occurred after the completion of clinic situation analyses.

Predominant language and racial groups for each of the study clinics were obtained from the 2001 national census data published at the ward level by the South African government (20). They were confirmed during visits to the study clinics.

**TABLE 2. Cluster level data of study clinics and the communities they serve**

	Clinic ID	Clinic racial group(s) by census ward	Language by census ward	TB nurse does C&T	TB nurse newly trained in HIV C&T for study	TB Nurse change during study	Rapid HIV test kits/ Cotrimoxazole regularly stocked	Baseline clinic C&T strategy
Intervention Clinics	C01 <sup>A</sup>	Mixed	Afrikaans	Yes	No	No	Yes/Yes	Advise
	C03 <sup>A</sup>	Coloured	Afrikaans	Yes	No	Yes	No/Yes	Advise
	C05 <sup>E</sup>	Black	Xhosa	Yes	No	No	Yes/Yes	Routine
	C06 <sup>G</sup>	Black	Xhosa	Yes	No	No	Yes/Yes	Self/advise
	C07 <sup>E,1</sup>	Black	Xhosa	Yes	No	No	Yes/Yes	Routine
	C09 <sup>G</sup>	Black	Xhosa	Yes	No	No	Yes/Yes	Self/advise
	C10 <sup>H</sup>	Mixed	Afrikaans	Yes	No	Yes	Yes/Yes	Self
	C15 <sup>A</sup>	Mixed	Afrikaans & Xhosa	No	No	No	Yes/No <sup>2</sup>	Advise
	C17 <sup>B</sup>	Black	Xhosa	Yes	Yes	No	No/No <sup>3</sup>	Routine
	C18 <sup>C,1</sup>	Black	Xhosa	Yes	No	Yes	Yes/Yes	Advise <sup>4</sup>
Control Clinics	C02 <sup>A</sup>	Coloured	Afrikaans	Yes	Yes	No	Yes/No	Advise <sup>4</sup>
	C04 <sup>D</sup>	White	Afrikaans	No	No	Yes	Yes/No	Self
	C08 <sup>E</sup>	Black	Xhosa	No	Yes	No	Yes/Yes	Advise <sup>4</sup>
	C11 <sup>M,1</sup>	Black	Xhosa	Yes	No	No	Yes/Yes	Self <sup>4</sup>
	C12 <sup>L</sup>	Mixed	Afrikaans & Xhosa	Yes	Yes	No	Yes/No	Routine
	C13 <sup>L</sup>	Mixed	Afrikaans & Xhosa	Yes	No	No	Yes/No	Advise
	C14 <sup>K</sup>	Black	Xhosa	Yes	No	No	Yes/Yes	Routine
	C16 <sup>J</sup>	Mixed	Afrikaans	Yes	Yes	No	Yes/Yes	Routine
	C19 <sup>I,1</sup>	Black	Xhosa	No	Yes	No	Yes/Unknown <sup>4</sup>	Self/advise <sup>4</sup>
	C20 <sup>A</sup>	Mixed	Afrikaans	Yes	No	No	Yes/No	Advise <sup>4</sup>
	Total							

**Sub-district 1, Sub-district 2, Sub-district 3; Nurse supervisor: A - M**

<sup>1</sup> Clinic does not keep written consent for HIV counseling and testing

<sup>2</sup> ARV clinic attached to primary care clinic

<sup>3</sup> Use only ELISA for HIV testing

<sup>4</sup> Booking system for HIV counseling and testing

Counseling and testing strategy definitions: **Advise** = Nurse advises patient to go through HIV C&T, **Routine** = Nurse HIV pre-test counsels all patients, **Self** = Patient responsible for seeking HIV C & T.

In four clinics the informed consent form was not kept; one of those clinics did not require written consent. The other three clinics sent the consent form home with the patient. In four study clinics, the TB nurse did not do HIV counseling and testing at baseline. In four different clinics, the TB nurse was replaced during the study period. This meant that three nurses did not receive documentation training from us, and one nurse received her opt-out training from a nurse who had attended the training rather than from us. Six clinics had a TB nurse newly trained in HIV counseling and training. One clinic in the control arm in which the TB nurse did not do HIV counseling and training at baseline had a staff change during the study period. Six clinics used a booking (appointment) system for scheduling HIV counseling and testing.

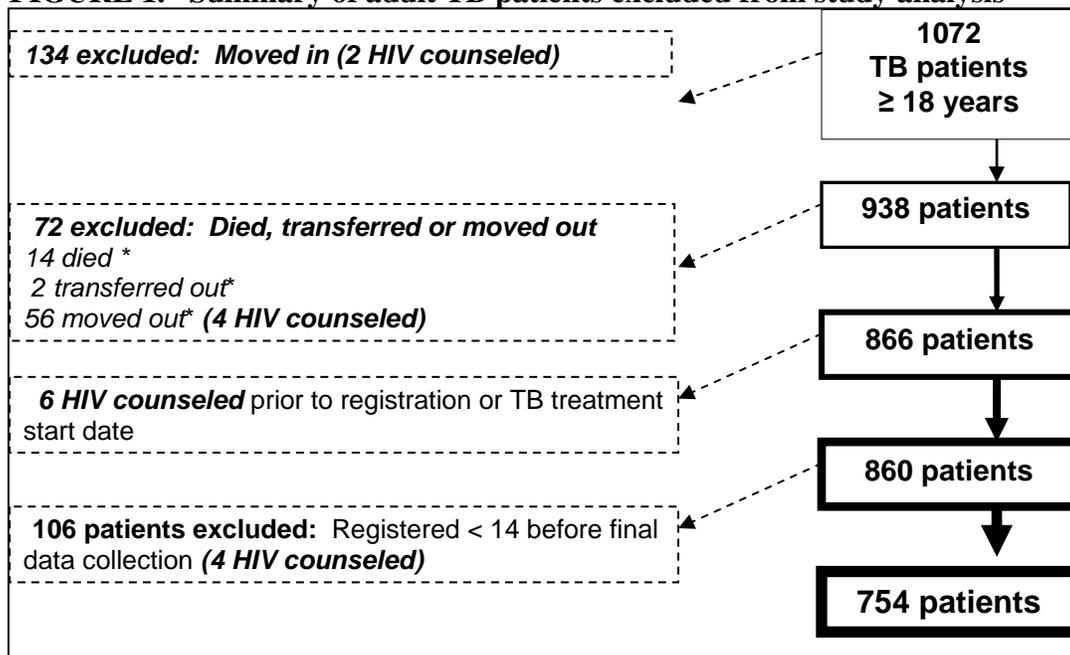
Baseline strategies for HIV counseling and testing were varied at baseline. Nurses at eight study clinics told us that they advised all TB patients to be HIV counseled and

tested, which we interpreted as the standard of care of voluntary counseling and testing. Four of these clinics also had a booking system. Six clinics reported that they routinely HIV counseled all TB patients. Three clinics had no reported HIV counseling and testing intervention at baseline, and two clinics reported they let patients self refer unless the patient looked very ill, at which point the nurse advised the patient to seek counseling.

**Study subjects**

Data on 1072 adult TB patients were collected covering the period August 12 through November 7, 2005. Data collection was deferred until August 15 in one clinic of the intervention arm due to the delayed training of one nurse.

**FIGURE 1. Summary of adult TB patients excluded from study analysis**



\* Died, transferred or moved out < 14 days after TB registration or TB Rx start, whichever was more inclusive

Analysis was carried out using data from 754 TB patients that fit the study criteria. Patients registered less than fourteen days prior to the final data collection were excluded. The quality of data diminished remarkably near the end. Seven clinics had fewer than 50 percent of the expected numbers of TB cases recorded during those last two weeks. We have no reason to believe that there were fewer TB cases registered, so we must assume that there was a lag in documentation that made those last two weeks unusable. A total of sixteen TB patients that received HIV counseling were excluded from the analysis; twelve of them because they did not fit study criteria and the other four because they were registered during the last two weeks. The final data set permits an assessment of all TB patients registered within the study period with a period of at least fourteen days to receive HIV counseling. See figure 1 for a summary of subject exclusion.

Overall, data from the study clinics were representative of surveillance data for the Nelson Mandela Metropolitan Municipality. Fifty-eight percent (435) of the TB patients were male (range 28-64 percent), 647 (86 percent) with pulmonary TB (range 72 – 96 percent), and 543 (72 percent) were sputum smear positive on at least one sputum specimen (range 68 – 100 percent). Two-hundred and forty four patients (33 percent) were being treated for TB for at least the second time, with so-called retreatment TB (range 10 – 44 percent). There was a moderately high correlation (phi coefficient = .65) found between pulmonary TB disease and having a positive sputum smear, which is to be expected. Eighty-nine (12 percent) of the TB patients had a chest x-ray (range 0-31 percent), 21 (28 percent) of them for patients diagnosed with extra-pulmonary TB disease.

TB patient age was between 18 (defined by the study inclusion criteria) and 86 years of age, with a mean of 36 years. Men were significantly older, on average, than women 36.9 (range 18-79) versus 34.7 (range 18-86) years of age ( $p = 0.02$ ). No associations were found between age and/or sex and site of disease, sputum positivity, chest X-ray or retreatment.

### Comparability of study arms

#### *Cluster-level analysis of individual-level data*

Comparison of individual-level data was completed using cluster-level analysis. The number of TB patients, age, sex, site of disease, sputum smear positivity and retreatment status were assessed using cluster-level analysis and can be seen in table 3. The intervention arm had a significantly higher proportion of patients with pulmonary TB (89 versus 81 percent,  $p = 0.02$ ). There were no other significant differences in individual level data between study arms.

**TABLE 3. Comparability of individual-level characteristics in intervention and control arms**

	Intervention Clinics				Control Clinics				<i>p</i> -value*
	<i>n</i>	<i>Mean</i>	<i>Range</i>	(%)	<i>n</i>	<i>Mean</i>	<i>Range</i>	(%)	
TB patients/clinic	352	35	18-52		402	40	19-71		0.46
Age of TB patients		36.5				35.5			0.39
Males	194	37.5	18-72		238	36.4	18-79		0.30
Females		34.9	18-78			34.5	18-86		0.79
Female TB patients	157	16	7-28	(45%)	162	16	7-28	(41%)	0.39
Pulmonary TB	317	32	16-48	(89%)	330	33	14-62	(81%)	<b>0.02</b>
Sputum smear positive	255	26	12-38	(72%)	288	29	10-52	(72%)	1.0
Retreatment patients	226	13	3-25	(35%)	284	12	3-29	(26%)	0.07

\**t*-test

#### *Analysis of cluster level variables*

A comparison of study arms, shown in table 4, showed that there were no statistical differences for any of the cluster-level variables. As would be expected, language and race were highly associated (Pearson's chi-square,  $p = 0.000$ , DF = 6. There was an association between nursing supervisor and subdistrict, as well (Pearson's chi-square,  $p = 0.000$ , DF = 24).

**TABLE 4. Comparison of cluster-level variables by intervention and control study arms**

	Intervention Clinics n =	Control Clinics n =	p-value*
TB Nurse did HIV C&T	9	7	0.58
Booking system	1	5	0.14
Bactrim in stock	8	4	0.17
Rapid HIV test in stock	8	10	0.47
TB Nurse newly trained in HIV C&T	1	5	0.14
RN change during study	3	1	0.58
Baseline clinic HIV C&T strategy			
Advise	4	4	
Routine	3	3	
Self	1	2	
Self/advise	2	1	1.00

\*Fisher Exact test

**Study outcomes using cluster-level analysis**

This analysis demonstrated significantly more TB patients in the intervention arm were HIV counseled than in the control arm (23 percent versus 8.7 percent,  $p = 0.03$ , table 10). The percentage HIV tested was greater in the intervention arm (22.4 percent versus 7.7 percent,  $p = 0.03$ ). There was a difference between the study arms in the percentage of patients offered counseling that accepted testing (intervention arm 97 percent versus control 79 percent), but the difference did not reach statistical significance in this analysis.

**TABLE 5. Study outcome measures using cluster-level analysis**

Study Outcomes	Intervention n = 352			Control n = 402			p-value*
	Number	Range	(%)	Number	Range	(%)	
Pre-test counseled	73	3.5 - 66.7	(23)	31	1.5 - 15.8	(8.7)	<b>0.03</b>
HIV tested	71	1 - 18	(22.4)	26	0 - 6	(7.7)	<b>0.03</b>
(%) counseled that tested			(97)			(79)	0.12
HIV test positive	31	0 - 10	(36)	11	0 - 3	(42.6)	0.75
HIV positives prescribed Cotrimoxazole	6	0 - 2	(29)	4	0 - 2	(33)	0.89
HIV positives referred to ARV clinic	7	0 - 2	(36.7)	2	0 - 1	(26.7)	0.33

\* t-test

The percentage of TB patients with a positive HIV test result was not significantly different between intervention and control arms (36 percent versus 42.6 percent). The numbers of HIV test positive patients that were prescribed cotrimoxazole and/or referred for HIV care was very small. There was no significant difference between study arms. Clinic-level results can be seen in appendix D.

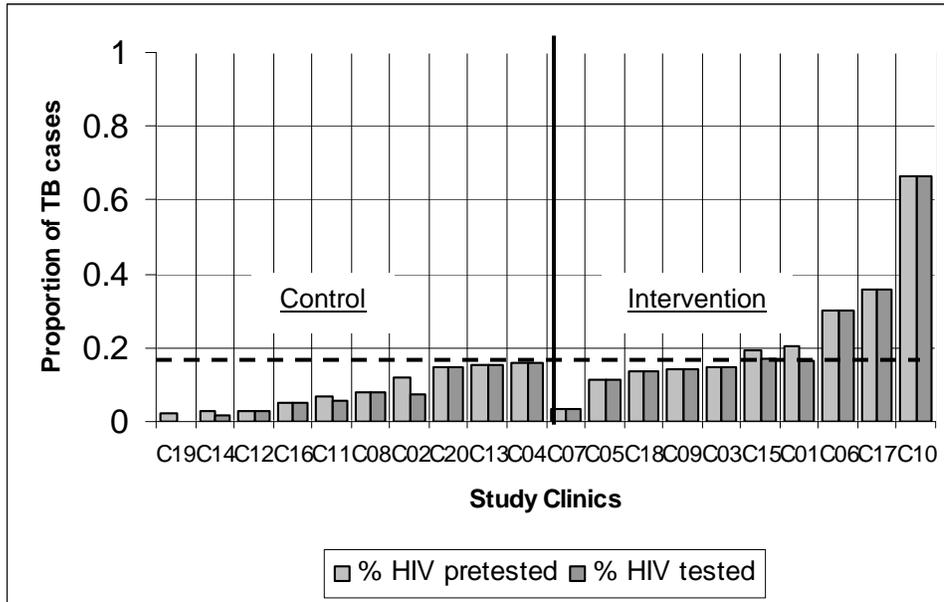
It should be noted that ten of the 42 TB patients that had a positive HIV test result were tested less than one month before the end of data collection. The protocol for prescribing cotrimoxazole is one month after the start of TB medication, meaning that we should expect only 32 of the HIV test positive patients to be prescribed the drug. Of the ten TB patients actually prescribed cotrimoxazole, two of them were started on the medication

less than one month following the start of TB treatment. During our baseline clinic assessments, seven of the study clinics reported that they were not regularly stocked with cotrimoxazole. During the study period there was no correlation between being prescribed cotrimoxazole or reporting problems with stock at baseline (phi coefficient = 0.03), and this was true for intervention and control study arms (phi coefficient = 0.07 versus 0.03).

**Study results at clinic level**

There was considerable variability between individual clinics related to the proportion of TB cases that received HIV counseling and testing, figure 2. The mean proportion of TB patients counseled for the study overall was 0.158. None of the control clinics reached the study mean and five of the intervention clinics exceeded the study mean. Only one clinic, in the intervention arm, HIV counseled and tested more than one half of their TB patients, counseling and testing 66.7%.

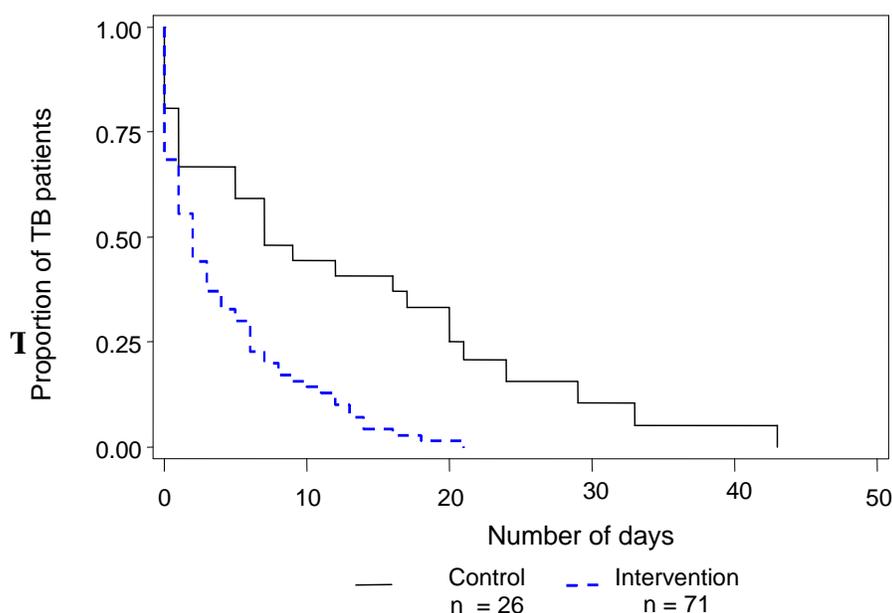
**Figure 2. Proportion of TB patients that received HIV counseling and testing by control and intervention clinics**



**Analysis of number of days to HIV test**

The mean number of days to test in the intervention arm was 5.2 (range 0 – 21 days) days versus 9.6 (range 0 – 43 days) in the control arm. Despite a visible difference in the time to test between the study arms, demonstrated by the Kaplan-Meier graph in figure 3, the difference was not statistically significant ( $p = 0.12$ ), not surprising given the small sample size.

**FIGURE 3. Time in days from TB registration to HIV test for all registered TB patient who received HIV counseling and testing: N = 97**



***Modeling the study outcomes***

No associations were found between individual or cluster level variables and the study outcomes. Several cluster level predictor variables were closely associated with one another. A booking system and baseline HIV and counseling strategies had the strongest association (Pearson’s chi-square,  $p = 0.000$ ,  $DF = 3$ ). A booking system was also significantly associated with whether or not the TB nurse did HIV counseling and testing at baseline (Pearson’s chi-square,  $p = 0.000$ ,  $DF = 1$ ). And finally, baseline HIV counseling strategies and whether the TB nurse did HIV counseling were also significantly associated (Pearson’s chi-square,  $p = 0.000$ ,  $DF = 3$ ). None of the clinics that reported routine HIV counseling of all TB patients at baseline had a booking system. All of the clinics that reported routine HIV counseling had TB nurses that carried out HIV counseling at baseline.

**TABLE 6. Model of potential predictors of HIV counseling using GEE Parameter Estimates**

Variable	Estimate	Standard Error	95 % Confidence Limits		Z	Pr >  Z
Intercept	-2.0792	0.3527	-2.7706	-1.3879	-5.89	<.0001
Intervention	0.8307	0.2773	0.2872	1.3741	3.00	<b>&lt;.0027</b>
TB nurse HIV counseled at baseline	0.1933	0.2141	-0.2263	0.6128	0.90	0.3667
Reported HIV C&T strategy at baseline	-0.1754	0.1561	-0.4814	0.1306	-1.12	0.2613
Booking system	-0.3349	0.2807	-0.8852	0.2153	-1.19	0.2329

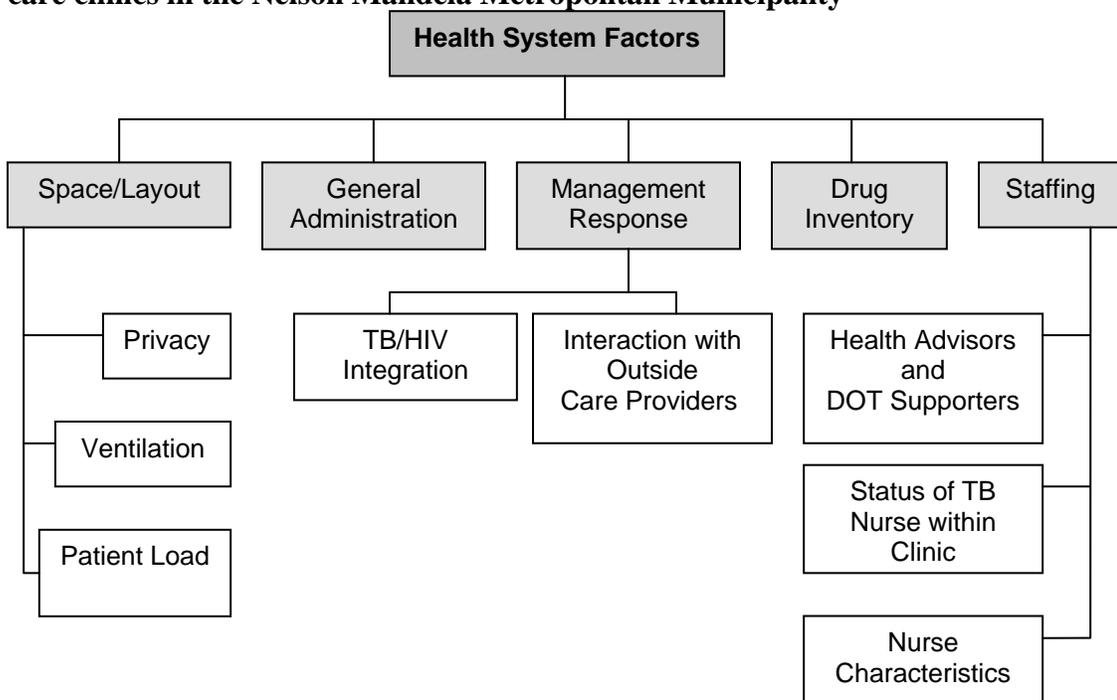
A model was constructed to determine whether baseline clinic factors associated with HIV counseling and testing would predict whether or not a TB patient received HIV counseling and testing. The results can be seen in table 12. The model revealed no association between the three factors measuring baseline clinic HIV counseling strategies and the study outcome of HIV counseling. The study intervention was a strong predictor of whether or not a patient received HIV counseling and testing.

### CHAPTER 3

#### QUALITATIVE STUDY RESULTS

Three major categories emerged from the analysis of transcripts from the three focus groups and seven key informant interviews. These were 1) health system issues, 2) HIV counseling and testing, and 3) impact and opinions of the opt-out study. A diagrammatic illustration of the health systems issues can be seen in figure 4.

**FIGURE 4. Health system factors related to HIV counseling and testing in primary care clinics in the Nelson Mandela Metropolitan Municipality**



#### Health system factors

According to one of the key informants, HIV has turned primary healthcare on its head. Only focus group three commented on how HIV had changed TB treatment. This may be because they had gone through less training, and were not as used to the changes as the intervention group nurses were. The sentiment in the group seemed to be that HIV

had complicated the work in the TB department, and burdened the TB treatment program. They also commented on the high prevalence of TB/HIV co-infected patients.

“I’ve got about 100 patients...at one stage a quarter of them was HIV positive, and that is a lot for that amount of TB patients. And if was just then, now if you check again now, you find half of them [are HIV positive.]” Focus group 3).

As HIV increases the prevalence of infectious diseases, it also places additional pressure on the healthcare system. Therefore, issues that emerged from the groups in terms of health system problems, may be more pressing due to the impact of HIV.

### ***Space/layout of clinics***

Focus group participants were asked to describe their clinic environments. Participants mainly mentioned space and layout, and its impact on privacy. Privacy was not only mentioned by nurses, but also by key informants when asked what would be a barrier to, or a facilitating factor in HIV counseling and testing.

Consistently across focus groups, nurses voiced dissatisfaction about layout and space; this was linked to overcrowding at the clinics. A participant in focus group one mentioned that due to the lack of space within the clinic, patients would have to wait outside. Nurses in both focus group one and two mentioned that they had to do “...everything in that room” (Focus group 1, Participant 1) not only TB related duties but also primary health care. A participant in focus group three described the space constraints forcing TB patients to mingle with other clinic patients.

“...So there is no space when you just walk in between the patients. And rooms as well – the TB patients they just sit next to the other patients. Others are bringing children for immunizations, others are coming for family planning, so it’s like a mix – there’s no space.” (Focus group 3).

An extreme example of a lack of space in the clinic, was when a key informant said that the day before her interview a death occurred in her clinic and the nurses did not know “...where to put the body” (Key informant 4).

Lack of space may also lengthen the time required for duties, and increase waiting time for counseling. Nurses noted having to wait for empty rooms and, in some cases, having to chase other staff and patients out of a room to be able to do confidential counseling. In general, nurses agreed that clinic layout and space compromised privacy and thus the quality of their HIV counseling.

### ***Privacy***

All participants except for two key informants mentioned lack of privacy as a barrier to HIV counseling and testing. Focus group one noted that mornings were especially chaotic, and the clinics offered more privacy in the afternoon. The impact of privacy was expressed by focus group two “... because if someone is being interrupted all the time, I

don't think will get through to the person.” (Participant 2). One key informant stated that the issues surrounding privacy were due to the clinics being inherited from the Apartheid system, thus they could not cope with the number of people visiting the clinic.

### ***Ventilation***

Only focus group one mentioned that the lack of clinic ventilation might affect their own health: “... that's a hazard to us.” (Participant 2). Two key informants also mentioned ventilation - one in context of the patients, in that as the patients were all sitting in one area, proper ventilation was important to prevent the spread of disease. The other key informant referred to ventilation as important to provide comfort while counseling. Focus group one's mention of hazard to themselves brings to mind questions about their own anxieties in dealing with an infectious disease and whether this impacts on their service.

“...That's why I usually test myself (laughter) Every year!...I take two sputum bottles for cultures, and sensitivity and also for x-rays...”  
(Participant 1).

### ***Patient load***

When asked about caseloads, and when asked about the clinic environment, most participants commented on the impact of patient load on the health service. This, again, is related to the impact of HIV on primary healthcare.

“Before HIV, TB was TB. Straightforward...now they're complaining, you've gotta do a physical examination on this person and then you find something else is there. Because the whole picture is different now. You're now with a sick sick sick person...the HIV has really put a burden on the TB program”. (Focus group 3)

The major characteristic of the clinics seemed to be that they were overcrowded, or “full”, which is also related to the available clinic space. Patient load had an obvious connection to staffing, as well as an impact on the relationship that is built between patient and provider. The major theme here was time; a high patient load and few staff resulted in less time per patient and possibly impacted on the quality of service. As illustrated by key informant 2:

“... to between 200-300 patients on treatment at any point in time, and there's only one TB nurse. ... and then there are all the clinic DOTS so how – you get lots and lots of patients then it is a fast queue and they're just coming for treatment. So there isn't much time to actually talk or.. or ja, build that relationship”.

Another key informant had resigned herself to the high patient load and lack of staff.

“...whole patient-nurse ratio and the fact that yes, but – but the reality is that it takes anything that you can do for a client on a specific day” (Key informant 4).

This was reinforced by a clinic nurse "...You don't follow up on your TB patients because you don't have a lot of time" (Focus group one, Participant 3).

### **Staffing**

Several issues were mentioned with regard to staffing in the clinics. The only question about staffing asked in the focus groups was how many people work in the TB department. This usually resulted in participants reporting numbers, and talking about health advisors and DOTS supporters. Therefore the frequency at which problems surrounding staff were mentioned highlights the importance of this issue to the everyday running of the TB clinic, and the nurses' experience of HIV counseling and testing.

All except one key informant mentioned staffing as an issue that impacted on the clinics. The consensus seemed to be that there is not enough staff.

"...It's maybe only one sister doing comprehensive now she has to do the antenatal, she has to do counseling, she is the only one that been a-a-a trained for VCT. She has to do all these things..." (Focus group 2).

This was echoed by another clinic nurse. "...when there's short staff you are forced to leave your TB rooms to and help in other services" (Focus group 3).

Management seemed to have addressed this problem by providing contract nurses; however, a participant in focus group three stated:

"...they keep changing, this week you have this one, whilst you start orientating this one, they take her away and give you another one, you know you spend more time orientating these chop-and-change nurses." (Focus group 3)

This issue seemed closely linked to staff rotation between the clinics. Skills were seen leaving the service, and others arriving needing orientation. A key informant also mentioned that rotation between clinics should stop to facilitate HIV counseling and testing for TB patients.

Nurses were also asked what their priorities or main tasks were in their respective clinics. While some provided detailed lists of their duties, it seemed that the tasks undertaken were numerous and varied. The groups' overall responses to this question seemed to indicate that they were overwhelmed by their responsibilities. Some participants would begin listing what their duties were on a given day, while others would remain quiet and look confused. In one group, after some silence, the group was asked whether it would be correct to say that there are NO priorities, that everything has to be done, to which the group responded with a relieved YES! In the words of key informant 4:

"..I tried as far as possible to- to manage what I had that specific day; whatever I couldn't manage that day- it would just be put off to another date." (Key informant 4)

Focus group three mentioned arriving for work earlier to attend to their duties, especially TB patients who needed to take their medication before work or school.

Both focus groups two and three indicated, when asked about their priorities, that they also had responsibilities in the primary health care department. At this stage, focus group one did not mention this issue, although they did relate many tasks such as injuries dressings which were unrelated to the TB department. In general, performing other non-TB-related duties and having no dedicated TB person was seen as a problem in all focus groups. Nurses had to alternate between their TB and other clinic duties; and when one nurse was away this was seen as affecting other nurses' tasks and workloads. Some nurses voiced the solution of dedicating only one person to the TB program or having separate TB units.

“You know I think if for TB to be managed properly, I think if we could have an outpatient unit...for TB patients and TB patients wouldn't be mixed with other patients, I think it would be managed properly because you would know that I am only looking after TB patients (agreement).”  
Focus group 3).

Time is again related to staff and the requirements of HIV counseling and testing. Groups noted that because HIV counseling and testing was time consuming, and there was insufficient staff, certain tasks that take longer had to be re-scheduled. This compromised immediate help for non-urgent cases and immediate counseling and testing.

Rescheduling also had an impact on the patients – nurses in focus group two mentioned how

“It's making the clients very furious, uncomfortable and at times in our area become very rude.(sic)” (Participant 1).

Not only does rescheduling present problems in terms of patients returning for further treatment or counseling, but it may impact on the relationship between patient and provider, and may impact on testing uptake. In the words of one key informant:

“If you don't have consistency, then it's not gonna work (sic)”(Key informant 4).

### ***Health advisors and DOTS supporters***

Most clinics seemed to have health advisors or DOTS supporters or both in their TB departments. They seemed to do vital tasks, from health education to observing treatment. One participant in focus group one mentioned that her DOTS supporter could relieve her when she took a break, and that she had left the DOTS supporter in charge while attending the focus group. Another participant in the group was skeptical at this practice, because she felt that the DOTS supporter was not sufficiently skilled to be in charge of the TB department. A nurse in focus group three mentioned that when she arrived at the clinic at which she was based at the time of the focus group, the health advisor was in fact running the TB clinic.

Nurses mentioned many tasks for DOT supporters and health advisors, but it seemed that not all of them would do tasks other than what they were originally assigned to do. Some only picked up medication and visited homes. In contrast, other health advisors and DOTS supporters were reportedly performing tasks that ranged from being the clerk in the department and counseling and educating, to putting together medications for the nurse to dispense. At times, however, despite the nurses' wishes, they would refuse to do tasks outside their assigned duties:

"at times they can become fed up and tell you that I'm not supposed to- I'm going out, I'm going for the visit" (Focus group 1, Participant 2).

There seemed to be guilt about the use of DOT supporters for tasks other than supervising medication in focus group two:

"We know that a DOT supporter's supposed to be at the house, to supervise in the community, we know, we're aware of that. But in the mornings they – because most of the people are working that they supervise, they give the treatment in the afternoon. So in the morning they will come to the clinic, and they will help the sister taking out the blue pieces for the sister, and putting the green card on the blue piece and tells the sister that this patient must get the injection or this patient must get the treatment and they will do the weighing. Just in the morning. But in the afternoons they will go back and they will supervise the treatment at home.(sic)" (Focus group 2, Participant 1).

Even though health advisors and DOTS supporters assisted in the TB department, not all nurses were satisfied with the quality of the help. One key informant stated that her lay counselors had counseled too quickly; she also felt that she could only

"try to – try to manage the lay counselors..." (Key informant 4).

Some nurses in focus group one felt that their DOTS supporters were "out of hand" and "unreliable". In addition, another key informant reported that there had been problems with lay health workers in terms of confidentiality. She also stated that after some retraining this issue had been corrected. Although it seems that DOTS supporters and health advisors are providing an important service in the clinics, it is clear that additional well-trained professional staff is needed to support the TB program in the clinics, thus facilitating HIV counseling and testing.

### ***Status of TB Nurse in clinic hierarchy***

In addition to the conflicts between professional nurses and health advisors or DOTS supporters, there also seemed to be strained relations between TB nurses and other staff at the clinics. All three focus groups mentioned that other staff would not assist them with their duties. If the TB nurse had taken leave, all TB administration work was left for them to do if they were absent, and would be waiting for them when they returned. TB nurses expressed their frustration:

“Because like for instance now I was on leave. I had to come in on one of my – when I was still on leave to come and do the stats. Because apparently nobody can do TB stats. (laughter) But I can do the primary health care stats and things, and I can do family planning and all the other services, but you will find they will just say no, you are the TB sister that’s your responsibility. I mean you come back from leave you get things like this (gestures high) you know, there’s lots of paperwork waiting for you, things are not done, and at the end of the day you don’t get to the things that is really important. (sic)” (Focus group 3)

“...if you are not there, that patient will wait for you. They will weigh the patient, give them treatment then the, administration patient and the coughing and everything, they, that will wait for you...because you are not there the TB nurse they won’t do it” (Focus group 1, Participant 4).

“...if you come back during the week of the stats, you find that there’s sputums (sic), they were not done...Nothing was done, they were just packed for you” (Focus group 2, Participant 1).

Instances such as the above may also have an impact on the HIV counseling and testing for new TB patients, as the nurse may prioritize documentation.

Focus groups one and three also mentioned that other staff are under the impression that TB nurses are not working while they are in fact performing their administrative duties. This was described by one participant as:

“...sleeping in front of the book.” (Focus group 1, Participant 1).

“...you find that they think the TB nurses are not doing anything, we are doing nothing because our work relies on writing down....so if they want to send somebody to...or fetch milk or do these other chores, they will send the TB nurse because they think you are free” (Focus group 3).

### ***TB Nurse personal characteristics***

The discussions and interviews revealed that the characteristics of the TB nurse, as well as their tasks, had an impact on the quality of service provided in the department. Both focus groups one and two noted that nurses in the department should be committed, dedicated – “...have a love for working with the TB patients” (Focus group 2, Participant 2). Key informants, on the other hand, noted that some individuals were not sensitive enough to the issues affecting the patients, and that some were disinterested in general.

Nurse characteristics were also related to the question of why some clinics had better outcomes than others. Issues raised by participants in this case were mainly on training, staffing, commitment and skill at counseling, with the most emphasis by key informants on training and skills of nurses. Participants in focus group two also stated laughingly that if a clinic did not have good results in the opt-out trial, the nurse responsible was

“lazy”. Some focus group participants noted that it takes an individual brand of motivation; for instance in two of the more successful clinics, the nurses said that they ‘make time’ to counsel their patients for HIV. Key informants also mentioned the importance of commitment and training, as well as “talent” for counseling as facilitating HIV counseling and testing.

“some nurses are incredibly committed and motivated to make a difference...that’s a very important factor, combined with whether they are supported or not by their superiors” (Key informant 2).

Another issue raised by a key informant was the amount of supervision and “skills mentoring” given to nurses at clinics – she felt that if some supervisors were not interested in the study, the clinic would not perform according to its potential.

### **Management response**

None of the focus groups referred to management in terms of the TB/HIV programs. Of the key informants, a health department representative described the support structures available, while another key informant reflected on the importance of management, specifically supervisors, in stimulating staff. One key informant expressed disappointment on the management’s response to clinic problems:

“...we keep on talking to management, we keep on telling management that is the situation, and the answer is ja, you just gotta cope. (sic)” (Key informant 4)

Another management issue mentioned by a key informant was the way in which training was handled, in that training should be in smaller interactive groups to facilitate interaction; and how at times what is directed at national level is not implemented at the clinic level due to a lack of communication. Management was congratulated, however, by this key informant, who thought that the supervisory system at clinics was good and very effective. The key informant also thought that improving management capacity could facilitate HIV counseling and testing.

### ***TB/HIV integration***

The integration of TB and HIV programs is important in order not to lose patients, especially in light of the high number of HIV positive patients among TB cases. Two key informants stressed the importance of integrating TB/HIV programs. One stated:

“... we’ve seen for instance in TB that it just doesn’t work if you have a big clinic and the TB unit is on the one side and then the HIV unit is on the other side... you have to refer patients from one side to the other side...firstly they’ll never arrive there...so if you really integrated the programs in one unit that would be the best approach...but unfortunately it doesn’t work like that...basically two vertical programs that are not interacting enough.” (Key informant 2).

Both key informants said that if patients were referred, patients might get ‘lost’ between the TB and HIV departments.

Intervention nurses’ focus groups were also asked what they thought of the level of integration between TB and HIV programs. Nurses in focus group one had experienced some problems with the HIV program in their clinics when using the opt-out [Official Patient] referral letter. They found that nurses at the ARV clinic would not accept HIV rapid test results and they would not write on the letter.

Focus group one stated that they felt that the TB and HIV programs worked well together, despite the above negative experience. Focus group two, on the other hand, felt that the opt-out study had improved the integration of TB and HIV programs. One key informant stated that, in her opinion, the programs were not integrated well; she supported her statements by stating that the various registers to be filled in and other administrative work was considerable in both programs. Another key informant felt that it was necessary to train people in order to integrate the TB and HIV programs.

### ***Interaction with outside care providers***

Another administrative aspect, possibly creating additional work, and which has implications for the management, is the way in which the clinics interact with outside health care organizations. Focus group two, and the key informant who had also been part of this group, mentioned interaction with outside organizations as having an impact on clinic work. She mentioned that there were regular breaches of confidentiality because HIV and other test results sent from the hospital were all contained in the same envelope and delivered to a clerk rather than a nurse.

“I think that it’s not fair towards your patients because when you do your counseling, you convince your patient about confidentiality that is not part of confidentiality.” (Key informant 5).

She also mentioned a conflict between the clinic policy and the procedures that private doctors follow. Specifically, private doctors would refer a patient to a clinic for TB treatment based on an X-ray, while the clinic requires a sputum test for TB diagnosis. This, according to the informant, created discord between the nurse and the patient, the latter of whom felt dissatisfied because they were denied TB medication straight away. HIV testing being completed before arrival at the clinic was articulated as a problem, and would certainly influence whether or not the TB nurse pursued HIV counseling and testing with a patient.

“...I’ve got a problem when they come from the doctors or from the hospital, they come with already being diagnosed HIV positive, so most of my patents are HIV positive and they have already be diagnosed” (Focus group 1, Participant 4).

### **Drug inventory**

Focus groups did not mention many issues with drug supply, and only focus group three mentioned having run out of TB drugs. A participant in this group mentioned a person, possibly a supervisor, nurses could contact should they run out of drugs. This group also stated that two different manufacturers producing the same drug presented difficulties, as the different appearance of the tablets sometimes incited doubt from the patients:

“...say the one manufacturer gives us Rimstar, which looks – it’s say it’s purple and its round. And then, maybe after two weeks, when we get our stocks, then we get the other one again, and it looks differently, its oblong and its different colour. And it takes time to explain to the patient that it’s the same drug but sometimes they also, you know, start wondering. Or they all of a sudden say no, this one is not working properly. (all agree) (sic)”(Focus group 3)

Focus group two also mentioned problems with drug supply, but this was explained as problems with manufacturers, not with supply from the health department. Focus group one stated that they had no problems with drug supply.

A nurse in focus group two mentioned a lack of equipment in her clinic. She related that at times she would have to do a test, such as a pap smear, and equipment for the procedure would be missing. While this does not seem directly related to TB and HIV counseling and testing, it is possible that the delay in performing a primary health care test would delay other patients being attended to at the clinic.

### **General administration**

General administrative work can add to the nurses’ already heavy workloads. The large amount of information that needs to be recorded and other administrative work was mentioned by focus groups one and three. Similarly, one key informant stated that the recording was not supportive of HIV counseling and testing. Participants in focus group one also mentioned that they had an added responsibility, delivering sputum specimens to a healthcare center to be tested. The nurses with driving licenses had to do this, because drivers from that center would not collect samples from the high-risk areas in which their clinics were situated.

Focus group three mentioned that the administrative work involved in the TB department affected their service efficiency. Focus group one mentioned that because of the heavy administrative load, they sometimes had to rush patients:

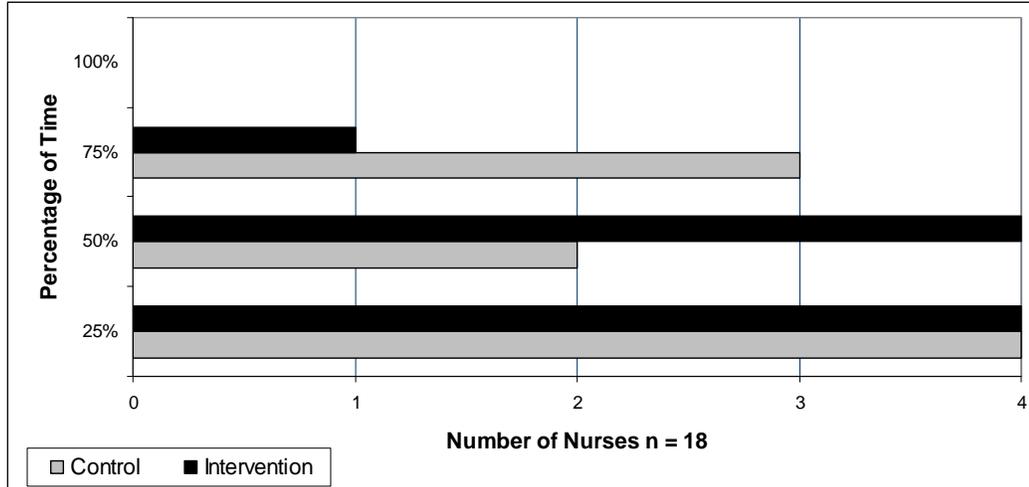
“Report, and labeling...It takes time.. For you to do that. Meaning that now you must rush rush your patient. (sic)”(Focus group 1, Participant 2).

Rushing patients through may have meant that aspects of the service, such as counseling, may have been delayed or possibly performed with less attention to the emerging issues.

The papers with the pie chart and instructions to shade the portion that represented the time spent during one work day in the clinic on the TB program activities were evaluated. A total of eighteen charts were completed. None of the nurses shaded in the entire chart.

One nurse from the intervention arm and three from the control arm shaded in three of the four pie quarters; four of the intervention arm and two from the control arm shaded in two of the four quarters, and four each shaded in only one quarter representing 25 percent of their time on TB program activities. On average, the nurses in both study arms reported less than 50 percent of their time was spent on TB. None of the TB nurses was dedicated to TB alone (see figure 5).

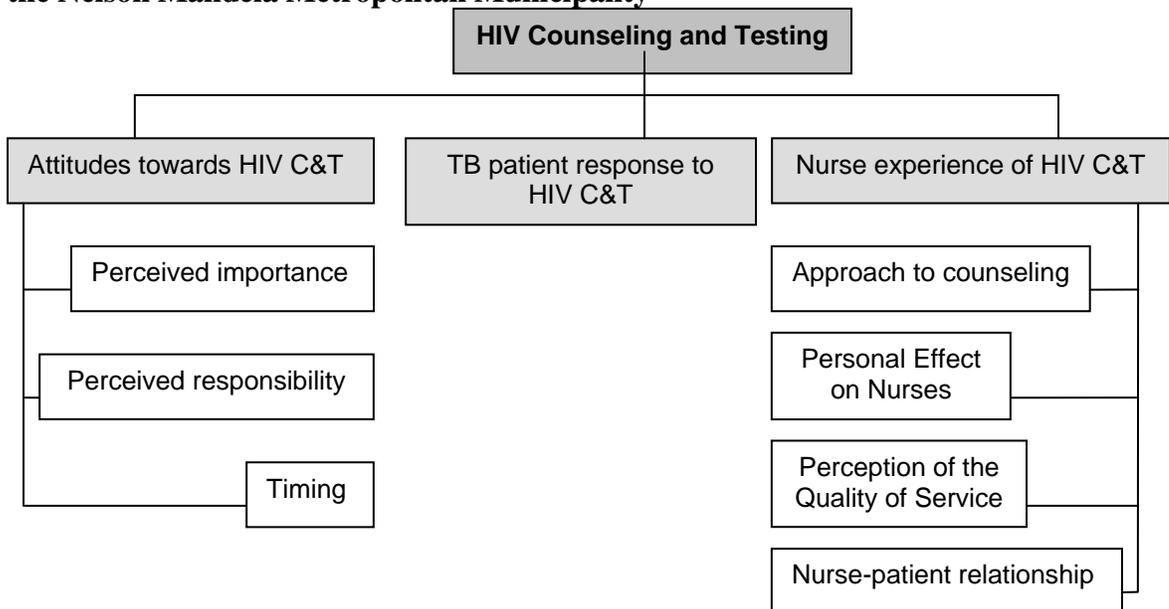
**FIGURE 5. Percentage of time available for TB program duties reported by TB nurses in both intervention arms**



**HIV counseling and testing**

HIV counseling and testing was influenced by the nurse’s attitudes and experiences and the TB patients’ responses to it. Categories can be seen in figure 6.

**FIGURE 6. Factors related to HIV counseling and testing in primary care clinics in the Nelson Mandela Metropolitan Municipality**



## **Attitude toward HIV counseling and testing**

### ***Perceived importance***

A factor that could affect nurses' service is the importance that they place on HIV counseling and testing. All respondents felt that this was important for TB patients. Reasons for its importance were mainly related to the link between TB and HIV.

In addition, most participants felt that the reason why HIV counseling and testing was important for TB patients was that when both patient and nurse knew the patient's status, the patient could be correctly managed. Focus group two also mentioned that HIV had an impact on all aspects of the patient's life.

### ***Perceived responsibility***

Most groups and stakeholders felt that it was the responsibility of the TB nurse to do HIV counseling and testing for TB patients. The reason for this was cited as the relationship between the patient and the nurses, usually described as an "attachment", "confidence" or "trust".

Perhaps significantly, only focus group one discussed in detail the DOTS supporters being able to take on HIV counseling and testing. This group was in favor of someone else except the TB nurse performing the counseling. One participant felt that there should be "a specialized somebody" (Focus group 1) for counseling and testing because the TB nurse does not have sufficient time. This group felt that the counseling could be left to the health advisors or DOTS supporters – although one participant expressed doubt:

"Now what if that person didn't touch on all those aspects?" (Focus group 1, Participant 1).

In contrast, another participant in the group stated that she did not see why DOTS supporters could not do the test, provoking a heated discussion:

"Participant 4: That is what I am asking, because if you pre-counsel somebody you have to do the test, and then the post-test counseling. So what is the problem, with those people not doing the test?"

Participant 3: They're not allowed to

Participant 4: Why?

Participant 3: They're not allowed to, because it's only the sister that can do it. It's just like that. It's only the sisters that can do it. (sic)." (Focus group 1)."

In contrast to the above, in focus group two, while noting that DOTS supporters could do counseling, some participants were not comfortable with the process because this exposed the patient to too many people. Similarly, a stakeholder noted that nurses wanted to do counseling themselves because they were not sure of the quality of others' counseling. Even a participant in focus group one stated that TB nurses taking the process from pre-counseling to post-counseling would be acceptable, "IF there are two sisters" (Focus group 1, Participant 2).

### ***Timing***

Timing of HIV counseling and testing was discussed both in terms of time of day, and in terms of the patient's condition at the time of counseling.

In terms of time of day, both focus groups one and two preferred to counsel in the afternoon, when the clinic was quieter. Participants in both groups asked patients to go home and return; however, one participant in focus group two stated that her clinic was too far from the community it served so it was too far for the patients to go home in the interim.

With regard to timing of counseling and the patient's condition, conflicting opinions emerged. One key informant referred to this as a "Catch-22 really" (Key informant 3) - while they did not want to pressure the patients to take the test, they did not want to lose patients by postponing the counseling either. "Postponing, postponing the VCT until you don't do it at all (sic)" (Focus group 1, Participant 2).

The feeling from all the groups seemed to be that this depended on the individual's condition, and therefore the counseling relied much on the willingness and judgment of the attending nurse.

"...any new case gets the treatment at the clinics. So they come daily. So you can see on the third day that it's the right time for the test. So then you ask your client, if he can take the treatment then wait for you for this counseling. If he agrees, then you can make time for him (Focus group 2, Participant 1).

Delaying the counseling to accommodate the wishes of the patients introduced the risk of never counseling at all.

"...they much come back to me to say when are they ready to, focus to see to the testing. Some of them say OK we can do it now, some say OK we come back. Another day. Because by giving them so many times, we forget because we're busy, and we don't do the test at the end of the day..."(Focus group 2, Participant 2).

All groups mentioned the system of booking patients for another day – and both intervention groups mentioned how this system results in patients not being tested for HIV. Focus group three as well as some key informants were quite adamant that TB patients had enough stress when diagnosed, and the issue of HIV testing should not be broached on the same day, as it is too shocking. This opinion was expressed less strongly in the intervention groups; however, even focus group two noted that the first day may not be appropriate for a long counseling session.

### **Nurse experience of counseling and testing**

The counseling process also places demands on the provider and the resources of the health system. These issues were mainly discussed by key informants – usually in the

context of time required for the process. Two key informants felt that, in the light of the South African situation, long counseling sessions were not feasible and that a shorter alternative should be sought. One key informant emphasized a difference between counseling and education, and that the counseling involved “unpacking” a patient’s life - physically, socially, sexually and spiritually, thus being more time-consuming.

Another key informant expressed how nurses feel about the requirements of HIV counseling and testing:

“Oh yessee it will take so long, you know. I can’t do it today because now the process is too long.(sic)” (Key informant 3).

Two key informants hoped that there could be a compromise between the long counseling session and “uninformed consent”, as they felt that the resources available did not allow for a long counseling session.

### ***Approach to counseling***

Both intervention groups as well as one stakeholder mentioned that counseling should begin by explaining the link between TB and HIV. A participant in focus group one stated that when the information on TB and HIV was given as a package, patients would return to be tested. In focus group three there was some discussion about how patients’ view of the link between TB and HIV discouraged them from the testing – as patients in the community thought that if one has TB, one also automatically has HIV. In their opinion, this reduced the number of patients attending at the health clinic for TB, and patients would arrive when their condition had deteriorated further than if they were not aware of the link between TB and HIV.

### ***Personal effect on nurses***

The strain that nurses may experience while doing their work may be one of the issues that affect their HIV counseling and testing. All focus groups referred to HIV counseling and testing as difficult. Participants in focus group one felt it was depressing and frustrating and “at times you feel like not coming to work the following day.” (Focus group 1, Participant 2). Focus group two referred to the stresses in less strong tones, such as “upsets you”, “drained”, and “difficult”.

Focus group three, on the other hand, felt that the process was taxing and one participant felt that rapid testing was speeding up the process too much. Another participant had found a way to slow down the rapid process - by placing results in an envelope to be read by nurse and patient in the afternoon. Few key informants mentioned stresses to the nurses, however, one emphasized the importance of support and another described support services soon to be available for clinic nurses. All focus groups became quiet when the topic of the effect of HIV counseling and testing on them was broached. The silence may have indicated discomfort about approaching this topic.

A participant in focus group one reflected on their experience of HIV counseling and testing with the following:

“Yeah you can become emotionally drained, definitely, like last week I – I’m going to use the word divorced. I divorced myself from the VCT. From the testing. And my clients. Because I found that I – I felt that I was emotionally drained, man. To see these patients. On a regular basis. Some of them respond well, some of them don’t respond well... (sic)” (Focus group 1, Participant 1).

### ***Perception of quality of service***

Both focus group one and two were under the impression that they were not providing quality service. Focus group three, on the other hand, mentioned the impact that the lack of time had on quality of service.

“Its [patient] load definitely not...manageable because we are only rendering... quantitative care (quantitative) instead of qualitative care – it’s not quality (not quality at all). One wants to render a quality service, you know, to our people, but the conditions does not allow.” (Focus group 1, Participant 1).

Focus group two also mentioned that HIV counseling and testing required one to “...go on and on and on...” (Focus group 2, Participant 4). Similarly, focus group 3 noted that counseling could not be rushed. Focus group 1 did not mention this issue.

One of the key informants summarized the relationship between insufficient staff and quality of service by saying:

“...unfortunately, if you’re not gonna give staff to see to the numbers that we are seeing every day, then you’re just pushing numbers then, you’re not seeing clients, you’re not seeing them in totality or holistically, you’re seeing NUMBERS. (sic)” (Key informant 4).

A clinic nurse believed the problem was related to not have staff dedicated to counseling alone.

“...I won’t say actual the staff shortage that’s really the problem, be we need people who are really doing only the counseling, VCT” (Focus group 2, Participant 2).

It seemed that insufficient staff and time impacted on the quality of service, possibly having a large impact on the HIV counseling and testing. In addition, nurses’ perception that they were unable to give quality service to their patients may have a negative affect their morale.

### ***Staff and patient relationship***

All of the issues discussed may exert influence on the nurse-patient relationship. In turn, this relationship may be one of the key issues impacting HIV testing uptake following

counseling. Accordingly, many key informants as well as the intervention groups emphasized the importance of the relationship between the staff and patient. In focus group one, nurses emphasized the relationship between them and their patients and HIV counseling and testing by stating: "... with your own patients we'd love to do VCT (sic)" (Focus group 1, Participant 2). Nurses and one informant also mentioned that patients get attached to them, and only want to see one nurse. One key informant noted that there was insufficient time in a busy clinic to build a good relationship. Similarly, a nurse in focus group two mentioned that "we're just pushing because we want the patients to get out of the clinic" (Focus group 2, Participant 2). Time, then, seemed to be an inhibiting factor to this relationship.

As noted in nurse characteristics above, the TB department in general required nurses that were committed to, and enthusiastic about, their work. It can be assumed that their characteristics impact on their relationship with the patients, and may also impact on HIV testing uptake. On the other hand, as noted by one key informant, training could also have an impact:

"Probably also one nurse may be better in building that relationship ermmm and.. understanding the patients' issues than another person – it may be related to whether they've been trained or not, but it can also be a - just a – talent (laughs), whether you have good communication skills or not, I think it's hugely important...(sic)" (Key informant 2).

In addition, a key informant noted that HIV counseling and testing could be facilitated if the patient dealt with one person only. This was reiterated by a clinic nurse.

"...I don't feel happy with the ... health workers doing the counseling. I don't feel happy because you expose the person to too many other people....The DOTS they do the counseling, which is right they help, yeah. Now the person goes to the sister must do the HIV test. Now she is, that patient's HIV positive. You understand? Now the patient must go back to the person that first, I mean he had a relationship with that first person." (Focus group 2, Participant 2)

### **Patient response to counseling, and testing uptake**

Nurses in focus groups were asked for their perception of the patients' reactions to HIV counseling and testing. Two stakeholders and focus group one reported more negative reactions from patients: shock and trauma. Focus group one also mentioned that at times, the patients were not surprised because they had been "diagnosed from the community" (Focus group 1), possibly indicating that community members had stigmatized a person based on their physical appearance.

Focus group one and two, as well as a key informant, mentioned that often patients arrived already knowing their status. A participant in focus group two told a story of a person she had tested in one clinic, and had seen again receiving counseling at another clinic. She said:

“They think, deny, from clinic one to clinic two”(Focus group 2, Participant 1).

The type of community in which the clinics were located was also seen as having an impact on counseling and testing uptake. One key informant stressed the importance of community response in facilitating nurses’ work. Another key informant stated that educating patients would facilitate HIV counseling and testing, and a participant in focus group one felt that there was a more positive attitude towards HIV counseling and testing:

“...change of attitude with the patient now. I think because of this ongoing health education”. (Focus group 1, Participant 2)

In contrast, yet another key informant was of the opinion that there is still a need for community education. She reported resistance to the testing, which led her to state:

“I really don’t know how we’re going to get more people to be tested. Unless there’s a thing where you don’t have a choice. But that won’t be a good thing because then people won’t come forward for the TB testing and things, you know, so you can’t do that. Definitely not” (Key informant 3).

The above may indicate that the person was both aware of the necessity and the importance of patient choice and autonomy, but also felt that the current situation required a faster process that would allow a more efficient flow of patients through the clinics. Community differences were also discussed by focus group three:

“it’s like a middle-class area, and ... they don’t believe... They don’t want to be tested.” (Focus group 3)

This may reflect an impression in the community that TB and HIV are problems that only affect someone else. Similarly, a key informant noted that there are wide differences between the communities that clinics serve, in that cultural backgrounds were different, stigmatization of HIV worse in some areas, and poverty and substance abuse more common in others. The participant felt that these prevented individuals from coming to be tested at some clinics. In contrast, another nurse in focus group three had experienced an influx of patients to be tested. The nurses thought it was because people wanted access to the state disability grant, which TB patients can claim if they are extremely ill, and/or if they also have HIV. A nurse in focus group two also noted that there was considerable enthusiasm for the test: “as if now you are bringing in the cure” (Focus group 2, Participant 1). She felt guilty when she was unable to counsel and test the patient when requested.

Other issues affecting patients’ response to counseling were family reaction upon diagnosis with HIV and the stigma present in communities that reduced the number of people arriving for testing. Many key informants felt that it was important to educate the family and community to inspire them to participate in getting people tested:

“...then a lot of emphasis on social mobilization, community awareness...” (Key informant 2)

Another issue raised by key informants was the importance of educational material that was both in the correct languages and culturally appropriate. This was not yet available everywhere in the Eastern Cape.

### **Impact and opinions of opt-out study**

Overall, the opt-out study was well received. Nurses especially appreciated the new Official Patient Referral Letter provided by the opt-out team. One key informant said that nurses were enthusiastic about the program and the new record keeping methods. The informant went on to explain that some of the nurses had incorporated some of the opt-out material into their daily work. This, however, could not be done without consultation with management, and in the words of the key informant “...we’ve put a stop to that...” (Key informant 1).

Positive reactions about the program included:

“I was really glad that this thing started. Because I’ve had problems with – with TB patients that’s not been counseled. And I was worried because, some of the sisters don’t – doesn’t see it as an important part, and this actually forced them to do the VCT. (sic)” (Focus group 2, Participant 2)

Responses to the training indicated that participants felt it was effective; the explanation of the policies regarding cotrimaxazole was found helpful and it was felt that the training helped nurses to see the importance of HIV testing for TB patients. An example of this was:

“The facilitators did it so well. To an extent that you – know – you are not fumbling when you are at the clinic.” (Focus group 2, Participant 1)

One participant in focus group two felt that implementing the program was at times difficult, and one key informant had negative impressions of the program. She spoke of her disillusionment about outside initiatives:

“...tired of the fact that people come with – idealistic ideas of what should be done, and what could be done, but it’s not marrying the realities of your situation.” (Key informant 4).

While participants in focus group two explained how they had adapted and learned, she had a more pessimistic attitude:

“..the reality is, when I didn’t have time, I would say: ‘let’s see one another in a week’s time. Then, when I have, we can discuss that other issue’”. (Key informant 4)

Another key informant also felt that the program made extra work for nurses – but also felt that it was important. One of the key informants stated that they felt the program was giving TB much needed attention.

### **Themes derived from the qualitative research**

Three major themes emerged from the study and can be seen in figure 7.

#### ***Theme 1***

A major theme of this study was the lack of staff in clinics and the high workload of the TB nurses. It was apparent that the nurses relished the opportunity to vent their frustrations with the health system, but in fact these issues are very real and complicate the day to day tasks in the TB program and the clinic in general. Some nurses found lay health workers helpful, but others considered their presence insufficient to decrease their workloads, and actually presented additional problems related to skills and need for supervision. On the one hand, TB nurses are designated to carry out TB program activities in much the same way they were carried out during the years when TB was still a vertical program, indicated by the specific recording required, but within their actual workday environment of a primary care clinic TB nurses are required to interrupt their TB duties to assist within the clinics when other staff are out and when patient loads demanded it. There appeared to be a lack of reciprocity in this arrangement; TB nurses were expected to pitch in, but when the TB nurse was absent the TB tasks were left for her return. All of these factors would lead to delays in HIV counseling and testing, irrespective of the efficiency or motivation of a particular TB nurse.

### **FIGURE 7. Major themes inferred from qualitative research**

**Theme 1:** TB nurses experience chronic frustration between knowing TB tasks need to be accomplished and not having the resources, including staff, to accomplish them.

**Theme 2:** TB nurses experience conflict between the need and importance of HIV counseling and testing and the health system's recognition of their difficulties.

**Theme 3:** TB nurses experience ambivalence in their roles as care providers and educators in the context of HIV counseling and testing.

#### ***Theme 2***

The conflict between conducting HIV counseling and testing and the resources available for nurses in the TB department seemed to emerge strongly in the transcripts. This theme is closely related to the first theme with regard to the need and importance of counseling and the health system's response to their difficulties in performing this task. At times there seemed to be an undertone of resignation at the obstacles confronting the nurses and that impression that management was likely to ignore the nurses' requests for help rather than provide assistance in reducing obstacles. The lack of effective management appeared to contribute to difficulty in setting priorities, which in turn contributed to the nurses' feelings of resignation.

### *Theme 3*

Despite the fact that it was never stated explicitly, there appeared to be universal support of HIV counseling and testing of TB patients; it seems there was implicit understanding that there was a health benefit for the patients knowing their HIV status. However, the TB nurses and key informants articulated varying levels of ambivalence about when and how HIV counseling and testing should be carried out. The role of nurse as care provider and educator appears to have been perceived as a contradiction to what was required to routinely HIV counsel TB patients. There appears to have been resistance to introducing HIV counseling too early for the patients, when they were still very ill from TB. Some nurses expressed reluctance to start counseling when they wouldn't have time to do it well; internal conflict was ongoing between the potential long-term gain for the patient and the short-term suffering perhaps caused by learning HIV status. Nurses expressed concern about their ability to provide positive HIV test results, both because of their awareness of time constraints and empathy for the TB patients.

## **CHAPTER 4**

### **DISCUSSION**

This study evaluated the impact of implementing the Opt-out Strategy on the uptake of HIV counseling and testing of newly registered TB patients in primary care clinics. The HIV counseling and test rates were significantly better in the clinics that received the training in the Opt-out Strategy than in the control clinics, however the overall proportion of those counseled and tested was small. The baseline estimates for HIV counseling and testing rates of 40 percent, given to us by the Provincial Health Department, were apparently based on hope rather than on surveillance. This became apparent when we were able to see that there was no standard documentation for HIV counseling and testing of tuberculosis before our study began, despite the province's official implementation of TB/HIV collaboration in May of 2004.

Pragmatic studies, such as ours, carried out in primary care settings, often have modest results. In Brazil, a cross-sectional study designed to assess the rate of HIV screening of TB patients in primary care clinics found that approximately 23 percent of the patients had been screened, and that perceived risk by the health worker determined who was tested (6). A cluster randomized trial that trained clinic TB nurses in Free State Province to use an algorithm for the diagnosis and management of respiratory diseases (including tuberculosis), had voluntary HIV counseling and testing rates of 9.7 percent in the intervention and 7.3 percent in the control study arms (21).

Studies that demonstrated high uptake of counseling and testing in tuberculosis patients have been carried out in hospitals (Malawi) (22), in vertical TB programs (Malawi) (5, 23), during interventions with extra staff dedicated to the process (ProTEST and Côte d'Ivoire) (24, 25), or by study staff (Haiti and Thailand) (4, 26).

Antenatal settings usually report relatively high rates of HIV counseling and testing (27) but a review of 18 South African pilot sites for the prevention of mother to child HIV transmission (PMTCT), two in each province, demonstrates that in the public sector, this is not always the case. The review evaluated the performance and uptake of components of PMTCT, including HIV counseling and testing. Three years following the start of the pilots, uptake of HIV testing differed greatly across provinces ranging from 14 to 92 percent, and averaged 56 percent. The lowest uptake was in the Northwest Province (14 percent), and next was the Eastern Cape at 34 percent (28). It was noted by the researchers that the Northwest and Eastern Cape provinces were both struggling to employ lay counselors; “many of the pilot facilities still rely on nurse counselors with a heavy workload (28)”. All but the sites in KwaZulu-Natal used the standard ‘opt-in’ strategy for HIV counseling and testing. In KwaZulu-Natal, where HIV test acceptance was nearly double that of the national average, counseling was considered a routine part of care (28).

There is evidence that a health department with a highly motivated and supportive administration can be successful. The Cape Town Metropole Region has made a concerted effort to increase the number of TB patients that receive HIV counseling and testing in their health care facilities. Using a combination of good surveillance and proactive management, HIV counseling and testing rates ranged from 38 to 83 percent counseled and more than 80 percent test acceptance in twelve Cape Town districts in the first quarter of 2004, for example, and showed improvement incremental improvements in each quarter. It is important to note that the Western Cape Province does not use a completely decentralized approach to TB control, perhaps making it easier to focus attention on TB-specific care (29).

In this study, the proportion of TB patients that accepted HIV testing was higher in the intervention arm. Our study introduced two factors that may have increased the uptake of testing. Although we did not change the fundamental content of HIV counseling, the training in the Opt-out Strategy did teach the nurses how to specifically address the link between TB and HIV. This may have translated into heightened awareness by the TB patients who may have responded with increased interest in testing. In addition, the concept of compulsory HIV counseling may have added an element of coercion into the counseling that made it more difficult for patients to refuse testing.

The TB patients counseled in the intervention arm were counseled and tested closer to the date of TB registration than those counseled in the control arm. Emphasis in the ‘opt-out’ training was on HIV counseling and testing as soon as possible, so we must assume that the training heightened awareness of the benefits of providing counseling and testing promptly. Evidence from the focus groups of nurses in the intervention arm supports this assumption.

“What I usually do is do the counseling there, and they must come back to me to say when are they ready to – for us to see to the testing. Some of them say OK we can do it now, some say OK we come back. Another day. Because by giving them so many times, we forget because we’re

busy, and 23- don't do the test at the end of the day. With not that patient." (Focus group 2, Participant 2).

"At times we ask them to come the following Postponing, postponing the VCT until you don't do it at all. Because day. (agreement) there's no chance for you to do that VCT (agreement) because the environment is not conducive at all." (Focus group 1, Participant 2).

Many nurses and key informants expressed their preference to wait until the patients had completed the intervention phase of their treatment before encouraging patients get HIV testing. Our results indicate that if patients were tested, they were tested within two weeks of registration, in both study arms. It is possible that more patients in this cohort did receive HIV counseling and testing later in their TB treatment, but this study was not designed to capture that.

The rate of counseling and testing appears to have been maintained throughout the study period, with perhaps an initial surge following the 'opt-out' training. Ten weeks is a short period of time, and other interventions may promote or negate our opt-out training, so we have no way of knowing whether the training will influence the TB nurses' behavior through time. Nurse managers and supervisors had conflicting opinions about the longer term effects:

"...I had hoped, you know, that the impact [of the opt-out study] would be much greater...it's something that you can't measure in the short-term...Maybe they will, shame. Over a longer time." (Key informant 3).

"With the opt-out study, it was the reports that I have been getting from the nurses – the forms that has been devised is very good and helpful. They're enjoying using it, and even take the remarks from that to – into the TB program. And – we've put a stop to that because – in our areas we don't just start to – without being allowed by the departmental managers and \*\*\*\* manager." (Key informant 1).

The proportion of patients that were HIV test-positive was and not significantly different. The proportions in both study arms were considerably lower than the estimated 60 percent national co-infection rate. No inference can be made about the proportions of patients that tested positive because of small numbers and the inability to determine whether the patients tested were representative of all TB patients. We found no associations between age, sex, site of disease or retreatment with HIV counseling or testing in either of the study arms, so this study offers no evidence that patients were counseled based on perceived risk. The discussions during the nurse focus groups revealed a variety of emotional responses to testing that may have influenced which patients were counseled and tested.

"...maybe I've got a soft heart, when I see the patient is very sick, yeas I do touch on the – on the pre counseling, ne, on the pretest counseling, but

usually with my patients, they like to – to tell me that aa, sister I don't think I'm ready now. If you say I can just take the treatment maybe for a week or two weeks, then I can think about... The test. So I usually allow them. When they feel better with it... I don't tell you you've got TB and I say again you are HIV positive.” (Focus group 1, participant 4).

“...most of them are poor, nothing to eat, they're poor, they just got TB and HIV positive.” (Focus group 2, participant 3).

“...Because at least with the ELISA, you used to take blood this week, and ask the patient to come the following week (agreement). And the result will come – then at least you you know that this patient is positive (gets loud) and you PREPARE! ...You prepare yourself because you have done the pretest counseling. At least you know who you are dealing with. So you know how to tackle this one.” (Focus group 3).

There was ample evidence that the TB nurses' time was limited and often fragmented. Their own assessment was that on average they spent less than half of their available time for TB program duties. None of the nurses were dedicated to only TB; they all had additional clinic responsibilities. The nurses frequently articulated the need for time to carry out adequate counseling.

The TB nurses consistently described that their TB tasks were perceived as less important within the clinic hierarchy. This may have influenced the TB nurses' ability to leverage any authority to prioritize HIV counseling and testing.

We learned from the nurse focus groups that the TB nurses were not always doing the HIV counseling themselves. There were a variety of opinions on the subject ranging from appreciation for the support of ancillary personnel, to the acknowledgement that more people involved with counseling one patient may not provide the best counseling experience for the patient. A study designed to evaluate the role of lay counselors in primary care clinics in the Western Cape Province described similar issues (30).

In addition to the issues of whether professionals or lay counselors, or a single person versus a series of people should be involved in counseling, there is the logistical complication that only nurses may perform the needle stick required to accomplish the HIV test. Both nurses and non-nurse counselors recognize the difficulties of finding a nurse to perform the HIV test after a non-nurse counselor has pre-test counseled the client (30). This was a point of confusion in one focus group.

Participant 4: “ That is what I am asking, because if you pre-counsel somebody you have to do the test, and then posttest counseling. So what is the problem, with those people [lay counselors] not doing the test?”

Participant 3: “They're not allowed to.”

Participant 4: “Why?”

Participant 3: “They’re not allowed to, because it’s only the sister that can do it. It’s just like that. It’s only the sisters that can do it.”

Participant 1: “Only nurses and doctors because there’s a lot of err...finer aspects like confidentiality and all those things. You are trained, you were trained you know. You are a professional somebody...”  
(Focus group 1).

### ***Cotrimoxazole***

The proportion of HIV test-positive TB patients that were prescribed cotrimoxazole was small. The reasons for this are not clear. Inventory did not show any relationship to whether a patient was prescribed the drug. The Cape Town Metropole Region had poor rates of cotrimoxazole prescriptions at the same time their counseling and testing rates were improving (29). The national treatment guidelines recommend the prescription of cotrimoxazole one month after the start of TB treatment, and in the ten TB patients actually prescribed the drug, two of them were started less than one month after they began TB treatment. We suspect that there was confusion about when to start treatment, the dose and the frequency. The treatment regimen is written as follows: “... provide cotrimoxazole 960mg either 3 times per week (Monday, Wednesday, Friday) or 5 times per week (daily from Monday to Friday)” (31). Providing cotrimoxazole close to the beginning TB treatment, as was done successfully in Malawi, may be an additional aide to increasing the proportion of eligible patients receiving the drug when it may be most helpful in reducing mortality (3, 32).

### ***Referral for HIV care***

The proportion of patients referred for HIV care was also small. During the focus groups, nurses reported they liked the Official Patient Referral Letter, although we saw only one in a patient’s record during data collection.

Participant 5: “...when I used this now thing of the...the referral, I don’t have a problem.”

Participant 1: “That referral letter makes life very easy. All the details is there, the date when they visited...whatever.” (Focus group 1).

We suspect that two factors played a major role in the small proportion of HIV-test positive TB patients being referred for HIV care. We learned during the focus groups that there was confusion about when TB patients should begin antiretroviral therapy. One nurse was particularly poignant in the description of her own epiphany when she learned the national guidelines during the opt-out training.

“...when we started the whole ARV VCT program it wasn’t a situation where you sat and you were oriented and you were informed...So you’re fumbling and falling and you’re learning and phoning another clinic ...and there we came on this course, and for me, what stood out was the fact that according to national guidelines on ARV’s it says that TB patients automatically form part of the criteria to be stated on ARV’s. Nothing

else is needed. Not a CD4 count, nothing. And for me that was ‘Oh my God’ and these people are already in a stage where they need help...”  
(Key informant 4)

Many nurses seemed to believe that all TB patients should complete the two-month induction phase prior to beginning drugs for HIV disease. We saw notes written in patient clinic records that documented the date when the nurse intended to refer the patient, and it coincided with the expected completion of the induction phase. Secondly, the nurses in the ARV clinics were not included in either the design of the referral form, nor were they informed or trained in its use. The idea of the referral was conceived by the Manager of Medical Services in NMMM, and the form was created shortly before the documentation began. Although it was introduced in probably less than ideal circumstances, this study did introduce the first formal referral system that included written documentation between TB and HIV programs.

#### *Variability between study clinics*

There was considerable variability between clinics within study arms, with only five of the intervention clinics exceeding the mean proportion (15.9 percent) of patients counseled. None of the control clinics exceeded the mean. Key informants told us that some nurses are simply more committed than others; some nurses seem to have special qualities that enable them to accomplish more than others.

“...Because some people are not ...wired...to be sensitive to those issues...” (Key informant 4).

“Some sisters are more committed than other, some don’t care. For some it is important to do things right. You need love for the work...” (Key informant 5).

“...some clinics someone is not interested, things are not working well.”  
(Key informant 6).

The nurse focus groups revealed the nurses’ perceptions that patient populations may have varied in their willingness to accept HIV counseling and testing.

“...Immediately you tell them they’ve got TB, they don’t want to be tested for HIV...” (Focus group 3).

“The area where I work, it’s like a middle class area,...they don’t want to be tested. You can counsel and counsel, are you ready already, no it’s difficult, many of them don’t want to.” (Focus group 3).

“But mine now, they started coming out now...because they think - ...because if you’ve got TB and HIV you can get the grant....” “If you have TB and HIV, ja.” “Or if your lungs are really destroyed, you must be quite sick (laughter).” “Dying virtually (laughter).” “Dead.” “When the

grant comes through you are dead. (laughter).” “You get it at the funeral” (laughter). ( Focus group 3)

“I’m not ready yet, I’m not ready yet. Today. Maybe next week.” (Focus group 3).

“...once you mention tests, it is as if you are bringing in the cure! (laughter). The way they want it – yes! They want to be tested!” (Focus group 2, Participant 1).

South African researchers have shown repeatedly that there is a low level of knowledge and high degrees of stigma about both TB and HIV within the South African population. Individuals that learn they are infected with HIV frequently do not share that information with anyone, including sexual partners (33) Everyone seems to have heard of both infections, but there is a wide spectrum of perceived causes and infectiousness for both. Some people believe that TB is hereditary, and thus do not perceive any risk of infection. Their knowledge varies by location and by age groups (34-37). In general, TB patients associated TB with dirt, poverty and poor nutrition (37, 38).

We did not find any association between race and/or language and whether or not a patient received counseling or testing. This was an indirect measure, based on the predominate racial groups and languages reported for the census ward a clinic served, so it may not be accurate. To fully understand the issue of whether racial or socio-economic factors influence willingness to counsel and test, it would be necessary to record the race of the patient and the counselor/nurse in addition to interviewing both. We could have collected individual level data on race, but without including the other potentially influential factors we believed it would be inappropriate to measure a variable we couldn’t necessarily interpret correctly.

### ***Potential biases***

Despite a wide range of factors that could have influenced the study outcomes, we found no evidence that they did. There may have been factors that were not measured, such as daily patient load, the race of the patients and/or nurses and structural factors associated with whether the TB nurses actually carried out the counseling and testing that may have influenced the outcome. From our assessments, randomization was successful and so these potential confounders, if they did play a role, could have diminished the size of the effect of the intervention, but would not provide an alternative explanation for the study outcome.

One nurse in the intervention arm did not attend the Opt-out Strategy training and was trained by the nurse from that clinic who had attended the training. That clinic had the highest proportion (66.7 percent) of TB patients counseled and tested. Possibly receipt of the training by another nurse implied a work-related training rather than a study, instilling a greater sense of urgency in accomplishing the task.

We do conclude that the data in the clinic registers and patient records was not recorded in real time. Both from anecdotal evidence, comments from clinic nurses, and the determination that documentation was not complete for the last two weeks of the data collection period in all study clinics at the final data collection, we have some concerns that the data collected may not have been a comprehensive record of what actually transpired. We are confident that what was documented was true; the concern lies with the timeliness of the record.

It is possible that the information shared during the focus groups and key informant interviews did not accurately represent the conditions in clinics and factors related to HIV counseling and testing. The qualitative researcher described the focus groups differently. Focus group one, that was comprised of nurses in the intervention clinics that did not performed below the study mean were described as a mix of those who were somewhat overbearing and those that were reticent to speak. Focus group two, which represented those intervention clinics that had performed well, included only three of the five nurses that had participated in the study, plus a nursing supervisor for more than one of the study clinics. The qualitative researcher was concerned that including a nurse of higher rank might influence what was shared during the group. Although there were also dominant speakers in this group as well, the group as a whole spoke in the collective, apparently viewing their individual experiences as part of the whole. Finally, focus group three was somewhat difficult to manage because of its size, but ultimately seemed the most balanced and relaxed. It is unfortunate that the group of clinics that performed the best were the least represented, making it more difficult to determine what factors may have contributed to their success.

Finally, there may have been variability in the number of TB patients who knew they were HIV positive prior to being registered at the clinic. We learned during the study that the clinics did not document HIV-related information in records of patients who presented to the clinic with known HIV status. Clinic nurses would mention to us that a particular patient was HIV positive, but there was no system for recording that information, making it impossible for us to collect.

“...with me I’ve got a problem, when they come from the doctors or from the hospital, they come with already being diagnosed HIV positive, so most of my patients are HIV positive and they have already been diagnosed.” (Focus group 1, Participant 4).

“Especially the TB clients, most of them come in with positive results.”  
“Especially from the hospital, because the hospital don’t make use of confidentiality. So they write on the referral letter RPD positive (agreement). Maybe the patient did not understand that, and when you ask them they said no, they want to do the HIV test.” (Focus group 2, Participants 2 and 1).

It appears from these reports that patients tested in hospitals are receiving their test results in a manner they do not always fully understand.

It is possible that the differences in the number of patients counseled and tested reflected the differences in the number of patients who knew they were HIV positive prior to TB registration. We doubt that this is true based on our baseline assessment of monthly clinic statistics. The monthly statistics report the number of newly registered TB patients and the number of newly registered TB patients who were HIV-test positive. When we were able to find documentation for both, we made a direct comparison of the monthly statistics with the documentation in the TB and HIV Counseling and Testing registers and found little correlation in most clinics for which there were complete records. We did note that in every case there was a discrepancy, the number of HIV positive TB patients reported was greater than the number documented in the clinic registers. This suggests that the TB nurses may have accounted for those patients that were known HIV positive in the monthly statistics despite not having documented in the patient's medical record. There is no evidence of more or less accuracy in the monthly statistics in one study arm versus the other, therefore, we do not believe that this would have influenced the study outcome other than by perhaps reducing the magnitude. If many clinics patients were already known to be HIV test positive and we could have identified them, we could have excluded them from the denominator, resulting in a larger percentage of eligible patients (but obviously not a greater number) that received counseling and testing.

### **Contamination**

Contamination occurs when the study intervention is introduced, completely or incompletely to a clinic allocated to the control arm of the study. Cluster randomization was the principal strategy to reduce contamination; the intervention was applied at the clinic level, not at the individual level. Four TB nurses were moved to other non-study clinic positions during the study. Three nurses transferred into the study clinics following the documentation training (two in the intervention arm and one in the control arm). No nurses trained in the opt-out strategy were transferred to clinics allocated to the control arm.

One nursing supervisor was responsible for three clinics in the intervention arm and two clinics in the control arm, providing an opportunity for the supervisor to have introduced the opt-out strategy to the control clinics. Despite this supervisor's outspoken support for the study, there is no evidence that she influenced the study outcome. Eighteen TB patients in the three intervention arm and ten TB patients in the two control arm clinics were HIV counseled in clinics that she supervised. If she had influenced the outcome it would have been in the direction that would have diminished the effect.

The TASC TB study was being conducted during the same time period as our study and was designed to address issues of TB/HIV collaboration. Our study clinics were chosen specifically because they were not participating in the TASC TB study, so we do not believe the TASC TB study was a source of

contamination. Again, if it had, there is no reason to suspect that the influence would have been differential between study arms.

The Municipality held a monthly TB meeting that was composed of designated TB nurses at all the clinics within the district. There was potential for contamination at these meetings, had strategies of HIV counseling and testing been a topic of discussion. The nurse manager that coordinated and led these meetings was queried directly by the student investigator four months following the conclusion of study data collection. The nurse manager denied any discussion of the opt-out study or opt-out strategy during any of the meetings, explaining that the meetings did not have a particular agenda; the meetings were simply an opportunity to problem solve. When interviewed earlier as a key informant, the manager did express a personal bias toward waiting for two months before doing HIV testing. Should that bias have been introduced at the monthly meetings, it may have contributed to the small effect size, but the effect would be expected to influence both study arms relatively equally.

### **Compliance with the intervention**

To a great extent, compliance with the intervention is one of the most important outcomes of pragmatic trials. It is obvious from the small magnitude of the effect that something got in the way of greater success. Was it non-compliance? There was evidence of some level of non-compliance in at least two factors. Documentation of the ‘R’ in the *Remarks* column of the Tuberculosis Register was carried out with great variability between clinics.

Participant 1: “...don’t want to use the R in your TB register, and prove that this patient has been counseled, the patient does have the VCT.”

Participant 2: “But how will this other person know that the patient’s don’t VCT? Our VCT book you mark with R”

Participant 1: “No no the VCT book it’s stated there TB or antenatal or whatever. It’s stated there.”

Participant 2: “The one they don’t really want the R with the ordinary TB, with the TB register...” (Focus group 2).

We learned at the conclusion of the study that one nursing supervisor interpreted the ‘R’ in the TB register as the symbol for drug resistant TB, making it clear that such an operational initiative must get input from everyone involved before being instituted. Nursing supervisors were not included in the opt-out training. All TB nurses involved in the study were aware that we were carrying out a study. This was the first exposure to research for many of the nurses and their supervisors. Despite the full cooperation and support of the health department, the study intervention was not a health department initiative or policy.

The nurses were universally supportive of the HIV counseling and testing of TB patients. They expressed appreciation and support for the Opt-out training and strategy. They appreciated the introduction of both the HIV Counseling and Testing Register and the Official Patient Referral Letter. Discussion from the focus groups and key informants

made it clear that the nurses were receptive to new information and eager to learn current treatment guidelines. However, there was considerable variability in the opinions expressed about the appropriate timing and circumstances HIV counseling and testing. It is possible that some of the TB nurses disagreed with HIV counseling TB patients early, and that despite the opt-out training, they followed their own beliefs.

### **Balance between internal and external validity**

A danger of pragmatic trials is that internal validity may be overly compromised in the effort to ensure generalizability (12). The principal strategies this study employed to strengthen internal validity were application of constrained cluster randomization, complete follow-up at all of the study clinics, and triangulation of qualitative and quantitative data. Randomization based on baseline data permitted us to successfully distribute the diversity of the study clinics evenly between the two study arms. If there were factors that influenced the uptake of HIV counseling and testing, the evidence from our evaluations indicates that they were not differentially represented in one study arm versus the other. All evidence points to strong internal validity.

The focus groups demonstrated the nurses' beliefs that TB patients had varying levels of readiness for HIV counseling and testing, and suggested that the variance might be related to race or socio-economic status. We did not measure these variables directly, but our indirect measures do not support that belief. The focus groups did provide extensive information from the TB nurses about the difficulties of carrying out HIV counseling and testing, helping to explain the small magnitude of the effect.

A more intensive intervention, or an intervention more specifically tailored to the needs of individual study clinics may have resulted in greater numbers of TB patients receiving HIV counseling and testing. However, our intention was to test an intervention that was reproducible in the very real environment of staff shortages, limited privacy and time constraints.

### **Strengths and limitations of this study**

A limitation of this study is that we do not know how many TB patients already knew their HIV status prior to TB registration. Clinics do not document HIV positivity that patients report to them, only HIV tests the clinic carries out themselves. We would suggest that this will be a major limitation in the surveillance of HIV infection in TB patients, as well. National plans to include HIV testing, prescription of cotrimoxazole and antiretrovirals into TB surveillance software do not include data fields for patients already known to be HIV positive (39).

A limitation of this study is that it was unable to gain the experience of patients who had attended HIV counseling and testing, or the attitudes of the community involved. Therefore, all references to the communities and participants were from the perspective of the nurses and other key informants.

We believe this study could have been more effective if it had been a health department initiative, aided by researchers, rather than a research project supported by the health

department. The nurses in the Municipality did not have much, if any experience with research, but they knew that the interventions were from the 'outside', and not health department initiatives. Given the high work load, it is not surprising that an intervention that was not required by the health department itself was not a high priority for the nurses. Researchers from other pragmatic South African studies of interventions in primary care settings have concluded similarly that not only the support but the involvement of supervisors and management are essential to the success of interventions (21, 40).

This study measured the impact of routine HIV counseling and testing using typical pre-test counseling prescribed by South African guidelines and with reinforcement of information linking TB and HIV. It is possible that if we had used an abbreviated pre-test counseling format, simply informing a patient of their right to refuse testing, that more patients would have received testing.

We do not know who actually did the HIV counseling. The Opt-out Strategy training targeted TB nurses, but in the focus groups nurses spoke about ancillary personnel participating in HIV counseling in some of the clinics. We have no way of determining whether the clinics in which nurses did the counseling and testing were more or less successful than clinics in which ancillary personnel may have completed the counseling in the context of patient uptake of counseling and testing.

## **Recommendations**

### ***Political support from the top down***

Just as the DOTS strategy depends on political will, so does the collaboration of TB/HIV services. Brazil, Thailand and Uganda have shown the world that strong and informed political leaders can save lives by speaking freely about the infections that put their citizens at risk and providing diagnostics and treatments free of charge. If a government's major purpose is to protect the security of its citizens, then surely South Africa, who showed the world how to avert civil war and post-apartheid retributions can rise to the dual challenges of TB and HIV.

Advocacy for TB and HIV program collaboration is difficult if not impossible when TB is virtually invisible within decentralized health care. Tuberculosis is the leading cause of death in Port Elizabeth; at the very least, we would suggest that TB program expenses be re-instituted as a line item in the Provincial budget so that districts exceptionally impacted can lobby for more funds.

The Department of Health of South Africa has a mandated Tuberculosis Register that can be found in every clinic where TB patients are evaluated and treated. The Register ensures standardized data collection that permits comparison between provinces and districts throughout the county. Already created (but not used) in the national electronic TB surveillance software, the Register could be expanded to include HIV-related information (41), with explicit instructions as to its use, including assignment of responsibility for its completion to the TB program. As more individuals receive HIV tests it is imperative that a surveillance mechanism is designed for capturing those

patients for whom HIV positive test results are known. Only with standard and well-understood surveillance tools can the state of HIV/TB collaboration be assessed and improvements measured.

The most recent TB guidelines were published before antiretroviral therapy could be legally prescribed from South African government clinics. Guidelines for HIV counseling and testing in the most recent manual focus on grief counseling (42), no longer a major component of post-test counseling in the era of antiretroviral therapy. The Health Department's *Tuberculosis and HIV/AIDS: clinic guidelines* need to be updated and should include more details related to dosing and schedules of recommended drug therapy. Placement of all clinic handbooks and guidelines containing information for which primary care clinic nurses are responsible needs to be mandated for every clinic, and we would suggest that their presence be an item to be assessed during supervisory visits. Nurses can only be held accountable for guidelines to which they have access.

### ***Facing the reality of few nurses and many patients***

There is a global nursing shortage that shows no signs of abating. Nurses are required to do more with less. TB nurses have frequently been cited for their lack of rapport with patients, leading to poor TB treatment adherence (37, 40, 43-45). We would suggest that nurses deserve more support than interventions that teach them more details about patient-centered care.

It is time that nursing education programs change the paradigms describing the nurse patient relationship that reflects the reality of hectic work environments. There are ways to relate therapeutically to patients that do not require a long-term relationship. Nurses should not have to feel guilty about not fulfilling an ideal that is not attainable (46).

The actual finger-prick required to perform a rapid HIV test must be done by a nurse, under current South African regulations. We suspect that in the hierarchy of task orientation that nurses may be threatened by people other than nurses carrying out this procedure. This hierarchy of tasks is not new; blood pressure was a physician task until it was delegated to nurses who have delegated it to para-professional staff. We would suggest that the same delegation be applied to the finger-prick; nurses can be held responsible for the task being carried out properly, but the task itself could be delegated.

Nurses need training in problem-solving. Nurses in our study clinics demonstrated difficulty in describing their priorities as they attempted to describe all of the work they were responsible for accomplishing. This may have contributed to low rates of HIV counseling. It also suggests weak supervision; nursing supervisors perform a critical function in articulating health department priorities and defining where new initiatives fit into the framework of care delivery. Some South African nursing programs now include critical thinking in their nursing curricula (47), which will hopefully make it easier for new graduates to prioritize.

Nurses need focused and comprehensive training in all initiatives for which they are responsible. The train-the-trainer model is clearly not sufficient in an environment where many staff are agency nurses and nurses are moved from one clinic to another on a regular basis. In the age of the internet, there is no reason why training cannot be current and universal. A rational and efficient cascade of policies and training materials generated at the national level could be distributed rapidly to provinces and provinces could then distribute their locally adapted versions, if necessary, at the district level. A catalogue of the latest publications, if not the publications themselves, should be available on the Health Department's website.

### ***HIV is just another infection***

In early 2004, former United States Ambassador to the United Nations Richard Holbrooke and World Medical Mission founder Dr. Richard Furman reported their experiences as members a delegation that visited four African countries, led by the then current Secretary of Health and Human Services, Dr. Tommy Thompson. Looking specifically at HIV-related programs in Kenya, Rwanda, Uganda and Zambia, the two men concluded that even with huge amounts of money, it would be impossible to effectively address the HIV epidemic without routinely testing everyone at every health care encounter (48). They acknowledged the power of stigma and proclaimed that the stigma must be defied for the health of the overall public.

This sentiment was taken a step further by an even more credible advocate, South African Justice Edwin Cameron. As a long-term expert and advocate on the issues surrounding HIV and AIDS in South Africa and beyond, and the first senior South African official to reveal his own HIV infection, Judge Cameron has reached the conclusion that “pre-test counseling may be luxury we can no longer afford.”

Pre-test counseling...is useful...There is also evidence that post-test counseling is useful and important....But where pre- or post-test counseling drains healthcare resources away from diagnosis and treatment of HIV, we must now acknowledge that it constitutes an impediment to the effective management of the disease. We must acknowledge that it is costing lives. It is true that AIDS is a dread disease, and that pre-test counseling assists those with it to adjust to their condition, But malaria, cancer and insulin-dependent diabetes are also dread, potentially fatal, diseases – yet no testing or counseling protocols inhibit their diagnosis and effective management. In a mass epidemic of HIV, where mass treatment is now a realizable fact, pre-test counseling may be luxury we can no longer afford (49).

Ironically, health care settings are places where stigma is pervasive, and our study clinics were no exception. Health care workers frequently have moral stances that lead them to blame patients for their disease. They may distance themselves from patients because they feel helpless in the face of AIDS; few of them have the specialized training to provide emotional support. Health care workers may have concerns about their own risks of infection; they may be afraid to learn their own HIV status (50).

HIV testing will lose its stigma when it becomes a normal part of every clinical evaluation. Directly Observed Therapy works well when it is applied universally; as soon as nurses are asked to evaluate risk, personal judgments that make both nurses and patients uncomfortable enter into the relationship. If HIV tests were done as part of routine care, both nurses and patients have the burden of judgment lifted. In that context, it seems most reasonable to include HIV testing in the overall evaluations for all TB suspects rather than waiting until a patient is a confirmed TB case (41).

There is ample evidence, that given the opportunity, TB patients will accept HIV testing. Despite the support it elicits, there is actually little evidence that pre-test HIV counseling has a benefit (51). It has been illustrated that test *results* can reduce risk behavior, particularly if the results demonstrate being HIV positive (52). HIV counseling with test results in hand, as is done with other medical test results, may be a more productive use of time.

Opt-out is a negative phrase for a positive outcome, making it difficult to explain and ultimately ineffective as a strategy that garners universal support. Other names that have been used for the strategy include *provider-initiated counseling* or *medical* or *diagnostic testing*, which are more accurate descriptions. In the spirit of normalizing HIV testing, I would suggest that it not have a special name. Routine HIV counseling and testing is just that.

### **Conclusion**

We are impressed that the introduction of a standardized documentation tool in addition to two-days training had a significant effect on the uptake of HIV counseling and testing in this primary care setting. Admittedly, the magnitude of the effect was small; thirty-seven TB patients received HIV counseling that we can attribute to our study intervention.

From what we could discern from both quantitative and qualitative analyses, there were a multitude of factors that hindered the success of HIV counseling and testing of TB patients in this setting. Given the multitude of restraints, we believe there is reason to be optimistic. This study represented the first attempt, in this setting, to enhance collaboration between TB and HIV programs at the clinic level. A standard HIV counseling and testing register was introduced and used appropriately by clinic staff. A standardized referral system that recorded clinical information was established between TB and HIV care delivery points. Misunderstandings and confusion about when patients should be referred and doses and schedules of cotrimoxazole were identified and corrected.

The very act of carrying out the study appears to have had a positive effect. The Nelson Mandela Metropolitan Municipality expressed positive feelings about the study because it focused attention on tuberculosis, the number one killer in their community; the training was well-received. Our study nurses and key informants articulated their support for the HIV counseling and testing of TB patients.

Insights gleaned from the qualitative study component have highlighted important issues related specifically to carrying out HIV counseling and testing in primary care clinics. Given leadership and financial support, and nurses appropriately trained and supervised, there is every reason to believe that the proportion of TB patients receiving HIV testing and appropriate follow-up care will increase. Randomized controlled studies designed to measure the contributions of these important factors should be encouraged.

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## **APPENDIX A: Clinic Situation Analysis**

With the guidance of the TB nurse, the clinic register, TB register, VCT log (if the clinic kept one) and monthly statistics for March, 2005 were reviewed.

### **Questions for the VCT Nurse:**

1. How many staff members in this clinics are VCT trained?
2. How many of these are professional nurses?
3. How many are staff nurses?
4. How many are lay counselors?
5. How many professional nurses implement VCT?
6. Are any TB nurses VCT trained?
7. Who does the pre-test counseling?
8. Who does the post-test counseling?
9. Who does the actual testing?
10. Do you use a VCT register for all patients that you counsel?
11. Is the clinic always stocked with rapid HIV tests?
12. How/Where do you record the number of patients offered counseling?
13. How/Where do you record the number who accept counseling?
14. How/Where do you record the number of patients who are offered testing?
15. How/Where do you record the number of patients who accept testing?
16. How/Where do you record if the patient is positive?
17. What is the referral process for ARVs is the patients has TB or is in Stage IV of the disease?
18. Do you see TB/HIV integration work in this clinic? How?
19. How do you think TB/HIV integration would best be implemented?
20. How would you improve the VCT register?

### **Questions for TB Nurse**

1. Number of newly registered TB patients (March 2005)
2. Number of newly registered TB patients HIV counseled & tested (March 2005)
3. What is your process for HIV counseling testing for TB patients?
4. Is cotrimoxazole always stocked for this clinic?
5. What is the process you follow when a patient is prescribed cotrimoxazole/ARVs?
6. Do you record HIV Counseling Testing for TB patients?
7. Do you see any TB/HIV integration? How?
8. How do you think TB/HIV integration would best be implemented?
9. Are you trained to do VCT?
10. If not, would like to be trained to do VCT?

## **APPENDIX B. Key informant interview guide**

- permission to take notes and to tape record
- Informed consent form

What do you think of voluntary counselling and testing for people who are diagnosed with TB?

- Do you think this testing should be done for people who have TB?
- When do you think is most appropriate to do this testing, (why?)
- Who should do the VCT?
- What do you think is the best way of getting patients to agree to VCT?

Do you have any general comments about the opt out study and your involvement in it?

What did you think of the way in which the study integrated into the other activities at the clinics?

What do you think impacted on the implementation of the opt-out study in clinics?

Do you think the nurses were welcoming of this intervention?

How did the study impact on your duties and workload?

Do you think the opt-out method is a valuable tool to increase HIV testing in TB patients?

Is there anything else you would like to raise about the Opt out study or VCT?

Thank you for your time.

## **APPENDIX C: Focus group interview guide**

### ***Introductory patter***

Hi, my name is Salla Munro, I am here on behalf of the study team which included Diana Pope, Andrea de Luca and THE SA LADY DR. Before we start, I would like to go through an informed consent form.

Any questions about the study?

Firstly I would like to thank you all for arriving in this focus group discussion. We really appreciate your time.

The way that I would like to have our discussion is that I put a question to you, and you discuss the question in the group. You can direct your responses to each other. I might every now and again ask questions to clarify what I am hearing. My purpose here is to guide the discussion, and to make a note of what is said.

The general rules are that we don't interrupt each other if possible, and that we are polite to each other. Everyone has their own view, and no-ones opinion is wrong.

Does anyone have any questions about this?

I would like to ask permission to tape record our discussion. As was promised earlier, I will make sure that when this information is published, no-one will know who you are. Is this OK?

For my own purposes, could everyone please say their names and ages for the tape? This helps me to put an age background to the group, and when I listen to the tape again I can distinguish between the different people. Remember that the tape will be destroyed and only the written information used – so your names will be left out.

I will also make some notes during this conversation, if this is OK with everyone?

Any last questions?

### ***ALL GROUPS:***

What do you think of voluntary counselling and testing for people who are diagnosed with TB?

- Do you think this testing should be done for people who have TB?
- When do you think is most appropriate to do this testing, (why?)
- Who should do the VCT?

- What do you think is the best way of getting patients to agree to VCT?

Have you done HIV counselling for patients diagnosed with TB?

- if response yes, how was it?

How did the patients respond to this?

Do you find that many patients want to have VCT?

Why do you think this is?

***FOR INTERVENTION GROUPS ONLY:***

Do you have any general comments about the opt out study and your involvement in it?

How did your new responsibilities in the study fit in with your other duties?

- How was your workload?
- Was everyone in the clinic supportive?

What was it like to implement the opt out study?

- What was easy about it?
- What was not easy about it?
- Did you feel the training prepared you well?

Is there anything else you would like to raise about VCT or the opt out study?

Thank you very much for your time.

**Appendix D: Clinic level data on study outcomes**

**Intervention Clinics – n = 10**

Clinic ID	# TB cases	# (%) pre-test counseled	# (%) HIV tested	(%) counseled that tested	# (%) HIV POS	# (%) Cotrimoxazole		# (%) ARV Referral
C01	29	6 (20.7)	5 (16.7)	(83)	2 (40)	2 (100)	Both < 1 month	1 (50)
C03	27	4 (14.8)	4 (14.8)	(100)	0	-		-
C05	52	6 (11.5)	6 (11.5)	(100)	1 (17)	0	> 1 month	1 (100)
C06	20	6 (30)	6 (30)	(100)	6 (100)	1 (20)	Only 1 of 6 had < 1 month	0
C07	28	1 (3.5)	1 (3.5)	(100)	0	-		-
C09	50	7 (14)	7 (14)	(100)	6 (86)	0	Only 1 of 6 had < 1 month	2 (33)
C10	18	12 (66.7)	12 (66.7)	(100)	2 (15)	0	1 < 1 month	2 (100)
C15	41	8 (19.5)	7 (17)	(87.5)	1 (14)	1 (100)	< 1 month	0
C17	50	18 (36)	18 (36)	(100)	10 (56)	2 (20)	3 of 10 had < 1 month	1 (10)
C18	37	5 (13.5)	5 (13.5)	(100)	2 (40)	0	Both had > 1 month	0
<b>10</b>	<b>352</b>	<b>73 (23%)</b>	<b>71 (22.4%)</b>	<b>(97%)</b>	<b>31 (36.9%)</b>	<b>6 (29.6%)</b>	<b>22/31 should be on drug</b>	<b>7 (36.7%)</b>

**Control Clinics – n = 10**

Clinic ID	# TB cases	# (%) pre-test counseled	# (%) HIV tested	(%) counseled that tested	# (%) HIV POS	# (%) Cotrimoxazole		# (%) ARV Referral
C02	41	5 (12.2)	3 (7.32)	(60)	2 (67)	2(100)	Both > 1 month	0
C04	19	3 (15.8)	3 (15.8)	(100)	0	-		-
C08	25	2 (8)	2 (8)	(100)	2 (100)	2(100)	Both > 1 month	1 (50)
C11	71	5 (7)	4 (5.6)	(80)	2 (50)	0	Both > 1 month	0
C12	32	1 (3.1)	1 (3.1)	(100)	0	-		-
C13	26	4 (15.4)	4 (15.4)	(100)	3 (60)	0	All 3 > 1 month	1 (33)
C14	64	2 (3.1)	1 (1.6)	(50)	1 (100)	0	> 1 month	0
C16	38	2 (5.3)	2 (5.3)	(100)	0	-		-
C19	45	1 (2.2)	0	0	-	-		-
C20	41	6 (14.6)	6 (14.6)	(100)	1 (17)	0	< 1 month	0
<b>10</b>	<b>402</b>	<b>31 (8.7 %)</b>	<b>26 (7.7%)</b>	<b>(79%)</b>	<b>11 (42.6%)</b>	<b>4 (33.3%)</b>	<b>10 of 11 should be on drug</b>	<b>2 (16.7%)</b>