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Evaluation of a Nurse-Led Antiretroviral Treatment Program in a Rural South African Primary Health Care Clinic

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Abstract

South Africa claims one of the world's largest burdens of HIV/AIDS infections. Shortages in human resources and infrastructure have resulted in delayed scale-up of HIV treatment programs. To address issues of physician shortages nurses in South Africa have been tasked with providing HIV treatment services in primary health care clinics. National implementation of nurse-initiated and -managed antiretroviral therapy began in 2010, with ongoing scale-up in the number of facilities providing this service.

This capstone project describes a nurse-led antiretroviral therapy program in a rural primary health care clinic in Limpopo Province, South Africa. Data from staff interviews, clinic observations, medical chart reviews, and a focus group, describe the clinic's model for delivery of antiretroviral therapy services and evaluate program performance from January 2011 until April 2013. Major program challenges include clinic infrastructure, community stigmatization of HIV, integration of HIV and non-HIV services, and increased professional nurse workloads.

A total of 92 adults and adolescents new to the clinic's program were started on treatment between January 1, 2011, and April 25, 2013. Overall mortality in patients starting treatment was 6.5% (6/92). Only 38 patients were enrolled in the ART program more than 12 months before chart reviews. At 12 months 68.4% (26/38) of these patients remained in care. CD4 positive T-lymphocyte counts and HIV viral load results were available for 57.7% and 69.2% of these patients, respectively. HIV viral load suppression (defined as an HIV viral load <400 copies/ml) was observed for 89.5% of those on treatment at 12 months. A statistically significant increase in mean CD4 positive T-lymphocyte count was observed at 12 months (147.6 cells/mm^3 vs. 438.1 cells/mm^3; p= .000008). Prescription of antibiotic prophylaxis within 2 months of starting antiretroviral therapy was 43.9% (26/82) in those with WHO stages 2-4 HIV disease.

This capstone project demonstrates that nurses can successfully manage HIV infection in the primary health care setting. Patients enrolled in nurse-led ART can achieve substantial improvements in immune function over a relatively short period. Greater attention should be directed at preventing opportunistic infections in HIV-infected patients managed in primary health care settings.

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Chapter 1

Introduction

An estimated 17.3% of South African adults ages 15 to 49 were living with human immunodeficiency virus (HIV) in 2011, representing the fourth largest HIV prevalence worldwide (Joint United Nations Programme on HIV/AIDS, 2012). Although the national prevalence has stabilized in recent years, the total number of HIV-infected people needing treatment is expected to grow (Republic of South Africa, 2012). This trend is largely explained by reductions in HIV mortality associated with antiretroviral therapy (ART). Through 2009 an estimated 3.7 million adult life years were gained in sub-Saharan Africa alone through the provision of ART (Mahy, Stover, Stanecki, Stoneburner, & Tassie, 2010). Lifelong ART, requiring daily dosing of three or more antiviral agents, remains the backbone of HIV/AIDS treatment.

Despite their disproportionate burden of HIV infections, South Africa has lagged behind higher income countries in ensuring access to ART. The country began providing public sector ART in 2003 nearly a decade after triple combination therapies became available in Europe and North America. Multiple factors contribute to ART availability in South Africa, with physician shortages recognized as a critical bottleneck in the scale-up of public sector HIV treatment programs (Bärnighausen, Bloom, & Humair, 2007; Kober & VanDamme, 2004). The World Health Organization (WHO) has promoted the transition of HIV medical management from physicians to nurses as one approach to mitigating HIV service gaps arising from physician shortages (WHO, 2008a). Pilot studies on task shifting of ART services to nurses have reported

favorable results (Callaghan, Ford, & Schneider, 2010).

Addressing Gaps in HIV Treatment Services in South Africa

In 2007 the country committed to providing universal ART access, establishing a national target to expand treatment to 80% of its eligible population by 2011 (South Africa National Department of Health, 2006). Significant gains in access have been documented since that time. ART coverage in 2011 was estimated at 75.2% for eligible adults and children (Republic of South Africa, 2012). Over 1.8 million people had initiated treatment, making South Africa's the largest ART program in the world (Republic of South Africa, 2012). As access to treatment expanded, national targets in 2011 included a new challenge: keeping 70% of ART patients alive and on treatment at 5 years (South Africa National Department of Health, 2011). However, with 1.8 million patients accessing public sector services, there is no documentation of how many remained in care after 12 months on treatment.

Current South African HIV guidelines recommend a monthly health care visit for those receiving ART (Health Systems Trust, 2012). This represents a tremendous demand for HIV services in an already strained public health sector. Less than 41% of registered physicians work in the public sector where 85% of the country's population receives its medical care (Human Sciences Research Council Development Policy Research Unit, & Sociology of Work Unit, 2008). Until 2010, ART required a physician drug prescription. Today physician shortages remain a major public health threat, and have been well documented in the South African media ("Doctor shortage hits rural South Africa", 2012; "E Cape dealing with medical staff shortage", 2012; "Shortage of doctors is beyond critical", 2011).

To address gaps in HIV service delivery arising from shortages of physicians, National

HIV treatment guidelines now grant authority for professional nurses to prescribe and manage ART (South Africa National Department of Health, 2011). This policy change effectively moved HIV treatment into primary health care (PHC) settings. Although physicians may practice within PHC facilities, in South Africa nurses dominate the PHC workforce. Over 10,000 primary care nurses have been trained to prescribe ART (Republic of South Africa, 2012).

Attention to the burden of ART programs on PHC facilities is critical. With the addition of ART programs to PHC, some are concerned that additional demands on nursing staff will result in decreases in overall PHC quality (van Rensburg, Steyn, Schneider, & Loffstadt, 2008). Existing shortages of public sector nurses may also constrain the expansion of HIV treatment programs in PHC settings (Janse van Rensburg-Bonthuyzen et al., 2008). Whether PHC facilities can meet community demand for treatment while maintaining high quality ART services will have sizable implications for South Africa's scale-up of nurse-led treatment models. In the context of a high HIV prevalence and a rapidly changing climate for HIV treatment, the purpose of this capstone project is twofold: to describe how nurse-led ART services have been implemented in a rural PHC in Limpopo Province, and to provide a systematic evaluation of the clinic's adult and adolescent ART program.

Health Care Quality: Definitions and Conceptual Model

Defining Health Care Quality

In South Africa, the *National Strategic Plan for HIV and AIDS, STIs, and TB* retains a strong focus on improving population-level ART access. However, in 2011 the plan expanded, including objectives for quality improvement in HIV services. New program standards were developed to ensure "… that people living with HIV and TB remain within the health care system, are adherent to treatment, and maintain optimal health" (South Africa National Department of Health, 2011, p. 15). Updated objectives highlight a growing national interest in quality of HIV care that extends beyond the domain of health care accessibility, a common priority for low- and middle-income countries (Peabody et al., 2007).

Multiple definitions of health care quality exist. Most definitions of quality include two distinct dimensions: technical care and the interpersonal patient-provider relationship (Donabedian, 1980). The quality of technical care has been defined as the "application of medical science and technology in a manner that maximizes its benefits to health without correspondingly increasing its risks" (Donabedian, 1980, p. 5). Technical aspects of care are prominent in the Institute of Medicine's (2001) widely cited definition of quality: "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (p. 244). The Institute of Medicine argues that health care should be safe, effective, patient centered, timely, efficient, and equitable.

Although the Institute of Medicine's (2001) quality aims include attention to patient preferences, its basic definition of quality lacks attention to the interpersonal dimension, the

patient-provider relationship. The interpersonal relationship is the vehicle by which technical care is delivered and must align with social norms and expectations to be successful (Donabedian, 1980). Establishing whether nurse-led ART services align with social norms is important, as preferences for health care in Limpopo are not assumed to be consistent with those in the United States. To this end, the following definition has been adopted for this capstone project: Quality is the degree to which ART-related services increase desired health outcomes in the clinic's population infected with HIV/AIDS, are consistent with current professional knowledge, and align with locally accepted norms and values for health care.

Conceptual Model

The Structure, Process, Outcome Model (SPOM) is a useful framework for evaluating health care quality (Donabedian, 1980). According to Donabedian (1980) the most proximal measure of health care quality is measurement of care processes. Good health care quality requires consistent performance of processes that produce desirable patient outcomes and meet client expectations. His work also develops two indirect approaches to evaluating health care services: assessments of structure and outcome. Structure is defined as "the relatively stable characteristics of the providers of care, of the tools, and resources they have at their disposal, and the physical and organizational settings in which they work" (Donabedian, 1980, p. 81). Outcomes are defined as "a change in a patient's current and future health status that can be attributed to antecedent health care" (Donabedian, 1980, p.82-83). A major concept underlying the model is that a relationship exists among these three constructs, such that structure influences the quality of care processes, and that certain patient outcomes can be attributed directly to provider's care processes.

In this capstone project, the three constructs of the SPOM provided a framework for examining the literature on nurse-led ART in PHC settings, informing the research methods, and organizing the presentation of results and discussion. ART program structures were conceptualized as characteristics of the individuals providing ART services, the tools and resources they have at their disposal, and the physical and organizational settings in which ART services are provided. ART processes were conceptualized as all technical and interpersonal aspects of ART care. Outcomes were conceptualized as measures of ART program effectiveness such as retention in care and improvements in health status.

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Chapter 2

Literature Review

The literature was reviewed to determine the quality of PHC-based nurse-led ART programs in sub-Saharan Africa. For the purposes of this capstone, nurse-led ART programs were defined as health care programs in which nurses were accountable for the medical management of HIV-infected individuals receiving ART. PHC settings were defined as any community-based facility providing integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs (Institute of Medicine, 1996).

Inclusion criteria were: English language research articles including research trials, observational studies, case studies, or program evaluations published in peer reviewed journals between January 1, 2002, and December 31, 2012. Studies describing program structures supporting ART programs, processes of ART care, and/or outcomes related to ART services in PHC settings were included. Studies limited to infant and pediatric populations were excluded, as were studies describing ART service delivery by lay or community health workers as these fell outside the scope of this review. Commentaries and editorials were also excluded.

CINAHL, Ovid-Medline, and Web of Science databases were searched for studies reporting on nurse-led ART in PHC settings. Searches were conducted using the following topical areas: nurse-led care (keywords: “nurse*”), primary health care (keywords: “primary care” or “primary health care”), HIV treatment (keywords: “antiretroviral therapy” or “ART”), and location (keyword: “Africa”. The combination of searches yielded 51 unique articles. Titles and abstracts were reviewed. Four additional articles were found through manual review of references in titles resulted from the above database searches. A total of 37 articles underwent

full-length review. Studies included in the final review were restricted to those reporting on ART-related service delivery by nurses in PHC settings. A total of 16 articles met all inclusion criteria and are reported in Table 1. No article reported on all three constructs of the SPOM.

Models of Nurse-Led ART Programs

Two distinct nurse-led treatment models emerged from the literature. The first, identified as "down referral", describes programs where physicians initiated patients on ART and provided follow-up until patients were deemed appropriate for monitoring in PHC. Patients on ART were referred to PHC facilities for nurse-led treatment and adherence monitoring, dispensing of ART, and support. Periodic physician visits allowed for review of patients' clinical status and ART prescriptions. Down referral ART programs were described in 12 articles (Brennan et al., 2011; Decroo et al., 2009; Humphreys et al., 2010; Janse van Rensburg et al., 2008; Long et al., 2011; O'Connor, Osih, & Jaffer, 2011; Sanne et al., 2010; Searle, Ramkissoon, & Govender, 2010; Stein, Lewin, & Fairall, 2007; van Rensburg et al., 2008; Wouters et al., 2008; Zwarenstein et al., 2011).

In the second model, nurses initiated eligible patients on ART and provided all routine HIV management including treatment and adherence monitoring, dispensing of ART, and changes to treatment regimens as permitted in HIV treatment guidelines. Complex medical cases were referred to physicians. In comparison to down referral programs, nurse initiated and managed ART (NIMART) represents autonomous diagnosis and treatment of uncomplicated HIV infected individuals by nurses. Three studies described NIMART programs (Bedelu, Ford, Hilderbrand, & Reuter, 2007; Cohen et al., 2009; Shumbusho et al., 2009). A fourth study compared outcomes of patients in down referral ART programs and NIMART programs (Fairall et al., 2012).

PHC based ART programs evolved in response to human resource shortages and community demand for HIV treatment. Although down referral and NIMART are described here as unique models of care, there is significant overlap in the ART services provided. Down referral models task shifted ART monitoring to nurses and were implemented in the public sector prior to the NIMART model. NIMART differs in its provision of prescriptive authority to nurses. Existing literature indicates that both models required significant infrastructure, staffing, resources, management, and provider support to ensure quality HIV care. Studies describing ART program structures are summarized below.

Structures of Nurse-Led ART Programs

In accordance with the SPOM, ART program structures were identified as PHC infrastructure, organizational characteristics, staff characteristics, resources, and program tools. Three descriptive case studies reported difficulties related to structure in down referral programs (Decroo et al., 2009; Janse van Rensburg et al., 2008; van Rensburg et al., 2008). A fourth down referral study measured correlations between nursing shortages and patient satisfaction as a secondary study aim (Wouters et al., 2008). Last, one qualitative study describing nurses' experience with early down referral implementation in Free State, South Africa, included key findings related to management and drug supplies (Stein, Lewin, & Fairall, 2007). Descriptions of structures impacting NIMART programs were included in two case studies (Bedelu, 2007; Cohen et al., 2009). Important structures reported in the literature included PHC infrastructure, program organization and management characteristics, human resources, and medications. Each is discussed below.

PHC infrastructure was identified as a significant challenge to down referral implementation. Specifically the number of consultation rooms available for ART services was

insufficient to accommodate the number of patients presenting for treatment (Decroo et al., 2009; Janse van Rensburg et al., 2008). Clinic space, however, was not directly identified as a challenge to NIMART program implementation. Cohen et al. (2009) found investments in infrastructure including furniture, storage cabinets, and communications equipment improved clinic flows.

Integration of ART with other PHC services was an important organizational characteristic of nurse-led HIV treatment programs. Down referral programs were described as vertically integrated, requiring referral up and down levels of care for HIV and ART services. In PHC facilities where ART services were provided by nursing specialists, separate queues and/or consultation rooms were needed to provide both general PHC and ART services within the same clinic space (Decroo et al., 2009; Janse van Rensburg et al., 2008; Stein, Lewin, & Fairall, 2007; Wouters et al., 2008).

There appears to be a trend towards greater integration of HIV services with other PHC in NIMART programs. For example, Cohen et al. (2009) described Basotho PHC facilities where nurses were responsible for providing all primary health services, including ART initiation and monitoring. This program was more consistent with a "one-stop shop" approach to ART services integration, in which ART services were accessible as part of the overall PHC package (WHO, 2008b, p.3).

Another important organizational characteristic of early nurse-led ART programs was ineffective program management by public health administrators. In three studies, poorly planned down referral implementation at the local and district resulted in rapid increases in PHC volumes (Decroo et al., 2009; Janse van Rensburg et al., 2008; Stein, Lewin, & Fairall, 2007). Demand for ART services overwhelmed clinic staff and resources in rural programs when

policies and planning initiatives failed to include nurses' experience with ART delivery and their daily support needs (Stein, Lewin, & Fairall, 2007).

Both down referral and NIMART programs were adopted in the context of human resource shortages. Implementation of down referral programs occurred against the backdrop of high rates of nursing vacancies (van Rensburg et al., 2008). Professional nurse shortages contributed to long clinic wait times and overall patient dissatisfaction with public sector HIV care (Wouters et al., 2008). Following PHC availability of NIMART, the utilization of clinic services doubled in one study, dramatically increasing nurse workloads (Bedelu et al. 2007). Fortunately, in South Africa, increases in the number of filled professional nurse positions have been reported in multiple districts following the transition to nurse-led management of HIV (Janse van Rensburg et al., 2008; Wouters et al., 2008).

In vertically integrated programs, filling of new ART positions depleted staffing in other PHC programs. In van Rensburg et al.'s study (2008), only 20.6% of professional nurses recruited for ART programs were new entrants into public health nursing. The majority of nurse ART specialists, 43.2%, transferred from other PHC facilities in the same district. Increased hiring of administrative staff, data capturer positions, and community health workers helped offset nursing burden associated with ART programs in both down referral and NIMART models (Bedelu et al, 2007; Cohen et al., 2009; Janse van Rensburg et al., 2008; van Rensburg et al., 2008). However, net decreases in the number of filled generalist PHC nursing positions threatened access to non-ART services.

A shortage of medications was the most commonly cited resource shortage hindering down referral facilities' efforts to improve community access to HIV treatment (Cohen et al., 2009; Decroo et al., 2009; Stein, Lewin, & Fairall, 2007; Janse van Rensburg et al., 2008). In

South Africa limited medication supplies resulted in restrictions on the number of patients receiving ART at designated PHC facilities (Stein, Lewin, & Fairall, 2007). For those on treatment, medication shortages resulted in stable patients being transferred to hospitals or other PHC facilities to avoid breaks in treatment (Decroo et al., 2009; Janse van Rensburg et al., 2008). However, improved ART drug supplies have been reported over time in South Africa. In one study, the number of ART medications available in Free State Province doubled in two years following ART program implementation (Janse van Rensburg et al., 2008). In contrast to down referral studies, only one NIMART study acknowledged drug supply issues as key program challenge (Cohen et al., 2009). The authors recognized both antiretroviral medications and other HIV-related medications as important resources for PHC programs.

Discussion. Existing literature demonstrates ART program structures contribute to PHC facilities' provision of high quality HIV services. Three major themes emerged regarding PHC structures. First, approaches to ART program integration have implications for the clinic size and human resources needed to sustain both ART-related and other PHC services. Vertically integrated ART programs separate HIV services from other PHC, requiring additional space, clinic staff, and resources. They may also introduce inefficiencies in clinic flow, due to the need for multiple PHC encounters to manage other medical conditions.

Second, nursing shortages remain a challenge for the national PHC system in South Africa. Nurse staffing was consistently viewed as a challenge in down referral and NIMART programs. Expanding nurses' responsibilities for provision of ART services increases overall nurse workloads. Shifting appropriate nursing tasks to lay workers can diffuse the burden of new ART programs; however, attracting and retaining new nurses will be necessary to scale-up NIMART programs in South Africa.

Last, medications are critical resources for ART service delivery. Historically, while shortages in antiretroviral medications hindered implementation of down referral programs, ensuring availability of all essential HIV-related medications will be critical for the success of NIMART programs**.**

Processes of Nurse-Led ART Programs

In accordance with the SPOM, processes included all acts of ART-related care. In South Africa, major criteria for determining ART eligibility includes WHO clinical staging (an assessment of HIV disease progression), results of CD4 positive T-lymphocyte count (CD4 count) testing, and medical co-morbidities such as tuberculosis infection, renal disease, liver disease, and anemia (Republic of South Africa, 2013). Four studies reported on one or more ART-related processes (Fairall et al., 2012; Shumbusho et al., 2009; Searle et al., 2010; Zwarenstein et al., 2011). Study designs used to measure ART processes included descriptive cohort analyses (Searle et al., 2010; Shumbusho et al., 2009) and interventional designs (Fairall et al., 2012; Zwarenstein et al., 2011). Both down referral and NIMART models were represented. The following pre-treatment processes were included in the literature and were derived from HIV treatment guidelines: WHO clinical staging, collection of baseline CD4 counts, tuberculosis screening, prescription of trimethoprim-sulfamethoxazole (TMP-SMX) prophylaxis, decision to initiate ART, and ART medication selection. Each is discussed below.

WHO clinical staging. WHO clinical staging allows for assessment of HIV disease progression without the use of blood testing, relying instead on patients' history and physical examination findings. It is used to guide HIV treatment decisions in resource-limited areas with limited access to clinical laboratory services (WHO, 2010). One study measured nurse compliance with WHO criteria for clinical staging (Shumbusho et al., 2009). Medical chart

review was used to assess nurse compliance with pre-ART screening performed in three Rwandan PHC facilities adopting a NIMART model for ART service delivery. Compliance with WHO clinical staging at ART program intake was 100% (n=435).

Collection of baseline CD4 counts. CD4 positive T-lymphocytes are a subset of white blood cells depleted by uncontrolled HIV infection and an important marker of HIV disease progression (Moir, Chun, & Fauci 2011). Similar to WHO clinical staging, CD4 counts are used to guide initiation of ART and opportunistic infection prevention therapies (National Department of Health, 2010). Two studies reported nurse compliance with CD4 count collection prior to initiation of ART. Study designs included a randomized trial (Fairall et al., 2012) and a retrospective cohort analysis (Shumbusho et al., 2009). In both studies, documentation of baseline CD4 counts at NIMART facilities occurred in greater than 90% of cases. In Fairall et al. (2012) baseline CD4 counts were collected in 93.5% of patients in NIMART programs versus 86.1% of patients receiving pre-ART care in down referral programs. In the second study, 99.8% of patients on ART had CD4 counts documented at the time of NIMART program enrollment (Shumbusho et al., 2009).

Tuberculosis screening and detection. Those with active tuberculosis and HIV infections have specialized treatment guidelines for concurrent management of their infections. As a result, tuberculosis screening must be included as part of ART care (WHO, 2010). Only one study reported compliance with tuberculosis screenings in patients eligible for ART. In Shumbusho et al. (2009) nurses documented tuberculosis screening for 97.9% of patients on ART program enrollment in three Rwandan NIMART sites.

Two additional studies measured whether patients were more likely to be diagnosed with tuberculosis based on ART program model (Fairall et al., 2012; Zwarenstein et al., 2011).

Comparisons of tuberculosis detection in geographic locations with similar tuberculosis rates provided an indirect measure of screening accuracy. In Fairall et al. (2012) the proportion of patients diagnosed with tuberculosis prior to ART was greater in NIMART programs as compared to down referral programs (20% vs. 13%; p= .001; Fairall et al., 2012). Tuberculosis detection was similar for patients already on ART at the start of the study, regardless of ART program model (4% in both).

In Zwarenstein et al.'s (2011) study, the proportion of patients with tuberculosis diagnoses were compared at down referral facilities based on the approach used for concurrent care of HIV, tuberculosis, and common co-infections. In one group ART and non-ART nurses were trained to use an integrated syndrome-based guideline for the diagnosis, treatment, and management of complications for HIV/AIDS, tuberculosis, and other conditions. In the second group ART nurses received the standard training required to provide down referral services. An increased likelihood of tuberculosis detection was reported at down referral programs using the syndrome-based guideline as compared to controls (7% vs. 6%; p= .038; Zwarenstein et al., 2011).

Prescription of TMP-SMX prophylaxis. TMP-SMX is an antibiotic that is effective in preventing *Pneumocystis jiroveci* pneumonia, toxoplasmosis, and other opportunistic infections associated with increased mortality in those with AIDS (WHO, 2010). In South Africa, TMP-SMX preventive therapy is recommended for all HIV-infected individuals with WHO stage 2-4 HIV disease or for those with CD4 counts less than 200 cells/mm^3 (Republic of South Africa, 2008). Two randomized trials evaluated compliance with TMP-SMX prescription in eligible South African patients. In Fairall et al. (2012) the proportion of patients receiving TMP-SMX prophylaxis was similar in NIMART and down referral programs. This finding was consistent in

two patient cohorts: those already on ART at study start (71% in NIMART programs vs. 81% in down referral programs; p= .424) and those who were not (72% in NIMART programs vs. 72% in down referral programs; p= .608). In the second study, Zwarenstein et al. (2011) reported an increased likelihood of TMP-SMX prophylaxis in PHC facilities using a syndrome-based guideline for management of HIV, tuberculosis, and other common co-infections as compared to PHC facilities who did not use the guideline (73% vs. 65%; *RR* =1.95).

Appropriate ART initiation. South African HIV treatment guidelines restrict provision of ART to patients meeting specific clinical criteria. One study evaluated nurses' decisions to start patients on ART in NIMART programs (Shumbusho et al., 2009). Medical chart reviews were conducted to evaluate nurse compliance with ART eligibility at three Rwandan PHC facilities (Shumbusho et al., 2009). Nurses prescribed antiretroviral medications to 96% of the 451 patients meeting treatment criteria. No ineligible patients were treated. The authors concluded that nurses were compliant with national treatment guidelines in their decisions to treat HIV.

ART medication selection. To avoid adverse effects, clinicians must select ART regimens based on the presence of conditions such as pregnancy, renal disease, hepatic disease, anemia, and tuberculosis (Republic of South Africa, 2013). Clinician choice of ART regimen was evaluated in two studies (Searle et al., 2010; Shumbusho et al., 2009). Both studies were non-comparison retrospective program evaluations, and included both down referral and NIMART programs. High rates of appropriate ART selection were reported in each. Of 2071 South African patients in down referral care, 94% were reported to be on first line ART regimens as recommended by South African HIV treatment guidelines in Searle et al. (2010). However, as this was a down referral program, patients received initial ART prescription from a physician.

The second study evaluated the appropriateness of initial ART prescription in a cohort of patients receiving NIMART services (Shumbusho et al., 2009). In the 435 patients started on ART, all but one patient's regimen was found to be consistent with Rwandan HIV treatment guidelines (Shumbusho et al., 2009).

Discussion. Process measures for evaluating PHC-based ART programs are largely derived from HIV treatment guidelines. Findings of this literature review suggest that nurses routinely perform pre-ART screenings and laboratory testing in accordance with HIV treatment guidelines. Differences in nurse performance were reported across studies, with known differences in ART models. For example, in the only randomized trial directly comparing ART-related processes in NIMART and down referral programs, NIMART nurses outperformed down referral nurses on all measures except TMP-SMX prophylaxis (Fairall et al., 2012). Variations in nursing performance may also reflect differences in program resources. Zwarenstein et al. (2011) demonstrated greater nursing compliance with pre-ART care at down referral facilities using syndrome-based treatment guidelines. However, it is unclear why worse compliance was observed for TMP-SMX prophylaxis in Fairall et al. (2012) and Zwarenstein et al. (2011) when compared to other reported process measures. This variation between measures suggests compliance in one area of care may not predict performance across the full range of ART services.

Outcomes of Nurse-Led ART Programs

To date, the most common approach to assessing quality of nurse-led ART has been evaluation of patient outcomes using medical chart review and secondary data sources. A total of 11 studies evaluated outcomes in patients receiving ART from nurses in PHC facilities. Study populations were largely South African. In total, three South African studies compared outcomes

in patients in down referral programs to outcomes in patients receiving ART monitoring from physicians (Brennan et al., 2010; Long et al., 2010; Sanne et al., 2010). Three additional South African studies reported patient outcomes following entry into nurse-led ART programs at either down referral facilities (O'Connor, Osih, and Jaffer, 2011; Searle et al., 2010) or NIMART facilities (Bedelu et al., 2007). Zwarenstein et al. (2011) compared patient outcomes based on the type of clinical guideline used in South African down referral programs. Finally, Fairall et al. (2012) compared patient outcomes in South African down referral programs to patient outcomes in South African NIMART programs. Among the three studies conducted outside South Africa, two documented patient outcomes following the start of ART in NIMART programs in Lesotho (Cohen et al., 2009) and Rwanda (Shumbusho et al., 2009). The third compared outcomes of ART patients based on the type of facility, comparing down referral PHCs to hospitals in Swaziland (Humphreys et al., 2010).

The characteristics of studies evaluating patient outcomes in nurse-led ART programs are summarized in Table 2. Patients in these studies had similar ages and gender distributions, favoring inclusion of women between the ages of 30 and 40 years. Although eligibility for nurse-led ART varied by study, the baseline characteristics of patients in down referral PHC suggest a trend towards use of down referral programs for monitoring stable patients (i.e., patients with already well-controlled HIV and improving immune status). Patients in NIMART programs had lower CD4 counts on ART program entry, reflecting poorer immune status in this group.

Across models of ART care, commonly reported outcomes included program retention, mortality, loss to follow-up (i.e. failure of patients to attend consecutive ART follow-up appointments), immune reconstitution, HIV viral load suppression, and changes in weight (Table 3). Important findings for each outcome measure are summarized below.

Mortality. Mortality ranged from 0% to 22% in 10 studies reporting outcomes on nurse-led ART (Bedelu et al., 2007; Brennan et al., 2011; Cohen et al., 2009; Fairall et al., 2012; Humphreys et al. 2010; Long et al., 2010; O'Connor et al., 2011; Sanne et al., 2010; Shumbusho et al., 2009; Zwarenstein et al., 2011). In PHC facilities, patients receiving nurse-led ART had a similar risk of death when compared to those receiving physician-led ART. In a direct comparison of nurse-led ART monitoring and physician-led ART monitoring, Sanne et al. (2010) reported no differences in patient mortality in PHC (3% in both). Similar rates of mortality were also reported between nurse- and physician-led ART when physician services were provided in a hospital setting (16.8% NIMART vs. 13.5% hospital care; $p = .147$; Bedelu et al., 2007).

It is unclear whether the type of ART facility independently predicts mortality. In Swaziland, mortality was lower for patients receiving care in PHC down referral programs as compared to hospital-based ART programs where nurses performed ART monitoring tasks (0% versus 2.5%; $p = .01$; Humphreys et al. 2010). However, in a modified intent-to-treat analysis this difference was not statistically significant after including individuals who refused PHC referral. Lower mortality from any cause was also reported in PHC down referral facilities compared to specialty ART facilities (0.3% vs. 1.5%; $p<0.05$; Brennan et al., 2011). Improved mortality in patients attending down-referral programs may be at least partially explained by differences in HIV disease characteristics in those transferred to PHC. For example, in Brennan et al. (2011), the odds of being transferred to a down referral PHC facility were greater for patients with less advanced disease. Mortality reported in the third observational study was identical to that reported in Long et al. (2010) as it was derived from data on the same patient cohorts (Long et al., 2010).

For patients already taking ART when transferred to a PHC facility, mortality did not differ based on the model of nurse-led ART. In Fairall et al.'s (2012) randomized trial time to death was similar regardless of whether patients received care in a NIMART or down referral facility (HR= 1.05; *p*= .684). Within down referral programs a syndrome-based approach to the management of HIV, tuberculosis, and other common co-infections also failed to decrease mortality when compared to standard down referral services (Zwarenstein et al., 2011).

Loss to follow-up. Loss to follow-up is defined as failure of the patient to attend consecutive ART follow-up appointments. A total of seven studies reported on loss to follow-up, with a maximum follow-up period of 2 years. Loss to follow-up was most commonly defined as failure to attend three or more monthly medical appointments. The shortest time period used to define loss to follow-up was 6 weeks without attending a medical visit (O'Connor et al., 2011). Across studies, loss to follow-up ranged from less than 1% to 13% (Bedelu et al., 2007; Brennan et al., 2011; Cohen et al., 2009; Long et al., 2011; Humphreys et al., 2010; O'Connor et al., 2011; Sanne et al., 2010; Searle et al., 2010; Shumbusho et al., 2009). No study of nurse-led ART programs reported greater loss to follow-up when compared to programs utilizing physician-led ART services. Data from observational studies suggest that loss to follow-up is similar in PHC down referral facilities and specialty ART facilities (Brennan et al., 2011; Long et al., 2011), as well as in PHC down referral facilities and hospitals (Humphreys et al., 2010). Within PHC facilities, loss to follow-up did not differ based on receipt of physician-led or nurse-led ART monitoring (Sanne et al., 2010).

In comparing NIMART and down referral models, Fairall et al. (2012) demonstrated that individuals already taking ART at entry into nurse-led care have similar rates of program retention. In this study 90% of patients in NIMART programs remained in care versus 91% in

down referral programs (p= .758). For those not taking ART at the start of the study, NIMART enrollment resulted in greater treatment retention when compared to down referral enrollment (63% vs. 58%; p< .001). Lower patient retention in down referral programs was attributed to the increased potential for patient loss during physician referral for ART prescription. It is also important to note that the low rates of program retention in the pre-ART cohort reflect both loss to follow-up and loss due to mortality.

HIV viral load suppression. When effective, ART suppresses the amount of HIV in the blood to low or undetectable levels. HIV viral load suppression is a validated measure of treatment success and was included as an independent outcome measure in five studies (Brennan et al., 2010; Fairall et al., 2012; Sanne et al., 2010; Searle et al., 2010; Zwarenstein et al., 2011). Definitions of HIV viral load suppression vary. For example, currently the U.S. Department of Health and Human Services (2013) defines HIV viral load suppression as an HIV viral load of less than 200 copies/ml. According to the WHO (2008), an HIV viral load less than 400 copies/ml may be taken as evidence of viral suppression in low- and middle-income countries (Bennett, Bertagnolio, Sutherland, & Gilks, 2008). Three randomized trials evaluated HIV viral loads in patients receiving PHC-based ART services in South Africa. Comparisons included nurse-led ART and physician-led ART at PHC facilities (Sanne et al., 2010), down referral programs with differing guidelines for HIV management (Zwarenstein et al., 2011), and down referral programs and NIMART programs in PHC facilities (Fairall et al., 2012). In randomized trials, patients receiving down referral services had similar rates of HIV viral suppression when compared to patients receiving services from facilities using other ART models.

Rates of HIV viral load suppression reported in non-experimental designs also demonstrate effectiveness of nurse-led ART in controlling HIV infection. In Brennan et al.'s

(2011) observational study, 96.7% of down referral patients had HIV viral loads less than 400 copies/ml at 12 months. HIV viral load suppression was reported for 93% of patients on treatment for 12 months in Searle et al.'s (2010) descriptive study. In the short-term, down referral is associated with rates of viral load suppression comparable to other ART models in South Africa. Direct comparisons of rates of HIV viral load suppression in South Africa and higher-income countries is limited by differences in outcomes definitions. For example, the U.S. Centers for Disease Control (2011) estimated that 77% of Americans taking ART achieved an HIV viral load less then 200 copies/ml. Rates of HIV viral load suppression in this review ranged from 70% in Fairall et al. (2012) to 97% in Brennan et al. (2011), but reflected an HIV viral load less than 400 copies/ml.

Immunologic reconstitution. Increases in CD4 counts following initiation of ART provide evidence of immunologic reconstitution in response to treatment. Four studies reported data on CD4 count changes, including two randomized trials (Fairall et al., 2012; Sanne et al., 2010) and two observational cohort studies (Brennan et al., 2011; Humphreys et al., 2011). Across studies, improvements to immunologic function were reported in those receiving HIV treatment regardless of clinician type or ART program type. In Sanne et al. (2010) no statistically significant differences in CD4 counts were observed for patients in PHC facilities who received nurse-led ART monitoring or physician-led ART monitoring. When comparing down referral services to ART specialty services, similar median CD4 increases were also reported in Brennan et al. (2011) and Humphreys et al. (2010). Interestingly, although no differences were noted when comparing nursing and physician services, Fairall et al. (2012) observed differences in mean CD4 counts at follow-up when comparing NIMART programs and down referral programs. Greater improvements in CD4 counts were demonstrated for two cohorts of patients:

those not taking ART at the start of the study (161.3 cells/mm^3 vs. 141.7 cells/$mm^{3;}$ p= .021) and those taking ART at the start of the study (438.8 cells/mm^3 vs. 418.4 cells/mm^3 ; p= .007).

Weight gain. South African HIV treatment guidelines include weight gain following ART initiation as a marker of clinical improvement (National Department of Health, 2010). Changes in weight were reported in two randomized trials (Fairall et al, 2012; Zwarenstein et al., 2011) and one cohort study (Humphreys et al., 2010); they were calculated from baseline weight and weight at last clinical follow-up. Fairall et al. (2012) observed greater weight gain in NIMART patients already taking ART at the start of the study when compared to down referral patients already taking ART at the start of the study. This difference was not observed for individuals who were not taking ART at the start of the study. Greater weight gain was also reported for patients receiving care at down referral facilities who used a syndrome-based guideline to manage HIV, tuberculosis, and other common co-infections versus down referral facilities who did not use the guideline (Zwarenstein et al., 2011). When comparing down referral patients to patients in HIV specialty care, Humphreys et al. (2010) failed to detect differences in weight gain between treatment groups. Because of the mixed findings on this variable, additional research will be necessary to determine what ART program characteristics impact patient weight gain following ART initiation.

Discussion. Nurse-led ART programs are an effective approach to improving ART access, reducing HIV mortality and keeping clients in care. A greater volume of research is available on the evaluation of down referral programs compared to NIMART programs. Although the quality of down referral studies varies, the consistency of findings on major outcomes is notable. Down referral programs result in rates of ART retention and patient mortality that are comparable to physician-based care in PHC facilities (Sanne et al., 2010) and

to physician-based care in specialty HIV treatment facilities (Brennan et al., 2011; Humphreys et al., 2010; Long et al., 2011). Other measures used to assess program effectiveness (HIV viral load suppression, immune reconstitution, and weight gain) demonstrate clinical improvements are common in down referral patients (Brennan et al., 2011; Fairall et al., 2012; Humphreys et al., 2010; Sanne et al., 2010; Searle, Ramkissoon, & Govender, 2010; Zwarenstein et al., 2011).

When compared to down referral programs, the risk of patient mortality does not appear to increase in NIMART programs. Indeed, the highest mortality reported in this review was derived from comparisons of down referral programs (Zwarenstein et al., 2011). Variations in mortality across the studies captured in this review appear to reflect differences in disease status in the populations studied. For example, the percentage of patients with CD4 counts less than 50 cells/mm^3 (the most advanced HIV disease) was consistently higher in studies reporting patient mortality above 10 percent (Bedelu et al., 2007; Cohen et al., 2009; Fairall et al., 2012; Zwarenstein et al., 2011). This is not a new finding and substantiates a need for earlier treatment of HIV infection. Studies in southern Africa have demonstrated worse treatment outcomes among those initiating ART at CD4 counts less than 200 cells/mm^3 (Ford et al., 2010; Fox et al., 2010).

Whether NIMART programs outperform other nurse-led ART models is less clear. NIMART programs may be more effective in keeping patients new to ART on treatment, and there is early evidence that NIMART patients experience greater gains in weight and CD4 counts in the first years of treatment when compared to down referral patients (Fairall et al., 2012). Yet weight improvements were also seen among patients receiving care at down referral clinics who used syndrome-based guidelines for medical treatment (Zwarenstein et al., 2011). It is evident

that additional studies are needed to determine which ART program characteristics have the greatest impact on HIV outcomes, as program model alone may not predict better outcomes.

Given that the most rigorous evidence in favor of NIMART arises from a single randomized trial, it is important to note that some PHC facilities where unable to transition entirely to nurse-led ART services (Fairall et al., 2012). Only 26% of patients initiated on ART at NIMART sites received their initial ART prescription from a nurse. The remaining patients were initiated on ART by a support team consisting of physicians and nurses within the PHC facility; all patients received nurse-led follow-up. The authors attributed disruptions in NIMART adoption to medication shortages and budget shortfalls at the province level (Fairall et al., 2012). This is an important consideration for policy makers, as some districts may lack the resources to implement and sustain effective NIMART programs. For resource-poor areas that have access to physician services, down referral programs can be considered acceptable alternatives for the provision of PHC-based HIV care.

Gaps in Knowledge and Implications for Research

Gaps in the literature of nurse-led ART exist for all three quality domains of the SPOM. First, the extent to which structure variables such as human resources and program tools influence ART processes and outcomes warrants further study. While common resource challenges were identified in down referral programs, it is not known whether the same resource challenges pose problems in NIMART programs. Interestingly, Fairall et al. (2012) cited shortages in staffing and supplies as potential causes for incomplete transition to NIMART in their cohort of PHC facilities. Given the ongoing scale-up of NIMART programs in South Africa, determining which structures are essential to the model's success will help ensure nurse-led ART programs are adequately resourced.

The formal processes of ART care in sub-Saharan Africa are outlined in national HIV treatment guidelines. With training, nurses demonstrated strong compliance with national HIV treatment guidelines in both down referral and NIMART programs (Fairall et al., 2012; Searle et al., 2010; Shumbusho et al., 2009; Zwarenstein et al., 2011). However, adherence to national HIV guidelines varied between process measures. In this literature review nurses prescribed TMP-SMX less frequently than they performed other ART-related tasks. This may be attributable to program differences other than model of ART care. For example, Zwarenstein et al. (2011) demonstrated increased prescription of TMP-SMX when syndrome-based guidelines were used to better integrate treatment of HIV, tuberculosis, and other common medical problems. Syndrome-based management is one approach to improving ART service delivery and is adaptable to down referral and NIMART program models. As such, further testing of integrated disease management models is suggested. Nurse and patient barriers to TMP-SMX prescription should also be explored.

Finally, both down referral and NIMART models can be effective in reducing HIV-related morbidity and mortality. Additional evidence will be necessary to validate whether NIMART programs can be more effective than other ART models. One clear benefit of NIMART is improved accessibility of HIV services in remote areas. Regardless of HIV disease severity, most patients receiving pre-ART services will remain at the same NIMART clinic for ART initiation and follow-up. Although patients new to ART were more likely to remain in care in NIMART programs (Fairall et al., 2012), it is unclear which program characteristics led to improved visit attendance. This is an important area for future research. If NIMART program characteristics that influence patient visit attendance can be identified, other models of nurse-led

ART could be adapted to include similar characteristics thereby promoting greater patient engagement in care.

Conclusion

There is growing evidence to support nurse-led PHC-based ART programs as a source of quality HIV care. PHC nurses demonstrated good adherence to national HIV treatment guidelines, both in preparation of patients for ART and in ART medication selection. This finding was observed in both down referral and NIMART programs. Nurse-led ART appears to be at least as effective as physician-led ART in keeping HIV positive individuals alive and on treatment. Assessment of care quality is needed at the clinic level to capture variations in staff performance and patient outcomes.

Studies captured in this review provide a list of tested process and outcomes measures that can be used for baseline review of ART program effectiveness and ongoing monitoring. Selection of quality indicators should be dependent on individual clinics' patient populations and program resources. However, a considerable benefit to using established quality measures is the availability of benchmarks against which comparisons can be made between similar clinics. To date, no single study has measured clinic performance across all three SPOM domains. This capstone project presents an effort to evaluate nurse-led ART in a rural South African PHC facility using three quality domains: structure, process, and outcome.

Chapter 3

Methods

Study Purpose and Rationale

The purpose of this study was to describe the model of nurse-led ART at a rural PHC clinic in Mutale, Limpopo, as well as to evaluate the quality of adult ART services provided there. This case study adds to the literature by describing critical program structures, processes of care, and relevant HIV/AIDS-related outcomes in ART programs. The findings provide baseline data to allow the clinic to internally benchmark program performance. To protect the identity of the PHC clinic, as agreed to with the Vhembe District and Limpopo Provincial Departments of Health, the clinic will be identified throughout this capstone as "the clinic."

Research questions

The overall research questions are as follows:

- How are ART services integrated into primary health care at the clinic?
- What aspects of the clinic's ART model promote or limit health care quality?

Using the SPOM, health care quality will be assessed through evaluation of the program's structures, processes, and outcomes. Thus, the research will attempt to answer these questions:

1. What structural resources support nurse-led ART at the clinic?
2. What are the formal and informal processes of ART care at the clinic?
3. How do professional nurses describe the effectiveness of integrating ART services into PHC?
4. What are the clinic's HIV/AIDS-related patient outcomes?

Research Design

This research has been organized as a descriptive case study. There were five data sources: onsite clinic observations by the author in July and August 2012 and again in April 2013; semi-structured interviews with nurses, a lay counselor, and a data capturer; review of patient medical records; review of archived District Health Information System reports; and a semi-structured focus group with the clinic's nurses.

Setting

The setting for this capstone was one of 16 PHC clinics located in Mutale, a rural municipality of Vhembe District. The clinic provided primary health care services to 8597 residents in 14 Venda villages (L.M., personal communication, July 18, 2012). The clinic was selected for its status as a designated public sector ART site. As a public sector PHC facility, the clinic was required to operate in accordance with South Africa National Department of Health regulations and standards for primary health care clinics. Clinic supervision was administered through the Vhembe District Department of Health and Limpopo Province Department of Health.

Common illnesses and ailments in the community were determined through a review of data on chief presenting complaints during clinic visits in three periods: December 10-24, 2010; December 10-24, 2011; and December 10-24, 2012. Visits for acute medical problems were the most common reason people presented for care. In the 2012 sample of chief presenting complaints, acute ailments accounted for 44.8% (316/705) of all clinic visits. Abdominal pain, cough, diarrhea, headache, and fever were the most common physical complaints.

Visits for management of chronic diseases appear to be increasing. In 2010 19% (152/800) of PHC visits were related to a chronic disease. By 2012 visits for chronic disease had

increased to nearly 25% (174/705). HIV, hypertension, mental health disorders, asthma, and diabetes were the most common conditions associated with a chronic disease visit. Estimates for the overall HIV prevalence in Vhembe are not available, but it is evident that HIV is an important source of morbidity in the clinic's service area. In 2011 the antenatal HIV prevalence in Vhembe was 14.6% (National Department of Health, 2012).. In South Africa antenatal HIV prevalence is typically greater than in the general population. For example in 2011, the national antenatal prevalence was 29.5% compared to an estimated general HIV prevalence of 17.3% among those ages 15-49 (National Department of Health, 2012).

To address community needs, the clinic offers multiple services for adolescents and adults with HIV infection including HIV counseling and testing, pre-ART medical services and counseling, treatment for the prevention of mother-to-child transmission of HIV, enrollment in the national ART medication program, routine prescription of antiretroviral medications, and ongoing medical management of HIV-infected individuals on treatment in the clinic. NIMART was implemented at the clinic beginning January 2011.

Sample

Sampling techniques differed for the three major sources of data collection in this study: interviews, focus groups, and medical chart review. Interviews were conducted with clinic staff with ART-specific job responsibilities. On recommendation of the clinic's operational manager, individuals from the following categories were selected to participate:

- Professional nurses: Nurses who are "qualified and competent to independently practice comprehensive nursing… and capable of assuming responsibility and accountability for such practice" (South African Nursing Council [SANC], 2005,

p.25). Registration as a professional nurse requires completion of a 4-year program of nursing study. Advanced professional nurse training differentiates general nurses from PHC nurses and clinical nurse specialists.

- Enrolled nurses: Nurses who are "educated to practice basic nursing" (SANC, 2005, p.25). Registration as an enrolled nurse requires completion of a 2-year program of nursing study.
- Lay counselor: A member of the community who received non-governmental organization (NGO) training approved by the department of health to provide HIV counseling and testing services. Lay counselors have no formal professional or paraprofessional tertiary education.
- Data capturer: an individual trained by the department of health to collect, manage, and report PHC program data.

Focus groups were conducted with professional nurses who completed formal NIMART training and who were present in the clinic on the day of participant selection. Retrospective medical chart review was completed for each patient age 15 and older that was started on HIV treatment in the clinic between January 1, 2011, and April 25, 2013.

Measures

In accordance with the SPOM, measures in this capstone project are described below for each quality domain. Measures for structure, process, and outcome were selected from the research literature based on their common use in evaluations of nurse-led ART.

Clinic structures. Clinic observations and staff interviews were exploratory in nature identifying major structures impacting the ART program. The following PHC structures were described in the literature and thus selected as foci for observations and topics in interview guides: PHC infrastructure, human resources, medications and supplies, program tools, and program organization and management.

For the measure of PHC infrastructure, clinic size, design, and the condition of clinic buildings were documented. External medical facilities important to the clinic's ART program were also documented. Assessment of clinic infrastructure was limited to buildings in which ART-related services were provided.

For the measure of human resources, the number and type of clinic staff were documented. Additional data were obtained on staff education and training. Staffing patterns were reviewed to identify the actual number of ART providers present during clinic hours. Daily clinical roles and formal job descriptions of staff members providing NIMART services were assessed to document other non-ART job responsibilities.

For the measure of medications and supplies, medications and other supplies frequently used in the ART program were documented. Medications included types and availability of antiretroviral medications, medications for the prevention and treatment of opportunistic infections and common co-infections, and medications used for symptom management of HIV. Supplies included medical laboratory supplies, general medical supplies, and onsite medical

equipment. Assessment of supplies was limited to those items used for delivery of ART-related services.

For the measure of program tools, both decisional aids and documentation systems were assessed. For decisional aids, the number, type, and physical presence of treatment guidelines, clinical protocols, and other clinical decision aids were documented. Data collection was limited to decisional aids used for the treatment of HIV and HIV-related conditions. For documentation systems, the organization of and resources for ART-related medical data collection, management, and storage were documented.

Last, for the measure of program organization and management the organizational structure of the clinic was documented, including the hierarchy of external supervisory positions. Within the clinic, existing quality management programs and data reporting systems were also identified.

Process Measures. Both formal and informal processes of care were evaluated. No formal measures were used to evaluate informal processes of care; instead during site observations this author documented routine clinical practices that were either inconsistent with or not outlined in national guidelines for HIV treatment. To evaluate formal processes of NIMART, process measures specific to initiation of ART and subsequent medical follow-up were selected in accordance with South Africa national HIV treatment guidelines (Republic of South Africa, 2010; Republic of South Africa, 2013). Measures were grouped into ART enrollment and treatment monitoring activities. ART enrollment measures reflected baseline screenings and laboratory tests, prescription of medications to prevent opportunistic infections, nurses' decisions to start HIV treatment, and selection of appropriate antiretroviral medications. This author selected the following ART enrollment measures:

- The proportion of patients with WHO clinical disease staging
- The proportion of patients with baseline CD4 count testing
- The proportion of patients with baseline weight measurement
- The proportion of patients with completed physical exam
- The proportion of eligible patients who received baseline serum creatinine testing
- The proportion of eligible patients who received baseline liver function testing
- The proportion of eligible patients who received baseline renal function testing
- The proportion of eligible patients who were prescribed TMP-SMX prophylaxis
- The proportion of patients who started on antiretroviral medications and were eligible for treatment based on then-current guidelines
- The proportion of patients prescribed a first line ART regimen

The following ART monitoring measures were selected:

- The proportion of patients whose weights were collected at each follow-up visit
- The proportion of patients with HIV viral loads collected at 6, 12, and 24 months
- The proportion of patients with CD4 counts collected at 6, 12, and 24 months
- The proportion of patients with documented changes in ART regimen

Operational definitions and data sources for process measures are included in Table 4.

Outcome measures. Qualitative assessments of NIMART effectiveness and ART-related health outcomes were included in this capstone project. Health outcome measures reflected the goals of antiretroviral treatment: to reduce the morbidity and mortality associated with HIV/AIDS. Health outcomes included retention in HIV treatment and clinical outcomes. Treatment retention measures included the following:

- Median/mean number of missed clinic visits

- The proportion of patients remaining on treatment at 6, 12, and 24 months
- The proportion of patients lost to follow-up at 6, 12, and 24 months

Clinical outcomes included the following:

- The proportion of deaths in patients on treatment
- The proportion of patients with an HIV viral load less than 400 copies/ml at 6, 12, and 24 months
- Mean CD4 at 12 and 24 months on ART as compared to mean CD4 at treatment start
- Mean weight at last weight collection as compared to mean weight at treatment start
- The proportion of patients with a post-treatment opportunistic infection

An operational definition and data source for each outcome is included in Table 4.

Patient demographics. Patient demographic data were collected during medical records review. For each medical record reviewed, patient age, date of birth, sex, pregnancy status, and date of HIV diagnosis were collected.

Research Procedures

The Institutional Review Board at the University of Virginia and the Ethics Review Board at the University of Venda approved the research. Permission to collect de-identified clinic and patient-level data was obtained from the Vhembe District Department of Health. In accordance with the SPOM, research procedures for each quality domain are described below.

Structures. Descriptions of structures supporting the clinic's ART program were collected from two primary sources: the author's observations during clinic visits and interviews with five clinic staff. The operational manager was selected for interview a priori due to her supervisory role of the ART program. The clinic's operational manager identified additional clinic staff with assigned ART program duties. This group served as a pool from which interview

participants were selected. Interviews were conducted with two additional professional nurses, one lay counselor, and one data capturer. All participants gave their informed consent prior to interviews. Interviews took place onsite with permission of the clinic's operational manager. A semi-structured interview guide was developed by the author and can be found in Appendix C. Interview questions were pretested with University of Venda nursing staff to validate appropriate translation in South African English. Interviews were audio recorded to provide a verbatim history of responses for content analysis.

Processes. Data related to the clinic's processes of ART were collected from three sources. Informal processes of ART care were documented during clinic observations, staff interviews used to document clinic structures described above, and a focus group. The focus group was conducted with formally trained NIMART nurses to explore nurses' perceptions on the effectiveness of integrating ART services into PHC. However, important descriptions of informal ART processes were also identified during the focus group. For this reason the focus group was also included as a source of process-related data. Four professional nurses participated in the focus group. All participants gave their informed consent. The focus group met onsite with permission of the clinic's operational manager. A focus group guide was developed by the author and pre-tested with University of Venda nursing faculty (Appendix F). As with staff interviews, focus groups were audio recorded to allow verbatim data collection for content analysis.

Data related to formal processes of ART care were collected from three sources. Policies, guidelines, and protocols outlining formal processes of ART care were identified during onsite clinic observations. Data concerning compliance with formal ART processes were obtained through retrospective review of ART patients' medical charts and archived District Health

Information System reports. Retrospective chart review was restricted to the following dates: January 1, 2011, through April 25, 2013. Only patients who received all elements of NIMART care (pre-ART, enrollment, and ongoing management) in the clinic were included in the chart review. Each ART patient's medical chart was audited using a standardized data collection tool available in Appendix D.

Outcomes. Data related to ART program outcomes were collected from multiple sources. Data on program retention and clinical outcomes were collected from two sources: retrospective review of ART patient's medical charts and monthly District Health Information System reports. Chart review was again limited to patients who received all elements of NIMART care and used the same standardized data collection tool to guide chart audits (Appendix D). A separate tool was used to guide data abstraction from archived District Health Information System reports (see Appendix E). Qualitative outcomes were collected from the same focus group with NIMART-trained nurses described above.

Data Analysis

Data entry and analysis were performed using Microsoft Excel 2010 and IBM SPSS Statistics v.22. Interview transcripts, focus group transcripts, and field notes were entered into Microsoft Excel 2010 for coding and categorization. Qualitative data was analyzed separately for each of the three quality domains (structure, process, and outcomes) using conventional content analysis techniques. Content analysis is a systematic and "dynamic form of analysis of verbal and visual data that is oriented toward summarizing the informational contents of that data" (Sandelowski, 2000, p. 338). In this capstone project a program characteristic or theme was determined to be important if it arose from more than one data source among observations, interviews, and the focus group.

Summary statistics were generated from quantitative data in patients' medical charts and District Health Information System reports. Percentages, means, standard deviations, and medians were calculated for each variable using Microsoft Excel 2010. Paired sample t-tests were performed for selected clinical outcomes using IBM SPSS v22 to evaluate for statistically significant differences in outcomes from start of treatment as compared to at 12 months on ART.

Chapter 4

Results

The following sections provide answers to the research questions posed in the third chapter. As in the previous chapters, the SPOM provided an organizational framework for the presentation of capstone project results. Structures, processes, and outcomes associated with the clinic's ART program are presented separately. Information on data sources used for each research question is included in its respective section below.

Structures

1. What structural resources supported nurse-led ART at the clinic?

This section outlines characteristics of key NIMART program structures at the clinic. Key program structures included infrastructure, human resources, medications and supplies, program tools, and program organization and management. Primary data sources in these sections were clinic observations and staff interviews. The focus group served as a third data source on program structures and was used to validate findings from clinic observations and staff interviews. Themes arising from clinic observation and staff interview data where selected as key findings when present in more than one data source. Descriptions of each key structure are provided below. Due to the large number of findings, this section ends with a brief summary of structure-related results.

PHC infrastructure. Infrastructure characteristics included size, design, maintenance, utilities, and locations of referral services. All interviewees identified inadequate PHC infrastructure as the most significant barrier to the provision of high quality PHC services, including NIMART. NIMART-related services were provided in two buildings, both housed

within a gated campus. One building was designated for labor, delivery, and post-natal care for mothers and newborns. Staff members referred to this building as the maternity ward. The second building is where all other PHC services were provided, and is referred to throughout this capstone project as the general clinic. The general clinic was the preferred site for all ART-related encounters. The general clinic housed two designated patient consultation rooms. There were two additional patient care rooms in the building: a wound care room and a fast track room. A pharmacy room provided storage for the clinic's medication stock and medical supplies. A patient waiting area and vital sign/triage station were located in the single general clinic hallway. A small toilet room was used for collection of urine samples, as well as supply storage. Lastly, a kitchen area served as a staff lounge and dining area. See Figure 2 for a depiction of the general clinic.

The two general clinic consultation rooms were inadequate to accommodate the number of staff available for ART and other patient care. Professional nurses performing patient consultations were given priority for room assignment and regularly assumed use of clinic consultation rooms, the fast track room, and the wound care room. Activities that could be performed by other clinic staff were fit into remaining available space. Examples of such activities included vital signs collection; laboratory sampling including blood, sputum, urine, and other tissue samples collection; HIV support group coordination; and ART adherence counseling. Because of space limitations most services other than vital signs collection were provided within general consultation rooms, as access permitted. For this reason, staff viewed having too few clinic rooms as the clinic's greatest infrastructure challenge.

Locations of the clinic pharmacy and waiting room were cited as barriers to maintaining patient confidentiality. The clinic pharmacy can be accessed only from the fast track room, so

patient consultations in that room are interrupted by staff dispensing medications. In the hallway, maximizing waiting room seating requires placing chairs in close proximity to consultation rooms (see Figure 2). One interviewee expressed concern that those in the waiting room area could overhear confidential patient-provider conversations. This was identified during interviews as a potential factor in loss to follow-up among NIMART patients.

Use of the maternity ward for NIMART and other general clinic activities interrupted clinic flow. ART adherence counseling and HIV support group activities were cited as the most common NIMART-related services to be provided in the maternity ward. Both activities are led by the clinic's lay counselor and/or professional nurses with support from other clinic staff. During adherence counseling, staff members identified and helped trouble shoot patient-specific ART adherence barriers. Support groups gathered HIV infected patients together to share common challenges of HIV infection and motivated patients to remain in care and live more healthfully.

Less commonly, a professional nurse used the maternity ward for client consultations. For example, one nurse elected to "admit" a patient to the clinic for short term monitoring. This patient was kept in a general clinic consultation room. The professional nurse then relocated to the maternity ward to consult with other patients. This impacted clinic efficiency, as it required the nurse to work between two buildings while monitoring a higher acuity patient. For general clinic patients who received one or more services in the maternity ward, triage and vital signs collection remained in the general clinic building. No general clinic supplies or medications were stored in the maternity ward for overflow use, which was inconvenient for the general clinic staff members working there. Thus, coordinating PHC services between two buildings contributed to longer clinic visits.

Other infrastructure issues included inadequate utilities and clinic maintenance services. Transient power and water outages occurred during clinic site visits in both calendar years. Of note, neither electricity nor water shortages were identified during interviews as impacting the quality of NIMART services. No sustained power outages occurred during clinic observations, but were identified as a cause for unexpected general clinic closures.

Building repairs and renovations were authorized and coordinated outside of the clinic. Requests for repairs and renovations were documented in a designated logbook for review during the area manager's clinic visits. The clinic's operational manager directly communicated items requiring more urgent to subdistrict administrators. Staff members reported slow responses to requests for general clinic repairs when compared to repairs needed to maintain routine clinic operations. For example, at one year following a documented request for repair of non-functioning water heaters in staff lodging areas, no administrative follow-up had been documented, whereas a broken medication refrigerator had been replaced.

In addition to clinic-based infrastructure, locations and acceptability of NIMART-related referral services were recognized as important aspects of this clinic's infrastructure. Both patients with certain co-morbid conditions and opportunistic infections and patients who failed to respond to first line ART regimens required referral to physicians. Outside of the clinic the single site for public sector HIV specialty care was the clinic's designated referral hospital. The hospital was located approximately 29km from the clinic. Interviewees reported that patients failed to present for specialty care at the hospital due to travel distance and high costs of transportation. Further, the hospital was locally known as "the place for HIV-positive people." The staff pointed out that the stigma associated with being identified as HIV-positive made patients shy away from regular hospital visits, which would increase their risk of HIV disclosure.

Thus, the clinic relied heavily on visiting physicians for access to non-emergent medical evaluation for NIMART patients.

Human resources. Human resources were characterized by the number and training of staff, nurse workloads, roles of external providers in the delivery of NIMART services, and involvement of community stakeholders who provide program support. Each is discussed below.

Nursing Staff. Over the last 10 years, the number of nurse and support staff increased in tandem with expectations for integrated delivery of PHC services. In July 2012 the clinic had budgeted positions for one operational manager, two enrolled nurses, two enrolled nurse auxiliaries, and eight professional nurses. Four professional nurse positions were to be filled by nurses who completed training in primary health care. The remaining professional nurse positions were to be filled by nurses with advanced training in clinical specialties. As of April 2013 the nurse staffing structure was as follows:

- One operational manager who is a professional nurse with primary health training
- Two enrolled nurses
- Two enrolled nurse auxiliaries
- Three professional nurses without primary health training or clinical specialty training
- Two professional nurses with primary health training
- Two professional nurses with advanced clinical specialty training, including one trained in advanced midwifery and one trained in ophthalmic nursing

Of note, one of the professional nurses with advanced specialty training was also trained by the department of health to serve as a HIV/AIDS program specialist. This individual trained PHC employees across the district in HIV/AIDS programs.

Despite having an HIV/AIDS program specialist onsite, no professional nurse positions were allocated solely to HIV programs. All professional nurses (with the exception of the clinic's operational manager) served in generalist roles. The operational manager supervised daily clinic operations and staff, served as a clinical resource to clinicians, and filled professional nurse staffing gaps as needed. Formal job descriptions for all professional nurse positions were developed by the department of health and provided an outline of duties. In terms of clinical practice, professional nurses provided patient consultations and dispensed medications in accordance with national protocols and guidelines. With the exception of counseling and preventive screenings, professional nurses provided all ART-related services. Only professional nurses formally trained in NIMART prescribed ART medication regimens. Professional nurses with and without formal NIMART training could provide ART preparation and monitoring services. However, NIMART-trained staff largely provided these services during clinic observations

Professional nurses also served as supervisors to enrolled nurses and enrolled nurse auxiliaries to whom they designated selected clinical tasks. The department of health provided written job descriptions for enrolled nurses and enrolled nurse auxiliaries. In terms of clinical duties, enrolled nurses supported professional nursing activities, performed selected procedures and collected laboratory samples as allowed by their job description. Enrolled nurse auxiliaries provided triage, including collection of vital signs and anthropometric data.

NIMART training and mentorship. Only formally trained NIMART nurses were authorized to provide the full range of ART-related services, including selection of ART medication regimens. For this reason formal NIMART training was identified as a critical structure supporting the program. As of July 2012, four professional nurses were trained in

NIMART (Table 5). Only nurses with primary health training or advanced clinical specialties had completed NIMART training. The prerequisite for NIMART training was completion of two PHC training programs: *Practical Approach to Lung Health and HIV/AIDS in South Africa* and *Integrated Management of Childhood Illnesses.* NIMART training included three components: education on HIV basics, in-clinic training led by a physician, and clinical mentoring by a certified NIMART mentor. During NIMART training, nurses initiated patients on ART under the direct observation of a physician and/or nurse mentor. After trainees demonstrated competency in treating HIV-infected patients, mentors and physicians transitioned from providing direct supervision to providing monthly program support visits. Nurses contacted the clinic's NIMART mentor with clinical questions as needed. For example, if a nurse had a question regarding the significance of an HIV-related laboratory result, she contacted the NIMART mentor for guidance. Joint review of complex medical cases by nurses and physicians during in-clinic physician visits provided additional opportunities for nurses to learn about HIV treatment.

Of the three professional nurses interviewed, one had not completed formal NIMART training. This individual lacked confidence in her ability to interpret HIV-related laboratory results and to select appropriate ART regimens. She reported limited opportunities for NIMART training for junior nursing staff. One NIMART-trained nurse reported sharing information obtained in training with other nurses. This individual described untrained nurses as being less confident in their ART management skills, but competent to perform follow-up laboratory testing as defined in program guidelines. Thus, it was evident that trained colleagues served as mentors, assisting untrained nurses in the clinic with questions and concerns as needed. Safe dispensing of ART by untrained professional nurses was reported once medication prescriptions were documented in patients' medical charts.

Clinic support staff. The clinic's non-nursing staff included a data capturer trained by the department of health. A formal job description developed by the department of health outlined his duties. The data capturer oversaw patient files and clinic registers, generated PHC program reports, and located patients who missed medical follow-up appointments for chronic disease management. Further, the data capturer helped nurses coordinate patient appointments with physicians at the clinic or hospital. As with the professional nurses, the data capturer reported increased workloads with implementation of the NIMART program. Increased workloads were attributed to two factors. First, NIMART increased the number and types of medical records needed in the clinic. Second, implementation of NIMART occurred in tandem with new data requirements for monthly District Health Information System reporting. Completing monthly reports required review of multiple medical records and was viewed as time consuming.

Staffing patterns. As of April 2013, the NIMART program was adequately staffed to avoid gaps in NIMART services. The clinic nurses were organized into two teams. Each team consisted of three to four professional nurses, one enrolled nurse, and one enrolled nurse auxiliary. The operational manager selected staff members for each team to ensure availability of a NIMART-trained provider during peak clinic hours. During off-peak hours (evenings and nights), at least one professional nurse remained on call to ensure continuous access to PHC services. Nursing teams worked in weekly shifts, seven days on duty and seven days off duty. On Wednesdays both nursing teams worked. Team meetings were held on Wednesday mornings to promote attendance by all nurses, the data capturer, and the lay counselor. The operational manager, lay counselor, and data capturer worked Monday to Friday during day shifts only.

External clinical support. External clinicians supporting the NIMART program included physicians, nurse mentors, and social workers. Physician services were available through general

PHC support in coordination with the referral hospital or as part of the NIMART training and mentorship program. Visiting physicians reduced the number of hospital referrals. There were multiple medical scenarios that required referral to a physician. For example, patients who failed to improve on first or second line regimens required evaluation by a physician for changes in medications. Physician evaluation was also required for treatment of common HIV-related conditions such as varicella zoster. For clinically stable patients most medical needs were addressed during physician appointments at the clinic; however some patients ultimately required referral to the hospital for tertiary care or outpatient HIV specialty care. In-clinic physician appointments were available at least once monthly.

In addition to physicians, the Foundation for Professional Development, a non-governmental organization (NGO), funded one NIMART mentor to support the clinic's ART program. The mentor was a nurse responsible for developing NIMART skills among staff members, supporting the delivery of ART services in the clinic, and liaising between nurses and physicians as needed to manage complex HIV cases. The mentor served 10 PHC facilities in Mutale, Limpopo. NIMART nurses viewed the clinic's mentor as an important clinical resource for HIV-related medical care. At the time of clinic observations the NIMART mentor visited the clinic on request.

Social work was identified as an important support service for patients with HIV infection; however no social workers were assigned to the clinic. In South Africa individuals with AIDS may be eligible for disability grants, food assistance, and other support programs. Assistance in locating and enrolling them in support services could be obtained from social workers at a larger nurse-led primary care facility in the area or the referral hospital. One interviewee recommended referral to social workers at the hospital's HIV specialty clinic over

social workers at the health center. This was due to concerns that social workers in the subdistrict stigmatize HIV-infected individuals. Distance and extended wait times were reported as additional barriers to accessing social work services.

Community health workers and other community based support. Community members with and without health training contributed to the clinic's NIMART program. These individuals included the clinic's lay counselor, home-based care workers, and royal families. Of these, the clinic's lay counselor had the greatest impact on routine ART services in the clinic. The lay counselor was an employee of the Foundation for Professional Development NGO. Her primary job duties were to provide HIV counseling and testing, medication adherence counseling, and to assist with HIV support groups. She received training on HIV counseling and testing from her employer and the department of health. Other staff members regarded her as an important part of the clinic team.

Interview participants identified home-based care as an important source of NIMART patient support. Home-based care workers provided basic community health services, triaged medical problems for home versus clinic care, supported medication adherence through informal counseling, and located individuals on ART who missed clinic appointments. Home-based care was organized and managed independently from the clinic but had an office located on the same property.

Clinician and non-clinician interviewees described village chiefs and their royal families as assets for engaging community members in health outreach activities. Each village in the clinic's service area had a traditional leadership structure headed by a chief. Royal families included the chief and his immediate family members. Chiefs held the highest decision-making authority in the villages, and largely supported the clinic's HIV interventions. Clinic staff

targeted royal families for inclusion in HIV/AIDS education programs given their high social status in the community. By advertising and attending department of health events, royal families boosted community participation in public health related activities. Village chiefs also provided assistance with complex patient issues. Some village chiefs served as key informants regarding the location of ART clients who were lost to follow-up. Chiefs were engaged as informal counselors for clients struggling with treatment adherence. Interviewees viewed village chiefs as respectful of villagers' rights to confidential medical care; however, one interviewee acknowledged that legal restrictions on disclosure made engaging community leaders in patient outreach more difficult.

Medications and supplies. HIV-related medications included antiretroviral medications, medications for the prevention and treatment of opportunistic infections, medications to treat common co-infections, and medications used for symptom management of HIV-associated medical conditions. HIV-related supplies included reusable medical equipment, single use clinic supplies, and equipment and supplies for clinical laboratory testing.

HIV-related medications. Both antiretroviral medications and other HIV-related medications were viewed as important resources for NIMART service delivery. Antiretroviral medications were ordered from the subdistrict's central pharmacy at the referral hospital. Clinic orders for antiretroviral drugs were based on the number of individuals actively enrolled in the clinic's ART program. Nurses ordered up to a maximum of 20 additional monthly pill supplies of medications included in preferred ART regimens. This practice ensured antiretroviral medication availability for new ART enrollees. Central pharmacy employees delivered ART medications monthly. Documentation requirements for ART included daily tracking of dispensed medications and monthly tracking of patients receiving each ART regimen.

Other HIV-related medications approved for PHC use were outlined in the document *Standard Treatment Guidelines and Essential Drugs List, Primary Health Care* (Republic of South Africa, 2008). For HIV-infected individuals, medications on the essential drug list included medications for prevention and treatment of opportunistic infections and medications for HIV symptom management. Not all essential HIV-related medications were available in the clinic. During a pharmacy audit of selected medications on July 17, 2012, 12.9% (4/31) were unavailable (Table 6). Three were medications used for treatment or prevention of opportunistic infections. One nurse expressed frustration that gaps in medication access resulted in hospital referrals for treatment of uncomplicated opportunistic infections. Clinic staff attributed shortages to administrative issues rather than the clinic's failure to order needed medications. Formal protocols outlined standards for managing medications. These included "first-in, first-out" and "first-expired, first-out" approaches to ordering, stocking, and distribution. Essential medications were ordered directly from health department supply depots.

Supplies. Medical supplies included reusable medical equipment, single use clinic supplies, and clinical laboratory supplies and equipment. Interviewees reported stable access to basic reusable medical equipment including scales, stethoscopes, blood pressure cuffs, and sharps and biohazard storage containers. Equipment for clinical assessments was shared between consultation rooms and triage areas. For example, blood pressure cuffs were available in the triage area but not kept in the clinic consultation rooms. Proper sharps and biohazard disposal containers were located in each consultation room, the wound care room, the fast track/triage room, and at the vital signs station.

Important NIMART-related clinic supplies included examination gloves and pill counting devices. Examination gloves were identified as an important resource based on clinic

observations and informal staff comments. However, during formal interviews participants did not identify existing glove shortages as a barrier to NIMART care. During the July 2012 site visit, gloves were rationed to ensure availability of examination gloves in the maternity ward. Glove use in the maternity ward was prioritized over use in the general clinic due to perceived increased risk of exposure to blood and body fluids during childbirth. However, pre-ART visits frequently required blood collection. It was unclear if the use of exam gloves and other barrier precautions were routinely used for the practice of blood sampling for laboratory testing in the general clinic.

In addition to more consistent glove supplies, one nurse requested access to pill counting devices to aid in performance of ART follow-up assessments. At the time of this capstone project nurses resorted to counted ART medications by hand or with tongue depressors during monthly adherence assessments. These practices slowed consultations and increased risk for contamination of patients' medication supplies.

Important supplies and equipment for clinical laboratory testing were differentiated based on laboratory testing pathways. First, limited point-of-care testing was available onsite including HIV rapid testing, hemoglobin testing, blood glucose testing, urine pregnancy testing, and dipstick urinalysis. Staff members completed training on each testing procedure prior to providing the service. Nurses described point-of-care testing as accurate, cost-effective, and important to ensuring timely medical services. Maintaining point-of-care testing capabilities required consistent access to testing supplies as well as maintenance of point-of-care devices. One nurse described onsite hemoglobin monitoring as an important resource for HIV programs; however the clinic's hemoglobin monitor was out of service throughout the July 2012 site visit. During site visits in April 2013 glucometer testing strips were also out of stock. Supplies for

point-of-care testing were ordered from the district department of health supply depot or the referral hospital's central pharmacy.

The National Health Laboratory Service performed the majority of the clinic's laboratory testing. The nearest laboratory was located at the referral hospital. National Health Laboratory Service employees transported specimens and supplies to and from the clinic. Commonly used laboratory supplies included specimen collection containers and lab requisition forms. Finalized lab results were available by phone and delivered in hard copy by the transport driver. Challenges related to laboratory services included delays in lab processing and weekday-only specimen transport rather than shortages in laboratory supplies.

Program Tools. Program tools recognized as impacting NIMART services included formalized clinical guidelines and clinic documentation systems.

ART-related guidelines. Historically the clinic's PHC services were organized into distinct wellness or disease programs, guided by formal national guidelines. HIV-related guidelines were identified as the most important program tools for professional nurses providing ART services. The clinic's programs have evolved to include HIV treatment of adults and adolescents in accordance with following national policy guidelines:

- Clinical Guidelines for the Management of HIV & AIDS in Adults and Adolescents (2010)
- HIV Counseling and Testing Policy Guidelines (2010)
- Guidelines for Tuberculosis Preventive Therapy Among HIV Infected Individuals in South Africa (2010)
- Practical Approach to Lung Health and HIV/AIDS in South Africa (PALSA PLUS) (2012)

- South African Antiretroviral Treatment Guidelines (2013)
- South African Antiretroviral Treatment Guidelines (2010)
- Standard Treatment Guidelines and Essential Drugs List, Primary Health Care (2008)

During 2012 clinic observations, at least one copy of an abbreviated treatment algorithm or a full-length guideline was available for provider reference, with the exception of the 2013 updates to the South African antiretroviral treatment guidelines. Interim updates to guidelines were communicated during staff meetings and provided in hard copy by way of memorandums from the department of health.

Documentation and data reporting systems. The clinic used a paper-based system for clinical documentation and external reporting. Standardized clinic registers known as "tick registers" were used to document clinic visits and the services provided. Patients also kept a record of their medical histories in personal notebooks. Nurses documented vital signs and treatment recommendations in the patients' notebook. Patients enrolled in a chronic care program were issued a medical chart that was maintained in the clinic. Chronic care programs included ART, mental health, hypertension, and diabetes. The standardized medical chart for patients enrolled in NIMART included sections for documentation of laboratory test results, medication-related screenings, and other HIV-related medical follow-up.

Professional nurses owned the greatest burden of clinic documentation. A patient encounter required documentation of the patient's demographic information, chief medical complaint, nursing services rendered, relevant laboratory testing results, treatment recommendations, and medications dispensed. For a patient receiving NIMART services, the nurse recorded information in a clinic register, the patient's notebook, and the patient's medical

chart. A patient receiving care for multiple chronic conditions required nurse documentation in all chronic disease charts.

Incomplete documentation was identified as a challenge to the quality of NIMART program data. Both the fast pace of clinical encounters and patient refusal of ART medical charts affected file management. Interviewees reported that nurses sometimes provided services without recording medical information in all the required locations. Incomplete documentation influenced follow-up care. Schedules for ART-related laboratory testing and preventive screenings were included in NIMART medical charts. Incomplete documentation reduced the usefulness of this built-in decisional support. To address documentation gaps, the clinic's data capturer reviewed clinic registers and chronic disease charts to assess their completeness and accuracy. He liaised with nurses to correct errors or gaps in program data.

External reporting requirements were defined by the district department of health and were outlined in District Health Information System report templates. Clinic reporting focused heavily on HIV and tuberculosis programs but also included measures of other chronic disease programs. The data capturer was responsible for generating and submitting District Health Information System reports. Electronic medical records were cited as one way to ease the burden of clinic reporting requirements but were not consistently used at the time of clinic observations. The clinic used one desktop computer for data entry of selected HIV and tuberculosis programs information.

Program Organization and Management Structures. This section describes NIMART program organization and management characteristics. Important findings included methods of ART service integration, administrative hierarchies, and quality assessment activities. Each is discussed below.

Integration of ART services. Nurse interviewees reported greater expectations for integration of HIV-related services in PHC following implementation of the NIMART program. This "supermarket approach" to care increased the length and complexity of patient-professional nurse consultations. At the time of this capstone project, the NIMART program shared clinic space, nurses, and resources with other PHC programs. NIMART training was required to start a patient on a new antiretroviral regimen, but all professional nurses could provide ART follow-up services. All nurse interviewees described NIMART as a time consuming addition to the already diverse set of PHC services provided. However, nurse interviewees expressed a preference for provision of NIMART services during disease-specific clinics to minimize the breadth of services offered on any given clinic day.

Administrative Chain of Command. The NIMART program was managed under parallel administrative hierarchies: a PHC chain of command and a special programs chain of command (Figure 3). The PHC chain of command was well defined; however, clinic staff reported that the operational manager and area PHC managers were the most visible administrators. The clinic's operational manager, a professional nurse, provided direct oversight of daily clinic activities and directly supervised clinic staff. The operational manager reported to the area PHC manager and her assistant. The area PHC manager was responsible for managing routine human resource issues, nominating PHC employees for training, addressing equipment and supply needs, overseeing PHC budgets, and monitoring overall performance of all PHC facilities in Mutale. As of July 2012 the area PHC manager position was vacant. The area assistant PHC manager was operating in a joint assistant/interim manager capacity.

In addition to PHC administrators, specialty program managers oversaw the clinic's HIV/AIDS, sexually transmitted infection, and tuberculosis (HAST) programs. The subdistrict

level HAST program manager ensured coordination of all HIV/AIDS services within Mutale PHC facilities. The HAST program manager provided consultation and technical support to the area PHC manager or directly to the clinic as needed. The subdistrict HAST manager reported to a special programs manager at the district department of health. HIV-related training priorities were selected for all Vhembe PHC facilities at the district level.

Strong working relationships were reported in and between clinic staff and subdistrict level administrators. Clinic staff viewed the strong teamwork between clinicians and non-clinicians as a major clinic asset. Positive relationships were also reported between the clinic operational manager and subdistrict PHC managers.

Information exchange was successful down the chain of command, but communication up the chain of command was not described. Clinic staff viewed subdistrict PHC managers as knowledgeable regarding district level events and activities that affected clinic practices. For example, subdistrict managers notified the clinic's operational manager of changes to district, provincial, and national policy guidelines that would affect ART eligibility. However, one nurse expressed frustration that the area PHC manager was not yet conversant with the NIMART program's day-to-day challenges. This nurse described subdistrict responsiveness to NIMART program needs as variable.

Quality management activities. Routine assessments of NIMART performance were included in PHC and HAST program management activities and during NGO support visits. During monthly site visits, the area PHC assistant manager collected clinic registers and a sample of medical charts for manual review. Documentation audits focused on completeness of clinical documentation and adherence to one or more PHC guidelines. Subdistrict managers were supportive of efforts to improve quality, and openly reviewed findings of audits with clinic

nurses. Areas for improvement were based on results of documentation audits. For example, when audits demonstrated gaps in clinic register documentation, this was selected as a focus for improvement over the following month. Managers also monitored clinic services through review of monthly District Health Information System reports. The subdistrict HAST program manager and the Foundation for Professional Development also conducted periodic reviews of clinic documentation. These audits focused solely on the clinic's HIV/AIDS programs, but were described by interviewees as similar in terms of process.

At the clinic level a professional nurse monitored NIMART performance. This individual was trained in NIMART and was selected by the clinic's operational manager. She was responsible for periodic review of ART patient files to identify gaps in care. There were no formal or informal guidelines to guide internal ART chart reviews or tracking of changes in clinical practice. Identified program challenges were discussed during scheduled staff meetings.

Summary.

The NIMART program is supported by a number of PHC structures represented in the SPOM. Major themes from this section relate to characteristics of PHC infrastructure, human resources, medications supplies, program tools, and program organization. Staff recognized inadequate clinic infrastructure as the most important barrier to NIMART service delivery. The number of clinic rooms was inadequate to accommodate the numbers of clinic staff available to provide services. Poor clinic design increased the risk for breeches in patient confidentiality and negatively impacted clinic flow. Human resource characteristics focused on the disproportionate use of professional nurses with advanced clinical training to provide NIMART care. This was partially due to the preferential selection of nurses with specialization in PHC or other areas for NIMART training. However, informal mentioning of untrained nurses and task-shifting HIV

counseling and testing responsibilities to lay workers reduced some of the workload reported by NIMART nurses. A strong sense of teamwork was reported between clinical and non-clinical staff, further mitigating challenges of increased clinic workloads. Clinical practice guidelines were recognized as critical program tools to support nurses who provide HIV-related care. These were readily available for reference during patient-nurse encounters. Program-specific medical records led to redundancy in charting and therefore increased the documentation burden on clinic nurses. Last, nurses appear to favor separation of HIV-related clinic visits from general clinic visits, a preference supported by scheduling of disease-specific clinic days and other factors. This contributed to incomplete integration of NIMART services with general PHC care.

Processes

2. What were the formal and informal processes of ART initiation and clinical follow-up?

This section outlines processes of ART initiation and clinical follow-up, both essential components of NIMART services in the clinic. Data sources included clinic observations and manual medical chart review. Although the intent of this capstone project was to identify informal and formal care processes, informal discussions with staff during clinic observations revealed that all major NIMART care processes were derived from the *South African Antiretroviral Treatment Guidelines (*Republic of South Africa, 2013; Republic of South Africa, 2010) and *Clinical Guidelines for the Management of HIV&AIDS in Adults and Adolescents* (National Department of Health, 2010). Thus, this section centers on nurse compliance with ART initiation and follow-up tasks outlined in the aforementioned guidelines. Compliance was assessed through review of patient medical charts.

Medical chart review was performed for 92 individuals ages 15 years and older who were

not on HIV treatment at enrollment in the clinic's ART program. This included 15 females who were pregnant at the time of ART enrollment. Five patients not actively on treatment at time of NIMART enrollment, but who had a history of treatment elsewhere were also captured in the review. Female gender was reported for 73.9% (68/92) of adults and adolescents started on treatment. Mean age at entry into the program was 38.9 years. In 2011 the mean CD4 count at start of treatment was 149.4 cells/mm^3. This increased to a mean baseline CD4 count of 213.1 cells/mm^3 in 2012. Advanced clinical HIV disease (defined as WHO Stage 3 or 4 disease) was reported in 44.6% (41/92) of ART patients at treatment start.

Guidelines in 2010 required start of HIV treatment within two months of a qualifying CD4 count or WHO clinical stage for most patients. Pregnant women who were eligible for lifelong treatment, patients with CD4 counts less than 100 cells/mm^3, and patients with WHO stage 4 disease were to start medications within two weeks (Republic of South Africa, 2010). In April 2012 the government announced interim updates requiring same-day start of HIV treatment in individuals with CD4 counts less than 200 cells/mm^3 (Matsoso, M.P., 2012). However, formal guideline revisions in 2013 allowed up to seven days for treatment for the following: pregnant or breast feeding women, patients with CD4 counts less than 200 cells/mm^3, WHO stage 4 disease, and patients co-infected with tuberculosis and having a CD4 count less than 500 cells/mm^3 (Republic of South Africa, 2013). Because of complex and changing guidelines, a conservative measure of appropriate ART enrollment was used and required start of treatment within 2 months of a qualifying event. Overall 85.9% (79/92) of patients were started on treatment within 2 months of having a baseline CD4 count collected. All patients had WHO staging documented in their medical record at time of treatment initiation (see Table 7). First line ART regimens were prescribed for 94.6% (87/92) of patients started on treatment. Prescription of alternative

regimens was clustered in the following period: June 11-14, 2012. Documentation of a treatment-qualifying event was missing for 12.0% (11/92) of patients who were started on ART. Of those on ART who did not have a documented qualifying event, 72.7% (8/11) of cases occurred when the treatment guidelines required CD4 counts less than 200 cells/mm^3 for most patients to begin treatment.

For all patients, baseline physical assessments and measurement of weight are expected as part of ART enrollment. Baseline physical assessments and weight were conducted for 62.0% (57/92) and 93.5% (86/92) of patients, respectively. Completion of a physical exam decreased each year. In 2011 77.8% (21/27) patients had a baseline physical exam documented in their medical chart compared to 57.4% (31/54) in 2012. From January to April 25, 2013, 54.5% (6/11) of patients had a baseline exam on record. Over time the proportion of patients with a documented baseline weight also decreased. In 2011 a baseline weight was documented for 96.3% (26/27) patients versus 94.4% (51/54) in 2012.

The majority of ART patients were started on a tenofovir-containing regimen (85.9%, 79/92). For those prescribed tenofovir, 92.4% (73/79) of patients received the recommended renal function testing prior to starting the medication. Concurrent baseline hemoglobin and alanine aminotransferase testing (indicated for those receiving other antiretroviral agents) was also high in this group at 97.5% (77/79) and 98.7% (78/79), respectively. In those started on nevirapine- and zidovudine-containing regimens 91.7% (11/12) received recommended laboratory testing to ensure safe medication use (Table 8).

Prescription of TMP-SMX occurred within two months of starting antiretroviral treatment in 43.9% (36/82) of patients with CD4 counts less than 200 mm^3 and/or WHO Stage 2-4 disease. Rates of prescription were greater in those with CD4 counts less than 50 cells/mm^3

versus those with CD4 counts greater than or equal to 50 cells/mm^3 (62.5% vs. 41.9%). Compliance with TMP-SMX prescription by year is reported in Table 9.

Weight assessments do appear to be important components of clinical follow-up. Following start of antiretroviral medications, 35.4% (29/79) of patients had a body weight documented for each follow-up appointment. Compliance rose considerably when weight collection was assessed by clinic visit rather than by patient. When looking at all ART follow-up visits, 80.7% (594/736) were associated with a documented body weight.

Compliance with HIV viral load monitoring was assessed at 6, 12, and 24 months of treatment. Viral load results were available for 62.0% (31/50) of patients on treatment for 6 months. At 12 months on treatment 69.2% of patients had a viral load result available. Only four patients reached 24 months on treatment. All were still eligible for HIV viral load testing at the time of medical chart review. Thus, compliance at 24 months of treatment was not calculated.

Compliance with CD4 count collection was assessed at 6, 12, and 24 months. Only those who started treatment prior to May 2012 were included in six-month calculations due to interim changes in treatment guidelines (Matsosos, 2012). Overall, 76.5% (13/17) of patients on treatment at 6 months received appropriate CD4 count testing. At 12 months on treatment, 57.7% (15/26) of patients had CD4 count results available. As with HIV viral load testing, all four patients on treatment at 24 months were eligible for CD4 count testing at the time of chart reviews (see Table 10).

Changes in antiretroviral medications were documented for 16.3% (15/92) of those started on treatment. Four patients required temporary medication changes due to tenofovir shortages. Eleven patients required long-term medication changes which followed two patterns: a

single medication change from zidovudine to tenofovir (6/11) or from stavudine to tenofovir (5/11).

Outcomes

3. How did nurses perceive the effectiveness of integrating ART services into primary care encounters?

This section describes professional nurses perceptions on NIMART effectiveness in PHC settings. Answers to this research question were derived from three sources: staff interviews, review of District Health Information Reports, and the focus group. Three professional nurses participated in the focus group. Participants included one nurse with advanced specialty training and two nurses with primary health training. All participants completed department of health-sponsored training in NIMART. Nurses identified patient outcomes associated with nurse-led ART as well as challenges to integrating NIMART with other PHC services. Health care quality was explored in terms of patient and provider expectations for ART services as well as social norms impacting the delivery of ART services in clinic.

NIMART was largely described as increasing local villagers' access to HIV services. Based on monthly District Health Information System reports, by the end of March 2013, 89 adolescents and adults (ages 15 years and older) with no prior HIV treatment history were eligible for enrollment in the program. Of these, 97.3% (72/74) eligible patients were started on antiretroviral medications. Another 50 patients already in treatment were referred to the clinic's ART program from other public sector clinics and hospitals. Thus, a total of 137 adults and adolescents received at least one ART service in the clinic since the program began in 2011.

Nurses associated the NIMART program with positive patient outcomes. Patients who remained in care were believed to be more compliant with their medication regimens, to have better immune function, and to more effectively control their HIV infections. Participants agreed that the ideal outcome for patients in the NIMART program was a normal life. This was defined as having a health status comparable to individuals without HIV infection. Most patients were thought to be successful in treatment.

Challenges to the delivery of NIMART services included HIV stigma, limited time to address patient needs during medical appointments, and differences between patient and provider expectations for ART-related clinic visits. Stigmatization of HIV was cited as the greatest challenge to retaining patients in the NIMART program. Although local villages differed in their attitudes and beliefs regarding HIV, disclosing one's HIV status in Mutale posed a risk of community stigmatization. Nurses identified lack of education, traditional medicine, and the beliefs of some religious groups as factors influencing stigmatization of HIV and its medical treatment. Fear of HIV stigma contributed to missed clinic appointments. Patients who elected to keep their HIV diagnosis confidential had difficulty explaining monthly clinic visits to family and friends. For this reason, patients who lacked family or other community support were viewed as having poorer outcomes. Home-based care teams were identified as an essential resource for providing surrogate support networks to such patients.

Partial integration of NIMART services in the clinic promoted stigma by differentiating HIV-infected patients from other clinic attendees. Receiving NIMART services on dedicated HIV clinics days increased the risk of accidental HIV disclosure through association with the clinic's HIV programs. Medical NIMART charts differ in appearance from other chronic disease

charts. Nurses described a common patient practice of refusing their medical charts at registration to avoid being seen with HIV-related documents.

Nurses had insufficient time to address barriers to medication adherence. This was attributed to earlier treatment of HIV and competing clinic demands. Prior to starting HIV treatment, patients required extensive preparation. Nurses expressed concern that current treatment guidelines required same-day ART initiation for some patients. These individuals had to forgo pre-treatment adherence counseling. Adherence counseling was viewed as effective, and nurses reported poorer medication adherence in those with little or no preparation for HIV treatment. After starting treatment, patients presented to follow-up appointments with other medical problems that needed to be addressed. Dual nurse responsibilities were also reported. For example, one nurse described having to speed through a patient encounter so that he could assist a laboring patient. Thus nurses felt they had inadequate time to address all patient needs during follow-up appointments.

Providers and patients had different expectations for ART care. Nurses wanted enough time with patients to complete interviews and physical examinations, identify medication problems, perform expected screening and laboratory testing, and address education gaps during ART visits. Nurses defined ART program quality in terms of guideline adherence and comprehensiveness of care. HIV-related guidelines were described as thorough, easy to understand, and effective when closely followed. Close adherence to guidelines was seen as essential to good care. One interesting aspect of guidelines adherence related to referral. Nurses reported limited authority to treat HIV at the PHC level, and relied on guidelines to determine when specialists should assume HIV management. For this reason appropriate referral to specialty HIV care was seen as an important aspect of NIMART quality.

Patients wanted short medical visits and easy access to medication refills. ART services available through private clinics aligned more closely with patient expectations for care. Private clinics were present in the greater Mutale area. Physicians at these facilities were generalists and did not have specialty HIV training. Private treatment was associated with fewer clinic visits and shorter wait times to see a provider. However, private HIV treatment was largely inaccessible to the community due to cost. Nurses also expressed concern that private practitioners were less likely to follow treatment guidelines.

4. What were the clinic's HIV-related patient outcomes?

This section outlines NIMART related patient outcomes based on results of medical chart reviews for the 92 patients who were started on treatment in the clinic. At the close of medical chart review on April 25, 2013, 64.1% (59/92) patients were alive and in care, 23.9% (22/92) were lost to follow-up, 5.4% (5/92) transferred care to another facility, and 6.5% (6/92) died. All deaths occurred in individuals with CD4 counts less than 200 cells/mm^3 at the start of treatment.

Among those with available results at 6 months, 88.2% (30/34) had a HIV viral load less than 400 copies/ml. At 12 months on treatment, 94.7% (18/19) of patients had a documented HIV viral load less than 400 copies/ml. Twenty-one patients had pre- and 12 month post-treatment CD4 counts available for analysis. A statistically significant increase in mean CD4 count was observed in this group (147.6 cells/mm^3 at baseline vs. 438.10 cells/mm^3 at 12 months; p= .000008).

Four patients reached 24 months on treatment. One had a documented HIV viral load at 24 months on treatment; this individual maintained viral load suppression. No patients had a CD4 count collected to assess for additional change in immune function following the first year

of treatment. A total of 71 patients had pre- and post-ART weights documented. A statistically significant increase in mean weight (from 61.5 kg at baseline to 63.5 kg at last measurement) was observed for the 71 patients who had pre- and post-treatment weights available ($p = .005$).

Patients who attended at least one follow-up (n=79) missed an average of 2.65 visits by the end of follow-up. No patient ART file included lab results or treatment information allowing for identification of opportunistic infection diagnosis.

Chapter 5

Discussion

The purpose of this capstone project is to add to the body of knowledge concerning delivery of nurse-led ART services in PHC. This work is unique in that a summary of NIMART program structures, processes, and outcomes is provided. The SPOM is used to organize discussion of the research findings. Each research question is discussed separately, incorporating a summary of key findings, comparison with what was found in the literature, and implications for nursing practice. Broader implications concerning the integration of HIV care delivery in primary care settings are also discussed. The chapter closes with limitations and conclusions.

Structures

1. What structures support nurse led-ART at the clinic?

At the time of this capstone project, the clinic's NIMART program was fully operational, providing local access to comprehensive HIV testing and treatment services. The program included a population of patients started on HIV treatment at the clinic and a population of patients already on treatment who transferred for ART monitoring. Integration of HIV services is defined as "co-location and sharing of services and resources for HIV care and primary care" (Odeny et al., 2013). In this clinic, space, clinicians, support staff, pharmacy resources, laboratory services, and leadership are shared between ART and non-ART programs. However, clinic structures continue to support organization of nursing care into distinct, disease-specific programs. NIMART services are preferentially provided on dedicated HIV clinic days.

Teamwork, clinic infrastructure, human resources, medications, and documentation systems were cited as important structures supporting the NIMART program. Challenges to

NIMART program adoption aligned closely with previous findings from the literature. Overall, interviewees reported positive, collegial relationships with outside providers, mentors, and administrative and support personnel. Within the clinic, mutual respect and co-worker support were key factors influencing employee satisfaction. Drawing on the clinic's existing culture of teamwork, managers should consider developing quality improvement teams rather than individual program champions to increase staff engagement in quality improvement activities (Davies, Homfray, & Venables, 2013).

In this capstone project, inadequate infrastructure was consistently described as the greatest barrier to ART service delivery. Gaps in PHC clinic infrastructure were common challenges in early down referral programs (Decroo et al., 2009; Janse van Rensburg, 2008). The current clinic is too small to accommodate the number of clinic staff available for patient care. Nurses attributed prolonged patient wait times to an inadequate number of consultation rooms. This has tremendous implications: wait times negatively influence patient perceptions of service quality in South Africa (Peltzer, 2009). Inadequate infrastructure can also undermine efforts to protect patient confidentiality during clinic encounters (Davies, Homfray, & Venables, 2013). In this setting waiting room design increased the risk of community members overhearing patient-provider conversations. District program planning requires new thinking on PHC infrastructure, including facility size and design.

NIMART is a complex intervention that requires adequate staffing resources. Although interviewees generally regarded the number of clinic nurses as adequate, professional nurses reported high workloads, a finding consistent across NIMART and down referral programs. Thus, concerns regarding the country's increased dependence on nurses to provide HIV management deserve consideration. In 2008 43.7% of public sector professional nurse positions

were vacant in Limpopo Province (George, Quintan, & Reardon, 2009). In this rural clinic, only one professional nurse position was vacant, however three positions were filled by professional nurses without the expected primary health care training. Of the seven professional nurses on staff, only those with advanced nursing credentials were selected for NIMART training. This resulted in a disproportionate burden of ART services on nurses with other specializations.

Clinical support staff, administrative staff, and community health workers are vital resources allowing expansion of professional nurses' roles by delegation of appropriate tasks to other categories of health workers (WHO, 2008a). In this clinic, task shifting HIV testing and adherence counseling to a lay counselor reduced burdens on nurses to provide these services. However, professional nurses reported little involvement of enrolled nurses and enrolled nurse auxiliaries in ART services. The limited utilization of mid-level nursing staff is notable, in that this group of workers is widely employed in ART programs in other resource-constrained areas (van Rensburg et al, 2008). Identifying appropriate clinical and administrative tasks for enrolled nurse or enrolled nurse auxiliary delegation may further reduce professional nurse workloads. Decisions to expand mid-level nursing roles should be paired with training and skills validation to ensure safe delivery of task shifted services.

Medication shortages impact NIMART services; however, shortages in medications other than antiretroviral agents are equally important. An essential aspect of HIV/AIDS management is prevention and treatment of common opportunistic infections. Although primary care protocols provide for treatment of selected opportunistic infections in PHC settings (National Department of Health, 2008) some medications commonly used for this purpose were not included on pharmacy or depot order forms. Expanding PHC access to all medications

outlined in the *Standard Treatment Guidelines and Essential Drugs List* (2008) is likely to improve the quality of HIV-related services.

Last, program-specific documentation requirements are burdensome to nurses. Some attribute increases in PHC documentation to the increased numbers of ART patients utilizing PHC services rather than requirements for more intensive recordkeeping in this population (Georgeu et al., 2012). However, in this clinic the burden appears to be compounded by fragmented documentation systems, whereby an NIMART patient's medical information is recorded in three or more locations. This process fosters incomplete recording of medical information and complicates data recall for clinical decision-making. Administrative structures contribute to redundant documentation by requiring separate reporting for individual PHC programs. Consolidating medical information offers a way to reduce charting duplication, support better integration of existing disease-specific programs, and decrease the burden associated with monthly reporting (Institute of Medicine, 2003). Electronic health records are one option for streamlining documentation systems, but will require concurrent improvements in electrical and communications systems. However, streamlining reporting requirements can have a substantial impact on nurse documentation burden without necessitating adoption of electronic health records (Uebel et al, 2013).

The examples above reflect key structures supporting the clinic's NIMART program. Despite ongoing challenges to infrastructure, human resources, medications, and documentation systems, clinic staff reported NIMART as necessary response to the local HIV/AIDS crisis. Though resource improvements were suggested to improve the quality of the clinic's NIMART services, current resource allocation ensured access to basic HIV treatment services.

Processes

2. What were the formal and informal processes of ART initiation and clinical follow-up?

This capstone project confirms that the clinic's nurses adhere to National HIV treatment guidelines when performing ART-eligibility assessments, collecting baseline laboratory tests, and prescribing antiretroviral medications. Pre-ART screenings appear to be fully adopted into ART initiation practices. All patients had WHO clinical disease staging on entry into the ART program. The lower rates of weight assessment and physical examination seen in this capstone project likely reflected gaps in documentation rather than missed opportunities for weight measurement: WHO clinical staging requires physical assessment and evaluation of changes in weight. Nurses were able to maintain high rates of baseline CD4 count collection and drug-specific laboratory screening despite increasing numbers of patients entering the program in 2012. Nurses also demonstrated capacity to prescribe effective ART regimens: Only five patients failed to receive first line treatment regimens at the start of treatment. All five patients were subsequently transitioned to a first line regimen. The clinic's success in expanding treatment to those with CD4 counts less than 350 cells/mm^3 (as required in updated treatment guidelines) is also notable and demonstrated through increasing mean/median baseline CD4 counts over time (Table 11).

Nearly 86% of patients were started on treatment within two months of baseline CD4 count collection. The relatively short interval from eligibility to start of HIV treatment seen at this clinic suggests nurses are able to overcome patient, provider, and other systems-level barriers. However, the low mean CD4 count observed in patients starting treatment in 2012 (213.1 cells/mm^3) suggests that many patients have advanced HIV disease at diagnosis, and would benefit from starting antiretroviral medications as soon as eligibility can be verified. Current treatment guidelines call for starting antiretroviral treatment within 7 days in high-risk

groups, including pregnant and breast feeding women, those with CD4 counts less than 200 cells/mm^3, those with WHO stage 4 disease, and those with tuberculosis and HIV co-infection and a CD4 count less than 500 cells/mm^3 (Republic of South Africa, 2013). Future program evaluations should assess clinic compliance with earlier start of ART in these groups.

One surprising finding in this study was the tendency for nurses to perform additional laboratory screenings beyond that required for each prescribed medication. Current *South African Antiretroviral Treatment Guidelines* (2013) outline drug-specific screenings. There were high rates of hemoglobin and alanine aminotransferase screenings in patients receiving tenofovir, which are screenings recommended for patients who receive zidovudine and nevirapine, respectively. With a transition to same-day ART access for certain patient groups, this bundled approach allows nurses to adjust regimens quickly in the event of laboratory-detected contraindications to one or more antiretroviral medications. However, this occurs at the expense of additional ART-related laboratory costs. With the increased reliance on tenofovir-containing regimens for HIV treatment, program planners should explore whether expansion of point-of-care testing can reduce unnecessary screenings in this population. Currently those on tenofovir require creatinine screening four times in the first year of treatment (Republic of South Africa, 2013).

Attention to opportunistic infection prophylaxis is lacking. It is a cause for concern that only 43.2% of individuals with CD4 counts less than 200 cells/mm^3 received the recommended prophylaxis against opportunistic infections. It is unclear whether this reflects missing data or an actual failure to prescribe TMP-SMX. Given the limited access to medications for the treatment of opportunistic infection in this clinic, a stronger focus on prevention is warranted. TMP-SMX is effective in reducing morbidity and mortality in patients with AIDS and is a widely available,

low cost intervention (WHO, 2006). Clinic managers should prioritize this intervention as a core component of nurse-led services. Suggested approaches to improving TMP-SMX coverage include training of health care workers and inclusion of TMP-SMX prophylaxis in District Health Information System reports or other medication monitoring systems (Date et al., 2009).

Compared to relatively high rates of laboratory testing at ART initiation, lower rates of nurse compliance were observed with follow-up laboratory testing. HIV viral load testing is the preferred approach to diagnose treatment failure in those on ART (WHO, 2013). In this clinic, 62.0% (31/50) of patients received HIV viral load testing after 6 months on treatment. Compliance with HIV viral load testing at 12 months increased to 69.2% (18/26). The clinic's performance with HIV viral load testing was comparable to that reported in both down referral and NIMART evaluations previously. Collection of routine HIV viral loads is not always included as a process measure of ART program performance, but previous studies found 60-95% of patients had 12-month HIV viral loads available for calculation of viral load suppression (Bedelu et al., 2007; Brennan et al., 2011; Fairall et al., 2012; Sanne, 2010). In this capstone project, compliance with viral load testing required a test within 30 days of the viral load due date. This allowed for blood sample collection one month before or after the actual test deadline, but it may be more restrictive than definitions of compliance used in other studies.

The low rate of compliance with HIV viral load testing is surprising given that professional nurses in this clinic associate undetectable HIV viral loads with treatment success. Nurses also describe manual pill counts as an important process of care during ART follow-up visits. It is possible that low rates of HIV viral load testing reflect over-reliance on adherence assessments to ascertain treatment success. However, additional research will be necessary to identify nurse barriers to HIV viral load testing. Reported barriers to HIV viral load testing in

South Africa largely focus on testing technologies and clinical laboratory capacities (Stevens and Marshall, 2010).

Compliance with routine CD4 count collection was similar to HIV viral load testing (57.7% vs. 61.5%, respectively). This is an expected finding as paired CD4 count and HIV viral load tests are required following 12 months on treatment. In April 2013, repeat CD4 count testing was no longer required at annual intervals (Republic of South Africa, 2013). This reflects a national shift towards HIV viral load monitoring as the primary measure of treatment efficacy.

Last, clinic observations revealed that weight collection typically occurs during collection of other vital signs and is documented medical records kept by patients. This may account for missing weight data associated with follow-up appointments. Overall 80.7% of follow-up visits were associated with a body weight, suggesting that nurses do routinely evaluate patient weight as part of the clinical encounter.

Outcomes

3. How did nurses perceive the effectiveness of integrating ART services into primary care encounters?

NIMART is viewed by professional nurses as effective in improving health outcomes of patients with HIV infection. This is consistent with qualitative findings on NIMART implementation in other South African clinics (Davies et al., 2013). In this clinic, ensuring confidentiality of patients' HIV status during medical appointments greatly contributed to patient retention in the NIMART program. Nurses discussed how patients' fear of HIV disclosure increased risk for program loss and ultimately for treatment failure. The importance placed on stigma as a factor in NIMART outcomes is notable.

There is limited evidence that co-location and sharing of HIV and PHC resources can reduce stigmatization of ART services utilization (Odeny et al., 2013). While the clinic does share space and resources between NIMART and other PHC programs, there are multiple factors that increase risk for accidental disclosure of patients' HIV status. For example, HIV-specific clinics are organized to accommodate nurse preference. As a result, patients attending clinic on these days are more likely to be associated with HIV. Use of NIMART medical charts that are conspicuously different in appearance from other charts distinguish HIV-infected patients from other clinic attendees. Finally, ART staffing concentrates NIMART patients within a small pool of nurses. There is anecdotal evidence that greater integration of ART services can promote greater adherence to medical follow-up by reducing the patient perceptions of stigmatization (Uebel, 2013). This is an important area for further study, as improving acceptability of services will be critical to retaining the clinic's patients in care for extended periods.

4. What are the clinic's HIV-related patient outcomes?

This study presents evidence that patients who continue in ART care have high rates of viral suppression. At 12 months 89.5% of ART patients with available HIV viral load results had undetectable viral loads. This is similar to findings from other studies in which nurses started patients on antiretroviral medications (Bedelu et al., 2007; Fairall et al., 2012). Statistically significant improvements in weight and immune function were also observed within two years. These findings confirm that NIMART programs can be effective in reducing HIV/AIDS associated morbidity in rural South Africa.

Definitions of loss to follow-up can result in differences in reported retention in care (Grimsrud, Cornell, Eggar, Boulle & Myer, 2013). In this capstone project, loss to follow-up

included patients who were prescribed ART but never presented for follow-up; loss to follow-up was defined as missing three consecutive clinic visits. Among the 22 of patients who missed three or more consecutive clinic visits, four had returned to care by the time the study ended. This is an important consideration given the life-long nature of HIV treatment. When calculating all patients actively attending visits at the end of chart review, the percentage alive and in care rose to 69.5%.

At 2 years, program retention in this study approached the national target of 70%. Active tracking of NIMART patients allows clinic staff to quickly identify those missing follow-up appointments. Intensified adherence interventions should be targeted to these individuals to foster improved treatment adherence. For example, HIV-infected individuals with severe mental illness may benefit from case management services (Joska, Obayemi, Cararra, & Sorsdahl, 2014). Weekly cellphone-based text reminders have been efficacious in improving ART adherence in low-income countries and represent a low cost approach to improving the clinic's NIMART outcomes (Pop-Eleches et al., 2011). Based on the number of patients who used cell phones during their clinic visits, cell phone uptake in the clinic's service area appears to be high.

It should also be considered that missed clinic appointments might not reflect discontinuation of antiretroviral therapy. The clinic's NIMART program is organized as part of a district health system, with multiple PHC facilities supported by an external hospital-based HIV specialty care program. This author was unable to track movement of patients across treatment sites. It is expected that some patients lost to follow-up accessed ART services in other treatment locations. The national goal is to keep patients alive and on treatment, but failure to distinguish retention in this clinic from retention in the larger district health system will lead to biased estimates of NIMART's effectiveness (Geng, 2011).

Overall, the 6.5% mortality reported in this capstone project is similar to other NIMART outcomes reported in the literature, including a larger, randomized trial reporting mortality as high as 20% at 24 months (Fairall et al., 2012). Deaths occurred exclusively in patients with CD4 counts less than 200 cells/mm^3, supporting findings that progression of HIV disease predicts risk for mortality (Fox et al., 2010). From a public health standpoint, these findings substantiate a need for treating HIV infected individuals with CD4 counts greater than 200 cells/mm^3, a problem addressed through 2012 interim updates to the national treatment guidelines.

Limitations

There were several limitations in this project. First, data abstraction was limited to District Health Information System reports and patient medical chart review. Given that multiple charts and registers are used for documentation of clinic services, it is possible that the procedures described in this capstone project failed to capture elements of NIMART care documented elsewhere. Missing data in patient ART files may further limit conclusions concerning the number of patients retained in care, as well as their clinical outcomes. Currently, the national quality target for retention in ART care is five years. Due to the recent implementation of the clinic's NIMART program, final endpoints for outcomes assessments were limited to 2 years. As risk of loss to follow-up and viral rebound are known to increase overtime, findings from this study should not be extrapolated to predict long-term outcomes.

While process and outcomes measures were prioritized based on their scientific validity, this capstone project has a limited number of process and outcomes measures. Process and outcomes measures were selected in accordance with South African national ART guidelines (National Department of Health, 2013; National Department of Health; 2010). However, not all recommendations for ART initiation and monitoring were included due the number and

complexity of clinical tasks associated with HIV treatment. This evaluation is restricted to major pre-ART assessments, proper drug prescription, and post-treatment monitoring. Process measures do not reflect guidelines for the management of patients with tuberculosis and HIV co-infections or hepatitis B or hepatitis C and HIV co-infections.

While structures, processes, and outcomes were included in the clinic's NIMART evaluation, no measures specific to patient satisfaction were collected. Donabedian (1980) recognized patient satisfaction as an integral component of quality health care services. However, HIV stigma in the larger South African community poses real risks to patients engaged in HIV care and related research. Indeed, staff recognized stigma as one the largest barriers to ART program retention. For this reason, nurse satisfaction with the ART program was selected as an alternate source of data. Last, as this research was organized to assess nurse-led ART services in one rural PHC clinic, the findings may not be generalizable to other clinics.

Conclusion

The clinic has multiple structures in place that support effective NIMART services. Nurses successfully identify patients meeting treatment criteria and are able to start them on treatment within two months. Strong compliance with recommendations for pre-ART care was observed, and increasing baseline CD4 counts suggest that nurses respond quickly to changes in treatment eligibility criteria. Relatively few patients have been on treatment for greater than 12 months, perhaps explaining greater compliance with early enrollment activities, specifically those focusing on ART initiation. With an increasing number of patients already established on ART, nurses must expand their attention to fostering long-term program retention, preventing opportunistic infections, and performing recommended laboratory testing to ensure early recognition of treatment failure.

The results of this capstone project can inform efforts to improve quality of ART services in PHC facilities. Detailed information on which PHC structures are necessary to support effective NIMART programs can aid PHC administrators to more effectively allocate scarce resources in rural communities. Data on the clinic's compliance with national treatment guidelines and NIMART-related outcomes can be used for benchmarking in this clinic and in similar PHC settings. Exploring barriers to nurse prescription of TMP-SMX and HIV viral load testing are suggested as a starting point for quality improvement activities in this clinic. Small changes in NIMART medical chart management may also improve acceptability of HIV-related services. At the administrative level, redesign of program files and clinic registers is suggested as a short-term intervention for reducing stigmatization of HIV services. However reorganization of larger PHC administrative structures maybe required for greater integration of PHC documentation systems. This is expected to have implications for PHC organization and management at the provincial levels.

On a national scale, nurses should lead efforts to improve HIV-related service delivery in PHC. This is likely to include testing of new care models and implementing evidence-based practice changes. In the U.S., nurses with advanced practice training are prepared to implement and evaluate clinical practice changes; however, in South Africa there is no standardized definition of advanced practice nurses. The South African Nursing Council (2011) recently acknowledged two categories of advance practice nurses as described by the International Council of Nurses: clinical nurse specialists and advanced nurse practitioners. In a 2011 policy statement, the council recognized PHC nurses as having similar roles as advanced nurse practitioners and is considering elevating PHC nurses to APN status following standardization of education and training requirements (South African Nursing Council, 2011). This offers an

exciting opportunity for the country to strengthen its PHC workforce and better prepare PHC facilities to lead advancements in HIV-related service delivery. Nurses in academic settings can support their PHC colleagues by partnering with PHC facilities to conduct needed research.

This capstone project demonstrates that NIMART programs can be effective in improving HIV outcomes in rural South Africa. From a policy standpoint this has tremendous implications for South Africa's nursing workforce. PHC settings will remain key access points for HIV and ART services, increasing the need for nurse advocacy during national, district, and local ART planning. Nurses who provide NIMART are largely positive regarding their role in community based HIV treatment but are challenged by flawed work environments and workloads and that threaten efficiency of PHC operations. Significant investments in PHC infrastructure and human resources will be needed to support their growing role in reducing HIV associated morbidity and mortality in Vhembe.

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Appendix A

Table 1

Summary of Studies Reporting Variables Consistent with Donabedian's Structure Process Outcome Model

Citation	ART Program Model	Research Design	Structures	Processes	Outcomes
Bedelu et al. (2007)	NIMART	Descriptive - Retrospective Cohort Analysis			X
Brennan et al. (2011)	Down Referral	Observational- Matched Cohort			X
Cohen et al. (2009)	NIMART	Descriptive-Case Study	X		X
Decroo et al. (2009)	Down Referral	Qualitative- Case Study	X		
Fairall et al. (2012)	NIMART and Down Referral	Parallel Cluster Randomized Trial		X	X
Humphreys et al. (2010)	Down Referral	Observational- Prospective Cohort			X
Janse van Rensburg et al. (2008)	Down Referral	Qualitative	X		
Long et al. (2011)	Down Referral	Observational- Matched Cohort			X
O'Connor et al. (2011)	Down Referral	Descriptive- Retrospective Cohort Analysis			X
Sanne et al. (2010)	Down Referral	Randomized Trial			X
Searle et al. (2010)	Down Referral	Descriptive- Retrospective Cohort Analysis		X	X
Shumbusho et al. (2009)	NIMART	Descriptive- Retrospective Cohort Analysis		X	X
Stein et al. (2007)	Down Referral	Qualitative	X		
van Rensburg et al. (2008)	Down Referral	Qualitative	X		

Table 2

Characteristics of Studies Reporting Health Outcomes

Study	Nurse-led ART Model	Setting	Design	Sample Size	Age (years) *a-median(IQR)* *b-mean(SD)*	% Female	Baseline HIV-related Characteristics		Nurse-Led ART Eligibility
							Treatment Group *a-median(IQR)* *b-mean(SD)*	Comparison Group *a-median(IQR)* *b-mean(SD)*	
Bedelu et al. (2007)	NIMART	Rural PHC and one rural hospital in Lusikisiki, South Africa.	Descriptive-Retrospective Program Evaluation	N=1025	N.R.	N.R.	PHC (Nurse) based Care: CD4<50 cells/mm^3= 19.2%	Hospital (Doctor) based Care: CD4<50 cells/mm^3= 26.3%	N.R.
Brennan et al. (2011); Long et al. (2011)	Down Referral	Urban PHC in Johannesburg, South Africa.	Observational Cohort	N=2772	Down Referral PHC: 35.2(31.0-40.7)[a] HIV Specialty Facility: 35.2(30.7-41.8)[a]	Down Referral PHC: 65.2 HIV Specialty Facility: 65.8	Duration on ART at Down Referral Eligibility[a]= 28.7(19.7-38.7) months	Duration on ART at Down Referral Eligibility[a]= 30.0(24.0-42.0) months	On treatment ≥ 11 months, no evidence of opportunistic infections, CD4 count >200 cells/mm^3, stable weight, and viral load suppression (<400 copies/ml).

Cohen et al. (2009)	NIMART	14 rural PHC in Scott Catchment, Lesotho.	Descriptive Case-study	N=4061	N.R.	N.R	N.R.	N.R.	ART initiation and follow-up care based on national treatment guidelines
Fairall et al. (2012)	NIMART and Down Referral	31 PHC facilities in Free State Province, South Africa.	Parallel Cluster-Randomized Controlled Trial: NIMART vs. Down Referral	Cohort 1 (Patients Not on ART at Study Start)					ART initiation and follow-up care based on national treatment guidelines
				N=9252	NIMART[a] =36 (30-43) Down Referral[a] =35 (29-42)	NIMART=67 Down Referral=69	NIMART: CD4 count <50 cells/mm^3 = 17%	Down Referral: CD4 count <50 cells/mm^3 = 18%	
				Cohort 2 (Patients on ART ≥6 months at Study Start)					
				N=6231	NIMART [a] = 38 (32-44) Down Referral[a] = 38 (32-45)	NIMART=70 Down Referral=73	NIMART: Duration on ART [a] = 13.9(6.8-21.7) months Viral load <400 copies/ml= 79%	Down Referral: Duration on ART[a] = 13.7 (7.3-22.3) months Viral load <400 copies/ml= 78%	
Humphreys et al. (2010)	Down Referral	15 rural PHC and 1 hospital in Lubombo, Swaziland.	Observational Cohort	N=474	PHC (Nurse) Care[b]= 39.3(10.9) Hospital Care[b]= 40.0(11.8)	PHC (Nurse) Care= 67 Hospital Care=68	PHC (Nurse) Care: Duration on ART[b]= 347(278) days WHO Stage 5 HIV disease: 20%	Hospital Care: Duration on ART[b]= 506(334) WHO Stage 5 HIV disease: 22%	Adults (ages 14+) on ART ≥4 weeks, CD4 count >100 cells/mm^3, and deemed stable by a medical officer. Criteria for determining patient

									stability not reported.
O'Connor, Osih, & Jaffer (2011)	Down Referral	4 urban PHC in Johannesburg, South Africa.	Descriptive-Retrospective Program Evaluation	N=3361	38.2[b]	71	Duration of ART[a]= 1.56 (0.64-2.24) years		On ART ≥6 months with improving CD4 count, undetectable viral load, no evidence of opportunistic infections, and good adherence to treatment.
Sanne et al. (2010)	Down Referral	2 urban PHC in Johannesburg and Cape Town, South Africa.	Randomized Controlled Trial: Nurse Care vs. Doctor Care in PHC	N=812	Nurse Care[a]= 32.3(28.0-36.6) Doctor Care[a]= 32.2(28.9-37.4)	Nurse Care= 73.5 Doctor Care= 67.7	Nurse Care: CD4 count <200 cells/mm^3= 64.4%	Doctor Care: CD4 count <200 cells/mm^3 = 63.0%	On ART <6 weeks, ≥ 16 years of age; CD4 count <350 cells/mm^3 or with a prior AIDS defining illness, and not in the first trimester of pregnancy.
Searle, Ramkissoon, & Govender (2010)	Down Referral	24 PHC in KwaZulu-Natal, South Africa.	Descriptive-Retrospective Program Evaluation	N=2071	37[a]	72	Undetectable viral load= 99.6% CD4 count[b]= 296 cells/mm^3		On ART ≥ 6 months and evaluated by a physician as stable on ART. Criteria for determining patient

									stability not reported.
Shumbusho et al. (2009)	NIMART	3 rural PHC clinics in Muhanga and Nyanza, Rwanda.	Descriptive-Retrospective Program Evaluation	N=435	39(33-46)[a]	63.4	WHO Stage 5 HIV Disease= 2.1%		ART initiation and follow-up care based on national treatment guidelines
Zwarenstein et al. (2011).	Down Referral	15 PHC facilities in five districts of Free State Province, South Africa.	Cluster Randomized Trial: Down Referral with Syndrome-based Guideline vs. Standard Down Referral	N= 9733	Guideline= 35.4[b] No Guideline= 35.6[b]	Guideline=65 No Guideline =66	Down Referral PHC with Guideline: CD4 count <200 cells/mm^3= 43% WHO Stage 3 or 4 HIV Disease= 58%	Down Referral PHC without Guideline : CD4 count <200 cells/mm^3 = 40% WHO Stage 3 or 4 HIV Disease= 60%	N.R.

Table 3

Key Health Outcomes Reported in the Literature

Study	ART Model	% Retained in care *a- at 12 months* *b- at 24 months* *c- overall*	% Mortality *a- at 12 months* *b- at 24 months* *c- overall*	% Lost to follow-up *a- at 12 months* *b- at 24 months* *c- overall*	CD4 change at 12 months (cells/ mm^3) *a- median (IQR)* *b- mean*	% with HIV viral load suppression *a- at 6 months* *b- at 12 months* *c- overall*	Mean weight gain (kg) at follow-up
Bedelu et al. (2007)	NIMART	81.0% PHC vs. 67.2% Hospital[c] (p<.001)	16.8% PHC vs. 13.5 % Hospital[c] (N.S.)	2.2% PHC vs. 19.3% Hospital[c] (p<.001)	N.R.	89.5% PHC vs. 78.0% Hospital[b] (p=.033)	N.R.
Brennan et al. (2011); Long et al. (2011)	Down Referral	98.3% PHC vs. 94.2% Specialty Clinic[a]	0.3% PHC vs. 1.5% Specialty Clinic[a]	1.4% PHC vs. 4.2% Specialty Clinic[a]	PHC: 55 (-24-127) cells/mm^3 Specialty Clinic: 59(-12-146) cells/mm^{3a}	96.7% PHC vs. 94.4% Specialty Clinic[b]	N.R.
Cohen et al. (2009)	NIMART	80.1%[a] & 76.5%[b] PHC	11.1%[a] & 14.1%[b] PHC	8.8%[a] & 9.4%[b] PHC	N.R.	N.R.	N.R.
Fairall et al. (2012)	Down Referral and NIMART	Cohort 1 (Not on treatment at study start)					
		63% NIMART vs. 58% Down Referral[a] (p<.001)	20% NIMART vs. 19% Down Referral[c]	N.R.	N.R.	72% NIMART vs. 73% Down Referral[c] (N.S.)	3.6 NIMART vs. 4.4 Down Referral (N.S.)
		Cohort 2 (On treatment at study start)					

		90% NIMART vs. 91% Down Referral[a] (N.S.)	N.R.	N.R.	Mean CD4 count at follow-up: 438.8 cells/mm^3 NIMART vs. 418.4 cells/mm^3 Down Referral (p=.007)	71% NIMART vs. 70% Down Referral [c] (N.S.)	2.0 NIMART vs. 1.2 Down Referral (p=0.045)
Humphreys et al. (2010)	Down Referral	N.R.	0.9% PHC vs. 2.5% Hospital[c] (p=.01)	2.4% PHC vs. 1.3% Hospital[c] (N.S.)	103 PHC vs. 85 Hospital[b] (N.S)	N.R.	1.09 PHC vs. 1.04 Hospital (N.S.)
O'Connor, Osih, & Jaffer (2011)	Down Referral	95.45%[c] PHC	0.2%[c] PHC	4%[c] PHC	N.R.	N.R.	N.R.
Sanne et al. (2010)	Down Referral	80.2% Nurse Group vs. 81.9% Doctor Group[c]	3% Nurse Group vs. 3% Doctor Group[c] (N.S.)	4% Nurse Group vs. 3% Doctor Group[c] (N.S.)	155 (119-193) cells/mm^3 Nurse Group vs. 158 (125-169) cells/mm^3 Doctor Group[a]	N.R.	N.R.
Searle, Ramkissoon, & Govender (2010)	Down Referral	84%[c] PHC	N.R.	13%[c] PHC	N.R.	97%[a] & 93[b] PHC	N.R.
Shumbusho et al. (2009)	NIMART	92%[a] & 80%[b] PHC	7% PHC	< 1%[c] PHC	97-128 cells/mm^3 (depending on WHO stage) PHC[b]	N.R.	1.8-4.4 (depending on WHO clinical stage)
Zwarenstein et al. (2011).	Down Referral	N.R.	20% Intervention PHC vs. 22% Control PHC[a] (N.S.)	N.R.	N.R.	85% Intervention PHC vs. 88% Control PHC[a] (N.S.)	2.3 Intervention PHC vs. 1.9 Control PHC (p<.001)

Note: N.S. denotes non-statistically significant result.

Table 4

Process, Outcomes, and Clinic Demographics Variables, Their Operational Definitions, and Data Sources

	Variable * All adult populations (ages 15+) unless stated otherwise	**Operational Definition**	**Data Source** 1-NIMART Patient Records 2- Clinic Attendance Register	**Type of Variable** 1-Processes 2-Outcomes
1	WHO clinical staging	Performance of WHO clinical staging has been reported as a proportion. **Numerator:** the total number of patients with WHO staging documented in their medical record at initiation of ART. **Denominator:** the number of patients initiated on ART.	1	1
2	Baseline CD4 count	Performance of baseline CD4 count testing has been reported as a proportion and calculated for each calendar year and overall. **Numerator:** the number of patients with a CD4 count test date within two months of ART initiation. **Denominator:** the number of patients initiated on ART.	1	1
	Baseline weight	Performance of weight measurement has been reported as a proportion and calculated for each calendar year and overall. **Numerator:** the number of patients with baseline weight dated within two weeks prior to ART initiation. **Denominator:** the number of patients initiated on ART.	1	1

	Physical exam at ART intake	Performance of physical exams has been reported as a proportion and calculated per calendar year and overall. **Numerator:** the number of ART patients with physical exam dated on day of program intake. **Denominator:** the number of patients initiated on ART.	1	1
3	Baseline serum creatinine	Performance of serum creatinine testing has been reported as a proportion and calculated for each calendar year and overall. **Numerator:** the number of patients with a serum creatinine test date prior to or on day of starting a tenofovir-containing regimen. **Denominator:** the number of patients initiated onto ART with a tenofovir-containing regimen.	1	1
4	Baseline alanine aminotransferase	Performance of baseline alanine aminotransferase testing has been reported as a proportion and calculated for each calendar year and overall. **Numerator:** the number of patients with an alanine aminotransferase test date prior to or on day of starting a nevirapine-containing regimen. **Denominator:** the number of patients initiated onto ART with a nevirapine-containing regimen	1	1

15	Baseline hemoglobin	Performance of baseline hemoglobin testing has been reported as a proportion and calculated for each calendar year and overall. **Numerator:** the number of patients with a hemoglobin test date prior to or on day of starting a zidovudine-containing regimen. **Denominator:** the number of patients who received a zidovudine-containing regimen as their initial ART regimen	1	1
7	TMP-SMX prophylaxis	Appropriate TMP-SMX prescription has been reported as a proportion and calculated for each calendar year and overall. **Numerator:** the number of ART eligible patients with CD4 counts <200 cells/mm^3, or WHO stages 2-4 disease and prescribed TMP-SMX prophylaxis within 2 months of ART initiation. **Denominator**: the number of ART eligible patients with CD4 counts <200 cells/mm^3 and/or WHO stages 2-4 disease.	1	1
8	Patients eligible for ART initiation	The proportion of patients started on antiretroviral medications that where eligible for treatment per calendar year and overall. Eligibility for ART was determined based on then current South African antiretroviral treatment guidelines. The following eligibility criteria applied to HIV infected patients from January 1, 2011 to May, 2012: • Any adolescent or adult with CD4<200 cells/mm^3 **OR** • Any patient with tuberculosis and CD4 count <350	1	1

		cells/mm^3 **OR** • Any pregnant women with CD4 count <350 cells/ mm^3 or WHO stage 3 or 4 disease **OR** • Any patient with WHO stage 4 disease (regardless of CD4 count) **OR** • Any patient with multidrug resistant or extremely multidrug resistant tuberculosis (regardless of CD4 count). Between May 1, 2012 to March 31, 2013, eligibility was defined as: • Any adult or adolescent with CD4 count <350 cells/mm^3 **OR** • Any patient with tuberculosis (regardless of CD4 count) **OR** • Any pregnant women with CD4 count <350 cells/mm^3 or WHO stage 3 or 4 **OR** • Any patient with WHO stage 4 disease (regardless of CD4 count) **OR** • Any patient with multidrug resistant or extremely multidrug resistant tuberculosis (regardless of CD4 count). As of April 1, 2013 eligibility was defined as: • Any adult or adolescent with CD4 count <350 cells/mm^3 **OR** • Any patient with tuberculosis (regardless of CD4 count) **OR** • HIV positive women who are pregnant or breast feeding **OR** • Patients with tuberculosis meningitis or cryptococcal meningitis **OR** • Patients with WHO stage 3 or 4 disease		

9	Appropriate ART regimen	Appropriate ART prescription has been reported as a proportion and calculated for each calendar year and overall. **Numerator:** the number of patients on first line ART regimens as identified in then current South African antiretroviral treatment guidelines. **Denominator:** the number of patients initiated on ART	1	1
10	Weight collected at each visit	Performance of weight measurement has been reported as a proportion and calculated for each calendar year and overall. **Numerator:** the number of ART patients with weight documented at each follow-up visit. **Denominator:** the number of ART patients in care at each interval.	1	1
11	Routine HIV viral load	Performance of routine HIV viral load testing has been reported as a proportion and calculated at six, 12, and 24 months post ART initiation. **Numerator:** the number of patients with documented HIV viral load results at six, 12, and 24 months post initiation. Viral results within 30 days of each due date were considered compliant. **Denominator:** the number of patients on ART at each time point.	1	1
12	Routine CD4 count	Performance of routine CD4 count testing has been reported as a proportion and calculated at six, 12, and 24 months post ART initiation	1	1

		Numerator: For those who reached six months of ART follow-up prior to May 2012 the numerator was the number of patients with CD4 count results at six 12, and 24 months. If individuals met the six month endpoint after May 1, 2012, then performance with CD4 count collection was assessed at 12 months only. CD4 results within 30 days of each due date were considered compliant **Denominator:** the number of patients on ART at each end point.		
13	Change in ART regimen	Changes in ART regimen were reported as a proportion and calculated per calendar year and overall. **Numerator:** the number of patients with documented changes to initial ART regimen. **Denominator:** the number of patients initiated on ART	1	1
14	Missed clinic visits	The median/mean number of missed monthly follow-up appointments per client initiated onto ART.	1	2
25	Retention in Care	The proportion of patients remaining on ART and having a documented clinical follow-up visit less than three months from the previous visit. Retention in care has been calculated at six, 12, and 24 months of follow-up. **Numerator:** the number of patients on ART with last clinic visit within three months of each deadline **Denominator:** the number of patients initiated on ART at each interval.	1	2
16	ART patients lost to follow-up	The proportion of ART patients with no follow-up visit for three or more months. Loss to follow-up has been	1	2

		calculated at six, 12, and 24 months of follow-up. **Numerator:** the number of patients with no ART follow-up visit for three or more months on meeting follow-up endpoint. **Denominator:** the number of patients initiated on ART by each endpoint.		
17	Death	The proportion of patients initiated onto ART who died. Death has been calculated per calendar year and overall. **Numerator:** the number of patients with documented death **Denominator:** the number of patients initiated on ART at each interval.	1	2
18	HIV viral load suppression	The proportion of ART patients with an HIV viral load of less than 400 copies/ml. Viral load suppression has been calculated at six, 12, and 24 months. **Numerator:** the number of patients in each interval with an HIV viral load result less 400 copies/ml. In the absence of a viral load collected on the month of an endpoint, an HIV viral load collected within two months of the endpoint was used. **Denominator:** the number of patients on ART in each interval with an HIV viral load result	1	3
19	Difference in Mean CD4 count at 12 months.	The difference in mean CD4 counts at baseline and 12 months on treatment. Mean CD4 counts were calculated using the baseline result and the result closest to the 12 month treatment date (excluding 6 month CD4 counts). Statistical analysis was performed using a paired Student t	1	3

		test.		
20	Difference in Mean Weight	The difference in mean weight at baseline and at last measurement. Statistical analysis was performed using a paired Student t test.	1	3
21	Post-initiation opportunistic infections	The proportion of patients diagnosed with either *Pneumocystis jiroveci* pneumonia or toxoplasmosis. **Numerator**: the number of patients initiated on ART with diagnosis of *Pneumocystis jiroveci* pneumonia or toxoplasmosis. **Denominator:** the number of patients initiated on ART.	1,2	3

Table 5

Trained Clinical Staff by HIV-related Program

Course Title	Staff trained	Total Trained	Training Required
Adherence Counseling	OM, PN	3	no
Basic Antenatal Care	OM, PN	4	no
Comprehensive Care, Management, and Treatment of HIV	OM, PN	3	no
Couples HIV Counseling	LC, PN	2	yes
HIV Counseling and Testing	LC, OM, PN	6	yes
Integrated Management of Childhood Illness	OM, PN	8	no
Medication Dispensing	OM, PN	3	no
Nurse Initiation and Management of ART	OM, PN	4	yes
Prevention mother to Child Transmission	OM, PN	6	yes
TB/STI/HIV Comprehensive Care	OM, PN	3	no

Note: Order of listing reflects order of program implementation within the clinic, thus HIV counseling and testing was the first HIV related service provided.
Legend: LC=lay counselor; OM=operational manager; PN=professional nurse

Table 6

Availability of Selected HIV-related Medications

Selected Medications included in HIV-related Guidelines	**In Stock on 7/17/2012**	**Notes:**
acyclovir		Requires referral/MD prescription
chlorpheniramine	X	
TMP-SMX (double strength)	X	
TMP-SMX (single strength)	X	
dapsone		Requires referral/MD prescription
efavirenz	X	
emtricitabine	X	Available as component of combination drug only
erythromycin		Temporary shortage
erythromycin syrup	X	
ethambutol	X	
influenza vaccine		Temporary shortage
fluconazole		Requires referral/MD prescription
gentian violet solution	X	
hydrocortisone 1%	X	
INH	X	
lamivudine	X	
loperamide	X	
lopinavir/ritonavir		Temporary shortage
nevirapine	X	
nevirapine syrup	X	
paracetamol	X	
paracetamol syrup	X	
pyrazidamide	X	
pyridoxine	X	
rifampicin	X	
stavudine	X	
streptomycin	X	
tenofovir	X	
tramadol		Requires referral/MD prescription
zidovudine	X	
zidovudine IV	X	

Note: HIV-related medications for adults and adolescents were selected clinical guidelines: Clinical Guidelines for the Management of HIV & AIDS in Adults and Adolescents (2010); Guidelines for Tuberculosis Preventive Therapy Among HIV Infected Individuals in South Africa (2010); Practical Approach to Lung Health and HIV/AIDS in South Africa (PALSA

PLUS) (2012); South African Antiretroviral Treatment Guidelines (2010); Standard Treatment Guidelines and Essential Drugs List, Primary Health Care (2008)

Table 7

Compliance with ART Initiation Guidelines

Variable	n/Total	Percentage
Physical Exam at ART Initiation		
2011	21/27	77.8%
2012	31/54	57.4%
2013	6/11	54.5%
Overall	57/92	62.0%
WHO Staging Documented at ART Initiation		
2011	27/27	100%
2012	54/54	100%
2013	11/11	100%
Overall	92/92	100%
Baseline CD4 Count Collection (within two months of ART initiation)		
2011	23/27	85.2%
2012	47/53	88.7%
2013	9/12	75%
Overall	79/92	85.9%
Baseline Weight Assessment (within two weeks of ART initiation)		
2011	26/27	96.3%
2012	51/54	94.4%
2013	9/11	81.8%
Overall	86/92	93.5%

Note: Data collection for 2013 is limited to the following period: January 1, 2013-April 25, 2013

Table 8

Regimen Specific Lab Testing (Retrospective Medical Record Review)

Variable	n/Total	Percentage
Baseline Alanine Aminotransferase in Patients on Nevirapine-containing Regimens		
2011	0/0	
2012	¾	75%
2013	0/0	
Overall	¾	75%
Baseline Hemoglobin in Patients on Zidovudine-containing Regimens		
2011	6/6	100%
2012	2/2	100%
2013	0/0	
Overall	8/8	100%
Baseline Serum Creatinine in Patients on Tenofovir-containing Regimens		
2011	20/21	95.2%
2012	43/47	91.5%
2013	10/11	90.9%
Overall	73/79	92.4%

Note: Data collection for 2013 is limited to the following period: January 1, 2013-April 25, 2013

Table 9

Trimethoprim-Sulfamethoxazole (TMP-SMX) Prescription

Variable	n/Total	Percentage
TMP-SMX for CD4<200 cells/mm3or WHO Stage 2-4 Disease (within two months of ART start)		
2011	11/24	45.8%
2012	20/50	40.0%
2013	5/8	62.5%
Overall	36/82	43.9%
TMP-SMX prescription by CD4 counts		
CD4 count <50 cells/mm3	5/8	62.5%
CD4 count <200 cells/mm3	22/51	43.2%
CD4 count ≥200 cells/mm3	14/31	45.2%

Note: Data collection for 2013 is limited to the following period: January 1, 2013-April 25, 2013

Table 10

Compliance with Routine Clinical Follow-up

CD4 Count Collection		
@ Six months follow-up (+/- 30 days)	13/17	76.5%
2011	8/12	66.7%
2012 (Jan-Apr only)	5/5	100%
@ 12 months follow-up (+/- 30 days)	15/26	57.7%
2012	12/20	60%
2013	3/6	50%
@24 months follow-up (+/- 30 days)		
2013	1/4	25%
HIV Viral Load Collection		
@ Six months follow-up (+/- 30 days)	31/50	62%
2011	6/12	50%
2012	22/30	73.3%
2013	3/8	37.5%
@ 12 months follow-up (+/- 30 days)	18/26	69.2%
2012	14/20	70%
2013	4/6	66.7%
@ 24 months follow-up (+/- 30 days)	1/4	25%
Weight at Each Follow-up Visit		
2011		
% Patients with Weight at Each Visit	7/23	30.4%
% Visits with Documented Weight	89/124	71.8%
2012		
% Patients with Weight at Each Visit	32/64	50%
% Visits with Documented Weight	357/428	83.4%
2013		
% Patients with Weight at Each Visit	38/64	59.4%
% Visits with Documented Weight	148/184	80.4%
Overall		
% Patients with Weight at Each Visit	29/79	35.4%
Overall- % Visits with Documented Weight	594/736	80.7%

Note: Data collection for 2013 is limited to the following period: January 1, 2013-April 25, 2013

Table 11

Demographics of Patients Enrolled in ART

Variable	n/Total	Percentage
Sex		
Male	24/92	26.1%
Female	68/92	73.9%
Age at ART Initiation		
Mean (SD): 38.9 (11.06) years		
Median: 37.4 years		
Median Age at Initiation by Sex		
Male: 38.7 years		
Female: 36.9 years		
WHO Stage at ART Initiation		
Stage 1	20/92	21.7%
Stage 2	31/92	33.7%
Stage 3	38/92	41.3%
Stage 4	3/92	3.3%
Baseline CD4 Counts (cells/mm^3)		
2011 Mean (SD): 149.4 (97.6)		
2011 Median: 120		
2012 Mean (SD): 213.1 (133.1)		
2012 Median: 189		

Appendix B.

Structure-Process-Outcome Model

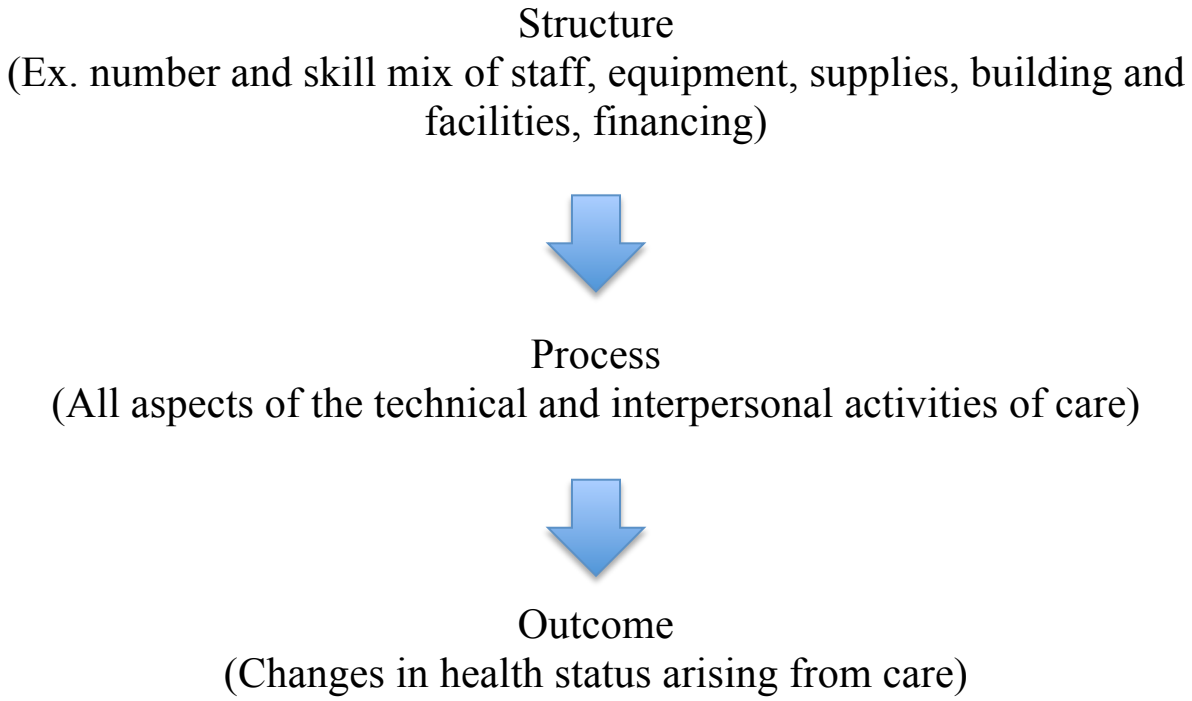

Figure 1. Structure Process Outcome Model used to guide the clinic's ART program evaluation. Adapted from "The Definition of Quality and Approaches to its Assessment," by A. Donabedian, 1980, Ann Arbor, MI: Health Administration Press.

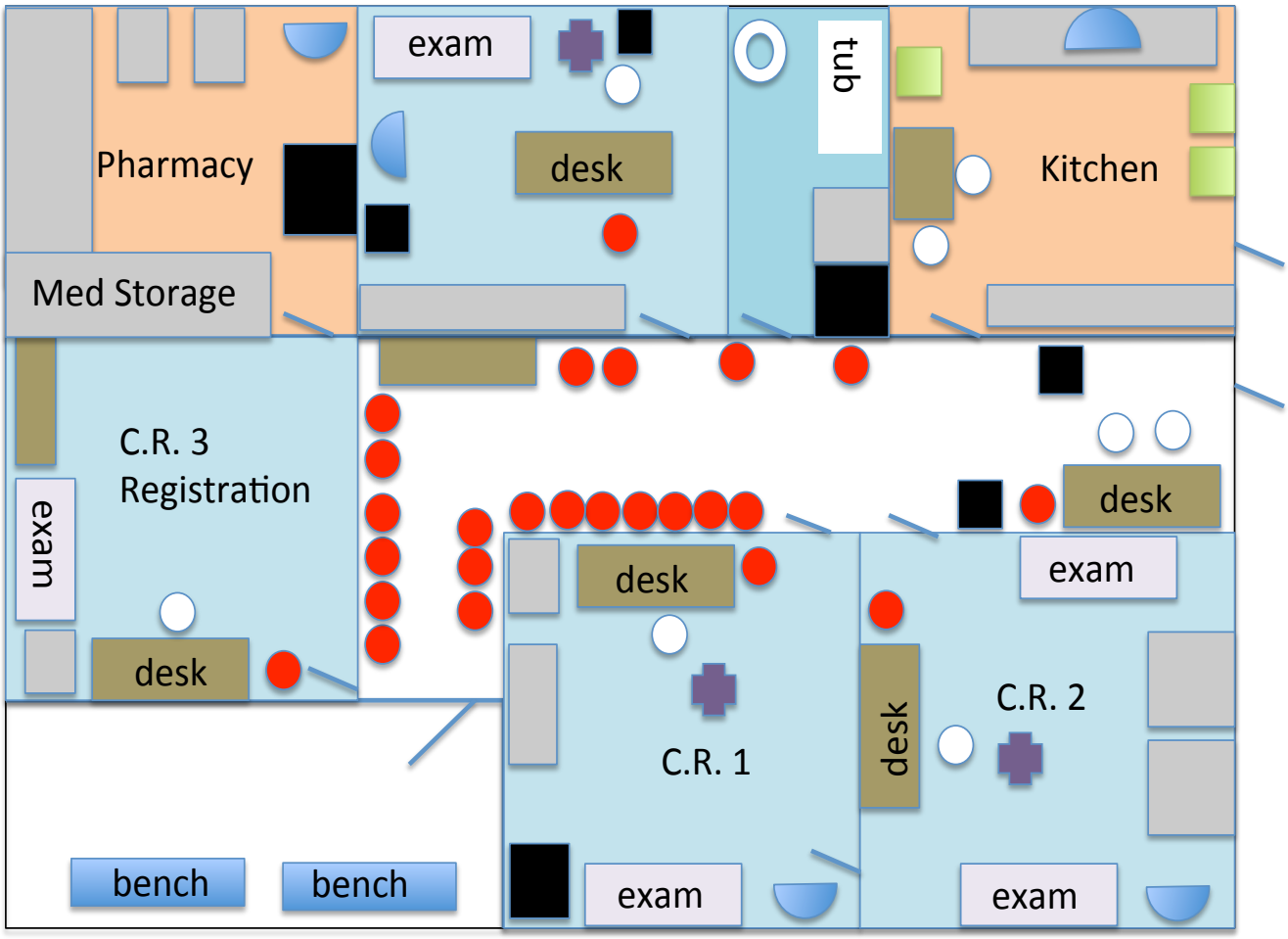

Figure 2. General Clinic Floor Plan. Red circles denote chairs for client seating. White circles denote seating for clinic staff. Purple crosses denote mobile medication trolleys. Exam=examination table; Desk=consultation desks.

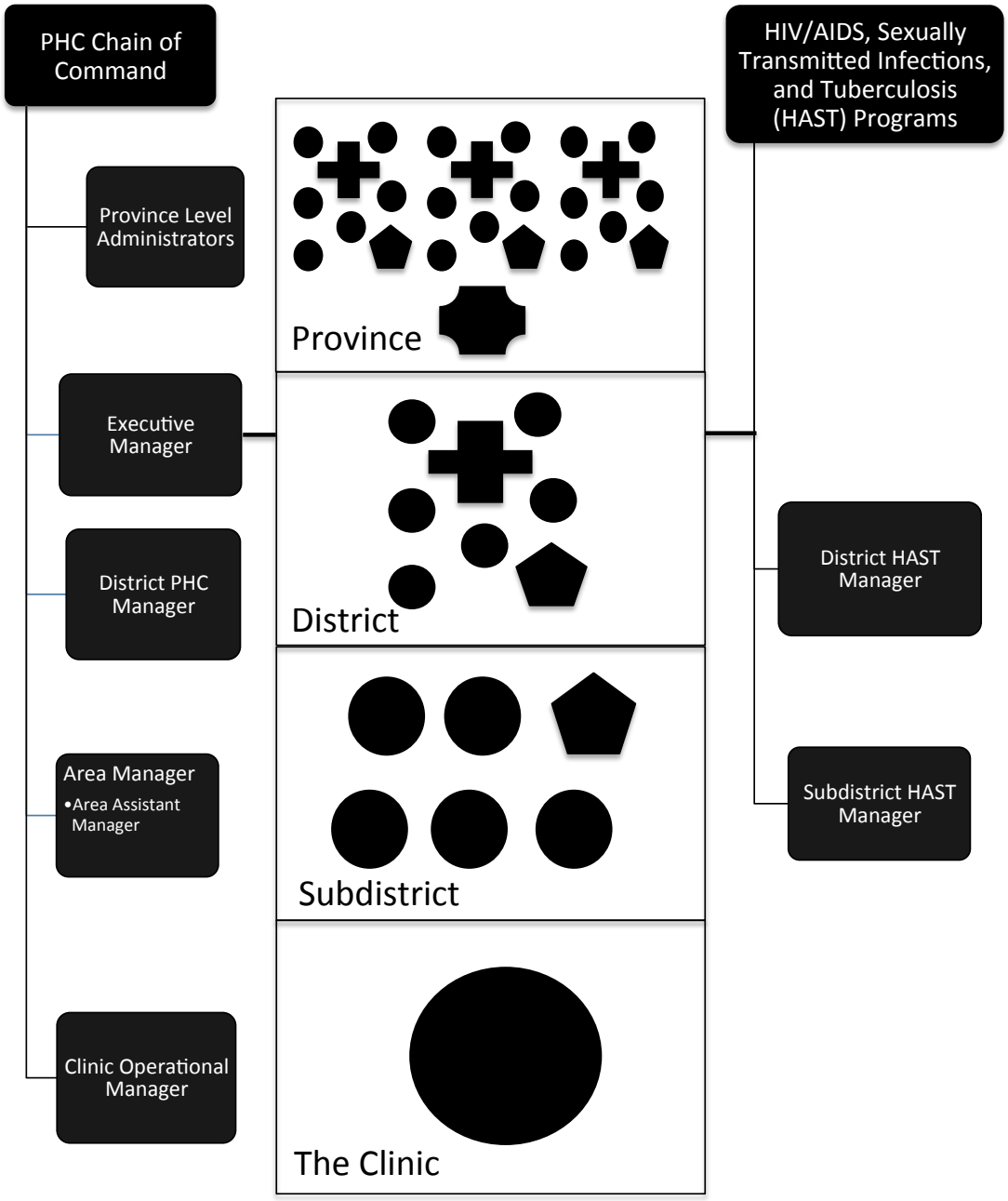

Figure 3. Administrative Hierarchies. Note that circles represent individual PHC clinics. Pentagons represent larger community health centers. Crosses represent hospitals. At the provincial levels hospitals include generalist facilities (as included at the district levels), and facilities with specialty services. PHC is organized around systems of satellite PHC facilities supported by larger hospitals.

Appendix C.
Key Informant Interview Guide

1. Introduction

Example script: *I am Julie Schexnayder, a nurse researcher from the University of Virginia in the United States. Today I will be asking you questions about the clinic and your role as an employee there. The interview is expected to last 1 hour and will be audio recorded to provide a record of your responses. Also, I want to remind you that your participation is completely voluntary. You can stop the interview at any time without penalty. Before we get started, do you have any questions?*

2. Interview topics:
    1. Tell me a little bit about your role in the clinic.
    2. Can you tell me a little about the history of the clinic?
    3. What is your personal history with the clinic?
    4. Tell me about the clinic's relationship with the District and Provincial departments of health.
    5. What laws and/or regulations affect the clinic's HIV program?
    6. What led the clinic to begin providing HIV services?
    7. How have HIV services changed at the clinic over time?
    8. What types of evaluations is the clinic subject too?
    9. How does the clinic receive its funding?
    10. How does the physical structure of the clinic affect the delivery of medical/nursing care?
    11. What different types of staff are employed at the clinic?
    12. Can you describe what ideal staffing of the clinic would be like?
    13. Who is responsible for providing HIV services at the clinic?
    14. Tell me about current staffing trends in the HIV program.
    15. What categories of staff are the hardest to retain?
    16. How do staff access training related to HIV management and treatment?
    17. What resources are available to help employees treat patients with HIV/AIDS?
    18. How is caring for HIV/AIDS patients different than caring for uninfected patients?
    19. How are drugs managed in the clinic?
    20. What laboratory services are available on site?
    21. What issues arise when sending laboratory specimens off to outside laboratories?
    22. How do you keep track of clinic supplies and equipment?
    23. What supplies and equipment do you have the trouble accessing, and/or keeping stocked?
    24. What are the most common administrative issues that arise in the clinic?
    25. What are the biggest challenges in providing HIV services?

26. How do you think the clinic's current panel of HIV services affects the clinic's budgeting/financing?

3. Potential probing questions:
    1. Would you mind telling me more?
    2. Could you please explain your response more?
    3. What does _____ mean?
    4. Could you give me an example?

4. Close-ended questions used to probe or direct order/selection of questions:
    1. How many _____ (nurses, doctors, medical assistants, etc.) are employed at the clinic?
    2. Has the clinic ever run out of _____ (drugs, supplies, etc.)?
    3. Who, or what category of staff is responsible for _____?
    4. Where are complex HIV infected patients referred to?
    5. How far away is the closest physician?
    6. Which communities make up the clinic's service area?
    7. Are you involved in external clinic reporting of HIV outcomes?
    8. Which outcomes does the clinic routinely collect data on?
    9. How many years have you been a _____?
    10. How long have you been employed at the clinic?

5. Closing comments

Appendix D.

Health Outcomes Data Collection Tool

Chart _____ **of** _____

DOB/AGE _____ **Gender** **M** **F**

Pregnant on Initiation **Y** **N** **Ever Pregnant on ART** **Y** **N**

Date of ART Initiation _____ **Initial Regimen** **Drug 1** _____
Drug 2 _____
Drug 3 _____

Date of Baseline CD4 _____ **Baseline CD4 Result** _____

Any Co-trimoxazole prescription **Y** **N**

Follow up visit:	Attended		Date of Last Visit	Weight Assessed		Last Weight	CD4		Last CD4 Result	Viral Load		Viral Load Result
Month 1	Y	N		Y	N							
Month 2	Y	N		Y	N							
Month 3	Y	N		Y	N							
Month 4	Y	N		Y	N							
Month 5	Y	N		Y	N		Y	N		Y	N	
Month 6	Y	N		Y	N		Y	N		Y	N	
Month 7	Y	N		Y	N		Y	N		Y	N	
Month 8	Y	N		Y	N							
Month 9	Y	N		Y	N							
Month 10	Y	N		Y	N							
Month 11	Y	N		Y	N		Y	N		Y	N	
Month 12	Y	N		Y	N		Y	N		Y	N	
Month 13	Y	N		Y	N		Y	N		Y	N	
Month 14	Y	N		Y	N							
Month 15	Y	N		Y	N							
Month 16	Y	N		Y	N							
Month 17	Y	N		Y	N							
Month 18	Y	N		Y	N							
Month 19	Y	N		Y	N							
Month 20	Y	N		Y	N							
Month 21	Y	N		Y	N							
Month 22	Y	N		Y	N							
Month 23	Y	N		Y	N		Y	N		Y	N	
Month 24	Y	N		Y	N		Y	N		Y	N	
Month 25	Y	N		Y	N		Y	N		Y	N	

Ever changed ART regimen **Y** **N** **If yes, new Regimen(s)** _____

ANY Toxoplasma/PCP **Y** **N** **Date of OI DX** _____

Appendix E.

Clinic Records and Monthly Reports Data Collection Tool

Column1	Column2	Column3	Column4	Column5	Column6	Column7	Column8	Column9
Month	# Clinic visits	Clinic headcount #	# ART visits	# Tx naïve eligible for ART	# Remaining in Care	# ART deaths	#LTFU	% VL suppress.
Jan-11								
Feb-11								
Mar-11								
Apr-11								
May-11								
Jun-11								
Jul-11								
Aug-11								
Sep-11								
Oct-11								
Nov-11								
Dec-11								
Jan-12								
Feb-12								
Mar-12								
Apr-12								
May-12								
Jun-12								
Jul-12								
Aug-12								
Sep-12								
Oct-12								
Nov-12								
Dec-12								
Jan-13								
Feb-13								
Mar-13								
Apr-13								

Appendix F.

Focus Group Interview Guide

1. Introduction and Ice Breaker

Example script: *I am_____, a research assistant from the University of Venda. Julie Schexnayder, a nurse researcher from the University of Virginia in the United States is also here and will be taking notes during the interview. Today I will be asking you questions about the clinic and your role as an employee there. The interview is expected to last no longer than 1.5 hours and will be audio recorded to provide a record of your responses. I want to remind you that your participation is completely voluntary. You can exit the interview at any time without penalty. Before we get started, do you have any questions?*

2. Ground Rules for Group Discussions
   - Importance of keeping interview comments confidential

3. Group discussion topics:
   - Tell me about a typical day for HIV care in clinic.
   - Tell me about your roles in managing HIV patients.
   - What goals do you have for patients starting ART?
   - In your clinic, how is managing HIV patients different from managing other patients?
   - What does quality HIV care mean to you?
   - Can you give me an example of when a patient received quality HIV related care? How did you know that the care was "high quality"?
   - What would you need to provide that type of care everyday?
   - How is HIV care in the private sector different than care provided in public primary care clinics?
   - What is the hardest thing about providing HIV services?
   - What role does the patient have in receiving quality care?
   - What resources are available to you to help you give good care?

4. Potential probing questions:
   - Would you mind telling me more?
   - Could you please explain your response more?
   - What does _____ mean?
   - Could you give me an example?
   - Has anyone else experienced _____?

5. Focus Group Closing Comments

Appendix G.

Journal of the Association for Nurses in AIDS Care (JANAC): Author Instructions

Source: Journal of the Association of Nurses in AIDS Care (2012). Retrieved from http://www.janacnet.org/authorinfo

Submission of Manuscripts

JANAC reviews manuscripts with the understanding that they have not been previously published and are not concurrently being considered for publication elsewhere. *JANAC* uses iThenticate© to detect similarities between submitted papers and previously published materials; we will not review submissions with excessive similarities to other publications. *JANAC* invites contributions in the form of featured manuscripts (maximum of 28 submitted pages); research, practice, or program briefs (8-10 pages); case studies (8-10 pages); topical columns and commentaries (6-8 pages); and media and book reviews (6-8 pages). Letters to the editor are encouraged. *JANAC* uses an online manuscript submission and review system. Please visit http://ees.elsevier.com/janac to submit your manuscript electronically. The Web site guides authors through the initial registration process, including the uploading of requisite files. Please note that original source files, not PDF files, are required. Inquiries regarding manuscript submission or status should be directed to the Managing Editor, Kristen Overstreet, via email at kristen.overstreet@mac.com or at 1-303-229-8129. All other inquiries should be directed to the Editor, Lucy Bradley-Springer, via e-mail at lucy.bradley-springer@UCDenver.edu or at 1-303-724-0811. All correspondence, including the Editor's decision and requests for revisions, will be delivered by e-mail to the corresponding author. Manuscript status information is always available for registered authors via the journal's online submission system.

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Feature manuscripts are evaluated by at least two members of the review panel according to their relevance and significance, the degree to which they advance knowledge, the quality of scholarly presentation, the integrity of research method, and clinical content relevant to nursing practice and HIV care. Authors may be asked to revise an accepted manuscript to conform to the standards and editorial style of *JANAC*.

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Submissions for featured articles should have the following components: title page, abstract, key words, manuscript body, clinical considerations, and references. Manuscripts may also include tables and figures as appropriate to the content of the paper; we will accept up to a combined total of 5 tables and figures. Manuscripts should be written and formatted in accordance with the *Publication Manual* of the American Psychological Association (APA, 2010), 6th ed. guidelines. Please see the *JANAC* Style Guide (available on our Web site at http://www.nursesinaidscarejournal.org/) for *JANAC*-specific style issues and

exceptions to APA formatting.

Other Submissions.

Submissions for research, practice, or program briefs; topical columns and commentaries; guest editorials; and letters to the editor are encouraged. These submissions are reviewed only by the editor, unless the editor determines a need for additional input. If a table or figure is included (limit to a total of 2 tables and/or figures per manuscript in this section), it should be submitted in a separate file as described below. These types of submissions do not include an abstract or a clinical considerations section; however, please provide a list of 3-5 key words.

Components of a Manuscript

Title page.

The title page should include contact information for each author, including each author's credentials, title/position, affiliation, and location (city and state and/or country). The title page should also include a conflict of interest statement and any desired acknowledgements.

Conflict of Interest Statement.

Authors are required to provide full disclosure on actual or potential conflicts of interest relevant to the subject matter of the manuscript that have occurred over the previous 2 years, over the duration of the research being reported on, and/or that can reasonably be expected to occur in the foreseeable future. Disclosures may include, but are not limited to, grants/funding, employment, affiliations, honoraria, consultancies, board positions, royalties, stock options/ownership, or expert testimony. Unless determined to be important to the review process, disclosures will be held confidential until an article is accepted for publication. Disclosure statements will appear with all articles published in the journal. Authors should contact the Managing Editor with questions or concerns, but should err on the side of inclusion when in doubt. Please see the full Conflict of Interest Policy on our Web site at http://www.nursesinaidscarejournal.org/ Disclosure statements should be made during the submission process and should disclose information for the overall study and for each author on the title page. If the author(s) has no conflicts of interest to declare, this must be stated. In this case, please use the following statement:

The author(s) report(s) no real or perceived vested interests that relate to this article (including relationships with pharmaceutical companies, biomedical device manufacturers, grantors, or other entities whose products or services are related to topics covered in this manuscript) that could be construed as a conflict of interest.

The following is sample text for disclosure:

This study was funded in part by ABC Corporation and grant #1-234-5678 from DEF Foundation. Kyle Smith reports having received lecture fees from XYZ Laboratories. Chris Brown disclosed consulting fees from 123 Inc. Madison Wall reports no financial interests or potential conflicts of interest.

Acknowledgements.

Please acknowledge all sources of funding in an Acknowledgment Statement on the title page of the manuscript. This is also an appropriate place to acknowledge assistance from non-author colleagues in the development and production of a manuscript.

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Abstracts should adhere to a maximum of 150 words, and should appear immediately above the body of the manuscript. You will also be asked to provide the abstract as part of the submission process. You may cut and paste your abstract into the submission box.

Key words.

Key words relating to the content of the manuscript should be listed in alphabetical order and separated by commas; do not capitalize key terms unless they are proper names. Key words should appear below the abstract for featured manuscripts and on the title page for all other manuscripts.

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Manuscript pages should be numbered consecutively. The author(s) are encouraged to use headers as outlined in APA (2010, 6th ed.) to format the manuscript. A clear and concise writing style is required.

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The reference section should represent current literature and appropriate historical references. References should be limited to no more than 30 for research manuscripts; review manuscripts may use more references, but with restraint; brief manuscripts should limit references to 10-15. All citations and references must follow APA (6th ed.) format.

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Tables, figures, and photographs are encouraged if they enhance or amplify the text. Tables and figures should be self-explanatory and enhance, not duplicate, the text. Tables and figures should be loaded as separate files. Tables and figures should be numbered, titled, and referenced in the most appropriate section of the manuscript text. Please follow APA (6th ed.) formatting for all tables and figures.

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Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3" (Retrieved from http://www.icmje.org/ethical_1author.html).

If your title page lists more than 6 authors, please explain in your cover letter how each author satisfies the criteria for authorship as stated above. Remember: it may be more appropriate to recognize individuals who have contributed but who do not meet authorship criteria in your acknowledgement statement.

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Dual submission.

It is unethical to submit a manuscript to more than one journal at a time for consideration of publication. A manuscript must be rejected or formally withdrawn by the author from one journal before it can be submitted to another journal.

Appendix H.

Draft of Capstone Project Formatted for Submission to JANAC

Evaluation of nurse-led antiretroviral therapy in a rural South African primary health care clinic

Julie Schexnayder, DNP(c), MPH, ACNP-BC, RN

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Conflict of Interest Statement

The authors report no real or perceived vested interests that relate to this article that could be construed as a conflict of interest.

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Abstract

South Africa has the fourth highest prevalence of HIV in the world at 17.9% in 2012. To ensure access to HIV treatment nurses initiate and manage HIV care at the primary health care level. In this descriptive case study we describe nurse-led ART in a rural South African primary health clinic. Retrospective chart review was performed for adults and adolescents initiated onto ART between January 2011 and April 2013 to assess a) nurse compliance with South African HIV management and antiretroviral therapy (ART) guidelines and b) key patient outcomes. Interviews and a focus group identified challenges to delivery of NIMART services. Of 92 individuals started on treatment, first line ART was selected for 87 (93.4%). Prescription of trimethoprim-sulfamethoxazole prophylaxis occurred in 43.9% with WHO stage 2-4 disease. At 1 year of follow-up 68.4% remained in care. Overall mortality was 6.5%. CD4+ T cell count and HIV viral load results were available for 57.7% and 69.2% of patients at 1 year, respectively. A viral load less than 400 copies/ml was observed for 89.5%. Outcomes of this clinic compare favorably with other ART cohorts in South Africa. Major program challenges include clinic infrastructure, community stigmatization of HIV, integration of HIV and non-HIV services, and increased professional nurse workloads. These findings suggest that ART can be safely delivered in rural primary care settings. However attention to prevention of opportunistic infections is lacking, and nurses identified systems level factors that threaten retention in care. These areas highlight areas for future research and clinic level quality improvement activities.

Key Words: HIV, integrated primary care services, nurse-led antiretroviral programs, South Africa, task-shifting

Outcomes of nurse-led antiretroviral therapy in a rural South African primary health care clinic

An estimated 17.9% of adults ages 15 to 49 were living with HIV in South Africa (SA) in 2012 representing the fourth largest HIV prevalence worldwide (Joint United Nations Programme on HIV/AIDS, 2013). The national prevalence has stabilized in recent years, however the total number of HIV-infected people needing treatment is expected to grow. An estimated 2.01 million South African adults were on antiretroviral therapy (ART) in 2012 (Joint United Nations Programme on HIV/AIDS, 2013). The National Strategic Plan 2012 - 2016 aims to ensure 80% of the HIV-positive patients eligible for ART are initiated on treatment by 2016. Based on World Health Organization (WHO) 2010 guidelines, 80% of eligible South Africans were on treatment based in 2012 (WHO, 2013). The national strategy also includes new targets for retention: keeping 70% of ART patients alive and on treatment at five years (South Africa National Department of Health, 2011). However, of the 1.8 million accessing public sector services in 2011, the proportion remaining in care beyond 12 months is unknown.

Multiple factors contribute to ART availability in South Africa, with physician shortages recognized as a critical bottleneck in the early scale-up of public sector HIV treatment programs (Bärnighausen, Bloom, & Humair, 2007; Kober & VanDamme, 2004). Transitioning medical HIV management from physicians to nurses has been promoted by the WHO as one approach to mitigating HIV service gaps arising from physician shortages (WHO, 2008), and pilot studies on task shifting of ART prescription to nurses in South Africa have reported favorable results (Bedelu et al., 2007; Fairall et al., 2012).

In 2010, policy changes enabled nurses to independently prescribe ART, effectively moving HIV treatment into primary health care. Nurse-initiated and managed ART (NIMART)

increases treatment access (Nyasulu, Muchiri, Mazwi, & Ratshefola, 2013) and is at least as effective as physician-initiated ART (Bedelu et al., 2007; Cohen et al., 2007; Fairall et al., 2012; Shumbusho et al., 2009). The purpose of this study was to describe NIMART services at a rural primary health clinic in Vhembe, Limpopo, and to evaluate outcomes in adult and adolescent populations (ages 15+ years) on ART. This study was conducted to provide baseline data to facilitate internal benchmarking of program performance.

Methods

This was a qualitative program evaluation performed using a descriptive case study design. Research procedures were approved by the Ethics Review Board at the University of Virginia (Charlottesville, Virginia) and the University of Venda (Vhembe, Limpopo)

Setting

The clinic is one of 16 public primary health care clinics located in a rural municipality of Vhembe District, Limpopo, and one of 10 designated *Comprehensive Care, Management, and Treatment* (CCMT) sites for HIV in the Mutale subdistrict. As a public clinic in accordance with SA National Department of Health guidelines and standards for primary health care clinics. Clinic supervision is administered through the Vhembe District Department of Health and Limpopo Province Department of Health.

The clinic's service area includes 14 villages, with a population of 8597 (2012 data). HIV is an important source of morbidity in the larger community. In 2011, the antenatal HIV prevalence in Vhembe was 14.6% (National Department of Health, 2012). Estimates for the overall HIV prevalence in Vhembe are not available. However, in South Africa antenatal HIV prevalence is typically greater than the general population HIV prevalence. For example in 2011, the national antenatal prevalence was 29.5% compared to an estimated general HIV

prevalence of 17.3% among those ages 15-49 (National Department of Health, 2012).

The NIMART Program

In this clinic programs for HIV infection in the adult and adolescent include *HIV Counseling and Testing*, *Prevention of Mother to Child Transmission*, and *CCMT*, the latter of which includes NIMART. NIMART was implemented at the clinic beginning January 2011. The NIMART program includes pre-ART medical services and counseling, enrollment into the national ART medication program, routine prescription of antiretroviral medications, and ongoing management of HIV-infected individuals on treatment within the clinic. The larger subdistrict ART program is organized as a system, with multiple community based CCMT clinics supported by a hospital-based ART site staffed by a physician.

With the exception of counseling and preventive screenings, ART services are provided exclusively by professional nurses and physicians. See Table 1 for a summary of NIMART roles by job title. Only nurses who completed formal NIMART training are authorized to initiate eligible patients on ART. Prerequisites for NIMART training are completion of two primary health training programs: *Practical Approach to Lung Health and HIV/AIDS in South Africa* and *Integrated Management of Childhood Illnesses*. NIMART training includes three components: education on HIV basics, in clinic training led by a physician, and clinical mentoring by a certified NIMART mentor. As of April 2013, four of the clinic's nurses completed NIMART training. Although NIMART training is required to initiate a patient on ART, any professional nurses may perform follow-up care. The clinic's professional nurses are function as generalists, providing all PHC services within their scope of training. No nurse positions are allocated solely to HIV programs.

Measures

Demographics.

Patient demographic data were collected during medical records review. For each medical record reviewed, patient age, date of birth, sex, pregnancy status was collected.

Compliance with National Guidelines.

Measures of the clinic's processes of ART care were derived from the *South African Antiretroviral Treatment Guidelines (*Republic of South Africa, 2013; Republic of South Africa, 2010) and *Clinical Guidelines for the Management of HIV&AIDS in Adults and Adolescents* (National Department of Health, 2010), and were grouped into Pre-ART, ART prescription, and treatment monitoring activities. Pre-ART measures included the percentage of individuals who received: WHO clinical staging, baseline CD4+ T cell count measurement, weight measurement, physical examination, and trimethoprim-sulfamethoxazole (TPM-SMX) prophylaxis against opportunistic infections (OI). ART prescription measures included appropriate start of treatment, and prescription of a first-line ART regimen. Treatment monitoring measures included the percentage of individuals with: weight measured at each follow-up visit, HIV viral load results at 6 and 12 months, CD4+ T cell count results available at 12 months, and changes in ART regimen.

Outcomes.

Outcomes variables selected for this capstone reflect the goals of ART treatment: to reduce the morbidity and mortality associated with HIV. Measures consider retention in HIV treatment as well as clinical outcomes. Measures of program retention include: mean number of missed clinic visits per patient, percentage program retention overall and at 12 months, and

percentage loss to follow-up overall and at 12 months. Clinical outcomes measures measured as percentages include deaths, occurrence of *Pneumocystis jiroveci* infection, and reduction in viral load to less than 400 copies/ml overall and at 6 and 12 months. Mean CD4+ T cell count at 12 months and mean weight at last collection were compared to baseline data. Changes in these variables were assessed through statistical testing.

Program Challenges.

Staff interviews were exploratory in nature identifying major structure variables impacting the ART program. Attention to the following categories guided clinic observations and interviews: PHC infrastructure, human resources, medications and supplies, program tools, and program organization and management. The focus group was exploratory in nature identifying nurse perceptions of NIMART effectiveness.

Data Collection

Retrospective review was restricted to the following dates: January 1, 2011 through April 25, 2013. Chart review was limited to ART files of adults and adolescents (ages 15 years or greater) not on treatment at enrollment in the clinic's ART program. The clinic assigns medical record numbers differently for patients already on treatment at referral into the program. These individuals were also excluded from the manual chart review, effectively limiting this evaluation to those individuals who received all elements of NIMART care (pre-ART, treatment initiation, and follow-up) in the clinic. Descriptions of structures supporting the clinic's ART program were based on interviews with clinic staff members. The operational manager was selected a priori for an interview due to her supervisory role of the ART program. The clinic's operational manager identified the remaining participants as having a role in the ART program. Informed consent was obtained from participating clinic staff members prior to interviews and focus

groups. Interviews took place onsite with permission of the clinic's operational manager. Semi-structured interview guides were developed by the first author for both interviews and focus groups. Questions were pretested with University of Venda nursing staff to validate appropriate translation in South African English.

Data Analysis

Data entry and analysis were performed using Microsoft Excel 2010 and IBM SPSS Statistics v.22. Summary statistics were generated from raw data in patient medical records. Percentages, means, and medians were calculated for using Microsoft Excel 2010. Paired sample t-tests were performed using IBM SPSS v22 to evaluate changes in mean CD4+ T cell counts, and changes in mean weight following start of ART. Interview and focus group transcripts were entered into Microsoft Excel 2010 for separate coding and categorization. Qualitative data was analyzed using conventional content analysis techniques. Content analysis is a systematic, "dynamic form of analysis of verbal and visual data that is oriented toward summarizing the informational contents of that data" (Sandelowski, 2000, p. 338).

Results

Medical chart review was performed for 92 individuals ages 15 years and older who were not on HIV treatment at enrollment in the clinic's ART program. This includes 15 females who were pregnant at the time of ART enrollment. Five patients not actively on treatment at time of NIMART enrollment, but who had a history of treatment elsewhere were also captured in the review. Demographics of those started on ART in the clinic are included in Table 2. Interviews were conducted with two additional professional nurses, one lay counselor, and one data capturer. Three professional nurses participated in the focus group. Participants included one

clinical nurse specialist and two nurses with primary health training. All participants completed department of health sponsored training in NIMART.

Nurse Compliance with HIV Guidelines

Overall 85.9% of patients were started on ART within two months of baseline CD4+ T cell count collection. Documentation of a treatment qualifying criteria was missing for 12.0% of treated individuals based on then current treatment guidelines. Of those started without treatment criteria, 72.7% cases occurred when criteria required CD4+ T cell counts less than 200 cells/mm^3 for most patients to begin treatment. First line ART regimens were prescribed for 93.4%. Performance with each compliance measure is summarized in Table 3.

Outcomes

As of April 25, 2013, 64.1% of those started on ART were alive and in care, 23.9% were lost to follow-up, 5.4% transferred care to another facility, and 6.5% died. All deaths occurred within six months of starting HIV treatment and in patients with CD4+ T cell counts less than 200 cells/mm^3. Patients who returned for at least one follow-up visit (n=79) missed an average of 2.65 visits. At 6 months on ART 88.2% had a viral load less than 400 copies/ml; this increased to 94.7% at 12 months. A statistically significant improvement was observed for mean CD4+ T cell count as compared to baseline (Table 4). Mean weight also increased, from 61.5 kg at baseline to 63.5 kg at most recent measurement (Table 4). No patient ART file included lab results or treatment information allowing for identification of OI diagnosis.

NIMART Program Challenges

Descriptions of structures supporting the clinic's ART program were based on interviews with five clinic staff. All individuals who were approached for interviews agreed to participate. The operational manager was selected a priori for an interview due to her supervisory role of the ART program. The clinic's operational manager identified the remaining participants as having a role in the ART program. Interviews were conducted with two additional professional nurses, one lay counselor, and one data capturer. Three professional nurses participated in the focus group. Participants included one clinical nurse specialist and two nurses with primary health training. All participants completed department of health sponsored training in NIMART. Informed consent was obtained from participating clinic staff prior to interviews and focus groups. Interviews took place onsite with permission of the clinic's operational manager. Semi-structured interview guides were developed by the first author for both interviews and focus groups. Questions were pretested with University of Venda nursing staff to validate appropriate translation in South African English.

Clinic Infrastructure.

All interviewees identified inadequate clinic infrastructure as the most significant clinic barrier to the provision of NIMART services. The number of general clinic consultation rooms is inadequate to accommodate the number of staff available for ART visits and all other patient care. Professional nurses are given priority for room assignment, requiring use of both consultation rooms and the wound care room. During weeks where the on duty nursing team includes four professional nurses the fast track is also used for nurse-patient PHC encounters. This was viewed as the clinic's greatest infrastructure challenge. There is no dedicated clinic space for laboratory samples collection, HIV testing, clinic support groups, or for ART

adherence counseling. Two nurses attributed long patient wait times to the limited number of consultation rooms.

Locations of the clinic pharmacy and waiting room were cited as barriers to maintaining patient confidentiality. The clinic pharmacy can only be accessed from the triage/fast track room, requiring regular interruption of patient consultations. In the hallway, maximizing waiting room seating requires placing chairs in close proximity to consultation rooms. One interviewee expressed concern that those in the waiting room area could overhear confidential patient-provider conversations. This was identified as a potential factor in loss to follow-up among ART patients.

Integration of HIV and non-HIV services.

Partial integration of ART services promotes stigma by differentiating HIV infected patients from other clinic attendees. Receiving ART services on dedicated HIV clinics days increases the risk of accidental HIV disclosure through association with the clinic's HIV programs. ART files differ in appearance from other chronic disease program files. Nurses described a common patient practice of refusing their medical files at registration to avoid being seen with HIV related documents.

Stigmatization of HIV Services.

Stigmatization of HIV was cited as the greatest challenge to retaining patients in the NIMART program. Although local villages differ in their attitudes and beliefs regarding HIV, disclosing one's HIV status in Mutale poses a risk of community stigmatization. Nurses identified lack of education, traditional medicine, and some religious groups as factors influencing stigmatization of HIV and it's medical treatment. Fear of HIV stigma directly

impacts ART treatment adherence in the clinic's service area. Patients who elect to keep their HIV diagnosis confidential have difficulty explaining monthly clinic visits to family and friends. For this reason, patients who lack support to engage in treatment were viewed as having poorer outcomes.

Nurse Workloads.

NIMART trained nurses have insufficient time during encounters to address all HIV-related issues. Nurses expressed concern regarding changes to treatment guidelines requiring same day ART initiation in some patients. These individuals forgo pre-treatment adherence counseling. Adherence counseling was viewed as effective, and nurses reported decreased treatment adherence in those with little or no preparation for the ART program. Following start of treatment, patients present to ART follow-up visits with other medical problems that need to be addressed. Dual nurse responsibilities were also reported. For example, one nurse described having to speed through a patient encounter so that he could leave to assist a laboring patient. Thus nurses feel they have inadequate time to address all aspects of HIV related care.

Documentation systems were implicated in increased nursing workloads. Professional nurses own the greatest burden of clinic documentation. A patient encounter requires written documentation of the patient's demographic information, chief medical complaint, and the nursing services rendered in a standardized department of health clinic register. For a patient receiving ART services the nurse must also document information in the patient owned record and the patient's ART program file. A patient receiving care for multiple chronic conditions during an ART encounter will require nurse documentation in each chronic disease file for which

the patient receives services. For this reason nurses may provide services without documenting in all relevant program files.

Discussion

This study presents evidence that patients who continue in the clinic's ART program have high rates of viral suppression. At 12 months 89.5% of ART patients with available HIV viral load results had undetectable viral loads. This compares favorably with previous studies where patients were started on HIV treatment by nurses (Bedelu et al., 2007; Fairall et al., 2012). Statistically significant improvements in weight and immune recovery were also observed. These findings confirm that NIMART programs can be effective in reducing HIV associated morbidity in rural South Africa.

Retention in care in this study approaches the national target of 70%. Nurses identified infrastructure and process factors that promote stigmatization of the clinic's ART services, however, actual reasons for patient loss where not assessed in this study. The ART program is organized as a system, with multiple community based CCMT clinics supported by an hospital-based ART site. By nature of this study design, this author was unable to track movement of patients across treatment sites. It is possible that some patients transferred care to other CCMT sites without clinic notification.

Despite moderate loss to follow-up in this study, overall mortality was low at 6.5%. By comparison, a South African randomized trial comparing NIMART to earlier models of ART monitoring in primary health care reported 20% mortality at 24 months (Fairall et al., 2012). One notable finding is this study is time to death: All deaths occurred within six months of starting HIV treatment, emphasizing the need for close follow-up of individuals starting on ART. As confirmed in the larger medical literature (Fox et al., 2010), level of HIV disease advancement

consistently predicts risk for mortality: Deaths occurred exclusively in patients with CD4+ T cell counts less than 200 cells/mm3. From a public health standpoint, these findings substantiate the need for treating HIV-infected individuals with CD4+ T cell counts greater than 200 cells/mm^3, a problem addressed through 2012 interim updates to the national treatment guidelines (Matsosos, 2012). The clinic's success in expanding treatment to those with CD4+ T cell counts less than 350 cells/mm^3, is demonstrated through increasing mean/median baseline CD4+ T cell counts over time (Table 2).

Limitations

There were several limitations in this project. Given that multiple files and registers are used for documentation of clinic services, it is possible that the procedures described in this study failed to capture elements of ART care documented in places other than patient medical records. This is substantiated by interview findings that documentation systems design promotes incomplete charting. Missing data in patient ART files may further limit conclusions concerning the number of patients retained in care, as well as their clinical outcomes. As risk of loss to follow-up and viral rebound are known to increase overtime, findings from this study should not be extrapolated to predict long-term outcomes.

Conclusions

In this clinic nurses successfully identified patients meeting treatment criteria and were able to initiate most within two months. Strong compliance with guidelines for pre-ART care was observed, and increasing baseline CD4 counts suggest that nurses respond quickly to changes in treatment eligibility criteria. Relatively few patients have been on treatment for greater than 12 months, perhaps explaining greater compliance with early enrollment activities, specifically those focusing on ART initiation. This finding substantiates a need for expanding

program monitoring to other aspects of care, namely follow-up laboratory screening and OI prevention and management.

Across levels of the PHC system, new approaches to HIV service integration should be explored. Additional research will be necessary to understanding how levels of ART program integration affect patient satisfaction and long-term retention in care. At the national and province levels, redesign of program files and clinic registers is suggested as a short-term intervention for reducing stigmatization of HIV services. However reorganization of larger PHC administrative structures maybe required for greater integration of PHC documentation systems.

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Table 1.

Numbers and Descriptions of Clinic Staff with Key NIMART Roles

Staff Member	Number	Definition/Education	Roles in NIMART
Data Capturer	1	• Individuals trained by the department of health to collect, manage, and report program data	• Manages patient files and clinic registers • Generates HIV programs reports as required by the department of health • Traces individuals with HIV infection who miss ART follow-up visits • Assists to coordinate onsite and referral physician visits
Enrolled nurse	2	• Nurses "educated to practice basic nursing" (SANC, 2005, p.25). Registration as an enrolled nurse requires completion of a 2 year program of nursing study	• Supports professional nurse activities • Performs selected screenings and laboratory collections
Enrolled Nurse Auxiliary	2	• Nurses "educated to provide elementary nursing care" (SANC, 2005, p.25). Registration as a nurse auxiliary requires completion of a 1 year program of nursing study.	• Triages patients at registration • Collects vital signs and anthropometric data for all patients
Lay Counselor	1	• A member of the community who received training from the Foundation for Professional Development, an NGO, to provide HIV counseling and testing services. Lay counselors have no formal professional or paraprofessional tertiary education.	• Individual and couples HIV counseling and testing • Prepares individuals for ART • Coordinates HIV support groups • Collects data (HIV and ART registers) • ART adherence counseling

NIMART Nurse Mentor	1	• A professional nurse by training who is certified in NIMART mentoring by the Foundation for Professional Development.	• Delivers onsite skills training to clinic nurses as part of formal NIMART training program. • Initiates complex patients on ART • Visits clinic at least monthly for consultation on complex patients, prescription of medications not stocked in clinic
Operational Manager	1	• A professional nurse by training.	• Oversees daily clinic operations • Supervises clinic staff • Fills professional nurse staffing gaps as needed • Serves as a clinical resource to staff • Communicates program needs up administrative chain of command
Physician	2*	• Individuals completing	• Delivers onsite skills training to clinic nurses as part of formal NIMART training program • Initiates complex patients on ART • Visits clinic at least monthly for consultation on complex patients, prescription of medications not stocked in clinic
Professional Nurse	7	• Nurse who are "qualified and competent to independently practice comprehensive nursing… and capable of assuming responsibility and accountability for such practice" (South African Nursing Council [SANC],	• Provides NIMART eligibility screenings and examinations • Prevents and manages select opportunistic infections • Enrolls individuals into the

	2005, p.25). Registration as a professional nurse requires completion of a four year program of nursing study	public ART program • Prescribes ARVs in accordance with national protocols and guidelines • Conducts monthly to bimonthly adherence assessments and dispense ARVs • Manages medication supplies

Note: Only one physician is allocated to the *Comprehensive Care, Management, and Treatment* program. This individual serves as a NIMART skills trainer and provides mobile clinic visits. A second generalist physician does not participate in NIMART training but may provide onsite ART related medical care during monthly clinic visits.

Table 2.

Patient Demographics and HIV Characteristics (n=92)

Demographics	Frequency	Percent
Male	24	26.1
Female	68	73.9
Pregnancy at ART initiation	15	22.1
Age at ART initiation		
Mean (SD): 38.9 (11.06) years		
Median: 37.4 years		
WHO Stage at ART Initiation		
Stage 1	20	21.7
Stage 2	31	33.7
Stage 3	38	41.3
Stage 4	3	3.3
Baseline CD4+ T cell counts (cells/mm3)		
2011 Mean (SD): 149.4 (97.6)		
2012 Mean (SD): 213.1 (133.1)		

Table 3.

Nurse Compliance with Selected ART Guidelines

Variable	Frequency	Percent
WHO staging at ART initiation	92	100.0
Baseline CD4+ T cell count measurement[1]	79	85.9
Baseline weight measurement	86	93.5
Physical Exam at ART initiation	57	62.0
TPM-SMX for CD4<200 cells/mm3 or WHO Stage 2-4 Disease[2]	36	43.9
TPM-SMX dispensing by CD4+ T cell counts		
CD4+ T cell count <50 cells/mm3	5	62.5
CD4+ T cell count <200 cells/mm3	22	43.2
CD4+ T cell count ≥200 cells/mm3	14	45.2
Prescription of first-line ART regimen	87	94.6
Baseline ALT in patients on NVP[3]	3	75.0
Baseline hemoglobin in patients on AZT[3]	8	100.0
Baseline serum creatinine in patients on TDF[3]	73	92.4
CD4+ T cell count at 12 months[4]	15	57.7
HIV viral load at 6 months[4]	31	62.0
HIV viral load at 12 months[4]	18	69.2
Weight at each ART follow-up	29	35.4

Note: 1) Compliance measured as documented CD4+ T cell count within 2 months of ART start.
2) Compliance measured as dispensing of TPM-SMX within 2 months of ART start in those with CD4+ T cell count <200 cells/mm^3 or WHO stage 2-4 disease.
3) Compliance measured as result documented on or before start of associated medication.
4) Compliance measured as documented result within 30 days of due date.

Table 4.

ART Related Outcomes

Variable	Frequency	Percent	$Mean_1$	$Mean_2$	95% CI	p-value
Missed Clinic Visits	--	--	2.7	--	--	--
Retention in Care	59	64.1	--	--	--	--
Loss to Follow-up	22	23.9	--	--	--	--
Death	6	6.5	--	--	--	--
Viral load <400 copies/ml at 6 months	30	88.2	--	--	--	--
Viral load <400 copies/ml at 12 months	18	94.7	--	--	--	--
CD4+ T cell count (cells/mm^3)	21	--	147.6	438.1	(188.361, 392.591)	.000008
Weight change (kg)	69	--	61.9	63.9	(.618, 3.325)	.005
PCP OI	n.d.	n.d.	--	--	--	--

Note: n.d.= no data