Part 0: Preamble

THESIS TITLE

Clinical Mentorship of Nurse-Initiated Antiretroviral Therapy (ART) in Khayelitsha, South Africa: A Quality of Care Assessment

NAME: Ann Green

STUDENT #: GRNANN015

SUPERVISOR(S): Vivian Cox & Mary-Ann Davies

THESIS SUBMITTED IN FULFILMENT OF A

MASTERS DEGREE IN PUBLIC HEALTH

AT THE SCHOOL OF PUBLIC HEALTH

AT THE UNIVERSITY OF CAPE TOWN

February 2013

DECLARATION

I, Ann Green, hereby declare that this is my original work and has not been presented before for the award of a Masters' Degree in Public Health.

Signature: _____ Date: _____

DEDICATION

I would like to dedicate this thesis to my amazing family and friends for all their support and encouragement to persevere.

THESIS ABSTRACT

Background: South Africa's National Strategic Plan calls for task shifting of HIV care from doctors to nurses by 2016 to increase access to ART. There is little research demonstrating sustainable success of competent HIV management by nurses after training and mentorship. In February 2011, Medecins Sans Frontieres (MSF) partnered with the City of Cape Town Department of Health to implement a NIMART mentorship programme and assess quality of clinical care provided by nurse graduates.

Methods: A before-after cross-sectional study was conducted on nurses completing mentorship from February 2011-September 2012. Routine clinical data from 229 patient folders and 21 self-assessment questionnaires was collected to determine the number of patients initiated on ART by individual nurses; quality of ART-management before and after mentorship; patient characteristics for doctor and nurse ART-initiations; and nurse self-assessments.

Results: 21 nurses were authorized by one nurse mentor with one part-time medical officer's support, resulting in nurses initiating 77% of eligible patients. Improvements in ART management were found for drawing required bloods (91% vs 99%, p=0.03), assessing adherence (50% vs 78%, p<0.001) and WHO staging (63% vs 91%, p<0.001). Nurse ART initiation indicators were successfully completed 95-100% of the time for 10 out of 16 indicators: clinical presentation, past medical history, prior ART history, WHO stage, STI screening, patient weight, baseline blood work (CD4 count, creatinine, and haemoglobin), treatment plan, and medications prescribed. Doctors initiated more patients with TB/HIV co-infection and Stage 3 or 4 disease than nurses; 24% of patients initiated by nurses were seen or discussed with a doctor in the month prior to initiation. Nurse confidence improved for the management of HIV-infected children and pregnant women, blood result interpretation, and long-term side effects following completion of the mentorship programme.

Conclusions: Implementation of a nurse-mentor driven NIMART mentorship programme leads to competent nurse initiation of a majority of eligible patients, enabling medical officers to manage complex patient cases. Nurses improved their confidence in performing HIV-related clinical tasks, nurses continued to initiate patients after training, the quality of initiation and management was satisfactory and doctors continue to treat the more complicated patients. These results suggest that in regions where the HIV burden places large demands on health services, a nurse mentoring model could assist in ensuring task-shifting and system efficiency.

ACKNOWLEDGEMENTS

I would like to acknowledge the following people for their help and support in completing this thesis.

To my co-supervisor, **Vivian Cox**, and to **Gabriela Patten** and **Mary Ibeto**, thank you endlessly for all of your support throughout the entire thesis process. Your guidance for data collection, analysis and write up were invaluable.

To my co-supervisor, **Mary-Ann Davies**, thank you for all your support during the study planning process and for the feedback during the writing of the thesis.

To **Nikiwe Mkhosana** and **Nombulelo Raphahlelo**, thank you for your tireless assistance in locating patient folders with a bright smile and shining attitude.

To the dedicated staff at **Khayelitsha City clinics** who were involved in this study, thank you for allowing me into your facility and for providing support throughout data collection.

TABLE OF CONTENTS

Part A: Protocol

NB: This protocol was written by the MPH candidate, Ann Green, and all data was subsequently collected by the candidate, excluding the nurse self-assessment.

STUDY PROTOCOL

Clinical Mentorship of Nurse-Initiated Antiretroviral Therapy in Khayelitsha, South Africa: A Quality of Care Assessment

Authors and Affiliations: Green, A.[1], Cox, V.[2], Ibeto, M.[2], Patten, G.[2], Davies, M.[3]

1 University of Cape Town School of Public Health &Family Medicine

2 Médecins Sans Frontières Khayelitsha

3 University of Cape Town Centre for Infectious Disease Epidemiology & Research

Background

With the highest number of HIV infections in the world, South Africa is one of the countries most severely affected by the AIDS pandemic. The most recent report of the Joint United Nations Program on HIV & AIDS (UNAIDS) estimates the total number of people living with HIV & AIDS (PLWHA) at 5.6 million in South Africa. The incidence rate in the country, however, has somewhat levelled off in recent years, and management of the high prevalence of HIV positive individuals is a key issue to address (UNAIDS, 2010).

A global call to expand antiretroviral treatment (ART) led to a pledge from the South African government, whereby on December 1, 2009, World AIDS Day, President Zuma made a declaration that access to ART would be increased to ensure access to treatment for all people in need. This expansion led to a massive push to enhance HIV & AIDS care and treatment services. However, the strain that such expansion has had on the human resources is notable. The surge that led to approximately 1,000,000 individuals on treatment by 2010 also meant an overworked, understaffed workforce in most cases (Zwarenstein et al., 2011).

To combat the epidemic and address some of the constraints on the health system, the South African government implemented a nurse-driven model that decentralized the administration of ART in all districts, as the previous model of doctor-led ART delivery was unrealistic in some areas with limited human resources and a large HIV burden. Research in other African regions, had suggested that such a strategy is a viable alternative in resource-limited settings (Assan et al., 2008; Morris et al., 2009; Humphreys et al., 2010) Under this model of care, trained nurses would be allowed to initiate patients onto ART and continue management of their subsequent treatment. However, this task shifting toward nurse-initiated and managed ART (NIMART) was not an immediate fix. Limitations to human resource capacity, infrastructure, drug supplies and clinical mentorship for newly trained nurses all contributed to inefficiencies in the system (UNAIDS, 2010).

Research has now proven NIMART to be non-inferior to doctor-monitored therapy. The Streamlining

Tasks and Roles to Expand Treatment and Care for HIV (STRETCH) trial conducted in Free State Province from 2008-2010 revealed a patient mortality rate of 20% among those initiated onto ART by nurses compared to a 19% mortality rate among patients initiated by physicians. While these results reaffirm that NIMART is a viable alternative, especially in resource-limited settings, the study was not able to prove significant improvements in patient time to ART initiation, nor a reduction in patient mortality rate (Fairall et al., 2012).

Outside of the STRETCH trial, there is little existing research that explores the performance of NIMART graduates as it relates to the clinical management of ART and the quality of care provided. For this reason, this study aims to explore the quality of clinical care received by patients on ART managed by NIMART trained nurses to assess the performance of NIMART graduates in the programme led by Médecins Sans Frontières (MSF), an international non-governmental organization operating in Khayelitsha, South Africa.

Study Setting

This study will be conducted in the South African township of Khayelitsha. The Khayelitsha sub-district has an estimated population of approximately 500,000 inhabitants, located on the outskirts of Cape Town in Western Cape Province, South Africa (Department of Social Services & Poverty Alleviation, 2006). The healthcare needs of township residents are served through 8 primary health clinics, three community health centres and a recently developed district hospital. As of 2010, Khayelitsha's HIV burden is one of the largest in the country with an antenatal HIV prevalence of 26% (Médecins Sans Frontières [MSF], 2011). Following the 2009 mandate for ART access, all 11 clinics were providing access to ART by 2011.The number of patients in Khayelitsha remaining in care increased from 100 at the end of 2001 to 24,386 as of August 2012 (MSF, 2011).

The introduction of nurse-driven ART initiation was a recent contributing factor to the increase in patients enrolled onto therapy. Since February 2011, MSF has been implementing a NIMART training

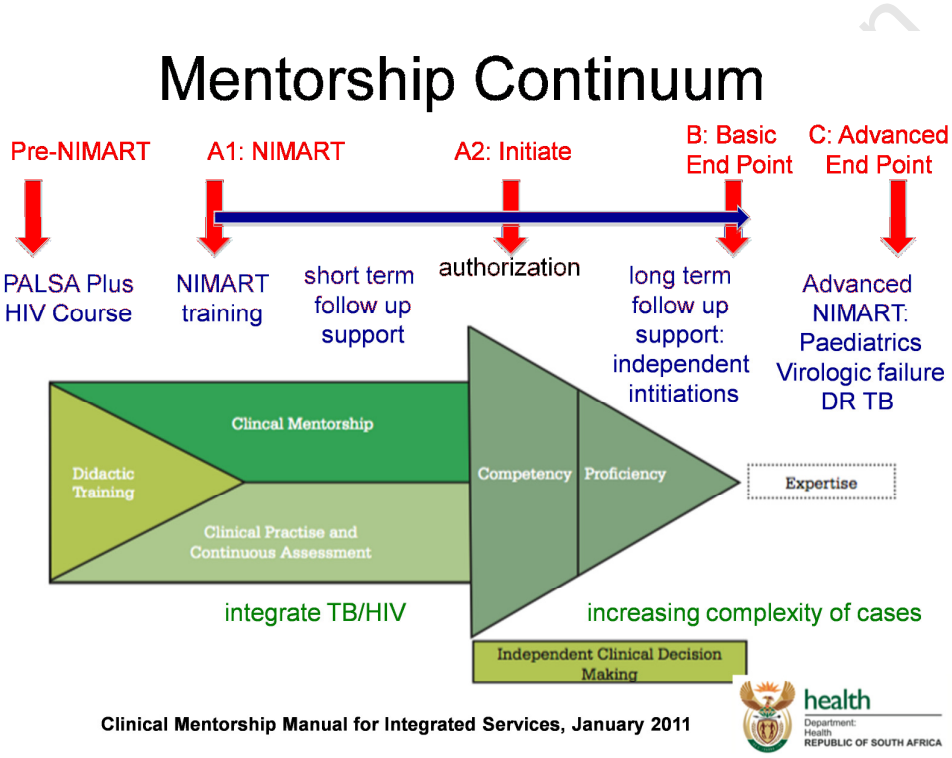
and mentorship program for nurses in Khayelitsha to become accredited to initiate ART in stable patients. To date, 40 nurses have been mentored through the MSF NIMART program, which follows the nurse-based, doctor-supported ART service model promoted by the Western Cape's Provincial HIV&AIDS, STI, and TB Directorate (Western Cape HIV&AIDS, STI & TB Directorate, 2012). The following are criteria for a professional nurse or clinical nurse practitioner to be authorized to initiate ART in the Western Cape:

- Undergone an approved short course training on HIV/ART
- Completed Palsa Plus training
- Be a registered clinical nurse practitioner
- Be a registered professional nurse with either 1 year of HIV/ART experience, or 4 years general clinic experience, after qualification
- Undergo an approved clinical nurse mentorship programme with at least 40 hours of on-site mentorship and 10 ART initiations

The MSF clinical mentor manager participates in a half day of mentorship at the end of a week-long training, in order to assess the mentee's competency to initiate ART and decide with the nurse mentor if the mentee can be authorized. If there is need for further mentorship, mentees remain in the programme for weekly site visits for up to three months. Point B on the mentorship continuum is defined as the point when a nurse trainee independently initiates stable patients without mentorship support (see Figure 1). Further requirements for the nurse to reach Point B include possession of clinical competency for the initiation and management of ART, along with authorization from the Provincial Department of Health under Section 38A of the Nursing Act. If the mentee is competent to initiate ART, the nurse mentor conducts two half day mentorship sessions within two weeks at the nurse's facility, where practical obstacles to nurse initiation are identified and addressed (MSF, 2013).

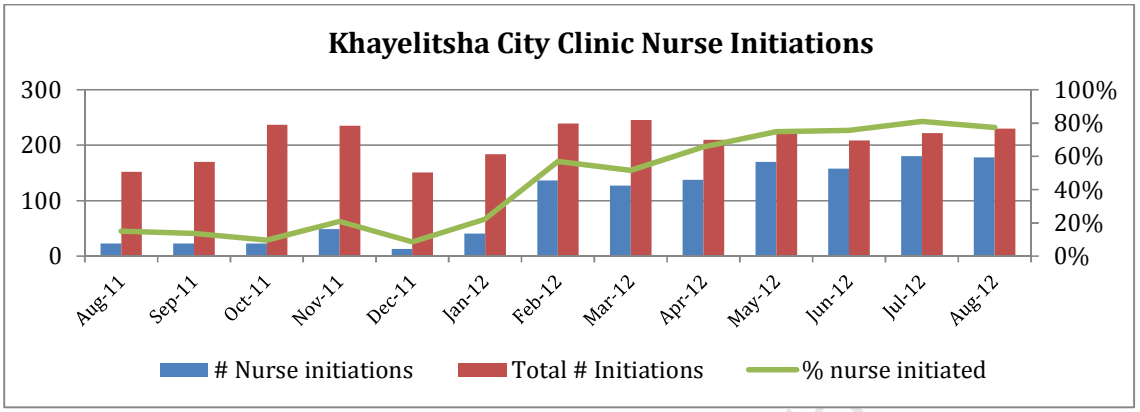
The Western Cape Department of Health requires a district level director to sign a provincial authorization form when mentorship is complete, recommending the nurse for authorization. Following authorization, the MSF nurse mentor is available for phone consultations, and once a month the mentee graduates are visited to track the number of patients initiated by nurses and perform case reviews as needed. The following diagram illustrates the training process for nurses, highlighting the role of mentorship (MSF, 2013).

Figure 1. NIMART Clinical Mentorship Model



According to a recent study looking at initiation rates for NIMART graduates within the other 7 South African provinces, of the 126 trained nurses that were sampled, only 72 (62%) nurses proceeded to actually initiating patients onto ART (Cameron, 2012). The South African Department of Health has set a goal to have nurses initiating 85% of patients eligible for ART by 2016 (South African Department of Health, 2011). Under this new model of care, mentorship is a key factor in the success of NIMART graduates in independent ART initiations. In Khayelitsha, 75% of the authorized

nurses are initiating ARVs in City Health primary health care clinics 18 months after the introduction of the mentorship programme, and over half of all patients starting ART are initiated by nurses (MSF, 2012).



In order to reach the 85% target, it is important to measure the performance of NIMART graduates, not only to assess the quality of care of nurse initiations, but also to advocate for continued provincial and facility management support of nurse mentorship programmes.

Aim

This study has two main aims, which are:

a.) to describe patient ART initiations of nurse graduates of the MSF NIMART mentorship programme

b.) to measure the quality of nurses' initiation and long-term clinical management of patients continuing ART

in Khayelitsha City Health primary health care clinics.

Objectives

The objectives of the study are:

1. *To report on the number and proportion of all patient initiations that were initiated by NIMART* mentored *nurses.*

2. *To report on the number of nurses completing the NIMART mentorship programme and*

receiving authorization *to prescribe.*

3. To compare the quality of ART management by nurses before and after completion of the NIMART mentorship programme, based on completion of ART stationary for the routine baseline and consultation sections (see Appendix 1).

4. To measure whether authorized nurses are initiating ART or referring appropriately after completion of the NIMART programme, based on completion of the ART stationary for initiation (see Appendix 2).

5. To compare the patient characteristics of those initiated on ART by nurses, with those initiated by doctors within the same clinic in terms of:

- *Baseline CD4 count*
- *TB status*
- *Age*
- *Gender*

6. To report on nurses' confidence to initiate and manage ART before and after completion of NIMART training and mentorship, using a self-assessment tool (Appendix 3).

Methods

Study Design:

This study will be a retrospective before and after cross-sectional study, including patient folder reviews and self-*assessments* of NIMART nurses before and after mentorship.

Population & Sampling:

The study population will be all nurses trained through the MSF-led NIMART training and mentorship. The sample will be drawn from the following MSF-supported City Health clinics through convenience sampling, and the data will be collected through patient folder review for the study period of February 2011 through September 2012, before and after the intervention:

- Kuyasa
- Luvuyo
- Mayenzeke
- Mathew Goniwe
- Site B Youth
- Site C Youth
- Town 2
- Zakhele

A random sample comprised of 10 folders for the before period and 10 folders for the after period will be obtained for one of the nurse graduates operating within each of the city clinics. The nurse graduate to represent *each* clinic will also be randomly selected.

Study periods:

Retrospective data from patient folders will be collected for a before and after period for each nurse graduate. The before period will be determined based on the nurse's authorization date, using data from the 6-month period prior to participation in the NIMART programme. The after period will be the post-authorization date to present.

Measurement: (instrument, list, validity of instrument)

Data regarding nurse training and authorization will be obtained from MSF records. Measurement of the quality of ART initiation and management will be conducted using the two data collection instruments in Appendix 1 & 2. The proportion of completed fields for each section will be calculated for each tool and analysed accordingly. Comparison of patient characteristics of those initiated on ART by nurses and doctors will be undertaken using routine clinical data, captured from Appendix 2 for nurse initiated patients and from the clinic's electronic register for doctor-initiated patients.

- **Data Collection Instrument**

  A structured template will be used to collect data via Excel and Epidata computer software. Data from paper-based registers will be entered manually for each record, and information from electronic patient databases will be imported directly.

- **Data Validation**

  For a subset of patients, data collected from the paper and electronic registers will be verified against the primary source of information outlined in the table above.

- **Sources of data**

  This study will *utilize* routine clinical data from patient folders and clinic registers.

Pilot study:

The study will be piloted in November at Town 2 clinic, whereby 10 chart reviews will be conducted to ensure availability and collection of all relevant data.

Analysis plan

For analysis of Objectives 1 and 2, the data will be summarized using appropriate descriptive statistics: frequency and percentage for categorical variables. Objectives 3 and 4 will be analysed by calculating the proportion of completion for the ART Management and ART Initiation data collection forms within the 10 folders reviewed for each nurse graduate and conducting chi-squared tests (see Annex 1 & 2). Objective 5, comparing patient characteristics, will be undertaken by calculating medians and inter-quartile ranges for continuous data and proportions for categorical data. Chi-squared tests will be calculated where appropriate. Objective 6 will be summarized using descriptive statistics. The data will be analysed using STATA statistical software.

Ethics

Consent and data confidentiality:

The basic principles of the South African Medical Research Council will be upheld, which include autonomy, beneficence, non-maleficence and justice (Medical Research Council of South Africa, 2000:24). Routine sources of data will be used from within each clinic, thus consent will not be obtained from either the individual patients or the nurse participants. The data to be collected is similar to the data reviewed during routine patient folder checks for quality control, and the nurses are aware of others accessing this information regarding their performance.

All data collected will be securely stored; paper based records will be kept in a locked device with restricted access, and electronic data will be password protected and only be available to the MSF researcher and one assistant capturing the data. Results of the study will not report on individual nurse performance, ensuring confidentiality and that no harm will come to participants.

Specific participant benefits:

While the NIMART program graduates may benefit from potential insight gained into strong and weak aspects of service provision, there are no direct benefits for the nurse graduates included in this research.

Community participation and benefits:

The results of the research will be used to improve upon the current model for NIMART training and mentorship, which aims to provide high quality care for the Khayelitsha community.

Feedback and dissemination of results:

The study results will be submitted to a peer-reviewed journal for publication. Results will also be disseminated among both the nursing staff and management teams at each clinic involved in the research as well as to staff of the MSF NIMART program.

Implications for policy and practice:

Study results will be analysed to determine the success of MSF NIMART graduates as it relates to long-term management of ART in patients. Based on the analysis results, the remaining Khayelitsha clinics may be assessed to determine if results are congruous. Overall, the mentorship process will be adjusted as needed to ensure the highest possible quality of training and subsequent care.

Collaborative partnerships:

Staff at the selected clinics; the City of Cape Town Khayelitsha sub-district ART programme manager, Dr. Virginia de Azevedo; and the University of Cape Town.

Ethics approval:

Ethics approval for this study will be sought from the University of Cape Town Human Research Ethics Committee. Additionally, permission to conduct the research will be obtained from the Western Cape Provincial Research Committee, as well as the sub-district supervisor and facility manager for each selected clinic.

Logistics

Time Frame:

This study will be undertaken between September 2012 and February 2013. Data collection will occur between October and November 2012. The Gantt chart in Figure 2 outlines the timeline for conducting the necessary tasks related to the research.

Figure 2. Research timeline

Task	Description	Month	September				October				November				December				January				February			
		Week	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
1	**Protocol Completion**																									
1.1	Draft for internal review																									
1.2	Feedback for revision																									
1.3	Final draft completed																									
1.4	Submission to ethics committee																									
1.5	Ethics approval																									
2	**Data Collection**																									
2.1	Sites 1-3																									
2.2	Sites 4-6																									
2.3	Sites 7-9																									
3	**Data Analysis**																									
3.1	Data cleaning																									
3.2	Analysis																									
4	**Write up**																									
4.1	Draft manuscript																									
4.2	Feedback for revision																									
4.3	Draft dissertation to UCT supervisor																									
4.4	Finalize dissertation																									
5	**Submissions**																									
5.1	UCT submission																									
5.2	Journal submission																									
6	**Results dissemination**																									

Budget:

Study Cost	**Amount**
UCT Researcher for 3 weeks	N/A *
Computer for data collection	N/A *
Transport for data collection	GIK **
Stationery and printing materials	GIK **
Total	-

* The research will be conducted as a Master's level mini-dissertation. The student will serve as the principal investigator and use her personal computer, thus no additional funds are needed.

**Salaried MSF personnel and equipment will be available for the research as gifts-in-kind, thus no additional funds are needed.

References

Cameron, D. 2012. "Nurse-initiation and maintenance of patients on antiretroviral therapy: Are nurses in primary care clinics initiating ART after attending NIMART training?" *South African Medical Journal* 102 (2):98-100.

Department of Social Services and Poverty Alleviation. 2006. "The Population Register Update: Khayelitsha 2005." Survey, Western Cape.

Fairall, L., et al. 2010. "Task shifting of antiretroviral treatment from doctors to primary-care nurses in South Africa (STRETCH): a pragmatic, parallel, cluster-randomised trial." *The Lancet*. 380: 889–98.

Médecins Sans Frontières. 2011. "Khayelitsha 2001-2011. ACTIVITY REPORT: 10 years of HIV/TB care at primary health care level." Activity report, Cape Town.

Médecins Sans Frontières. 2012. Unpublished MSF programme data, Western Cape.

Médecins Sans Frontières, Khayelitsha. 2013. Clinical Mentorship Programme. Report and Toolkit, Khayelitsha.

Medical Research Council of South Africa. 2000. *Guidelines on Ethics for Medical Research: General Principles including research on children, vulnerable groups, international collaboration and epidemiology.* 4th ed. South Africa: MRCSA.

South African Department of Health. 2011. "National Strategic Plan for HIV and AIDS, STIs and TB, 2012-2016." Strategic Plan, South Africa.

UNAIDS, WHO. *UNAIDS Report on the global AIDS epidemic 2010.* UNAIDS Geneva, 2010.

Western Cape's HIV&AIDS, STI and TB Directorate. 2012. "Framework for Nurse Initiating and Management of Antiretroviral Therapy: Criteria of Mentors in NIMART." Circular, Cape Town.

Zwarenstein, M., et al. 2011. "Outreach education for integration of HIV/AIDS care, antiretroviral treatment, and tuberculosis care in primary care clinics in South Africa: PALSA PLUS pragmatic cluster randomised trial." *BMJ: British Medical Journal*. 342.

Part B: Structured Literature Review

LITERATURE REVIEW

Objectives of Literature Review

A review of existing literature was conducted in order to provide context for the subsequent mini-dissertation entitled, "Clinical Mentorship of Nurse-Initiated Antiretroviral Therapy in Khayelitsha, South Africa: A Quality of Care Assessment". The objectives of the literature review include examination of task shifting trends globally, exploration of strengths and weaknesses related to nurse-initiated antiretroviral therapy and clinical mentorship and identification of potential gaps in the literature on the topic.

Literature Search Strategy

The search strategy for the literature review focused on articles and documents addressing topics related to nurse-initiation of antiretroviral therapy in low-resource settings. The following terms were included: nurse-initiated ART, nurse-managed ART, task shifting, ART in low-resource settings, ART in low-income settings and clinical mentorship. The terms were searched within online databases such as EBSCOhost, PubMed and BioMed Central via MEDLINE as well as the Cochrane Central Register of Controlled Trials.

When conducting the literature search, there was no preference given to study design. Those ranging from cross-sectional studies to randomized control trials were included, and quantitative and qualitative research was considered for this literature review. There were no exclusions based on date of publication; however, for studies with multiple publications the most current articles were selected for inclusion.

The selected studies were included for their relevance to the topic of nurse initiation and management of antiretroviral therapy (NIMART), as well as to the provision of healthcare in resource-limited settings. The initial search for studies on NIMART yielded limited results, but

extending the search to include task shifting provided a wider array of literature. Published, peer-reviewed studies as well as "grey" literature such as policy documents and reports were included. Only literature written in English was selected.

Interpretation of Literature

Background

Worldwide, there are more than 34 million people infected with HIV; however, only approximately six million are actually accessing antiretroviral therapy (ART) (UNAIDS, 2011). It is believed by many that if every HIV-infected individual could learn their HIV status, engage with the health care system, initiate ART as appropriate and practice evidence-based preventive health measures, the world could potentially be free of the HIV burden within generations (Doshi, Del Rio & Marconi, 2011:48). With this in mind, the Millennium Development Goals set out to achieve universal access to treatment for HIV & AIDS for all those who need it by the year 2010 (Wagstaff & Claeson, 2004). Although complete universal access was not achieved by 2010, many countries accepted this challenge and put policies in place to help make universal access to ART a reality.

For South Africa, one of the countries most severely affected by the AIDS pandemic, the call to action was clear. Facing the highest number of HIV infections in the world, on December 1, 2009, World AIDS Day, President Zuma made a declaration that access to ART would be increased to ensure access to treatment for all people in need. Additionally, the SA President later launched a national HIV counselling and testing (HCT) campaign to test 15 million people and screen them for TB by June 2011, sending a message to the rest of the world for a new beginning in South Africa's fight against its HIV & AIDS burden (Pillay, White & McCormick, 2012).

To combat a large HIV burden while addressing the unrealistic human resource constraints created by the previous doctor-led model for ART delivery, the South African government chose to implement a nurse-driven model that decentralized the administration of ART in all districts. Specific

guidelines for clinical mentorship of nurses were released in early 2011, which suggested that other countries should implement similar guidelines (NDOH, 2011). Under this new model of nurse-initiated and managed ART (NIMART), trained nurses would now be responsible for initiating patients onto ART and their continued ART management and treatment. As with any new initiative there are advantages and disadvantages, and South Africa's experience with this model to date has left some not completely on board. Limitations to human resource capacity, infrastructure, drug supplies and clinical mentorship for newly trained nurses have all contributed to inefficiencies in the system, and the need for further research has been realized (UNAIDS, 2010).

Task Shifting for ART Management

Due to the increasing demands on the South African health system, alternative methods for managing the care and treatment of HIV & AIDS were deemed a priority for the country. The concept, however, of shifting health-related tasks to a cadre of lower level professionals is not a new idea. Dating back as far as the 1800s, French Officiers de Santé were an acknowledged group of non-physician health care workers tasked with caring for the population. In the mid-nineties, "barefoot doctors" served as a cadre of community health workers in China that helped improve access for rural citizens, and throughout Africa, non-physician clinicians have filled various roles within the health system for decades. The concept of task shifting can cover a wide range of areas, defined by the World Health Organization (WHO) as the "rational redistribution of tasks among health workforce teams, whereby specific tasks are moved, where appropriate, from highly qualified health workers to health workers with shorter training and fewer qualifications in order to make more efficient use of the available human resources for health"(WHO, 2008). Even for ART management, specifically, there exists many approaches to maximizing human resources.

A systematic review conducted in 2010 on task shifting for HIV care and treatment in Africa included 25 original articles from 10 different countries. The most common intervention studied was the delegation of tasks from doctors to nurses and other non-physicians. Overall findings concluded that

task shifting is an effective strategy for combating shortages in human resources for health in HIV care and treatment (Callaghan, Ford & Schneider, 2010).

Specifically, the CIPRA-SA randomized non-inferiority trial, conducted in South Africa, found nurse-monitored ART to be non-inferior to doctor-monitored therapy. The trial took place from February 2005 – January 2009, providing robust results in favour of task shifting to appropriately trained nurses (Sanne et al., 2010). Another South African study followed doctor-initiated patients that were down-referred to a primary care facility managed by nurses, starting in February 2008 through January 2009. Findings from this study revealed that twelve-month outcomes of stable ART patients were as good as and, in some cases, better than those patients that were maintained under hospital-based ART care (Long et al., 2011).

Other African countries, such as Mozambique, have adopted a modified approach of task shifting for HIV care, whereby the role of nurses was to stage patients and conduct other preparatory clinical tasks while the initiation of ART remained a responsibility of physicians. Successful staging done by the nurses allowed more time for the physicians to focus on ART initiation. However, it should be noted that the number of patients initiated on ART did not have a significant increase, as was the case for some models that included nurse-managed ART (Assan et al., 2008). A similar approach to HIV-related task shifting was adopted in Zambia in 2009. Non-physician clinicians were utilized to manage initial patient requirements for ART, and clinicians were consulted only for complex patients. Quality assessments of clinical care quality indicators demonstrated general improvements in patient chart completion despite rapidly growing patient volumes (Morris et al., 2009). Additionally, a controlled prospective study in Swaziland compared nurse-led primary care for ART with the usual hospital care, revealing that patients were less likely to miss an appointment and more likely to be satisfied with staff's ability to manage their condition under the primary care based treatment (Humphreys et al., 2010). Further supporting this notion, patient outcomes in a 2011 South African cohort study for stable patients down-referred to a nurse-led primary healthcare clinic

for ART care and treatment were equal, if not better, than outcomes of doctor-managed ART sites (Brennan et al., 2011). However, it should be noted that it is difficult to adequately adjust for the fact that healthier patients are both more likely to be down-referred and to have better outcomes.

Clinical Mentorship

With the onset of task shifting in a clinical setting, consideration of the model for training the transitioning workforce becomes important. From a review of 82 research abstracts, Stewart and Krueger (1996) were able to identify six essential attributes of mentoring: teaching-learning process, reciprocal role, career development relationship, knowledge differential between participants, duration of several years and resonance. Specifically for nurse training, a shift can be seen from early nursing literature in the 1970's into the late 1990's when an emphasis on mentorships began to emerge. These mentorship programs varied in approach, some including peer support and role modelling, but typical programs centred on an "intense, personal, and concentrated relationship with one or more experts with the aim of professional development" (Byrne & Keefe, 2002). Esper (1995) made recommendations for the mentoring of nurses that are making specialty transitions. Horizontal peer mentoring strategies appear to be a motivating factor in nursing (Hall, 1998), suggesting these models could supplement the traditional vertical models of training hierarchy. Such strategies have subsequently been introduced as a hybrid "training forward" model whereby successful trainees in turn help mentor new nurses trainees (Byrne & Keefe, 2002). Many NIMART programs have now incorporated this training forward concept into their mentorship structure (Fairall et al., 2012).

NIMART in resource-limited settings

For some regions the human resource constraints facing a country's healthcare system led to consideration of nurse initiation of ART. One study in Malawi detailed a multi-levelled task shifting approach to patient initiations onto ART. The research spanned 8 years, from 2003-2009, as ART

initiations were transitioned from the responsibility of doctors to clinical officers and eventually to nurses. The findings provide the feasibility of universal access to life-saving ART treatment is can be achieved and sustained in resource limited settings through shifting of tasks to medical assistants and nurses (Bemelmans et al., 2010).

In South Africa, as early as 2006, Médecins Sans Frontières was supporting a nurse-initiated program to deliver decentralized HIV services and community support. The project was able to achieve 95% coverage in the rural area of Lusikisiki, with approximately 2,200 individuals on ART in 2006 (Bedelu et al., 2007). Such encouraging results may have greatly influenced the subsequent rollout of NIMART.

A NIMART training model was later piloted on a large scale in South Africa. The Streamlining Tasks and Roles to Expand Treatment and Care for HIV (STRETCH) randomized trial in Free State Province, conducted by the Knowledge Translation Unit at the University of Cape Town Lung Institute from 2008-2010, revealed a patient mortality rate of 20% among those initiated onto ART by nurses compared to a 19% mortality rate among patients initiated by physicians, thereby reinforcing results that show nurse-managed ART to be non-inferior to doctor-monitored therapy. Discouraging results from this study were 1) a lack of improvement in patient time to ART initiation and 2) lack of a reduction in patient mortality (Fairall et al., 2012).

Another country with similarly urgent needs to address a large volume of patients requiring HIV & AIDS care and treatment was Rwanda. Results from piloting NIMART within three rural Rwandan health facilities revealed a high level of nurse compliance with national treatment guidelines. Additionally, findings from the NIMART pilot were able to show that patient outcomes, for retention, mortality and CD4 response, were comparable to those from the national treatment program of Rwanda (Shumbusho et al., 2009). Another 2008 study conducted in Rwanda focused on assessing the potential time saving aspects of NIMART. According to Chung et al, nearly 45 minutes

of physician time can be saved for every one-hour worked by a prescribing nurse under the NIMART task shifting structure. These findings resulted in adoption of a NIMART program by the Rwandan Ministry of Health (Chung et al., 2008).

These findings mentioned above, make for strong arguments in favour of programs such as NIMART for enhancing HIV & AIDS care and treatment access. In fact, in 2008, the WHO released a new set of guidelines and recommendations on task shifting that assigned tasks related to ART initiation and management under the purview of nurses as well as doctors (WHO, 2008). Despite all this, there is still debate over whether nurse-initiation of ART is sustainable.

In a December 2012 Lancet article, Naranbhai et al. contested the results of the STRETCH trial, claiming that "the findings show suboptimal retention and virological suppression rates" and provide "no evidence of the long-term effectiveness and sustainability of task-shifting" (Naranbhai et al., 2012). However, the authors of the STRETCH trial published a rebuttal, arguing that the studies were not designed to do that. Instead, the trial proved feasibility (Bachmann & Fairall, 2012). The current debate has sparked research interest in the area. A Cochrane review is planned that will examine literature on task shifting from doctors to non-doctors for initiation and maintenance of HIV/AIDS treatment (Kredo et al., 2012).

Considering the current debate, finding the correct balance in human resource training, management and support to ensure quality care must now be a key priority for provision of ART and overall program implementation. Based on research in Cameroon of Yakam et al., the introduction of new actors amidst complex layers of human resources constraints creates role conflicts and often confusion and/or frustration. The hierarchy and interactions between actors at each level can potentially hinder successful implementation (Tanthchou & Gruenais, 2009). Thus, it becomes even more important to evaluate the results of task shifting for ART care and treatment.

NIMART evaluation

In South Africa, with the introduction of NIMART programs throughout the country comes a mandate to evaluate the existing programs in order to ensure delivery of quality care and identify room for improvement of the program. Not only is there a need to evaluate NIMART programs, but the model for clinical mentorship must also be considered. Organizations providing NIMART training sessions for nurses that qualify for the program have undertaken the responsibility to measure effectiveness of the training provided. For instance, the Knowledge Translation Unit (KTU) of the University of Cape Town Lung Institute, has conducted various studies in addition to the STRETCH trial, that were aimed at ascertaining nurse graduate impressions from the training as well as confidence levels in ART initiation (Georgeu et al., 2012). In 2008, the KTU conducted a process evaluation to document training procedures, explore the perceived value of the targeted training manual devised by the KTU and compare KTU's training approach against the provincial training model (Stein et al.). Stein et al. note that the model's inclusion of training for all on-site nurses, as opposed to the common model, which trains ART nurses only, was seen to better facilitate integration of AIDS care within the clinic context. The overall findings from the evaluation suggest that on-going managerial review of infrastructural and system-level changes is a necessary component of implementation (Stein et al., 2008).

A Tanzanian study by Kurowski recommends that productivity in terms of staff performance and employee supervision serve as a starting point for addressing some of the human resource constraints in low-income settings (Kurowski, 2007).For South Africa, productivity of nurse graduates was once a point of contention. A report from the National Department of Health of South Africa (NDOH) indicated poor performance towards ART initiation indicators conducted by NIMART nurse graduates in each province, reporting rates for nurse graduates actually initiating at less than 50% in 5 provinces, with the lowest performing province at only 8% (Stender, 2011). However, further research from a 2012 cross-sectional study by Cameron et al revealed that 62% the nurses surveyed

(79/126) had started initiating new adult patients on ART. The main barrier to initiation for this evaluation was allocation to other tasks in the clinic as a result of staff shortages (Cameron et al., 2012). Reiterating the need for continuous evaluation, another Mozambican study resulted in suspension of the country's in-service ART training for *tecnicos de medicina* (a position with a higher certification than nurse but not authorized clinicians) due to poor evaluation findings for quality of care. The Mozambican Ministry of Health subsequently defined new clinical guidelines, revised scopes of work and initiated a nationwide re-training and clinical mentoring program for these health professionals, but further research is required to define clinically effective methods of health-worker training to support HIV/AIDS care in Mozambique and similarly resource-constrained environments (Brentlinger et al., 2010).

Gaps or Needs for Further Research

Outside of the STRETCH trial, there is little existing research that explores the performance of NIMART graduates as it relates to the clinical management and initiation of ART and the quality of care provided. Additionally, there is little data on the effectiveness of clinical mentorship programs (Workneh et al., 2013). As NIMART programs become more ubiquitous in low-resource settings, further research is needed to examine these aspects of nurse-driven ART treatment, long-term ART management and their related clinical mentorship. Such research will be able to inform training programs and ideally translate into an improved health system for HIV & AIDS care and treatment.

Literature Review References

Assan A, Mudender F, Brentlinger P, Vallejo J, Bacon O, Martinez P, Ghee A, Branigan E, Smith M., 2008.Task-shifting in Mozambique: evaluating antiretroviral therapy as newly implemented by mid-level health professionals. *AIDS 2008 - XVII International AIDS Conference*.

Bachmann, M.O. and Fairall, L., 2012. Sustainability of task-shifting for antiretroviral treatment–Authors' reply. *The Lancet,* 380(9857), pp. 1908.

Bedelu, M., Ford, N., Hilderbrand, K. and Reuter, H., 2007. Implementing antiretroviral therapy in rural communities: the Lusikisiki model of decentralized HIV/AIDS care. *Journal of Infectious Diseases,* 196(Supplement 3), pp. S464-S468.

Bemelmans, M., Van Den Akker, T., Ford, N., Zachariah, R., Harries, A., Schouten, E., Hermann, K., Mwagomba, B. and Massaquoi, M., 2010. Providing universal access to antiretroviral therapy in Thyolo, Malawi through task shifting and decentralization of HIV/AIDS care. *Tropical Medicine & International Health,* 15(12), pp. 1413-1420.

Brennan, A., Long, L., Maskew, M., Sanne, I., Jaffray, I., MacPhail, P., Fox, M. 2011. Outcomes of stable HIV-positive patients down-referred from a doctor-managed antiretroviral therapy clinic to a nurse-managed primary health clinic for monitoring and treatment. *AIDS*, 25(16), pp. 2027-2036.

Brentlinger, P.E., Assan, A., Mudender, F., Ghee, A.E., Torres, J.V., Martinez, P.M., Bacon, O., Bastos, R., Manuel, R. and Li, L.R., 2010. Task shifting in Mozambique: cross-sectional evaluation of non-physician clinicians' performance in HIV/AIDS care. *Human Resources for Health*, 8(1), pp. 23.

Byrne, M. & Keefe, M., 2002. Building Research Competence in Nursing Through Mentoring. *Journal of Nursing Scholarship*, 34(4):391-396.

Callaghan, M., Ford, N. and Schneider, H., 2010. A systematic review of task-shifting for HIV treatment and care in Africa. *Human Resources for Health*, 8(8).

Cameron, D., Gerber, A., Mbatha, M., Mutyabule, J. and Swart, H., 2012. Nurse initiation and maintenance of patients on antiretroviral therapy: Are nurses in primary care clinics initiating ART after attending NIMART training? *SAMJ: South African Medical Journal,* 102(2), pp. 98-100.

Chung, J. 2008. Quantification of Physician-time Saved in a Task Shifting Pilot Program in Rwanda. Paper presented at the HIV/AIDS Implementers' Meeting. 3-7 June 2008. Kampala.

Colvin, C.J., Fairall, L., Lewin, S., Georgeu, D., Zwarenstein, M., Bachmann, M., Uebel, K.E. and Bateman, E.D., 2010. Expanding access to ART in South Africa: the role of nurse initiated treatment. *SAMJ: South African Medical Journal,* 100(4), pp. 210-212.

Doshi, R.K., Del Rio, C. and Marconi, V.C., 2011. Social Determinants of HIV Health Care: A Tale of Two Cities, Understanding HIV/AIDS Management and Care - Pandemic Approaches in the 21st Century, Dr.FysonKasenga (Ed.), InTech, pp.33-58

Esper,P.S., 1995. Facing transition – nurse clinician to nurse educator. *Journal of Nursing Education*, 34(2):89-91.

Fairall, L., Bachmann, M.O., Lombard, C., Timmerman, V., Uebel, K., Zwarenstein, M., Boulle, A., Georgeu, D., Colvin, C.J. and Lewin, S., 2012. Task shifting of antiretroviral treatment from doctors to primary-care nurses in South Africa (STRETCH): a pragmatic, parallel, cluster-randomised trial. *The Lancet*, 380, pp.889-898.

Garone, D.B., Hilderbrand, K., Boulle, A.M., Coetzee, D., Goemaere, E., Van Cutsem, G. and Besada, D., 2011.Khayelitsha 2001-2011: 10 years of primary care HIV and TB programmes: review.

Georgeu, D., Colvin, C., Lewin, S., Fairall, L., Bachmann, M., Uebel, K., Zwarenstein, M., Draper, B. and Bateman, E., 2012. Implementing nurse-initiated and managed antiretroviral treatment

(NIMART) in South Africa: a qualitative process evaluation of the STRETCH trial. *Implementation Science,* 7(1), pp. 66.

Hall, L., 1998. Mentoring relationships of New Zealand nurses: Results of an empirical study. *Collegian*, 5(1):32-35.

Humphreys, C., Wright, J., Walley, J., Mamvura, C., Bailey, K., Ntshalintshali, S., West, R., Philip, A. 2010. Nurse led, primary care based antiretroviral treatment versus hospital care: a controlled prospective study in Swaziland. *BMC Health Services Research*, 10, pp. 299.

Kredo, T., Bateganya, M., Pienaar, E.D. and Adeniyi, F.B., 2012.Task shifting from doctors to non-doctors for initiation and maintenance of HIV/AIDS treatment. The Cochrane Library.

Kurowski, C., Wyss, K., Abdulla, S. and Mills, A., 2007. Scaling up priority health interventions in Tanzania: the human resources challenge. *Health policy and planning,* 22(3), pp. 113-127.

Long, L., Brennan, A., Fox, M.P., Ndibongo, B., Jaffray, I., Sanne, I. and Rosen, S., 2011. Treatment outcomes and cost-effectiveness of shifting management of stable ART patients to nurses in South Africa: an observational cohort. *PLoS medicine,* 8(7), pp. e1001055.

Mcpake, B. and Mensah, K., 2008. Task shifting in health care in resource-poor countries. *The Lancet,* 372(9642), pp. 870-871.

Morris, M.B., Chapula, B.T., Chi, B.H., Mwango, A., CHI, H.F., Mwanza, J., Manda, H., Bolton, C., Pankratz, D.S. and Stringer, J.S.A., 2009. Use of task-shifting to rapidly scale-up HIV treatment services: experiences from Lusaka, Zambia. *BMC Health Services Research,* 9(1), pp. 5.

Naranbhai, V., Karim, Q.A., Naidoo, K., Yende-Zuma, N. and Karim, S.S.A., 2012. Sustainability of task-shifting for antiretroviral treatment. *The Lancet,* 380(9857), pp. 1907-1908.

Stewart, B., & Krueger, L., 1996. An evolutionary concept analysis of mentoring in nursing. *Journal of Professional Nursing*, 12(5):311-321.

South African National Department of Health, 2011.Clinical Mentorship Manual for Integrated Services.

Pillay, Y., White, C. and McCormick, N., 2012. How times have changed-HIV and AIDS in South Africa in 2011. *SAMJ: South African Medical Journal,* 102(2), pp. 77-78.

Sanne, I., Orrell, C., Fox, M.P., Conradie, F., Ive, P., Zeinecker, J., Cornell, M., Heiberg, C., Ingram, C. and Panchia, R., 2010. Nurse versus doctor management of HIV-infected patients receiving antiretroviral therapy (CIPRA-SA): a randomised non-inferiority trial. *The Lancet,* 376(9734), pp. 33-40.

Shumbusho, F., Van Griensven, J., Lowrance, D., Turate, I., Weaver, M.A., Price, J. and Binagwaho, A., 2009. Task shifting for scale-up of HIV care: evaluation of nurse-centered antiretroviral treatment at rural health centres in Rwanda. *PLoS medicine,* 6(10), pp. e1000163.

Stein, J., Lewin, S., Fairall, L., Mayers, P., English, R., Bheekie, A., Bateman, E. and Zwarenstein, M., 2008. Building capacity for antiretroviral delivery in South Africa: A qualitative evaluation of the PALSA PLUS nurse training programme. *BMC Health Services Research,* 8(1), pp. 240.

Stender, S.C., 2011. *'NIMART', nurses, health systems.* HR stats, South African National Department of Health, JHPHIEGO.

Tantchou Yakam, J. and Gruenais, M.E., 2009. Involving new actors to achieve ART scaling-up: difficulties in an HIV/AIDS counselling and testing centre in Cameroon. *International nursing review,* 56(1), pp. 50-57.

Wagstaff, A. and Claeson, M., 2004. The Millennium Development Goals for health: rising to the challenges. World Bank Publications.

Webster, P.D., Sibanyoni, M., Malekutu, D., Mate, K.S., Venter, W.D.F., Barker, P.M. and Moleko, W., 2012. Using quality improvement to accelerate highly active antiretroviral treatment coverage in South Africa. *BMJ quality & safety,* 21(4), pp. 315-324.

WHO, 2008. Task shifting: rational redistribution of tasks among health workforce teams: global recommendations and guidelines. http://www.who.int/workforcealliance/knowledge/resources/taskshiftingguidelines/en/index.html (accessed March 24, 2012).

Part C: Journal “Ready” Manuscript

TITLE PAGE

Clinical Mentorship of Nurse-Initiated Antiretroviral Therapy in Khayelitsha, South Africa: A Quality of Care Assessment

Green, A.[1]

1 MPH, School of Public Health and Family Medicine, UCT

Correspondence:

Ann Green. Vanderbilt Institute for Global Health, 2525 West End Avenue, Suite 750, Nashville, TN 37203. Phone: 615-322-9374. Fax: 615-343-7797. annfordgreen@gmail.com

Conflicts of Interest and Source of Funding: There were no conflicts of interest for any of the authors involved in this manuscript. The MSF Operational Centre in Brussels funds all MSF operations in South Africa, including Khayelitsha.

Conferences: Abstract accepted as an oral poster presentation at the International AIDS Society Conference, 30 June– 3 July 2013, in Kuala Lumpur, Malaysia.

ABSTRACT

Introduction. To combat the AIDS epidemic and address constraints on the health system, the South African government implemented a nurse-driven model that decentralized administration of anti-retroviral treatment (ART) for HIV positive patients by introducing nurse initiated and managed ART (NIMART).

Methods. A before-after cross-sectional study was conducted on nurses completing mentorship from February 2011-September 2012. Routine clinical data from 229 patient folders and 21 self-assessment questionnaires was collected to determine the number of patients initiated on ART by nurses; quality of ART-management before-after mentorship; patient characteristics for doctor and nurse ART-initiations; and nurse self-assessments.

Results. Twenty-one nurses were authorized by one nurse mentor with one part-time medical officer's support, resulting in nurses initiating 77% of eligible patients. Improvements in ART management were found for drawing required bloods (91% vs 99%, p=0.03), assessing adherence (50% vs 78%, p<0.001) and WHO staging (63% vs 91%, p<0.001). Nurse ART initiation indicators were successfully completed 95-100% of the time for 11 of 16 indicators: clinical presentation; patient weight; baseline blood work (CD4, creatinine, haemoglobin); STI screening; WHO stage, correlating with medical history; medications prescribed appropriately; ART start date; and return date documented. Doctors initiated more patients with TB/HIV co-infection and Stage 3 and 4 disease than nurses. Nurse confidence improved for management of HIV-infected children and pregnant women, blood result interpretation, and long-term side effects.

Conclusions. NIMART training improves both nurse confidence and quality of care and appears to be an effective approach for freeing up doctors to manage patients with more advanced disease.

Key Words: nurse-initiated ART, nurse-managed ART, task shifting

INTRODUCTION

South Africa is one of the countries most severely affected by the AIDS pandemic, with an estimated 5.6 million people living with HIV & AIDS (PLWHA). As the incidence rate in the country has somewhat levelled off in recent years, management of the high prevalence of HIV positive individuals is a key issue to address. Consequently, South Africa has the largest antiretroviral programme in the world.[1] To address some of the constraints on the health system, the South African government implemented a nurse-driven model that decentralized the administration of anti-retroviral treatment (ART) for HIV positive patients.[2] Under this model of care, trained nurses initiate patients onto ART and continue management of their subsequent treatment. However, limitations to human resource capacity, infrastructure, drug supplies and clinical mentorship for newly trained nurses have all contributed to inefficiencies in the system.

Nurse-initiated and managed ART (NIMART) has been shown to be non-inferior to doctor-monitored therapy,[3] but there is little existing research that explores the performance of NIMART graduates in the clinical management of ART and the quality of care provided. According to a recent study of initiation rates for NIMART graduates within seven South African provinces, of the 126 trained nurses that were sampled, only 72 (62%) nurses proceeded to actually initiating patients onto ART.[4] The South African Department of Health has set a goal to have nurses initiating 85% of patients eligible for ART by 2016.[5] Under this new model of care, mentorship is a key factor in the success of NIMART graduates in independent ART initiations. This study aims to explore the quality of clinical care received by patients on ART managed by NIMART trained nurses and to assess the performance of NIMART graduates in the training and mentorship program led by Médecins Sans Frontières (MSF), operating in Khayelitsha, South Africa.

METHODS

This study was conducted in the South African township of Khayelitsha, a sub-district with an estimated population of approximately 500,000 inhabitants, located on the outskirts of Cape Town in Western Cape Province, South Africa.[6] The healthcare needs of township residents are served through 8 primary health clinics, three community health centres and a recently developed district hospital.

Study design -

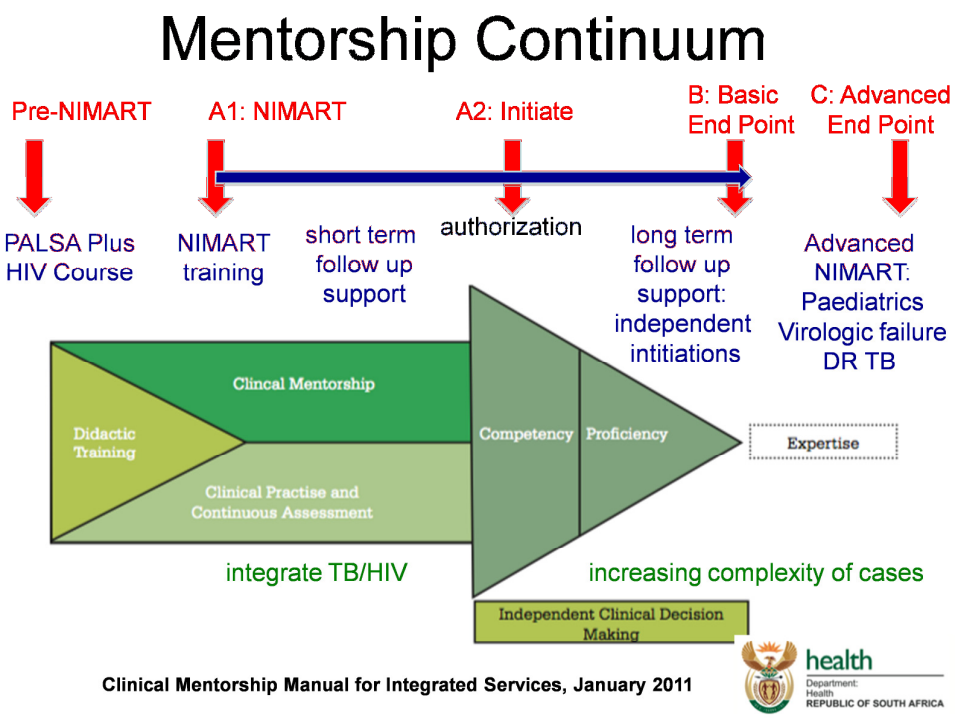
This was a before-after cross-sectional study involving patient folder reviews of clinic ART stationery and self-assessments completed by NIMART nurses before and after mentorship was undertaken.

Study setting -

As of 2010, Khayelitsha's HIV burden is one of the largest in the country with an antenatal HIV prevalence of 26%.[7] Following the South African government's 2009 mandate for ART access, the programme expanded rapidly with all 11 clinics providing access to ART by 2011. The subsequent 2011 government mandate for nurse-driven ART initiation was a recent contributing factor to the increase in patients enrolled onto therapy.

Since February 2011, MSF has been implementing a NIMART training and mentorship program for nurses in Khayelitsha to become accredited to initiate ART, though it should be noted that intensive support for nurse training had been provided since 2001. To date, 40 nurses have been mentored through the MSF NIMART programme, which introduced one full time nurse mentor and one part time medical officer as mentors. The mentorship programme follows the nurse-based, doctor-supported ART service model promoted by the Western Cape's Provincial HIV&AIDS, STI, and TB Directorate as depicted in Figure 1 below.[8]

Figure 1. NIMART Clinical Mentorship Model for Integrated Services



This study aimed to measure the quality of nurses' clinical management of patients on ART and the quality of nurse initiation of patients onto ART, compare patient characteristics for those initiated on ART by doctors and nurses and assess the levels of confidence in performing HIV-related tasks for nurse graduates in Khayelitsha City Health primary health care clinics. The study only assessed these measures in the City Health clinics and did not include the Khayelitsha community health centres.

Study population -

All nurses trained through the MSF-led NIMART training and mentorship were included in the study population. A random sample of these nurses were selected, one from each of the City Health clinics.

Data collection -

The study sought to report on the number and proportion of all patient initiations that were initiated by NIMART mentored nurses as well as the number of nurses completing the NIMART

mentorship program and receiving authorization to prescribe ART. Data for these objectives were collected from programmatic records obtained by MSF Khayelitsha. Additionally, data were collected and assessed on four levels of analysis: quality of nurse ART management before and after NIMART training; quality of nurse ART initiations; comparison of patient characteristics for doctor and nurse ART initiations; and comparison of self-assessment data before and after NIMART training. Data for assessing the quality of nurse ART management before and after NIMART training, the quality of nurse ART initiations and data for comparison of patient characteristics for doctor ART initiations were collected through patient folder review. Data for assessing the level of nurse confidence was collected from a self-assessment survey that captured each nurse's perception of individual confidence on a level of 1-5 (1 = not very confident; 2 = somewhat confident; 3 = confident; 4 = very confident; 5 = confident if using manual).

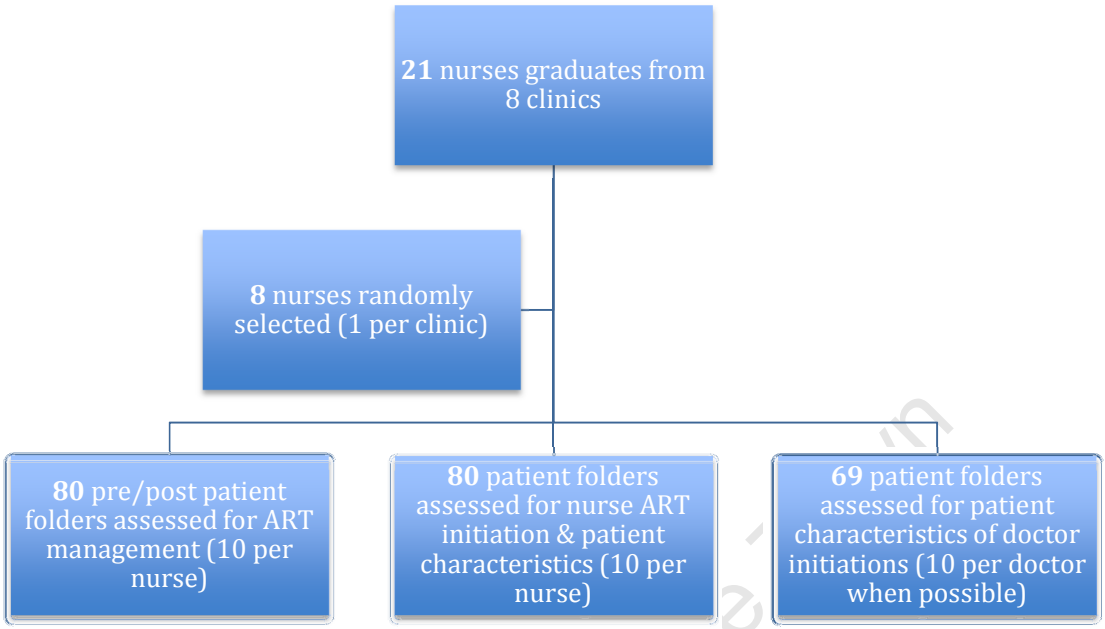
Study period -

The study period for reporting the number and proportion of NIMART nurse patient initiations and the number of nurses completing the NIMART mentorship program spans the mentorship programme from February 2011 to September 2012. The period for measuring quality of nurse ART management prior to mentorship was determined based on the nurse's authorization date, using data from February 2011 through the start date of each nurse's participation in the NIMART program, the "before period". The period for assessing ART management after mentorship was defined as the post-authorization date to September 2012, the "after period". For measuring the quality of nurse initiations and for collecting patient characteristics of nurse and doctor ART initiations, the study period was based on nurse authorization date through September 2012. The self-assessment questionnaires were completed at the start date of the NIMART mentorship programme training, prior to conducting the training. The same questionnaire was then repeated at the final date of the respective training.

Sample selection -

For data on quality of nurse ART management, a nurse graduate was randomly selected from each of the Khayelitsha city clinics using a computer-generated program from random.org that includes a list randomizer function.[9] Patient folders were then randomly sampled for the selected nurses, identifying ten folders for the before period and ten folders for the after period. Eighty patient folders in total were reviewed for the before and after periods assessing quality of nurse ART management. ART visit dates within patient folders were selected from a randomly generated list of visit dates within the study period. A second random sample of nurses was selected for assessing nurse graduate ART initiation, and an additional 80 patient folders were randomly selected and reviewed for ART initiations by the selected nurse graduates. ART initiations by doctors were assessed by randomly selecting a total of 69 patient folders from a sampling frame of all doctor-led ART initiations at each clinic during the study period, again utilizing random.org.[9] Figure 2, below, depicts a flow diagram for the sample selection process. Data for assessing nurses' confidence to initiate and manage ART before and after completion of NIMART training and mentorship was collected using a self-assessment tool designed by MSF.

Figure 2. Sample selection flow diagram



Data analysis -

For analysis of the number and proportion of all patient initiations by NIMART mentored nurses and the number of nurses completing the NIMART mentorship program and receiving authorization to prescribe ART, the data were summarized using appropriate descriptive statistics: frequency and percentage for categorical variables. The quality of nurse ART management and ART initiations were analysed by calculating the proportion of completion for the ART management and ART initiation indicators selected for the study within the 10 folders reviewed for each nurse graduate and conducting chi-squared tests. The indicators assessed for ART management and initiation include variables related to necessary blood work, patient counselling, medication and side effect management and adherence. Patient characteristics of both doctor and nurse ART initiations were analysed by calculating medians and inter-quartile ranges for continuous data and proportions for categorical data. Chi-squared tests were calculated where appropriate. Self-assessment data was summarized using descriptive statistics and rank sum tests. Where applicable the data was analysed using STATA statistical software version 12.[10]

RESULTS

There were 21 nurse graduates from the NIMART mentorship program during the study period. By September 2012, 77% (173/223) of ART initiations in Khayelitsha clinics included in the study were conducted by nurse graduates. Three graduates resigned from their position during the study period. Twenty-one self-assessments were conducted before the NIMART mentorship program and again after completion of the program, two for each nurse graduate. Two nurses' before and after surveys for self-assessment analysis were excluded due to differing survey formats in the before and after period.

In terms of assessing the quality of nurse ART management following the NIMART mentorship program, there were significant improvements in the collection of required bloods, patient HIV staging and nurse adherence assessment and documentation. See Table 1 - Nurse ART Management in Khayelitsha Clinics. Of the 80 patient folders, one patient out of 80 was referred to a doctor in the before period and two patients out of 80 in the after period.

TABLE 1. Quality of Nurse ART Management in Khayelitsha Clinics	n = 80 patient clinical folders reviewed				
Indicator	Before	%	After	%	p-value
ART date recorded	80	100	79	98.8	0.316
Last viral load > 400	4/54*	7.41	3/65*	4.6	0.519
Treatment plan documented for patients with viral load > 400	2/4*	50	1/3*	33.3	0.659
Creatinine clearance recorded	13/74*	17.56	10/65*	15.4	0.73
Documented result of most recent bloods	74	92.5	75	93.8	0.755
Last required bloods drawn	73	91.25	79	98.8	**0.03**
TB screen done	63/76*	82.89	68/74*	91.9	0.098
STI screen done	71	88.75	75	93.8	0.263
Family planning offered	33/56*	58.93	37/55*	67.3	0.362
Pap smear recorded /referenced	4/60*	6.67	6/57*	10.5	0.455
Clinical presentation entered	80	100	80	100	
Problem list entered	33	41.25	36	45	0.632
Adherence assessed and documented	40	50	62	77.5	**< 0.001**
Stage entered	50	62.5	73	91.3	**< 0.001**
Stage correlates with known medical history	45	88	58	79.5	0.119
Treatment plan documented	58	72.5	66	82.5	0.13
Referred to doctor	1	1.25	2	2.5	0.56
Medication entered	80	100	80	100	
ARV dose entered correctly	64	80	64	80	
Cotrimoxazole prescribed	12	15	8	10	0.339
Should Cotrimoxazole have been prescribed	21	26.25	15	18.8	0.256

* Number of patients where particular indicator is applicable.

Analysis of nurse-managed ART initiation revealed that nurse graduates documented baseline CD4 count, calculated and entered patient HIV stage in accordance with patient medical history, and documented the ART initiation date and the prescribed medication 100% of the time. See Table 2 - Quality of Nurse ART Initiations in Khayelitsha Clinics. In >90% of records reviewed, nurse graduates documented patient weight, past medical history, prior ART history and haemoglobin; screened for sexually transmitted infections and documented patient treatment plan and return visit date. Patient pap smear data was only recorded in 14% of female records reviewed. Cotrimoxazole was prescribed in 76% of the 51% of all patients requiring it.

TABLE 2. Quality of Nurse ART Initiations in Khayelitsha Clinics n=80

	Number recorded	%
Patient weight documented	76	**95**
Patient BMI documented	60	75
Past medical history documented	73	91.3
Prior ART/history documented	73	91.3
If yes, was patient discussed with doctor	0	
Documented as 'No ART history'	33	41.3
Baseline CD4 documented	80	**100**
Creatinine documented	79	**98.8**
Creatinine clearance (CrCl) documented	43	53.8
If CrCl <50, was patient discussed with doctor	0	
Not applicable	77	41.3
If CrCl <50 and discussed by doctor, treatment documented	0	
Haemoglobin documented	78	**97.5**
Alanine aminotransferase (ALT) documented	70	87.5
If ALT >100, was patient referred to doctor	0	
ART initiation date recorded	80	**100**
TB screen done	61	76.3
On treatment	17	21.3
Investigation pending	1	1.3
STI screen done	76	**95**
Eligible for family planning	59	73.8
Family planning offered	42	71.2
Eligible for pap smear	59	73.8
Pap smear date recorded or referenced	8	13.6
Clinical presentation entered	80	**100**
Problem list entered	62	77.5
Stage entered	80	**100**
Stage correlates with known medical history	80	**100**
Treatment plan entered	74	92.5
Was patient seen or discussed with doctor in prior month	19	23.8
Medication entered	80	**100**
ARV dose entered correctly	66	82.5
Should Cotrimoxazole have been prescribed	41	51.3
Cotrimoxazole prescribed	30	37.5
Return date documented	79	**98.8**

Patient characteristics among those ART-initiated by doctor vs. nurse reveal that doctors are initiating patients with more advanced disease in Khayelitsha clinics. See Table 3 - Patient Characteristics. The median weight, body mass index and haemoglobin levels were lower and median alanine aminotransferase (ALT) as well as proportion with TB and WHO Stage 3 and 4 diseases was higher.

TABLE 3. Patient Characteristics	n= 80	n= 69	
	Nurse	Doctor	p-value
Age (median)	28 (IQR 24-35)	31 (IQR 24-39)	0.5654
Gender			0.352
Male	20 (25%)	22 (28%)	
Female	60 (75%)	47 (62%)	
Weight (median)	66 (IQR 61-78)	59 (IQR 52-70)	**<0.001**
Weight not recorded	3	0	
Infants	0	2	
BMI (median)	26 (IQR 23-31)	22 (IQR 19-26)	**0.0014**
Weight not recorded	3	0	
BMI not recorded	19	25	
Infants	0	2	
Creatinine (median)	62 (IQR 50-73)	66 (IQR 51-81)	0.2161
missing	1	2	
Creatinine clearance (median)	103 (IQR 80.5-125.5)	120 (IQR 71.5-154)	0.5926
missing	38	41	
Haemoglobin (median)	12 (IQR 11-13)	11 (IQR 9-13)	0.0463
missing	2	8	
Alanine aminotransferase (median)	18 (IQR 14-24)	26 (IQR 19-38)	**<0.001**
missing	11	6	
TB status			**<0.001**
On TB treatment	17	27	
Screen positive	0	0	
Screened negative	61	30	
Investigation Pending	1	1	
Not Screened	1	11	
Pregnant	3	1	0.453
WHO stage			**<0.001**
Stage 1	42	11	
Stage 2	11	13	
Stage 3	22	28	
Stage 4	5	12	
Missing Stage	0	5	

Self-assessment data revealed a significant increase in nurse confidence level for nearly all clinical tasks measured. Nurse confidence had a highly significant increase for management of paediatrics, body mass index calculation, creatinine clearance, prescribing with concurrent illness, side effect diagnosis and when to refer, HIV positive patients wanting to become pregnant and non-drug management of post-exposure prophylaxis. See Table 4 - Nurse Graduate Self-assessment.

The majority of uncertainty in nurse graduates prior to the NIMART mentorship program related to the care and treatment of children both before starting ARVs and ART initiation. Following the

mentorship program, cardiac failure, nurse understanding the ARV register and procedures for lactate testing were the areas with the lowest scores for confidence among the nurse graduates. TB screening, diagnosis and management in adults; Cotrimoxazole prescription in adults; and management of the Department of Health first line regimen in adults were areas in which there was not a significant increase in confidence level.

TABLE 4. Nurse Graduate Self-assessment	n=21	n=21	
	Pre	Post	
	mean score	mean score	p-value
Section 1: Baseline Knowledge			
Modes of transmission - adults	3.3	3.8	0.0083
Modes of transmission - children	2.905	3.737	0.0060
Clinical course - adults	2.619	3.7	0.0016
Clinical course - children	2.278	3.5	0.0004
Signs and symptoms - adults	3.19	3.905	0.0014
Signs and symptoms - children	2.6	3.65	0.0043
Use of manuals – positive prevention & HIV	3.25	3.75	0.0247
Use of Department of Health stationery	2.8	3.789	0.0003
Core differences between adults & children	2.263	3.524	0.0013
Section 2: Before ARVs			
HIV counselling and testing - adults	3.25	3.85	0.0008
HIV counselling and testing - children	2.111	3.714	<0.0001
Diagnosis - adults	3	3.8	0.0003
Diagnosis - children	2	3.55	<0.0001
Staging - adults	3.3	3.905	0.0053
Staging - children	1.8	3.619	<0.0001
Body Mass Index calculation and management	3.2	3.952	<0.0001
Paediatric weight chart and management	1.789	3.474	<0.0001
TB screening - adults	3.476	3.857	0.1279
TB screening - children	2.476	3.476	0.0046
Pap smears and HIV	2.95	3.8	0.0007
Common opportunistic infections - adults	2.952	3.762	0.0013
Common opportunistic infections - children	2.1	3.381	0.0003
TB diagnosis and management - adults	3.05	3.571	0.0799
Drug side effects	2.905	3.824	0.0187
Cotrimoxazole use - adults	3.429	3.714	0.1654
Cotrimoxazole use - children	2.048	3.81	<0.0001
Section 3: Starting ARVs			
Eligibility criteria to start - adults	2.857	3.667	0.0029
Eligibility criteria to start - children	1.65	3.429	<0.0001
Fast-tracking criteria	2.762	3.75	0.0001
Blood result interpretation - adults	2.5	3.762	0.0003
Working with creatinine clearance	2.1	3.905	<0.0001
Individual ART contra-indications	2.35	3.81	0.0004
Pre-start adherence counseling	2.55	3.7	0.0003
Department of Health 1st line regimen - adults (ARVs, doses, side effects)	3	3.714	0.0870
Department of Health 1st line regimen - children (ARVs, doses, side effects)	1.65	3.476	<0.0001

Prescribing w concurrent illnesses - TB, epilepsy, hypertension, diabetes	1.857	3.75	<0.0001
Normal course on ARVs	2.737	3.905	<0.0001
Side effects and their management:			
Skin, haematology, liver, kidney, psychiatric	2.143	3.6	0.0010
Recognition of side effects	2.667	3.429	0.0530
Understanding IRIS	2.35	3.571	0.0031
Long-term side effects	2.053	3.667	0.0002
Failing regimen - warning signs	2.4	3.667	0.0002
Diagnosis - clinical, immunological, virological	1.842	3.619	<0.0001
When to refer	2.333	3.857	<0.0001
Section 4: HIV & Pregnancy			
Family planning	3.095	3.762	0.0012
Wanting to fall pregnant	2.19	3.9	<0.0001
During pregnancy	2.571	3.7144	0.0005
After pregnancy - mother	2.35	3.762	0.0003
After pregnancy - child	2.1	3.5	0.0006
Section 5: Post-exposure Prophylaxis			
Non-drug management and administration	2.05	3.762	<0.0001
Drug regimen and indications	2.15	3.65	0.0006
Section 6: General			
Management of weight loss	2.7	3.571	0.0066
Routine clinical examination	2.438	3.667	0.0001
Cardiac failure	1.667	3.118	0.0005
Enlarged liver	1.81	3.313	0.0009
Neck stiffness	2.15	3.5	0.0009
Procedures for lactate testing	1.571	3.2	0.0001
Understanding the register	2.111	3.167	0.0186

DISCUSSION

The percentage of nurses initiating ART in Khayelitsha (77%) is an encouraging step toward reaching the 2016 goal of 85% nurse initiations. This study found that the NIMART mentorship program appears to have improved certain aspects of the quality of ART care provided by nurses as well as their self-assessed confidence in knowledge and management of HIV. The quality of nurse initiation of patients onto ART following training was satisfactory, and doctors were able to focus on patients with more advanced disease.

The study findings complement previous NIMART studies conducted in sub-Saharan Africa, whereby nurse ART management and initiation are recommended as effective strategies for addressing HIV care and treatment in low-resource settings.[11] However, this study has shown a higher percentage of nurse initiations than other studies.[4] When considering the rate that nurse graduates of the NIMART mentorship program are initiating patients requiring ART initiations, it is important to note this is a relatively small percentage of the total nurses working in City Health. This demonstrates the capabilities of as well as the potential strain on these nurse graduates. While three nurse graduates resigned following the nurse mentorship program, one of those nurses resigned to take a higher post as a nurse mentor for the TB/HIV Care Association in Khayelitsha.

Quality of Nurse ART Management

Actions consistently performed by nurse graduates –

The nurse graduates successfully completed a variety of ART management indicators both before and after the mentorship program. Documentation of ART start date, blood results, STI screening, clinical presentation and prescribed medications were all consistently managed appropriately, which is indicative of the level of experience in managing ART prior to participation in the nurse mentorship programme.

Actions that need improvement -

The documentation and incorporation of pap-smears into services rendered for female patients was the lowest performance indicator for assessing the quality of nurse ART management. With increasing levels of cervical cancer throughout South Africa, improvement in this area must be addressed in future nurse trainings.[12] TB screening rates for nurse ART management were also considered low, as TB screening among nurse graduates managing ART should be 100%. While the TB screening rates did improve from 83% to 92%, there is room for improvement in the mentorship program, as low TB screening is likely to lead to adverse patient outcomes.

Also having a potentially adverse affect on patient outcomes is the low calculation rates of creatinine clearance (CrCl) for follow up monitoring among nurse graduates. However, the low numbers may be due to the fact that the ART stationery did not have a specific field for entering CrCl. It is possible that there is missing data with CrCl being calculated, but not recorded due to absence of a specific field in the stationery. Revised ART stationery introduced into all Khayelitsha clinics after the study period specifically prompts for CrCl, which may help encourage calculation and recording of this indicator.

Also among the low performing indicators was the ratio of Cotrimoxazole (Bactrim) being prescribed in patients that were eligible. Prescription of Cotrimoxazole is an effective, affordable method for strengthening the immune system of HIV+ patients, thus it is imperative that the mentorship program place a strong focus on improving these rates moving forward.

Additionally, for nurse ART management, there are low numbers of patients being referred to doctors within the clinics in the study. However, this does not imply that nurse graduates are not appropriately seeking professional guidance from doctors. The low proportion of referral to doctor may result from the fact that the patients initiated by nurses are characteristically not as ill. The low level of doctors present within City clinics may contribute to the low levels of referrals. It is also possible that consultation with doctors is not documented in patient folders.

Actions that improved with mentorship –

Following completion of the NIMART mentorship program, there were improvements in indicators for drawing required bloods, assessing adherence and WHO staging. While the significant improvement in assessing adherence is encouraging (77.5%) there is still substantial room for improvement. Monitoring of patient adherence is crucial considering it is a key barrier to keeping patients enrolled in treatment, and it will be important to continue focus on this area in future mentorship trainings.

Quality of Nurse ART Initiation

Overall, the nurse graduates have high levels of completion for the majority of clinical indicators for ART initiation. Based on the results, it appears that nurses pay more attention to creatinine clearance (CrCl) when initiating patients onto ART compared to when managing ART in patients already initiated. It should be noted that nurses consistently recorded creatinine during initiations. As mentioned, the updated ART stationery may help close the gap on calculation of CrCl.

Similar to nurse ART management results, improvements are needed in rates of TB screening and pap smears. There are low numbers of co-infected TB/HIV+ patients among nurse graduates; however, this could be due to a significant proportion of co-infected patients starting ART from TB services elsewhere in the clinics, hence lower numbers of eligible patients on TB treatment being referred to the ARV unit. Better documentation of patient problem lists is also needed. Of these results, the percentage of patients eligible for Cotrimoxazole that did not receive it is disconcerting. Emphasis must be placed on this in future trainings.

Patient Characteristics between Doctor & Nurse Initiations

Study findings suggest that doctors are initiating patients with more advanced disease than nurses, which is consistent with findings from some previous studies.[11] This may affect the down referral of patients from doctors to nurses and may also impact the interpretation of patient outcomes when comparing nurse and doctor ART initiations.

Nurse Confidence

The NIMART mentorship program aimed to improve nurse confidence in HIV-related services for paediatrics, pregnant women, blood result interpretation and long-term side effects, suggesting a successful design of the training curriculum as these areas all showed significant improvements in nurse confidence level for the post-survey. It is important to note that these areas of greatest improvement in nurse confidence had the lowest confidence scores before training.

It is noted that some areas that did not see a significant increase in confidence level, such as TB screening and Cotrimoxazole prescription in adults, are in line with some of the areas needing improvement for nurse ART management and initiation. The mean score for nurse confidence level in these areas was high in the pre-test (3.5, 3.4, respectively), possibly contributing to the lack of significant increase post-training. Despite the high confidence level in performing these tasks, neither was completed as frequently as intended. Certain areas, such as calculation of creatinine clearance (CrCl), had a highly significant improvement in nurse confidence level; however, that did not appear to translate into a high level of completion for calculating CrCl when assessing quality of nurse ART management. These factors will need to be taken into consideration for future mentorship trainings, being aware that confidence is not necessarily equal to competence and completion of routine practices.

Many clinical tasks related to paediatric HIV and treatment had low confidence scores on the pre-test and substantial improvement in the post-test, however we did not specifically evaluate whether this resulted in more paediatric ART initiations. This is important as paediatric ART management has proven to be an especially challenging area in resource limited-settings, and the literature on task-shifting of ART management for children is limited.[13] The implications of this for children's access to HIV treatment suggest that nurses in the study are now more confident, and potentially more competent, in handling paediatric HIV patients, improving quality of patient care and treatment. These results are a testament to the valuable role that mentorship and training can play in improving access to paediatric ART.

Limitations

As this study was designed to provide descriptive statistics on the quality of nurse ART management and initiation, it was not powered to compare quality of nurse care against that of doctors. However, the study did capture patient characteristics to ascertain if there were significant differences in the patients being seen by each. The study did not look at patient outcomes, which

are a key measure for whether the program is working. The retrospective patient folder review introduced a possibility for some missing data, such as data capture of TB screening or CrCl, as specific forms were not created for this study. Slight differences in the ART stationery existed between patient folders. Specifically, the TB symptom list for some folders included a checklist of boxes to aid completion of the register, which may have influenced documentation of TB symptoms.

There was some movement of nurse graduates from clinic to clinic, as well as nurse resignations, during the study period. This was accounted for by following the nurse records at the new clinic location. Additionally, some clinics did not have ten available doctor ART initiations during the study period, due to clinic size and level of doctor involvement. The small number of nurses reviewed (8 of 21) may limit generalizability of results.

This study did not assess nurse management of pre-HAART, which could be an important element to consider when assessing appropriateness of task shifting to nurses for HIV care. Additionally, the research is nurse-based only and does not explore counsellor based HIV care.

Conclusions

Implementation of a nurse-mentor driven NIMART mentorship programme leads to competent nurse initiation of a majority of eligible patients, enabling medical officers to manage complex patient cases. Nurses improved their confidence in performing HIV-related clinical tasks, nurses continued to initiate patients after training, the quality of initiation and management was satisfactory and doctors continue to treat the more complicated patients. These results suggest that in regions where the HIV burden places large demands on health services, a nurse mentoring model could assist in ensuring task-shifting and system efficiency. Further research is needed to determine whether NIMART training for nurses increases access to care in terms of whether patient enrolment is increased, waiting time reduced and number of initiations for patients with higher CD4 counts increased.

ACKNOWLEDGEMENTS

The author would like to acknowledge Drs Vivian Cox, Mary Ibeto and Gabriella Patten of Médecins sans Frontières, Khayelitsha; Dr. Mary-Ann Davies of the University of Cape Town's Centre for Infectious Disease Epidemiology and Research; Dr. Virginia de Azevedo of the City Health Department of Cape Town, South Africa; and the dedicated staff at Khayelitsha City clinics for their continued support throughout the research.

REFERENCES

1. UNAIDS. *UNAIDS Report on the global AIDS epidemic 2010.* WHO, Geneva; 2010.

2. South African National Department of Health. Clinical Mentorship Manual for Integrated Services; 2011.

3. Fairall, L., Bachmann, M.O., Lombard, C., Timmerman, V., Uebel, K., Zwarenstein, M., Boulle, A., Georgeu, D., Colvin, C.J. and Lewin, S. Task shifting of antiretroviral treatment from doctors to primary-care nurses in South Africa (STRETCH): a pragmatic, parallel, cluster-randomised trial. *The Lancet*. 2012; 380: 889-898.

4. Cameron, D., Gerber, A., Mbatha, M., Mutyabule, J., Swart, H. Nurse-initiation and maintenance of patients on antiretroviral therapy: Are nurses in primary care clinics initiating ART after attending NIMART training? *South African Medical Journal*. 2012; 102 (2):98-100.

5. South African National Department of Health. National Strategic Plan for HIV and AIDS, STIs and TB, 2012-2016. Strategic Plan, South Africa; 2011.

6. Department of Social Services and Poverty Alleviation. The Population Register Update: Khayelitsha 2005. Survey, Western Cape; 2006.

7. Médecins Sans Frontières. Khayelitsha 2001-2011. ACTIVITY REPORT: 10 years of HIV/TB care at primary health care level." Activity report, Cape Town; 2011.

8. Western Cape's HIV&AIDS, STI and TB Directorate. Framework for Nurse Initiating and Management of Antiretroviral Therapy: Criteria of Mentors in NIMART. Circular, Cape Town; 2012.

9. Random.org, November 19, 2012. 2012. Available at: http://www.random.org/lists/.html

10. StataCorp. Stata Statistical Software: Release 12. College Station, TX: StataCorp LP, 2011.

11. Callaghan, M., Ford, N. and Schneider, H. A systematic review of task-shifting for HIV treatment and care in Africa. *Human Resources for Health.* 2010; 8(8).

12. International Agency for Research on Cancer. GLOBOCAN 2008 Fast Stats: South African Republic. Available: http://globocan.iarc.fr/factsheet.asp [October 11, 2012]. 2010.

13. Workneh, G., Sherzer, L., Kirk, B., Draper, H., Anabwani, G., Wanless, R.B., Jibril, H., Gaetsewe, N., Thuto, B. and Tolle, M. Evaluation of the effectiveness of an outreach clinical mentoring programme in support of paediatric HIV care scale-up in Botswana. *AIDS Care*. 2013; 25 (1):11-19.

Part D: Appendices

APPENDIX 1: DATA COLLECTION TOOL - NURSE ART MANAGEMENT

Data Collection Tool: NURSE ART MANAGEMENT

Name of NIMART Nurse

_____

Routine Baseline Data		
	Yes / No response	**Detailed response**
Patient File No.	[redacted]	Not field for comparison
Date of consultation		
Date of ART initiation		
CD4 at ART start & date		
Last CD4 & date		
Last Viral Load & date		
Last Creatinine Clearance and date		
Documented result of last bloods on ART stationary?		[redacted]
Consultation Data		
Last required bloods drawn? *(use routine blood chart)*		[redacted]
TB screen done?		
STI screen done?		
Family Planning offered? *(N/A for male patients)*		
Pap smears date recorded? *(N/A for male patients)*		
Clinical presentation entered?		
Problem list entered? (If yes document problem list)		
Stage entered?		[redacted]
Stage correlates with known medical history? *(use staging chart)*		
Plan entered?		
Referred to doctor?		
Medication entered? (If yes document the medication entered)		
ARVs doses entered correctly? *(use dosing chart)*		[redacted]
Is cotrimoxazole prescribed if last CD4 <200 (or if stage 2/3/4 and patient is between initiation and 1st CD4 post initiation)?		[redacted]

APPENDIX 2: DATA COLLECTION TOOL – NURSE ART INITIATION

Data Collection Tool – NURSE ART INITIATIONS

Name of NIMART Nurse

_____

	Yes / No response	Detailed response
Patient File No.	[redacted]	
Patient's DOB		
Date of consultation		
Patient's Weight		
Baseline CD4 documented (If yes, what is it?)		CD4 =
Creatinine documented (If yes, what is it?)		Cr =
Creatinine clearance (CrCl) documented (If yes, what is it?)		Cr Cl =
Hb documented (If yes, what is it?)		Hb =
ALT documented (If yes, what is it?)		ALT =
TB screen done? (If yes, how many TB symptoms documented?)		
STI screen done?		[redacted]
Family planning offered? *(N/A for male patients)*		
Pap smears date recorded? *(N/A for male patients)*		
Clinical presentation entered?		
Problem list entered? (If yes document problem list)		
Stage entered? (If yes, what is it?)		
Stage correlates with known medical history? *(use staging chart)*		[redacted]
Plan entered?		
Pt seen or discussed with doctor over last 1 month?		
Medication entered? (If yes, document drug, dose, frequency and duration prescribed)		
ARVs doses entered correctly?*(use dosing chart)*		[redacted]
Is Cotrimoxazole (Bactrim) prescribed if last CD4 <200 (or if stage 2/3/4)?		
Return date entered (If yes, what is the date?)		

APPENDIX 3: DATA COLLECTION TOOL – NURSE SELF-ASSESSMENT

(pre & post NIMART Mentorship Programme)

NIMART training curriculum – SELF-ASSESSMENT

CATEGORY	not very confident	somewhat confident	confident	very confident	Confident if using manual
Baseline knowledge					
Modes of transmission - adults					
Modes of transmission - children					
Clinical course - adults					
Clinical course - children					
Signs and symptoms - adults					
Signs and symptoms - children					
Use of manuals – positive prevention and HIV guide					
Use of DoH stationery					
Core differences between adults and children					
Before ARVs					
HIV Counselling & Testing - adults					
HIV Counselling & Testing - children					
Diagnosis - adults					
Diagnosis - children					
Staging - adults					
Staging - children					
BMI – calculate and manage					
Paediatric weight charts and management					
TB screening - adults					
TB screening - children					
Pap smears and HIV					
Common opportunistic infections - adults					
Common opportunistic infections - children					
TB diagnosis & management - adults					
Drug side effects					
Cotrimoxazole use - adults					
Cotrimoxazole use - children					

CATEGORY	not very confident	somewhat confident	confident	very confident	confident if using manual
Starting ARVs					
Eligibility criteria to start - adults					
Eligibility criteria to start - children					
Fast-tracking criteria					
Blood result interpretation - adults					
Working with creatinine and creatinine clearance					
Individual ARV contra-indications					
Pre-start adherence counseling					
DoH ARVs, doses and side-effects DoH 1st line regimens - adults					
DoH ARVs, doses and side-effects DoH 1st line regimens - children					
Prescribing with concurrent Illnesses – TB, epilepsy, Hypertension, diabetes, Asthma/COAD					
Normal course on ARVs					
Side-effects and their management					
Skin, haematology, liver, kidney, psychiatric					
Recognition of serious side-effects: Skin, lactate, pancreatitis, hepatitis					
Understanding IRIS					
Long-term side-effects					
Failing regimen – warning signs					
Diagnosis – clinical, immunological, virological					
Why NB and when to refer					
HIV and pregnancy					
Family planning					
Wanting to fall pregnant					
During pregnancy					
After pregnancy mother					
child					

CATEGORY	not very confident	somewhat confident	confident	very confident	Confident if using manual
Post-exposure prophylaxis					
Non-drug management – administration					
Drug regimens and indications					
General					
Management of weight loss					
Routine clinical examination					
Cardiac failure					
Enlarged liver					
Neck stiffness					
Procedures for lactate testing					
Understanding the register					

APPENDIX 4: UCT ETHICS COMMITTEE APPROVAL

UNIVERSITY OF CAPE TOWN

Faculty of Health Sciences
Faculty of Health Sciences Human Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
e-mail: sumayah.ariefdien@uct.ac.za

20 November 2012

HREC REF: 615/2012

Ms A Green
c/o Dr M Davies
School of Public Health & Family Medicine
Falmouth Building
FHS

Dear Ms Green

PROJECT TITLE: CLINICAL MENTORSHIP OF NURSE-INITIATED ANTIRETROVIRAL THERAPY IN KHAYELITSHA, SOUTH AFRICA: A QUALITY OF CARE ASSESSMENT

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the Ethics Committee has **formally approved** the above-mentioned study.

Approval is granted for one year till the 28 November 2013.

Please submit a progress form, using the standardised Annual Report Form, if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

Please supply the Provincial Research Committee's approval before starting the project.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC. REF in all your correspondence.

Yours sincerely

Signature removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS

Federal Wide Assurance Number: FWA00001637.
sAriefdien

APPENDIX 5: INSTRUCTIONS FOR AUTHOR OF JOURNAL WHOSE FORMAT HAS BEEN USED

INSTRUCTIONS FOR AUTHOR OF JOURNAL WHOSE FORMAT HAS BEEN USED

JAIDS: Journal of Acquired Immune Deficiency Syndromes

Instructions for Authors

Accessed at: http://edmgr.ovid.com/jaids/accounts/ifauth.htm

This article will be submitted as an Implementation and Operational Research article under the Epidemiology and Prevention section.

SCOPE

JAIDS: Journal of Acquired Immune Deficiency Syndromes is a peer-reviewed, multidisciplinary journal directed to an audience of physicians and researchers. The journal publishes original work in the form of Original Articles, Implementation and Operational Research*, Rapid Communications, Critical Reviews, Brief Reports, and Letters to the Editor*. *JAIDS* does not publish case reports. (*published online only)

MANUSCRIPT SUBMISSION

A submitted manuscript must be an original contribution not previously published (except as an abstract or preliminary report), must not be under consideration for publication elsewhere, and, if accepted, must not be published elsewhere in similar form, in any language, without the consent of Lippincott Williams & Wilkins. Each person listed as an author is expected to have participated in the study to a significant extent. Although the editors and referees make every effort to ensure the validity of published manuscripts, the final responsibility rests with the authors, not with the journal, its editors, or the publisher.

All submissions will be rigorously peer-reviewed by members of the Editorial Board and by other specially qualified individuals as well. In the interests of rapid reviewing of contributions, only one of the Editors-in-Chief will, in general, make the final determination as to the acceptability of a submission, after collecting the referee's comments. Contributors may recommend specific names of reviewers from the Editorial Board, as well as other individuals they deem especially well qualified. However, the Editors-in-Chief will not be bound to follow such suggestions.

In general, the instructions for preparation of manuscripts should follow the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts Submitted to Biomedical Journals. In case of questions, please feel free to contact the Editorial Office of any one of the Editors-in-Chief.

Authors must submit their manuscripts to the relevant section through the Web-based tracking system:

Basic and Translational Science (**http://jaids-basicscience.edmgr.com**)

Clinical Science (**http://jaids-clinical.edmgr.com**)

Epidemiology and Prevention (**http://jaids-epidemiology.edmgr.com**)

The site contains instructions and advice on how to use the system, guidance on the creation/scanning and saving of electronic art, and supporting documentation. In addition to allowing authors to submit manuscripts on the Web, the site allows authors to follow the progression of their manuscript through the peer review process. Authors should not send hard copies of the manuscript or artwork to the editorial office. Address all inquiries regarding manuscripts not yet accepted or published to the Journal's editorial office. The editorial office will acknowledge receipt of your manuscript via e-mail.

Editorial Office Addresses :

Basic and Translational Science
David D. Ho, MD
The Aaron Diamond AIDS
Research Center
455 First Avenue
New York, NY 10016
917-797-6056
tklemt@adarc.org

Clinical Science
Paul A. Volberding, MD
UCSF AIDS Research Institute
50 Beale St.
Suite 1300
PO Box 0886
San Francisco, CA 94105-0886
tel: 415.597.4982
fax: 415.597.8160
email: jaids@ucsf.edu

Epidemiology and Prevention
William A. Blattner, MD
Institute of Human Virology
725 W. Lombard Street, S419
Baltimore, MD 21201
(410) 706-1292
Fax: (410) 706-1944
LZiehm@ihv.umaryland.edu

Authorship

An author is considered to be someone who has made substantive contributions to a published study. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. More specifically, authorship credit requires *a*) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; *b*) drafting the paper or revising it critically for important intellectual content; and *c*) final approval

of the version to be published. Contributors must meet conditions for *a, b*, and *c*—all 3—to be eligible for authorship. All persons listed as authors must meet the 3 criteria above, and all persons who meet the above criteria must be listed as authors. Please note that acquisition of funding, collection of data, or general supervision of a research group, alone, does not justify authorship.

For large, multicentre group studies, individuals who accept direct responsibility for the manuscript must be identified. Those individuals will be required to complete the ***JAIDS*** Copyright Transfer Agreement.

Contributors who do not meet the criteria for authorship should be listed in the acknowledgments section. Persons providing technical help, writing assistance, or a department chair providing general support are examples of persons who should not be included as authors, but who should be listed in the Acknowledgments section.

Conflicts of Interest

Authors must state all possible conflicts of interest in the manuscript, including financial, consultant, institutional and other relationships that might lead to bias or a conflict of interest. If there is no conflict of interest, this should also be explicitly stated as none declared. All sources of funding should be acknowledged in the manuscript. All relevant conflicts of interest and sources of funding should be included **ON THE TITLE PAGE** of the manuscript with the heading "Conflicts of Interest and Source of Funding". For example:

Conflicts of Interest and Source of Funding: A has received honoraria from Company Z. B is currently receiving a grant (#12345) from Organization Y, and is on the speaker's bureau for Organization X – the CME organizers for Company A. For the remaining authors none were declared.

In addition, each author must complete and submit the journal's copyright transfer agreement, which includes a section on the disclosure of potential conflicts of interest based on the

recommendations of the International Committee of Medical Journal Editors, "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (www.icmje.org/update.html). The form is readily available on the manuscript submission page http://www.editorialmanager.com/jaids-basicscience/ and can be completed and submitted electronically. Please note that authors may sign the copyright transfer agreement form electronically. For additional information about electronically signing this form, go to http://links.lww.com/ZUAT/A106.

Copyright

All authors must complete and sign a copy of the journal's Copyright Transfer Agreement and submit it when submitting the original manuscript online.

Compliance with NIH and Other Research Funding Agency Accessibility Requirements

A number of research funding agencies now require or request authors to submit the post-print (the article after peer review and acceptance but not the final published article) to a repository that is accessible online by all without charge. As a service to our authors, LWW will identify to the National Library of Medicine (NLM) articles that require deposit and will transmit the post-print of an article based on research funded in whole or in part by the National Institutes of Health, Wellcome Trust, Howard Hughes Medical Institute, or other funding agencies to PubMed Central. The Copyright Transfer Agreement provides the mechanism.

Patient Anonymity and Informed Consent

It is the author's responsibility to ensure that a patient's anonymity be carefully protected and to verify that any experimental investigation with human subjects reported in the manuscript was performed with informed consent and following all the guidelines for experimental investigation with human subjects required by the institution(s) with which all the authors are affiliated. Authors

should mask patients' eyes and remove patients' names from figures unless they obtain written consent from the patients and submit written consent with the manuscript.

Protection of Human Subjects and Animals in Research

When reporting experiments involving human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000.

For research involving animals, authors should indicate whether the procedures followed were in accordance with the standards set forth in the *Guide for the Care and Use of Laboratory Animals* (published by the National Academy of Science, National Academy Press, Washington, D.C.).

Permission to photocopy articles: Authors must submit written permission from the copyright owner (usually the publisher) to use direct quotations, tables, or illustrations that have appeared in copyrighted form elsewhere, along with complete details about the source. Permission to reproduce copies of articles for non-commercial use may be obtained from the Copyright Clearance Center, 222 Rosewood Drive, Danvers, MA 01923; Telephone: 978-750-8400; Fax: 978-750-4470; Web: www.copyright.com ; E-mail: customercare@copyright.com. For permissions to reuse the material for other purposes: Please go to the Journal website and click the ''Permissions'' link above the title of the paper in the abstract or html window for the relevant article. Alternatively, send an e-mail to customercare@copyright.com or e-mail journalpermissions@lww.com. Translation Rights & Licensing queries: Please contact Silvia Serra, Translations Rights, Licensing & Permissions Manager, Wolters Kluwer Health (Medical Research) Ltd, 250 Waterloo Road, London SE1 8RD, UK. Phone: +44 (0)207 981 0600; E-mail: Silvia.Serra@wolterskluwer.com. Any permissions fees that might be required by the copyright owner are the responsibility of the authors requesting use of the borrowed material, not the responsibility of Lippincott Williams & Wilkins.

PREPARATION OF MANUSCRIPT:

Manuscripts that do not adhere to the following instructions will be returned to the corresponding author for technical revision before undergoing peer review.

ARTICLE LIMITATIONS – BEGINNING WITH JULY 15, 2010 SUBMISSIONS:

Article type	**Limitations**	**Abstracts**
Original Articles	3500 words + 5 figures/tables - if more then use Supplemental Digital Content	Structured; 250 words
Implementation and Operational Research *(published online only)*	3500 words + 5 figures/tables - if more then use Supplemental Digital Content	Structured; 250 words
Rapid Communications	2000 words + 2 figures/tables	Unstructured, 150 words
Critical Reviews	3000 words + 2 figures/tables	Unstructured; 150 words
Brief Reports	2000 words + 2 figures/tables	Unstructured; 100 words
Letter to the Editor *(published online only)*	1500 words; 1 figure/table	none

ARTICLE TYPES

Original Articles

The above guidelines apply to the original article format. Articles should be limited to 3500 words + 5 figures/tables. If additional space is needed, then use Supplemental Digital Content options. There should be a structured abstract of 250 words or less.

Implementation and Operational Research (NEW ARTICLE TYPE)

JAIDS is now accepting manuscripts for a new focus area of interest: Implementation and Operational Research. In the context of HIV/AIDS with advances in HIV therapy and care, expansion of global access to treatment, care and prevention Implementation and Operational Research, while having particular relevance to global health is an important domestic focus as well. However the lessons learned through this research discipline are particularly relevant to guiding best practices in low-resource settings as antiretroviral drug access is expanded. Articles that encompass the translation of knowledge, practices, and technologies into clinical care of adult and paediatric patients with HIV/AIDS and their evidence-based effectiveness in "real world settings" are of particular interest.

All manuscripts should be submitted through one of the existing three sections: Basic and Translational Science, Clinical Science, or Epidemiology and Prevention using the article type Implementation and Operational Research. Structure of article is the same as Original Article. **If accepted for publication, articles are published ONLINE ONLY with titles appearing in the print and online edition table of contents.**

Rapid Communications

Articles accepted as Rapid Communications will normally be published within 8 weeks of acceptance. When submitting a paper for consideration as a Rapid Communication, please adhere to the following guidelines:

- Submit your paper to Editorial Manager and designate the article type as "Rapid Communication." Please indicate to the Editor in a cover letter file why the paper merits special attention.
- The paper should not exceed 2000 words and 2 figures/tables.
- The paper should include an unstructured abstract (150 words or less), key words, methods, results, discussion, and reference sections.
- The title page should include the corresponding author's telephone and fax numbers and e-mail address.
- Authors will receive proofs of their article for review by e-mail and will be expected to return corrections by fax within 24 hours of receipt. Changes received after this deadline will not be accepted.

Papers that are not accepted as Rapid Communications may be considered as full-length articles.

Critical Reviews

Papers reviewing the literature on a particularly timely and interesting topic will be considered for publication in ***JAIDS***. Authors are encouraged to keep review articles to less than 3000 words and 2 figures/tables with an unstructured abstract of 150 words or less. In general, review articles written as work-for-hire by industry employees will not be considered for publication. All funding, writing assistance, and other relationships to possibly conflicted sources must be fully disclosed at the time of submission.

Brief Reports

Brief Reports are short versions of clinical studies. They represent observations that are preliminary, speak for themselves, or offer new insight into a recognized condition. Submissions should not exceed 2000 words + 2 figures/tables with an unstructured abstract of 100 words or less.

Letters to the Editor

Letters to the Editor can provide additional comment on an article published in *JAIDS*, or can be a very concise report on study findings. Letters should be no more than 1500 words and 1 figure/table. **Beginning with July 15, 2010 submissions, Letters to the Editor will be published ONLINE ONLY. Title will appear in print and online edition table of contents**.

Online Submission

Manuscript files must be uploaded into the Editorial Manager online interface. Most word-processing file formats are acceptable. Editorial Manager will then create PDF files of the authors' submission, and the author must view and approve the files before they will be submitted to the editorial office. Please be sure that the manuscript file contains complete text for your submission (title page and abstract), as this is the file that will be downloaded by the reviewers and publisher. Please see the sections below for instructions regarding Figure and Table files. Once the paper has been accepted for publication, and final versions of the manuscript, figures, and table files have been uploaded to the Editorial Manager interface, PDF files will not be used for typesetting. This is important to note for Table and Figure files, which may lose formatting when converted to PDF, but will remain intact in their original file format.

Title Page

A title page must be included in the manuscript file. Include on the title page: *a*) complete manuscript title; *b*) authors' full names, academic degrees, and affiliations; *c*) name and address for correspondence, including fax number, telephone number, and e-mail address; *d*) address for

reprints if different from that of corresponding author; *e*) meetings at which parts of the data were presented (including title of conference, city, and date); *f*) sources of support; and *g*) a running head of no more than 40 characters. The title page must also include disclosure of funding received for this work from any of the following organizations: National Institutes of Health (NIH); Wellcome Trust; Howard Hughes Medical Institute (HHMI); and other(s).

Abstract and Key Words

The abstract should be structured and limited to 250 words depending on article type. It must be factual and comprehensive. Limit the use of abbreviations and acronyms, and avoid general statements (eg, "the significance of the results is discussed"). List 3 to 6 key words or phrases.

Text

Organize the manuscript file into sections with appropriate section headings. The sequence should be as follows: title page, abstract/key word page, introduction, methods, results, discussions, acknowledgments, references, tables, figures and figure captions.

Authors should type, whenever possible, all mathematical and chemical symbols, equations, and formulas, and identify all unusual symbols the first time they are used. Define abbreviations at first mention in text and in each table and figure. If a brand name is cited, supply the manufacturer's name and address (city and state/country).

Abbreviations

For a list of standard abbreviations, consult the Council of Biology Editors Style Guide (available from the Council of Science Editors, 9650 Rockville Pike, Bethesda, MD 20814) or other standard sources. Write out the full term for each abbreviation at its first use unless it is a standard unit of measure.

References

The authors are responsible for the accuracy of the references. Key the references (double-spaced)

at the end of the manuscript. (If using End Note, set the style output to *JAMA*.) Cite references in text in order of appearance. Cite unpublished data, such as papers submitted but not yet accepted for publication, or personal communications, in parentheses in the text. If there are more than 3 authors, list only the first 3 authors and then use et al. Refer to the List of Journals Indexed in Index Medicus for abbreviations of journal names. Sample references are given below:

Journal Article

1. Schambelan M, Benson CA, Carr A, et al. Management of metabolic complications associated with antiretroviral therapy for HIV-1 infection: recommendations of an International AIDS Society-USA panel.*J Acquir Immune DeficSyndr.* 2002;31:257–275.

Book Chapter

2. Wortmann RL, Bentzel CJ. Renal handling of uric acid. In: Massry SG, Glassock RJ, eds. *Massry and Glassock's Textbook of Nephrology*. Phiadelphia: Lippincott Williams & Wilkins, 2001;90–92.

Entire Book

3. Mandell GL, Mildvan D, eds. *Atlas of AIDS*. 3rd ed. Philadelphia: Lippincott Williams & Wilkins; 2001.

Software

4. Epi Info [computer program]. Version 6. Atlanta: Centers for Disease Control and Prevention, 1994.

Online Journals

5. Friedman SA. Preeclampsia: a review of the role of prostaglandins. *ObstetGynecol* [serial online]. January 1988;71:22–37. Available from: BRS Information Technologies, McLean, VA. Accessed December 15, 1990.

Database

6. CANCERNET-PDQ [database online]. Bethesda, MD: National Cancer Institute, 1996. Updated March 29, 1996.

World Wide Web

7. Panel on Clinical Practices for the Treatment of HIV Infection. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. Department of Health and Human Services and Henry J. Kaiser Foundation, January 28, 2000. Available at: http://www.hivatis.org/guidelines/AA599.pdf.

Paper Presented at a Conference

8. Koenig L, Ellerbrock T, Pratt-Palmire M, et al. Prospective predictors of medication adherence: a study of the first six months of highly active antiretroviral therapy (HAART) using electronic monitoring [WePeB5818]. Presented at: XIV International AIDS Conference; 2002; Barcelona.

Figures

Cite figures consecutively in the text, and number them in the order in which they are discussed. Submit all artwork in camera-ready form through Editorial Manager. Authors must submit figures as separate electronic files. High-quality hard copies may be requested once the manuscript has been accepted for publication. Lettering should be large enough that it will remain legible after figure reduction; typewritten or unprofessional lettering is unacceptable. Figure parts (A, B, C) may be left unlabeled (but clearly marked on back) for professional placement by the journal's printer.

Figure Legends

Legends must be submitted for all figures. They should be included in the manuscript file, should be brief and specific, and should appear on a separate manuscript page after the references. Use scale markers in the image for electron micrographs, and indicate the type of stain used.

Color Figures

The journal accepts for publication color figures that will enhance an article. Authors who submit color figures will receive an estimate of the cost for color reproduction. If they decide not to pay for color reproduction, they can request that the figures be converted to black and white at no charge.

Digital Figures

Electronic art should be created/scanned and saved and submitted as either a TIFF (tagged image file format), an EPS (encapsulated postscript) file, or a PPT (Power Point) file. Line art must have a resolution of at least 1200 dpi (dots per inch), and electronic photographs—radiographs, CT scans, and so on—and scanned images must have a resolution of at least 300 dpi. If fonts are used in the artwork, they must be converted to paths or outlines or they must be embedded in the files. Color images must be created/scanned and submitted as CMYK files. Files should be submitted electronically through the Editorial Manager interface. Please note that artwork generated from office suite programs such as Corel Draw and MS Word and artwork downloaded from the Internet (JPEG or GIFF files) cannot be used.

Supplemental Digital Content (SDC)

Authors may submit SDC via Editorial Manager to LWW journals that enhance their article's text to be considered for online posting. SDC may include standard media such as text documents, graphs, audio, video, etc. On the Attach Files page of the submission process, please select Supplemental Audio, Video, or Data for your uploaded file as the Submission Item. If an article with SDC is

accepted, our production staff will create a URL with the SDC file. The URL will be placed in the call-out within the article. SDC files are not copy-edited by LWW staff, they will be presented digitally as submitted. For a list of all available file types and detailed instructions, please visit http://links.lww.com/A142.

SDC Call-outs

Supplemental Digital Content must be cited consecutively in the text of the submitted manuscript. Citations should include the type of material submitted (Audio, Figure, Table, etc.), be clearly labeled as "Supplemental Digital Content," include the sequential list number, and provide a description of the supplemental content. All descriptive text should be included in the call-out as it will not appear elsewhere in the article.

Example:

We performed many tests on the degrees of flexibility in the elbow (see Video, Supplemental Digital Content 1, which demonstrates elbow flexibility) and found our results inconclusive.

List of Supplemental Digital Content

A listing of Supplemental Digital Content must be submitted at the end of the manuscript file. Include the SDC number and file type of the Supplemental Digital Content. This text will be removed by our production staff and not be published. Example: Supplemental Digital Content 1.wmv

SDC File Requirements

All acceptable file types are permissible up to 10 MBs. For audio or video files greater than 10 MBs, authors should first query the journal office for approval. For a list of all available file types and detailed instructions, please visit http://links.lww.com/A142. Please do not submit pdfs.

Tables

Create tables using the table creating and editing feature of your word-processing software (eg, Word, Word-Perfect). Do not use Excel or comparable spreadsheet programs. Group all tables together and upload them in a separate file. Cite tables consecutively in the text, and number them in that order. Key each on a separate sheet, and include the table title, appropriate column heads, and explanatory legends (including definitions of any abbreviations used). Do not embed tables within the body of the manuscript. They should be self-explanatory and should supplement, rather than duplicate, the material in the text.

Style

Pattern manuscript style after the *American Medical Association Manual of Style* (9th edition). Stedman's Medical Dictionary (28th edition) and Merriam-Webster's Collegiate Dictionary (11th edition) should be used as standard references. Refer to drugs and therapeutic agents by their accepted generic or chemical names, and do not abbreviate them. Use code numbers only when a generic name is not yet available. In that case, supply the chemical name and a figure giving the chemical structure of the drug. Capitalize the trade names of drugs and place them in parentheses after the generic names. To comply with trademark law, include the name and location (city and state in USA; city and country outside USA) of the manufacturer of any drug, supply, or equipment mentioned in the manuscript. Use the metric system to express units of measure and degrees Celsius to express temperatures, and use SI units rather than conventional units.

Obligation to Register Clinical Trials

JAIDS has adopted the standards of the International Committee of Medical Journal Editors with regard to the registration of clinical trials. As a condition of consideration for publication, data from research projects "prospectively assigning human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a

health outcome" ***must be registered*** in a public trials registry. The Protocol Registration System (http://prsinfo.clinicaltrials.gov/) offered through the U.S. National Institutes of Health is one such registry.

GenBank Accession Numbers

When manuscripts include or describe original nucleotide or amino acid sequence data, the sequence must be submitted to the GenBank/EMBL/DDBJ sequence database and an accession number obtained from them. This accession number must be returned to the journal, where it will be placed after the Key Words on the title page in the printed article. URLs for the 3 members of the International Nucleotide Sequence Database Collaboration (GenBank/EMBL/DDBJ) are as follows (respectively): http://www.ncbi.nlm.nih.gov/BankIt/, http://www.ebi.ac.uk/embl/, http://www.ddbj.nig.ac.jp/.

Page Proofs and Corrections

PDF files of the copyedited, typeset pages and support documents (eg, reprint order form) will be sent to the corresponding author via e-mail. Complete instructions will be provided with the e-mail for downloading and printing the files and for faxing the corrected pages to the publisher. It is the author's responsibility to ensure that there are no errors in the proofs. Changes that have been made to conform to journal style should be allowed to stand if they do not alter the authors' meaning. Only critical changes improving the accuracy of the content will be made. Changes that are stylistic or are a reworking of previously accepted material will not be allowed. The publisher reserves the right to deny any changes that do not affect the accuracy of the content. Authors may be charged for alterations to the proofs beyond those required to correct errors or to answer queries. Proofs must be checked carefully and corrections faxed within 24 to 48 hours of receipt, as requested in the cover letter accompanying the page proofs.

Reprints

Reprint orders should be submitted to the Reprints Department (1-800-341-2258 or reprintsgroup@LWW.com). Payment for reprints or a purchase order number must accompany your order form. Orders without these cannot be fulfilled. More information can be obtained at http://www.lww.com/periodicals/author-reprints/